

Final Report

Select Investigative Panel

of the Energy & Commerce Committee
December 30, 2016

Select Investigative Panel

of the Energy & Commerce Committee



Select Investigative Panel

Final Report

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Executive Summaries

I. Congress Establishes the Select Investigative Panel

- David Daleiden, an investigative journalist, released undercover videos beginning in July 2015, recorded while posing as the head of a company interested in the fetal tissue procurement business. In numerous meetings with abortion providers and companies involved in the transfer of fetal tissue, Daleiden recorded doctors, executives, and staff-level employees discussing various aspects of the fetal tissue procurement industry.

- The videos and other materials that Daleiden acquired detailed the relationship between fetal tissue procurement companies, including Advanced Bioscience Resources, DaVinci Biologics, and StemExpress, and several abortion clinics.

- The exposé followed an investigation Daleiden conducted through a not-for-profit group he founded, the Center for Medical Progress (CMP). CMP's first project, the "Human Capital" investigation, took almost three years. Working under the guise of a tissue procurement business in order to gain access to the top levels of Planned Parenthood, Daleiden, Susan Merritt, and other activists recorded numerous videos documenting conversations in which Planned Parenthood executives discussed the procurement of fetal tissue from aborted fetuses.

- The investigation culminated with the release of eleven videos documenting the practices of local abortion clinics and groups affiliated with the fetal tissue procurement industry. Daleiden and his colleagues filmed hundreds of hours of meetings and conversations. According to the *Washington Post*, they filmed 500 hours of footage at two conferences alone.

- Multiple clips show abortion providers and executives admitting that their fetal tissue procurement agreements are profitable for clinics and help keep their bottom line healthy. Multiple clips also show them admitting that they sometimes changed the abortion procedure in order to obtain a more intact specimen, and some use the illegal partial birth abortion procedure.

- Planned Parenthood Federation of America (PPFA) also revealed that they intentionally had not set a policy about "remuneration" for fetal tissue because "the headlines would be a disaster." While the organization's executives told affiliates to "think, 'New York Times headline'" if this went badly, at the end of the day, they thought "[selling fetal tissue] is a good idea."

- Congress responded to the videos by holding hearings and initiating investigations. The Energy and Commerce Subcommittee on Oversight and Investigations initiated an investigation of fetal tissue transfers. The Committee on Oversight and Government Reform and the Judiciary Committee conducted hearings and also initiated investigations.

- On October 7, 2015, Rep. Virginia Foxx (NC-5) managed the floor debate for H. Res. 461, a proposal for a centralized and comprehensive congressional investigation. During debate, Rep. Mimi Walters (CA-45) noted, "This resolution would create a select panel to investigate a number of claims related to Planned Parenthood's activities involving abortion and fetal tissue procurement. Like many Americans, I was horrified by the recent videos which depicted Planned Parenthood employees callously discussing the trafficking and sale of aborted babies' tissues and organs." Rep. Marsha Blackburn (TN-7) summarized:

> I want to clearly state this is about getting answers of how we treat and protect life in this country. The select panel will act to centralize the investigations that are at the Energy and Commerce Committee, Judiciary and Oversight Committees, and bring it all under one umbrella. Over the past several weeks, we have had lots of serious questions. They are troubling questions that have been asked. I think that the investigations we have had have raised a lot of those questions. It is imperative that we centralize these operations and bring it together under one umbrella.

- Congress passed H. Res. 461 by a recorded vote of 242 yeas and 184 nays. Rep. Blackburn was named Chairman of the Panel.

- The Panel did not design its investigation to prove or disprove the credibility of tapes released by the Center for Medical Progress (CMP); however, the Panel viewed the videos as a series of serious claims made by a citizen advocacy group.

- The Panel's investigation identified four business models involving fetal tissue procurement:

    - *The Middleman Model.* This model comprises a middleman and tissue procurer who obtains tissue directly from a source such as an abortion clinic or hospital and then transfers the tissue to a customer, usually a university researcher.

    - *The University/Clinic Model*. This model comprises a particular university that has formed a close relationship with a nearby abortion clinic and regularly acquires tissue from that clinic for research purposes.

    - *The Biotech Company/Clinic Model*. This model comprises a close relationship between a particular biotech company and one or more nearby clinics.

    - *The Late-Term Clinic Model*. This model is of particular concern due to the intersection of late-term abortions, the potential for live births during the abortion procedure, and the transfer of tissues or whole cadavers from that clinic to research entities.

- The Panel designed an investigative work plan based on these business models.

II. Applicable Laws, Regulations, and Commissions

- Federal and state laws germane to the Panel's investigation can be grouped into four broad categories, with some overlap: (1) laws protecting human research subjects and patient privacy; (2) laws regulating anatomical gifts for transplantation, therapy, research, and education; (3) laws protecting late-term and born-alive infants; and (4) laws pertaining to public funding for fetal tissue research and abortion providers.

A. Laws protecting human research subjects and patient privacy

- Laws protecting human research subjects and privacy are rooted in the principles set forth in the Belmont Report.

- Research subjects must be respected as autonomous persons, researchers must adhere to the Hippocratic ideal, and the benefits of research must outweigh the risks to human research subjects.

- The Panel examined the legal and ethical importance of informed consent under the Belmont principles. During the Panel's hearing on *Bioethics and Fetal Tissue*. Rep. Vicky Hartzler (MO-4) addressed an important statement in the Belmont Report regarding informed consent—that "inducements [to consent] that would ordinarily be acceptable may become undue influences if the [research] subject is especially vulnerable."

- Mrs. Hartzler asked an ethics expert if a form known to be widely used by abortion clinics to obtain a mother's consent to donate fetal tissue complied with "HHS's mandate against inducement." The form stated that "[r]esearch using the blood from pregnant women and tissue that has been aborted has been used to treat and find a cure for such diseases as diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS."

- The witness agreed that this was an important question, because the "idea of the promise of cures" found in the form was a "very powerful motivator." The witness also indicated that the "consent" form was deficient in other ways: "The concern I have is that the standards that we have typically for fetal tissue donation are just absent here. And so in addition to the voluntariness, there is just the thoroughness of the consent [that] seems to be missing in this form."

- The testimony provided by witnesses invited by both the majority and minority raised concerns that the principles embodied in the Belmont Report, and later incorporated into

federal regulations, are not being followed by abortion providers seeking consent for the donation of human fetal tissue.

- In response to the Belmont Report, HHS and the FDA significantly revised their human subjects regulations in 1981. The Common Rule applies to research projects that receive funding from federal agencies, requiring three steps to be fulfilled before the research can take place: 1) the human subject must give informed consent; 2) an Institutional Review Board (IRB) must review the proposed research project; and 3) the institution conducting the research must file an assurance of compliance with the federal agency that is providing the funding.

- The Panel's investigation revealed evidence that the IRB process used by some fetal tissue procurement businesses is often grossly insufficient. For instance, on March 29, 2016, the Panel issued a subpoena to BioMed IRB which required it to produce documents sufficient to show BioMed IRB's ongoing oversight, within the definition of federal regulations, of any entity involved with fetal research or transplantation of fetal tissue for which it issued an IRB approval. BioMed IRB's executive director informed the Panel on April 4, 2016, that in regards to those records, "there are none." This is an apparent direct violation of federal regulations.

- The Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule (Privacy Rule) protects all individually identifiable health information held or transmitted by a covered entity or its business associate and calls this information protected health information (PHI). PHI identifies an individual, or can reasonably be believed to be useful in identifying an individual, and includes demographic data relating to an individual's health condition, provision of health care, or payment for the provision of health care to the individual.

- The Panel's investigation indicates that StemExpress and Planned Parenthood Mar Monte (PPMM), Planned Parenthood Shasta Pacific (PPSP), and Family Planning Specialists Medical Group (FPS) committed systematic violations of the HIPAA Privacy Rule from about 2010 to 2015. These violations occurred when the abortion clinics disclosed patients' individually identifiable health information to StemExpress to facilitate the TPB's efforts to procure human fetal tissue for resale.

B. Laws regulating anatomical gifts for transplantation, therapy, research, and education

- Laws regulating anatomical gifts are also heavily centered on the need for informed consent. Additionally, federal and many state laws explicitly prohibit the sale of human body parts.

- The National Organ Transplant Act (NOTA) provides that "[i]t shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. . . . Any person who violates [] this section shall be fined not more than $50,000 or

imprisoned not more than five years, or both." The term "human organ" is defined to include fetal organs and subparts of organs.

- The Uniform Anatomical Gift Act (UAGA), a model statute first available in 1968 and most recently amended in 2009, was written to facilitate organ donation for transplantation, therapy, research, and education by ensuring that state laws are consistent across the country.

- The UAGA, adopted in every state in some form, includes stillborn babies and fetuses in the definition of "decedent" for purposes of obtaining consent from a relative before the deceased infant's body is donated for experimentation or transplantation. In the UAGA's official notes, the drafters explain that the inclusion of stillborn babies and fetuses ensures that they "receive the statutory protections conferred by this [act]; namely that their bodies or parts cannot be used for transplantation, therapy, research, or education without the *same appropriate consents* afforded other prospective donors."

- The Panel learned that the University of New Mexico (UNM) and the late-term abortion clinic Southwestern Women's Options (SWWO) have an extensive history in which SWWO provided fetal tissue to UNM researchers. SWWO's provision and UNM's acquisition of and research using aborted infant remains appear to violate New Mexico's anatomical gift act, the Spradling Act.

- Under the NIH Revitalization Act of 1993, it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce."

- Laws regulating the donation of human organs, including human fetal organs, are relevant for the Panel's investigation, given the possibility that both tissue procurement businesses (TPB's) and abortion providers are profiting from fetal tissue procurement.

- During the Panel's April 20, 2016 hearing, *The Pricing of Fetal Tissue*, Panel members asked witnesses to examine evidence that payments paid by customers to a TPB for fetal tissue exceeded costs incurred by the business by a factor of 300 to 700 percent. Further, the evidence *did not* demonstrate that in many instances the "compensated" abortion clinics incurred any actual costs.

C. Laws protecting late-term and born-alive infants

- Laws protecting late-term unborn infants and infants born alive during abortion procedures recognize that the "right to an abortion" does not equal the right to a dead child. Federal laws prohibit a specific abortion procedure that occurs seconds before livebirth, and explicitly provide that infants born alive enjoy all of the constitutional rights available to other Americans.

- During the Panel's investigation, staff reviewed tissue procurement notes, email exchanges among researchers, TPB's and abortion clinics, invoices, and more—all indicating that researchers want fetal tissue from late-gestation infants that has not been tainted by feticidal agents (*e.g.*, digoxin).

- The Panel also learned that abortion providers may modify abortion procedures, in apparent violation of the law, to increase the odds of getting an intact infant cadaver (*e.g.*, increase the number of laminaria placed in a patient's cervix to achieve greater dilation). Clearly, these factors increase the likelihood that unborn infants are born alive during late second-trimester abortions, and raise the question whether these infants' civil rights are recognized by abortion providers.

D. Laws pertaining to public funding for fetal tissue research and abortion providers

- Finally, laws pertaining to public funding for fetal tissue research and abortion providers need reforming. In particular, while federal law contains numerous restrictions on public funding for abortion, abortion providers receive millions of federal dollars ostensibly for other purposes.

- Government investigations and whistleblower testimonies have revealed that abortion providers often fail to separate public funding from abortion-related costs.

- The Charlotte Lozier Institute and Alliance Defending Freedom have documented that—based on 51 known external audits or other reviews of Planned Parenthood affiliates' financial data and practices, and 61 federal audits of state family planning programs by HHS-OIG—Planned Parenthood affiliates have overbilled $132.4 million in Medicaid and other healthcare funding programs. These audit results are troubling, given their limitations in scope, detail, and timeframe; in fact, of 57 U.S. Planned Parenthood affiliates, only 19 have been audited.

- The Obama administration has denied or threatened to deny federal Medicaid funding to states that have attempted to withhold Medicaid reimbursement from abortion providers. Further, the Seventh and Ninth Circuits have interpreted Medicaid's "free choice of provider" provision—guaranteeing Medicaid recipients' freedom to choose their family planning providers—as a legal impediment to prohibiting abortion providers from receiving federal Medicaid funding.

- However, in *Planned Parenthood v. Indiana* the Seventh Circuit *upheld* Indiana's prohibition on abortion providers receiving funding through the federal Disease Intervention Services agency (DIS), for the diagnosis and monitoring of sexually transmitted diseases. The Seventh Circuit explained that the key difference between the provision upheld and the provision struck down was that the DIS program did *not* have a federal statutory limitation (similar to Medicaid's "free choice of provider" provision) on how states could determine eligibility.

- Title X is the only federal grant program dedicated solely to providing family planning and related preventive care and is viewed as setting the standard for publicly funded family planning services. Priority is given to low-income families. Title X provides that "none of the funds appropriated … shall be used in programs where abortion is a method of family planning." Public and private entities may obtain grants.

- Since 2011, numerous states have enacted laws requiring subrecipients of Title X funds to provide comprehensive healthcare to patients and/or refrain from performing abortions. In response, the federal government is actively circumventing the Title X prioritization laws in at least eight states by directly contracting with private entities such as Planned Parenthood.

- Further, on Sept. 9, 2016, HHS issued a proposed rule stating that "[n]o recipient making sub awards for the provision of services as part of its Title X project may prohibit an entity from participating for reasons unrelated to its ability to provide services effectively." In the proposed rule background, HHS states that "13 states have placed restrictions on or eliminated sub awards with specific types of providers. . . ."

Chapter III. Panel Hearings

- The Panel held two public hearings to examine critical issues within its jurisdiction. In the first hearing on *Bioethics and Fetal Tissue*, the Panel noted that there have been several government-sponsored discussions on bioethics, but none directly on the transfer of fetal tissue since the 1980s.

- The hearing revealed substantial concern about the consent process for the donation of human fetal tissue used by abortion clinics and tissue procurement businesses (TPBs). Evidence revealed that self-interested staff, whose pay depends on the numbers of specimens donated, were assigned to obtain consent from patients.

- Additional evidence showed that tissue technicians and the abortion clinics violated the patient's privacy rights under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Still other evidence revealed that some TPBs misrepresented that the consent forms and methods of tissue harvesting comply with federal regulations regarding Institutional Review Boards (IRBs). This evidence points toward conduct focused on profit and not on patient welfare.

- The Panel's next hearing, *The Pricing of Fetal Tissue*, sought the judgment of seasoned federal prosecutors to compare the federal statute prohibiting profit from fetal tissue sales with the first tranche of materials from the investigation.

- Two former U.S. attorneys and a senior federal litigator agreed that based on the materials presented to them, they would open a case against a TPB. The former

prosecutors also suggested that accounting and bank records would be critical to understanding whether there was a violation of federal law. Minority witnesses agreed with this approach and urged the panel to obtain such records.

Chapter IV. The Criminal Referrals

The Select Investigative Panel has made numerous criminal and regulatory referrals and investigations are underway around the nation.

1) The Panel learned that StemExpress and certain abortion clinics may have violated the HIPAA privacy rights of vulnerable women for the sole purpose of increasing the harvesting of fetal tissue to make money. Referred to the U.S. Department of Health and Human Services.

2) The Panel uncovered evidence showing that StemExpress may have violated federal regulations governing Institutional Review Boards (IRBs). Referred to the U.S. Department of Health and Human Services.

3) The Panel discovered that the University of New Mexico may have been violating its state's Anatomical Gift Act by receiving tissue from a late-term abortion clinic (Southwestern Women's Options). Referred to the Attorney General of New Mexico.

4 & 5) The Panel conducted a forensic accounting analysis of StemExpress' limited production and determined that it may have been profiting from the sale of baby body parts. Referral sent to El Dorado, California District Attorney, and the U.S. Department of Justice.

6) The Panel discovered that an abortion clinic in Arkansas may have violated the law when it sent tissue to StemExpress. Referred to the Attorney General of Arkansas.

7) The Panel discovered that DV Biologics, another tissue procurement company, may have been profiting from the sale of fetal tissue, and was not collecting California sales tax from purchasers of the baby body parts. The Orange County District Attorney has filed a lawsuit and the Panel sent a supplemental referral.

8) The Panel learned that Advanced Bioscience Resources appeared to have made a profit when it sold tissue to various universities. Referred to the District Attorney for Riverside County, California.

9) The Panel discovered that an abortion clinic in Florida, at least in part through its relationship with StemExpress, may have violated various provisions of federal and state law by profiting from the sale of fetal tissue. Referred to the Attorney General of Florida.

10) The Panel learned that Planned Parenthood Gulf Coast may have violated both Texas law and U.S. law when it sold fetal tissue to the University of Texas. Referred to the Texas Attorney General.

11 & 12) The Panel has uncovered evidence from former employees and a patient of a late-term abortionist in Texas alleging numerous violations of federal and state law at one or more of the practitioner's clinics. The allegations include eyewitness accounts of the doctor killing infants who show signs of life both when partially outside the birth canal, in violation of the Partial-Birth Abortion Ban Act, and after they are completely outside the birth canal, in violation of the Born-Alive Infants Protection Act and Texas murder statutes. Referred to the Texas Attorney General, and the U.S. Department of Justice.

13) The Panel has discovered information that StemExpress may have destroyed documents that were the subject of congressional inquiries, document request letters, and subpoenas, in violation of 18 U.S.C. § 1519. Referred to the U.S. Department of Justice.

14) The Panel made a supplemental referral to the Attorney General of New Mexico based on information produced in document productions by the University of New Mexico (UNM) and Southwestern Women's Options (SWWO), deposition testimony by *Doctor #5*, and a complaint and affidavit with supporting documents submitted by a former patient at SWWO. It details the alleged failure of SWWO and UNM to provide informed consent to women prior to using tissue from abortions for research at the university.

15) Over the course of its investigation, the Panel has uncovered documents and received testimony from confidential informants indicating that several entities, including four Planned Parenthood clinics and Novogenix, may have violated federal law, specifically Title 42 U.S.C. § 289g-2, which forbids the transfer of fetal tissue for valuable consideration. Referred to the U.S. Department of Justice.

Chapter V. Case Studies of the Fetal Tissue Industry – The Middleman Model

A. StemExpress

- StemExpress' business model was designed to obtain fresh fetal tissue from a large number of abortion clinics and provide on-demand fetal tissue to researchers around the world. StemExpress sought to sell fetal tissue "on demand" through an online procurement application.

- In 2010, StemExpress' revenue was $156,312. During 2011, that figure more than doubled to $380,000, and a year later, in 2012, StemExpress' revenue nearly tripled to $910,000. By 2013, its revenue was $2.20 million, and in 2014 the revenue had once again more than doubled to $4.50 million.

- In an attempt to expand the number of abortion clinics from which it procured fetal tissue and provide fetal tissue to a larger number of researchers, StemExpress developed and distributed a brochure aimed at abortion clinics nationwide. Further, they attempted to enter partnership agreements with the National Abortion Federation and Planned Parenthood Federation of America. If those agreements had been consummated, StemExpress would have had access to virtually every abortion clinic in the nation.

- The Panel learned that StemExpress embedded its tissue technicians at the Planned Parenthood facilities. StemExpress' embedded tissue technicians had advance knowledge of the abortions scheduled at PPFA clinics. The Panel determined that clinic personnel gave StemExpress' tissue technicians access to patients' personal medical information, in violation of federal law. The Panel determined that StemExpress' tissue technicians obtained consent to donate fetal tissue from women scheduled to undergo an abortion, procured the fetal tissue, packaged it, and shipped it directly to StemExpress' customers.

- When they obtained consent to donate fetal tissue at Planned Parenthood affiliates, the StemExpress tissue technicians used Planned Parenthood's consent form. A Planned Parenthood executive testified that the Planned Parenthood consent form was misleading and could possibly be coercive. Federal regulations bar such coercion.

- StemExpress used a consent form similar to Planned Parenthood's form at the independent abortion clinics. That form purportedly was approved by BioMed IRB, a commercial IRB that was sanctioned by the federal government for multiple violations of federal regulations. The Panel issued a subpoena to BioMed IRB; however, they produced no documents and told the Panel they had no records reflecting supervision of StemExpress' procurement activities.

- StemExpress entered contracts to procure fetal tissue from three Planned Parenthood affiliates and five independent abortion clinics. StemExpress paid those abortion clinics a total of $152,640 for fetal tissue. The Panel determined that the Planned Parenthood affiliates at which StemExpress procured fetal tissue had no legally reimbursable costs.

- The Panel sought to determine whether the doctors working at the abortion clinics changed their abortion procedures in order to increase the amount of fetal tissue StemExpress could obtain and thereby generate more revenue for the clinics. The director of one independent women's clinic from which StemExpress procured fetal tissue admitted that the abortion clinic changed its clinical practices to procure more liver. A Planned Parenthood executive acknowledged making changes to obtain tissue as well.

- The Panel uncovered evidence that StemExpress may have violated 18 U.S.C. § 1519 through StemExpress' potential destruction of documents that were the subject of congressional inquiries, document request letters, and subpoenas. The Panel made a criminal referral to the U.S. Attorney General.

- The Panel uncovered evidence that StemExpress may have violated 42 U.S.C. § 289g-2, and Cal. Health & Safety Code § 125320(a) by the receipt of valuable consideration in the form of a profit on its procurement and sale of fetal tissue. The Panel made a criminal referral to the U.S. Attorney General and the El Dorado, California District Attorney.

- The Panel uncovered evidence that StemExpress may have violated the Health Insurance Portability and Accountability Act of 1996 (HIPAA) by accessing women's private health information. StemExpress did not have a medically valid reason to see that information. The Panel made a referral to the U.S. Department of Health and Human Services.

- The Panel found evidence that StemExpress may have violated federal regulations on informed consent and Institutional Review Boards. The Panel made a referral to the U.S. Department of Health and Human Services.

- The Panel issued a subpoena to StemExpress that required the production of its banking and accounting records. StemExpress refused to produce any of those records. Due to StemExpress' refusal to comply with repeated subpoenas, the Panel recommended that the House of Representatives hold StemExpress in contempt of Congress.

B. DaVinci Biosciences, LLC/DaVinci Biologics, LLC

- The Panel sought to determine whether DaVinci Biosciences, LLC (DaVinci), and DaVinci Biologics, LLC (DVB) may have violated 42 U.S.C. § 289g-2 and an equivalent provision of the California Health and Safety Code.

- The Panel determined that DaVinci and DVB appeared to operate a profit-driven business.

- The Orange County, California District Attorney filed a lawsuit that alleged DaVinci and DVB appeared to operate a profit-driven business and thus violated 42 U.S.C. § 289g-2.

- DaVinci and DVB charged considerably more for fetal tissue and cell lines derived from that tissue than the costs it incurs.

- The firms' business and marketing plans show that officers and directors pushed their employees to sell more and more tissue, and thus increase DaVinci and DVB's bottom line.

- The company's sole source of fetal tissue was Planned Parenthood of Orange and San Bernardino Counties (PPOSBC).

- DVB senior executives made charitable contributions to PPOSBC before the company's contract to procure fetal tissue from PPOSBC was signed.

- The DVB executives made further contributions to PPOSBC before the first procurement, and those contributions continued.

- The Panel uncovered evidence that DaVinci and DVB may have violated provisions of the California Tax Revenue and Tax Code. The Panel made a referral to the Orange County (California) District Attorney.

C. Novogenix Laboratories, LLC

- The Panel sought to determine whether Novogenix Laboratories, LLC (Novogenix) complied with all applicable federal and state laws.

- The Panel determined that Novogenix may have violated 42 U.S.C. § 289g-2, provisions of the California Health & Safety Code and the California Revenue and Tax Code, and federal regulations.

- Novogenix had a contract to procure fetal tissue from Planned Parenthood Los Angeles (PPLA). The contract provided that Novogenix would reimburse $45 per donated specimen.

- Invoices produced to the Panel by some of Novogenix's customers show that it received a total of $170,980.59 from seven research institutions between June 2011 and December 2015. The Panel cannot determine either the total number of Novogenix' customers, nor its revenue.

- Novogenix represented that it lost a total of $160,540.03 on its fetal tissue operations, but conceded that its counsel created the firm's expenses and revenue document. The Panel cannot rely on the expenses and revenue document to determine whether Novogenix actually lost money on its fetal tissue operations, because it was created by Novogenix's counsel, and Novogenix produced no primary source accounting records.

- The list of expenses included an unknown amount for attorney fees. Such fees are not included under the list of allowable reimbursements under 42 U.S.C. § 289g-2. The list of expenses also included minimal amounts for delivery to researchers. Invoices produced to the Panel by Novogenix customers show the firm charged delivery fees of up to $122.43 per shipment, raising further questions about the reliability of the attorney-created cost document.

- PPLA personnel obtained consent from patients to donate tissue from their aborted fetuses using the standard Planned Parenthood Federation of America (PPFA) consent form. That form contends that fetal tissue has been used to find a cure for such diseases as diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS. There is no cure for those diseases.

- Numerous witnesses, including senior PPFA officials, testified that the consent form is misleading and unethical due to its contention that fetal tissue has been used to find a cure for diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS.

- Federal regulations provide that entities cannot coerce pregnant women into the donation of fetal tissue. PPFA officials acknowledged to the Panel that the language in the PPFA consent form may be coercive. Therefore, Novogenix may have violated federal regulations.

- The California Revenue and Tax Code requires entities that collect sales tax on transactions made over the Internet within the state of California. The Panel has determined that Novogenix sold its services to customers in California; it should have collected tax on some of those transactions.

D. Advanced Bioscience Resources, Inc.

- Advanced Bioscience Resources (ABR), a non-profit corporate foundation, was started in 1989 as a resource for "biomedical, scientific, and educational purposes." It obtains fetal tissue from abortion clinics and offers it to researchers for a fee. ABR generally pays abortion clinics a flat per-tissue fee regardless of the type or amount of tissue procured. The tissue is obtained by tissue technicians embedded by ABR in abortion clinics. The technicians harvest, package, and ship the tissue to the researchers. The abortion clinic staff obtains consent from the patients for fetal tissue donations. ABR's business model is similar to that of StemExpress.

- The Panel conducted an investigation of ABR and uncovered evidence that ABR may have violated 42 U.S.C. § 289g-2 and the California Health and Safety Law. Therefore, the Panel sent criminal referrals to U.S. Attorney General Loretta Lynch and the District Attorney of Riverside County, California, urging both to investigate whether ABR violated federal and state statutes and regulations, and to take appropriate action if the investigations reveal criminal behavior.

E. Human Fetal Tissue Repository (Albert Einstein College of Medicine)

- The Panel sought to determine whether the Human Fetal Tissue Repository (HFTR) fully complied with applicable federal law and regulations. HFTR only produced a partial list to the Panel of the entities from which it received and to which it distributed fetal tissue. The Panel had insufficient evidence to determine whether HFTR complied with the applicable federal law.

- The Panel sought to determine how HFTR disposed of its stored fetal tissue after its closure. The Panel had insufficient evidence to make that determination; however, there are indications that Albert Einstein College of Medicine (Einstein) offered the tissue to the Planned Parenthood Federation of America (PPFA).

- HFTR received fetal tissue from three New York City hospitals and distributed the tissue to researchers at Einstein and fourteen other educational and research institutions.

- The Panel sought to determine HFTR's procurement procedures, including whether it had contracts with the hospitals from which it procured fetal tissue. Due to the lack of records provided by Einstein, the Panel had insufficient evidence to determine whether HFTR had contracts with those medical facilities; how much, if anything, HFTR paid for the tissue; whether the hospitals or HFTR obtained consent; how the consent was obtained; and the content of the consent form.

- The Panel sought to determine the number of women from which HFTR obtained fetal tissue, and the number of fetal tissue samples HFTR obtained. Documents produced by Einstein to the Panel show that a total of 2,701 subjects were "enrolled" in HFTR studies. The Panel had insufficient evidence to determine the number of fetal tissue samples HFTR obtained.

- The Panel sought to determine whether HFTR complied with the applicable federal regulations on research. HFTR required researchers to do the following: submit summaries of their IRB-approved protocol; provide a copy of their IRB approval letters; state what tissues they will use for their study and why they must use human tissue generally and fetal tissue in particular; and agree to use the samples in compliance with all applicable laws and regulations.

- Based solely on HFTR's limited productions, The Panel determined that it appeared HFTR complied or at least attempted to comply with the applicable HHS regulations. The Panel has insufficient evidence to make a conclusive determination whether HFTR and the research institutions to which it supplied fetal tissue fully complied with the applicable federal regulations.

Chapter VI. Case Studies of the Fetal Tissue Industry—The University/Clinic Model

- The Panel identified several research institutions across the United States, mostly state universities and virtually all recipients of federal as well as state funding, that have formed a close relationship with one or more abortion clinics.

- These institutions regularly acquire tissue from those clinics for research purposes and in some cases disseminate fetal tissue to other research institutions. Typically, the research institution requests specific human fetal organs or tissue, of a specific gestational age, from an abortion clinic, and the clinic informs the research institution when they have abortions scheduled that may produce the desired fetal body parts. Over time, the clinic thus learns which human fetal organs and tissue are useful to the research institution and often alerts the research institution to their availability without prior solicitation. Once

available, the research entities make arrangements to transfer the fetal organs and tissue from the clinic.

- In some cases, the research institutions also have relationships with tissue procurement companies. In still other cases, partnerships do not involve the transfer of fetal tissue between the clinics and universities, but they share medical school faculty and residents in common, raising additional issues about the role of government-funded institutions in driving demand for fetal tissue.

- The Panel sought to understand these and other factors relevant to its analysis of fetal tissue transactions under 42 U.S.C. § 289g-2 and to determine what role, if any, government funding plays in the transactions between abortion clinics and universities.

- The Panel examined the relationship between the University of New Mexico (UNM) and Southwestern Women's Options (SWWO), a late-term abortion clinic near the university that performs abortions through the third trimester. A tissue technician employed by UNM traveled to SWWO to procure human fetal organs or tissue an average of 39 times a year since 2010.

- The transfer of fetal tissue from SWWO to UNM was one part of an aggressive campaign under which leadership personnel at UNM medical school: (1) expanded UNM's role both in providing abortions and in training new abortion providers; (2) expanded UNM's referral for abortion services to outside clinics, including the clinic from which it obtained fetal tissue; (3) supplied residents and fellows to perform abortions for SWWO during the period that UNM was obtaining fetal tissue from that clinic; (4) expanded the faculty of UNM by providing "volunteer faculty" status to local abortionists; (5) provided staff physicians for the Planned Parenthood in Albuquerque from UNM faculty after that clinic transitioned from one owner to another; and (6) leveraged their status to organize UNM employees and students for partisan political activities.

- The close relationship between UNM and SWWO led to allegations of shoddy clinical practices, including failure to utilize a consent form for fetal tissue donation and improperly combining consent for tissue donation with consent for the underlying abortion procedure. The Panel found the consent practices appeared to violate both federal and state law governing informed consent. It also found that the transfer of fetal tissue from SWWO to UNM for research purposes is a systematic violation of New Mexico's Spradling Act, under which tissue from aborted infants cannot be anatomical gifts.

- While UNM may not have made direct payments to SWWO for the fetal tissue it received, UNM did provide the clinic a substantial value in the form of personnel offered to the clinic, in addition to conferring upon at least three staff physicians at SWWO faculty positions. Those positions gave them numerous benefits—including professional liability insurance coverage for UNM activities, access to university facilities, and

discounts. Because they did not have teaching responsibilities, these faculty members provided UNM no apparent benefit apart from the fetal tissue that came from SWWO, giving their relationship the components of an exchange of fetal tissue for valuable consideration.

- At a minimum, this arrangement violates the intent and spirit of 42 U.S.C. § 289g-2. Additionally, SWWO made a statement to the Panel that it "does not participate 'in research, study, or other work involving fetal tissue,'" which appears to be belied by both the internal and published documents that constitute evidence that the clinic and its personnel did in fact participate in fetal tissue research beyond supplying the tissue to UNM.

- The Panel's investigation into the nation's largest fetal tissue bank, the University of Washington's Birth Defects Research Laboratory (UW BDRL), and outside abortion clinics provides another example of the interdependence of clinics and public research institutions. UW BDRL received over $600,000 from the NIH for FY 2015. Over the last five years, over a dozen clinics have provided UW BDRL fetal tissue, and 40 universities or other public research institutions have been recipients of fetal tissue. UW BDRL claims that recipients of tissue are charged a flat fee of $200 regardless of the nature of the tissue researched and that the only payments it makes to clinics are to cover costs.

- The university failed to make a complete production, however. The Panel's independent research found that UW BDRL deploys doctors to outside abortion clinics and that numerous physicians on the staffs of those clinics hold faculty positions at UW BDRL. The invoices produced by UW BDRL are heavily redacted, rendering it impossible without more information to conduct a full forensic analysis under 42 U.S.C. § 289g-2 of payments made to and by UW in connection with transfers of fetal tissue.

- The Panel conducted an investigation of Planned Parenthood Gulf Coast (PPGC), a Planned Parenthood Federation of America (PPFA) affiliate that had its own research department. The Panel uncovered evidence that PPGC may have violated 42 U.S.C. § 289g-2 and Texas Penal Code § 48.02, which bar the offer to sell or transfer fetal tissue in its procurement of fetal tissue for the University of Texas Medical Branch (UTMB) and Baylor College of Medicine (BCM). The Panel also uncovered evidence that PPGC may have violated Texas Penal Code § 37.08, which makes it a crime to lie to a law enforcement officer during the course of an investigation. The Panel referred those potential violations of state law to the Texas Attorney General.

- The Panel determined that PPGC may have violated PPFA's own guidelines on programs for the donation of fetal tissue. PPFA required its affiliates that engage in fetal tissue donation to document their actual costs through an independent accountant, or accept no reimbursement. A PPGC official testified that PPGC determined its reimbursement from UTMB and BCM by back of the envelope calculations. PPGC thus had no actual knowledge of its costs.

- The Panel determined that PPGC charged UTMB $150 per executed consent, $50 if the UTMB technician did not transport the tissue, $2,000 a year in administrative and training fees, and $1,500 in staff time. Had PPGC obtained 500 patient consents for UTMB, as specified in an unexecuted contract, UTMB would have paid PPGC $75,000 for consents alone. PPGC sought to enter into a contract with BCM that contained similar payment terms. The Panel determined that BCM's Institutional Review Board (IRB) had approved the contract to procurement fetal tissue from PPGC.

- The BCM-PPGC contract negotiations terminated after a PPGC official told BCM the affiliate would not commit to the procurement or provision of fetal tissue, and stated that Texas academic institutions "cannot remain publicly silent" about their need for human fetal tissue, yet expect that "research collaboration with Planned Parenthood will remain intact." Those comments were made after the Center for Medical Progress videos were made public. A PPGC official testified that the videos were the reason for the statement.

- Nearly a year later, PPGC's attorney told Texas law enforcement officials that the reason the BCM arrangement never came to fruition was that BCM's IRB did not approve it. The Panel determined that comment was false. PPGC officials knew that BCM's IRB had approved the research project, despite the representations of PPGC's attorney to Texas law enforcement officials.

- The University of Minnesota (UM) is an example of a university that obtains fetal tissue from procurement companies—in this case, Advanced Bioscience Resources (ABR) and StemExpress—in addition to an area clinic. UM disclosed that "approximately 10 researchers at the University of Minnesota" have used such tissue "currently or in the recent past" and that UM was the recipient of well over $1 million in NIH grants for projects that used fetal tissue. UM's produced invoices from ABR show charges ranging from $275 to $2,675 that reflected ABR's varying fee schedule for different types of fetal tissue, raising questions of liability under 42 U.S.C. § 289g-2 that have been examined in the above analysis of ABR and StemExpress.

- UM's underlying fetal tissue practices potentially violate Minnesota's Anatomical Gift Act, which does not permit the donation of fetal tissue resulting from induced abortions, and another law requiring disposal of fetal remains by cremation or burial. Following disclosure of its practices, UM changed its policy to require such tissue to come from sources outside Minnesota, raising the question of whether Congress should pass legislation that would prohibit the crossing of state lines to evade state restrictions on fetal tissue use.

- Between 2010 and 2015, Colorado State University (CSU) received $3.5 million in NIH grants to support projects using fetal tissue, and it had a contractual relationship with Planned Parenthood of the Rocky Mountains (PPRM) under which CSU personnel were permitted to collect tissue from the PPRM clinic. The contract permitted reimbursement by CSU to PPRM for its "reasonable expenses incurred during the tissue process," but questions surround the actual charges, including a $1,500 charge to the University for

"Administrative Start Up" and $1,600 for consent and processing for 10 specimens. Amid the public scrutiny surrounding fetal tissue practices, CSU halted acquisition of fetal tissue from any vendors implicated in the investigation.

- Two university training programs for abortion providers, the Ryan Residency Training Program in Abortion and Contraception and the Fellowship in Family Planning, began at the University of California San Francisco (UCSF)'s Bixby Center for Global Reproductive Health. Funded by the Susan Thompson Buffett Foundation, both programs deploy and pay doctors to provide abortion and contraception services. The Fellowship in Family Planning spread to around 30 other universities and presently has 246 graduated fellows. The Ryan Program now claims 80 sites in the U.S. and Canada. UCSF is also directly involved in fetal tissue research, a component of research projects for which the university received $17.5 million from the NIH.

- Planned Parenthood of the St. Louis Region and Southwest Missouri (PPSLR), reportedly the only clinic in Missouri that provides abortions, was referenced in one of the undercover CMP videos as extensively involved in fetal tissue research, a matter that merits further inquiry. In a separate investigation, the Majority Caucus of the Missouri State Senate concluded, PPSLR "may very well have violated both state statute and Department of Health regulations in their [fetal] disposal practices."

- The Panel's investigation found that five PPSLR physicians also hold faculty positions at the Washington University School of Medicine, which offers the Ryan Fellowship as a vehicle to deploy medical residents to perform abortions at PPSLR. Further investigation is warranted into whether monetary payments or other value is exchanged among the entities' shared personnel.

- The University of Wisconsin, School of Medicine and Public Health (UW SMPH) has deployed both faculty members of its Ob/Gyn department and medical residents (by way of the Ryan Fellowship) to work at a clinic designated by Planned Parenthood of Wisconsin (PPWI). This relationship appears to have been part of a broader plan that included the procurement and transfer of fetal tissue to UW SMPH for research. The school maintains it has not obtained fetal tissue from PPWI since November 2010. The deployments continue, however. UW SMPH has more recently obtained fetal tissue for research from the Albert Einstein College of Medicine, UW, and ABR. The average charge in a UW invoice produced to the Panel, which is under $300, is lower than the lowest charge by ABR in its invoices, which range from $310 to $2,200. Given the problematical nature of ABR's practices under 42 U.S.C. § 289g-2, further investigation is warranted.

- The University of Michigan (UMich) conducts research using fetal tissue obtained from tissue procurement businesses and universities. Physicians from UMich's Health System staff a Planned Parenthood clinic in Ann Arbor, Michigan, and medical students are eligible to provide abortions there through the Ryan Fellowship. One doctor who is both medical director for Planned Parenthood and an associate professor in UMich's Ob/Gyn

department told a Center for Medical Progress journalist that the "University of Michigan IRB . . . tend to be pretty easy about stuff and actually not require informed consent." She also claimed research projects involving fetal tissue involve "grants to the agency to cover my time," raising the question of whether the grants she refers to cover more than the permissible reimbursements for costs under 42 U.S.C. § 289g-2.

Chapter VII. Case Studies of Late-Term Abortion Clinics

- The business practices and procedures of late-term clinics implicate numerous legal and ethical concerns. When human infants are born alive in late-term abortion clinics or hospitals, abortion providers are obligated to ensure that these infants are afforded all of the protections guaranteed by federal and state law. A careful investigation of late-term abortion providers is necessary to ensure that entities are complying with the federal Born-Alive Infants Protection Act, Partial-Birth Abortion Ban Act, 42 U.S.C.§ 289g, *et seq.*, federal regulations pertaining to human fetal tissue research, and state laws, including anatomical gift laws.

- The significance of this inquiry includes the issue of the taxpayers' indirect support of late-term abortion. In fact, most of the doctors west of the Mississippi who openly perform third-trimester abortions have faculty positions at either the University of New Mexico or the University of Colorado. The broad public disapproval of such practices raises the question of why institutions that receive public funds should carry the tacit imprimatur imparted by institutional affiliation.

- The Panel investigated several abortion providers and clinics across the country: [Abortion Doctor #1], [Abortion Doctor #2], [Abortion Doctor #3], the University of New Mexico, and Southwestern Women's Options. Due to the gravity of the allegations against [Abortion Doctor #3], the Panel made a criminal referral forthwith to both the United States Attorney General and the Texas Attorney General on December 7, 2016.

Chapter VIII. Case Studies of the Fetal Tissue Industry – Planned Parenthood

- Planned Parenthood executives who spoke with the Panel noted that 2016 is the 100th anniversary of the founding of Planned Parenthood. A closer look at the history of the organization, however, leaves little to celebrate. The organization was founded by eugenicists who believed in limiting the rights of people to form families and have children if they had mental or physical disabilities or were of the "wrong" race.

- Harvard studies about Planned Parenthood's business model have pointed out financial struggles the organization has faced in recent years, including smaller margins and lower revenues. Substantial evidence exists that Planned Parenthood clinics—at least 51

times—have overbilled Medicaid and improperly billed items to cover the costs of abortion services, in violation of the Hyde Amendment.

- During some of Planned Parenthood's difficult financial years, tissue procurement companies like StemExpress saw an opportunity to market their services to Planned Parenthood affiliate clinics and even the entire Federation. This move was welcomed by top Planned Parenthood executives, some of whom were remarkably candid about the revenue possibilities for clinics.

- However, the relationships that have formed between tissue procurement companies, abortion clinics, and universities are fraught with questionable practices, including the possible use of illegal, late-term abortion practices to procure fetal tissues and organs, violations of federal laws and regulations on patient consent, and systematic violations of patients' HIPAA rights.

- PPFA doctors have failed to comply with their own requirement obligating abortionists to certify in writing that they have not changed the method of the abortion to facilitate fetal tissue donation. The PPFA executive in charge of this requirement admitted to Panel staff that she has never signed a document certifying this. She additionally admitted that she regularly changed the method of abortion to facilitate intact fetal specimens.

- The Panel found no compliance with an additional PPFA requirement in a memorandum sent to affiliates by PPFA's legal department. That requirement obligated affiliates to rely on an auditor before entering into a fetal tissue donation program to ensure that fees covering allowable costs did not exceed valuable consideration. In fact, one executive told Panel staff she only uses "back of the envelope" methods to determine costs associated with the donations.

- Not only did the Panel find a shocking lack of compliance with both internal and federal regulations, but executives admitted to undercover journalists that the PPFA exercises very little control of their affiliated clinics. One even said that if clinics wanted to profit from the transfer of fetal tissue, "We can't stop them. We only have carrots and sticks."

- Accounting documents from a tissue procurement company, StemExpress, and its bank reveal substantial payments to Planned Parenthood clinics. Some expenses associated with fetal tissue donation—like storage and preservation—are allowed under federal regulations, but the Panel's analysis of these accounting records found that *both StemExpress and Planned Parenthood* claimed the same expenses.

- One of the expenses Planned Parenthood frequently claimed was "staff time" related to fetal tissue donation. However, the Panel's analysis of hundreds of Planned Parenthood job descriptions revealed that none mention the acquisition, handling or transfer of fetal tissue.

- Planned Parenthood claims it made no profit. The Panel, therefore, asked for accounting documents to prove this. Instead of turning over the records that could have proved them innocent, PPFA refused. Its lawyers wrote that "[t]he affiliates have each performed a good-faith accounting of their costs associated with facilitating fetal tissue donation, and have demonstrated conclusively that those costs exceeded the payments they received."

- "We didn't profit because we say we didn't profit" is not compliance with congressional requests for documents. Because Planned Parenthood refused to provide actual documents supporting their claim, the Panel resorted to analyzing accounting documents from middlemen companies who contracted with Planned Parenthood affiliates.

Chapter IX: Biomedical Research and Human Fetal Tissue

A. The United States Biomedical Research Enterprise is a Success: The Select Panel recognizes and supports the success of the United States biomedical research enterprise.

- The 2014 gross expenditure on Research and Development (R&D) in the United States exceeded $485 billion, or nearly 27% of the global R&D budget.

- The 2012 biomedical research expenditures in the United States exceeded $119 billion, with the next largest national investment being made by Japan, at just over $37 billion

- Between 2000-2013, the Unites States published approximately 40% of all papers in the area of stem cell research, with the next closest contributor (the United Kingdom) producing less than 10% of all published research in this rapidly advancing field.

B. Scientific societies and universities have made misleading claims about fetal tissue research: The Select Panel has received letters from 21 institutions that claim to provide evidence for the value of human fetal tissue research. The assertions of these letters fall into 8 general classes and have been uncritically repeated in the Minority report. In reality, **not a single responding institution provided substantive evidence for the value of fetal tissue research.**

- **Claim: The activities of the House Select Panel have identified scientists using fetal tissue, thereby putting them at risk:**

  False. The names, institutions and collaborators of individuals conducting human fetal research are made publicly available by the NIH.

- **Claim: Fetal tissue was used to produce vaccines for polio, measles, mumps and rubella.**

  False. These vaccines were all first produced using animal cells, not fetal tissue.

- **Claim: Fetal tissue is used for modern vaccine manufacture.**

  False. Not a single vaccine licensed in the United States is manufactured using fetal tissue.

- **Claim: We need fetal tissue to cure Zika and other brain diseases.**

  False. Fetal tissue is not widely used for Zika research and vaccines for similar viruses have not been based on human fetal tissue research.

- **Claim: Fetal tissue is important for a wide range of research.**

  False. Human fetal tissue is used in a tiny fraction of all NIH-funded research: 0.2% of the over 76 thousand NIH-funded projects.

- **Claim: Fetal tissue is important for clinical trials**.

  False. In over 100 years of unrestricted clinical research, human fetal tissue has failed to provide a single medical treatment: Human fetal tissue is used for only 0.01% of the over 230 thousand FDA-approved clinical trials—and thus far, no trials using human fetal tissue have reported positive results for patients.

- **Claim: Fetal tissue is required for scientific models such as the "humanized mouse."**

  False. Alternatives exist and are widely used.

- **Claim: Human fetal tissue is "necessary" to validate adult and induced-pluripotent stem (iPS) cells.**

  False. Almost no papers using adult and iPS cells also use fetal tissue.

C. Response to the claim that "The Select Panel Has Thwarted Life-Saving Research:" The Minority report asserts that human fetal tissue is important for research on many diseases. In reality, human fetal tissue research makes a vanishingly small contribution to clinical and research efforts, if it contributes at all (Table 1, below).

D. Analysis of "successful," long-standing human fetal-tissue research: Over the last five years (2010-14), the NIH has awarded 329 grants using human fetal tissue. **This represents 0.2% of all grants.** The Panel selected 34 "successful" fetal tissue grants that have been funded for over ten years and analyzed them in detail to objectively answer three important questions:

1. How many successful grants actually require human fetal tissue to perform the proposed experiments (*i.e.*, there are no alternatives proposed by the investigator or used in the literature)? **Answer - Eight grants of 34 (24%) actually require fetal tissue.**

2. How productive are projects involving human fetal tissue compared to non-fetal research? **Answer - Non-fetal projects produce 2.3x as many papers as fetal projects.**

3. What is the importance/impact of papers using human fetal tissue compared to non-fetal papers? **Answer - Non-fetal papers receive 2.1x more citations than fetal tissue papers.**

Conclusion: Human fetal tissue constitutes only a tiny fraction of the overall research effort. Moreover, research involving human fetal tissue is less productive and has lower importance/impact when compared to non-fetal research from the same laboratories.

E. Recommendations for improving access to ethical and appropriate scientific models

- **Recommendation 1:** Congress will appropriate funding to the NIH for a trial of expanding the organ-donation network to included preterm and stillborn infant donors, ***excluding*** tissue from elective termination of pregnancy.

- **Recommendation 2**: The NIH will undertake a study of research demand for adult human tissue and possible methods for facilitating the acquisition of this tissue for research.

- **Recommendation 3:** The NIH will establish guidelines for the use of human fetal tissue (modeled on the guidelines for animal research) and will mandate that these guidelines be applied to all grants proposing the use of human fetal tissue.

- **Recommendation 4**: The NIH will adopt a three-tiered classification system for proposals involving human fetal tissue as indicated below:

  Class 1: Fetal tissue is required for the proposed study. There are no reasonable alternatives.

  Class 2: Fetal tissue is not essential for the study. There are some scientific advantages to the use of fetal tissue, but alternatives exist.

  Class 3: Fetal tissue is not essential for the study. There are no scientific advantages to the use of fetal tissue, and alternatives exist.

- **Recommendation 5:** The NIH will report to Congress on the use of parent-donated tissue from natural demise of preterm children, anticipated by Recommendation 1 above, and Congress shall appropriate funds for an expansion of this program and disallow grants funded by federal dollars to utilize human fetal tissue obtained from induced abortion.

Table 1: Contribution of human fetal tissue to disease research.

Diseases Identified in the Minority Report	Grants Awarded 2015			Clinical trials			Peer Reviewed Papers		
	Fetal	Total	%	Fetal	Total	%	"Fetus"	Total	%
Alzheimer's	0	1362	0.0%	0	1956	0.0%	109	75704	0.1%
Amyotrophic lateral sclerosis	0	152	0.0%	3	360	0.8%	33	14859	0.1%
Diabetes Mellitus	6	2382	0.3%	1	14807	0.01%	1486	353110	0.4%
HIV/AIDS	74	4935	1.5%	0	7950	0.0%	372	87756	0.4%
Infant and Childhood Leukemia	0	339	0.0%	0	750	0.0%	21	1996	1.1%
Age-related Macular degeneration	5	187	2.7%	10	1371	0.7%	15	18826	0.1%
Preterm birth*	4	355	1.1%	0	3375	0.0%	503	9006	5.6%
Spinal cord injury	0	249	0.0%	8	907	0.9%	49	41461	0.1%
Vaccine research	28	2509	1.1%	0	7024	0.0%	509	280174	0.2%
Zika/Brain Disorders**	158	52338	0.3%	0	18	0.0%	6	1926	0.3%
Diseases Arising in the Fetus and/or Affecting Children	**Grants Awarded 2015**			**Current clinical trials**			**Peer Reviewed Papers**		
	Fetal	**Total**	**%**	**Fetal**	**Total**	**%**	**"Fetus"**	**Total**	**%**
Attention Deficit Disorder	0	121	0.0%	0	1277	0.0%	23	23079	0.1%
Autism	2	506	0.4%	0	741	0.0%	43	17711	0.2%
Batten Disease	0	15	0.0%	0	23	0.0%	7	1761	0.4%
Epilepsy	2	397	0.5%	0	1404	0.0%	289	141397	0.2%
Hydrocephalus	0	15	0.0%	0	135	0.0%	275	21192	1.3%
Intellectual disabilities	10	1025	1.0%	0	541	0.0%	1255	86516	1.5%
Pediatric AIDS	0	467	0.0%	0	350	0.0%	8	1586	0.5%
Pediatric cancer	0	760	0.0%	0	1642	0.0%	302	56854	0.5%
Spinal muscular atrophy	0	34	0.0%	0	157	0.0%	15	1050	1.4%
Sudden Infant Death Syndrome	1	31	3.2%	0	89	0.0%	78	7094	1.1%

Grant data is from the NIH project reporter database. Clinical data is from the clinical trials database. Publication data is from the PubMed database (queried for disease name, "fetus" and "humans" as MeSH terms.)

* The NIH does not have a spending category for preterm birth; grant data is for the broader category "Conditions affecting the embryonic and fetal periods," many of which result in preterm birth or fetal demise.

**The NIH does not have a spending category for Zika; grant data is for the broader category "Brain Disorders"

Chapter X. Recommendations

- The Panel recommends that Congress take numerous actions to provide direct protections for women and infants, including:
    - Ensuring that all donations of fetal tissue are made with informed consent;
    - Clarifying the law to ensure that abortion providers do not harm women in order to procure fetal tissue;

- Directing the Department of Health and Human Services to conduct greater oversight over misleading consent forms, IRBs, HIPAA violations, and abortion provider competence to care for infants born alive during abortion procedures;

- Ensuring that the Department of Justice allocates resources to prosecute persons or entities that profit from the sale of fetal tissue;

- Enacting a law to protect unborn infants after 20 weeks gestation;

- Directing the Department of Health and Human Services to establish protocols for abortion providers to provide emergency care to infants born alive during abortions;

- Establishing criminal penalties to enforce the Born-Alive Infants Protection Act, and;

- Establishing an office in the Criminal Division of the Department of Justice to ensure the enforcement of the Partial-Birth Abortion Ban Act, the Born-Alive Infants Protection Act, and other measures recommended in this report.

- The Panel also recommends that Congress take actions to ensure good stewardship of taxpayer funds, including:

  - Defunding Planned Parenthood and ensuring that grants no longer available to Planned Parenthood are awarded to healthcare providers that provide comprehensive preventive healthcare for their patients and that do not perform abortions (that are not covered by Medicaid under the Hyde Amendment);

  - Providing greater flexibility to states to enact laws prohibiting abortion providers form receiving Medicaid reimbursement and giving states discretion to choose subrecipients of Title X funding consistent with state policy, and;

  - Prohibiting federal funding of research involving tissue derived from induced abortions in conjunction with the establishment of a program that would fund sources of ethically obtained fetal tissue (*i.e.*, fetal tissue from *spontaneous* abortions (miscarriages) or stillbirths) for research.

- The Panel recommends that Congress take actions to improve biomedical research, including:

  - Appropriating funding to the NIH for a trial of expanding the organ-donation network to include preterm and stillborn infant donors, ***excluding*** tissue from elective termination of pregnancy.

- Directing NIH to undertake a study of research demand for adult human tissue and possible methods for facilitating the acquisition of this tissue for research.

- Directing NIH to establish guidelines for the use of human fetal tissue (modeled on the guidelines for animal research) and mandating that these guidelines be applied to all grants proposing the use of human fetal tissue.

- Directing NIH to adopt a three-tiered classification system for proposals involving human fetal tissue as indicated below:

  Class 1: Fetal tissue is required for the proposed study. There are no reasonable alternatives.

  Class 2: Fetal tissue is not essential for the study. There are some scientific advantages to the use of fetal tissue, but alternatives exist.

  Class 3: Fetal tissue is not essential for the study. There are no scientific advantages to the use of fetal tissue, and alternatives exist.

- Directing NIH to report to Congress on the use of parent-donated tissue from natural demise of preterm children, anticipated by Recommendation 1 above, and Congress shall appropriate funds for an expansion of this program and disallow grants funded by federal dollars to utilize human fetal tissue obtained from induced abortion.

Chapter XI: Compliance with Congressional Subpoenas

- Virtually every entity and individual from whom the Panel sought documents did not fully comply, regardless of whether the documents were required to be produced pursuant to a subpoena, or were requested via a letter.

- The chart below graphically demonstrates the level of non-compliance by entities and individuals with the Panel's document request letters and subpoenas.

Preface

The Select Investigative Panel prepared the following *Final Report* for the U.S. House of Representatives and the general public. H. Res. 461 established the Panel on October 7, 2015. The Resolution charged the Panel to investigate and report on the following:

> (1) medical procedures and business practices by entities involved in fetal tissue procurement;
> (2) any other relevant matters with respect to fetal tissue procurement;
> (3) Federal funding and support for abortion providers;
> (4) the practices of providers of second and third trimester abortions, including partial birth abortion and procedures that may lead to a child born alive as a result of an attempted abortion;
> (5) medical procedures for the care of a child born alive as a result of an attempted abortion; and
> (6) any changes in law or regulation necessary as a result of any findings made under this subsection.

The Panel's duties included completing a final, formal report to Congress no later than December 31, 2016.

Chairman Blackburn set the priorities of the Panel, directing that the interests of vulnerable women and children always inform the investigation and that the investigation encompass the nation's entire fetal tissue industry. The Chairman's direction was clear from the beginning: We must investigate alleged wrongdoing and then propose solutions to the problems we uncover. Recognizing that the transfer of fetal tissue for profit is a federal criminal offense, the Chairman focused the investigation on exacting detail, including bank and accounting records, all with a perspective that the motive for illicit profit could contaminate collateral activities in four important ways.

First, the sale of fetal tissue for profit could have a corrupting effect on the treatment of women facing an abortion decision. The Panel's work has revealed that this corruption extends to the method of obtaining consent from the patient, which is both deceptive and unlawful. Also, those entrusted with patient medical information may violate Health Insurance Portability and Accountability Act (HIPAA) privacy rights in order to enable businesses to match their customer orders for human fetal tissue with particular patients.

Second, the Panel was concerned with a history of babies being born alive and the sale of fetal tissue at some late-term abortion clinics. The Panel's investigation has revealed that whole baby cadavers of a viable age are transferred from some abortion clinics to researchers. The induction abortion procedure has increased the likelihood that infants will be born alive during abortions, even while the gestational age of viability has lowered due to medical advancements.

This intersection, coupled with a profit motive, became part of the Panel's focus throughout its tenure.

Third, the Panel found evidence that some abortion providers altered abortion procedures in a manner that substitutes patient welfare with a financial benefit for both the abortion clinic and the procurement business. Since this conduct violates federal law, a thorough investigation of the practice was critical to understanding the effectiveness of the current statute.

Fourth, the Panel discovered that profit motives taint the integrity of the nation's celebrated history of voluntary organ donation. In recent decades, much work has been done to create the highest ethical and moral standards, both in law and practice, while making progress toward healing and curing disease. Selling human fetal tissue for a profit endangers this system and threatens the future of finding cures. Thus, the Panel made recommendations that improve the tissue and organ donor system in an ethical way.

The Chairman weighed these four areas of inquiry and held the Panel's first hearing on *Bioethics and Fetal Tissue*. There have been several government-sponsored discussions on bioethics, but none directly on the transfer of fetal tissue since the 1980s. The hearing revealed substantial concern about the consent process for the donation of human fetal tissue used by abortion clinics and procurement businesses. Evidence revealed that self-interested staff, whose pay depends on the numbers of specimens donated, were assigned to obtain consent from patients. Additional evidence showed that tissue technicians and the abortion clinics violated the patient's HIPAA rights. Still other evidence revealed that some middleman companies misrepresented that the consent forms and methods of tissue harvesting comply with federal regulations regarding Institutional Review Boards (IRBs). This evidence points toward conduct focused on profit and not on patient welfare.

The Panel's next hearing, *The Pricing of Fetal Tissue*, sought the judgment of seasoned federal prosecutors to compare the federal statute prohibiting profit from fetal tissue sales with the first tranche of materials from the investigation. Two former U.S. attorneys and a senior federal litigator agreed that, based on the materials presented to them, they would open a case against a middleman company. The former prosecutors also suggested that accounting and bank records would be critical to understanding whether there was a violation of federal law. Minority witnesses agreed with this approach and urged the Panel to obtain such records.

Although the Panel has made significant progress using heavily redacted subpoenaed documents, the Minority has publicly advocated that the Panel be disbanded and has privately attempted to obstruct the Panel's fact-finding mission. At every turn, the minority has urged that the Panel's requests for information be ignored and even urged noncompliance with congressional subpoenas. At the behest of the minority, many individuals who have received congressional subpoenas have heavily redacted critical information, and some have refused to comply at all. Still others have communicated in writing that they have relied upon Minority memoranda to support their noncompliance.

A. Understanding the Final Report with Redacted Names

From the beginning of the Panel's investigation, the Chairman directed that the work focus on the transactions described in H. Res. 461, in particular the transfer of fetal tissue, the methods of abortion, and the stewardship of federal taxpayer dollars. The Legislative Branch passes and evaluates laws that govern all Americans and thus, in its Final Report, the Panel has redacted the names of individuals who engaged in those transactions and substituted descriptive nouns in their place. This allows the reader to understand the role played by an individual without disclosing the actual name of the individual.

During the Panel's investigation, several persons sought to make themselves publicly known by making personal comments in the press, including a university researcher, a late-term abortion doctor, and the CEO of a tissue procurement company. These names are also redacted from the report and replaced by descriptive nouns. The names of other individuals who perform more functionary roles, such as tissue procurement technicians or medical assistants, are also redacted and substituted with descriptive nouns. The Panel received information from confidential whistleblowers, such as former abortion clinic managers or former employees of fetal tissue procurement companies. These names are also redacted. The names of university researchers and medical students whose names appeared on the documents that were part of the transactions examined by the Panel are also redacted. Individuals abortion doctors' names are redacted. The Panel has also redacted addresses and telephone numbers where they identify particular individuals.

The Panel conducted depositions and transcribed interviews of several individuals. Those individuals' names and titles are redacted, and the transcript of their testimony before the Panel is used to explain their role.

Finally, the Panel has not redacted that names of staff of the U.S. House of Representatives, the names of lawyers who represented particular individuals or entities, the names of persons who testified before the Panel in open congressional hearings, and the non-transactional names on academic papers that the Panel relied upon to understand the role of human fetal tissue in research.

The redaction key is outlined below. The Report's exhibits, which number 3,647 pages, are also redacted. They can be found at: https://energycommerce.house.gov/news-center/letters/select-investigative-panel-final-report. Additionally, the redaction key is repeated in each individual Chapter. The Minority proposed and the Majority accepted a set of redaction placeholders for the witnesses who were deposed by the Panel and persons who volunteered to be interviewed by the Panel with a written transcript of their interview. Each attorney for the person deposed or interviewed was invited to suggest edits for the transcripts. The consensus placeholders are listed first below followed by the Report's additional redaction placeholders.

Redaction placeholders for depositions and interviews:

May 6, 2016 deponent: [Clinic A Dr. #1] Testified that she was an OBGYN abortion provider, a faculty member of University of New Mexico, and an employee of Southwestern Women's Options clinic.

May 11, 2016 deponent: [Dr. Administrator] Testified the she was an OBGYN abortion provider, a faculty Member at the University of New Mexico.

July 21, 2016 interview witnesses:

[Clinic B Staff #1] Testified that she was a medical worker at an abortion clinic in Maryland.

[Clinic B Staff #2] Testified that she was a medical worker at an abortion clinic in Maryland.

[Clinic B Staff# 3] Testified that she was a medical worker at an abortion clinic in Maryland.

[Clinic B Staff #4] Testified that she was a medical worker at an abortion clinic in Maryland.

October 6, 2016 interview witness: [PP Witness #1] Testified that she is an OBGYN abortion provider in Los Angeles, California, an executive with Planned Parenthood Federation of America (PPFA) who is in charge of the PPFA Manual of Medical Standard and Guidelines.

October 19, 2016 interview witness: [PP Witness #2] Testified that she is a manager of research projects at Planned Parenthood Gulf Coast.

November 1, 2016 interview witness: [PP Witness #3] Testified that she is a university professor, an OBGYN abortion provider, and serves on the PPFA National Medical Committee.

November 17, 2016 interview witness: [PP Witness #4] Testified that she works for the Consortium of Abortion Provider Services at PPFA, which provides technical assistance to PPFA affiliate clinics.

Additionally, each individual Chapter contains a redaction key with additional names:

Chapter I Redaction Key: No redactions

Chapter II Redaction Key:

[PP Witness #1] is an abortion provider in Los Angeles, California, an executive with Planned Parenthood Federation of America (PPFA)

who is in charge of the PPFA Manual of Medical Standard and Guidelines.

[PP Doctor #1] is an abortion provider in Los Angeles, California, who also works for the Medical Directors' Council

Chapter III Redaction Key: No Redactions

Chapter IV Redaction Key: Names Redacted from Referral Letters

Chapter V Redaction Key:

StemExpress, LLC:

[PP Witness #1] is an abortion provider in Los Angeles, California, an executive with Planned Parenthood Federation of America (PPFA) who is in charge of the PPFA Manual of Medical Standards and Guidelines.

[PP Doctor #1] is an abortion provider in Los Angeles, California, who also works for the Medical Directors' Council.

[the Founder and CEO] is the founder and CEO of StemExpress, LLC (StemExpress).

[ABR's Procurement Manager] is the procurement manager at Advanced Bioscience Resources, Inc.

[FDA Consumer Safety Officer # 1] is a consumer safety officer at the U.S. Food and Drug Administration.

[FDA Consumer Safety Officer # 2] is a consumer safety officer at the U.S. Food and Drug Administration.

Novogenix Laboratories, LLC:

[PP Witness #1] Testified that she is an OBGYN abortion provider in Los Angeles, California, an executive with Planned Parenthood Federation of America (PPFA) who is in charge of the PPFA Manual of Medical Standard and Guidelines.

[PP Doctor #1] is an abortion provider in Los Angeles, California, who also works for the Medical Directors' Council

[Founder and Executive Director] is the founder and executive director of Novogenix Laboratories, LLC (Novogenix).

[Supervisor Consumer Safety Officer] is a supervisor consumer safety officer at the U.S. Food and Drug Administration.

[Consumer Safety Officer] is a consumer safety officer at the U.S. Food and Drug Administration.

DaVinci Biosciences, LLC / DaVinci Biologics, LLC:

[DVB Executives] are the owners and managers of DaVinci Biosciences, LLC (DaVinci) and DaVinci Biologics, LLC (DVB).

[DVB Executive # 1] is the president of DaVinci and DVB.

[DVB Executives # 2 and 3] are founding members and officers of DaVinci and DVB.

Human Fetal Tissue Repository:

[Einstein Executive #1] is an Einstein Executive Dean

[Einstein Executive #2] is an Einstein Vice-President, Government and Community Relations

[Einstein Executive #3] is an Einstein Vice-President, External Affairs

Chapter VI Redaction Key:

[Clinic A Dr. #1] is an employee of Southwestern Women's Options and a faculty member of the University of New Mexico.

[Dr. Administrator] is a faculty member of the University of New Mexico.

[NM Doctor #2] is a faculty member of the University of New Mexico.

[NM Doctor #3] is a director of Southwestern Women's Options and a faculty member of the University of New Mexico.

[NM Doctor #4] is a faculty member of the University of New Mexico.

[NM Doctor #5] is an employee of Southwestern Women's Options and a faculty member of the University of New Mexico.

[NM Doctor #6] is an employee of Southwestern Women's Options.

[Dr. Administrator #2] is a faculty member of the University of New Mexico.

[NM Research Doctor] is a faculty member of the University of New Mexico.

[NM Patient] was a patient at Southwestern Women's Options.

[WA Clinic Director] is Executive Director and co-founder of the Cedar River Clinics.

[WA Doctor #1] is a faculty member at the University of Washington and also works at the Cedar River Clinics.

[WA Doctor #2] is a physician who works at the Cedar River Clinics.

[WA Doctor #3] is a faculty member at the University of Washington and also works at the Cedar River Clinics.

[WA Doctor #4] is a faculty member at the University of Washington and also works at the Cedar River Clinics.

[WA Doctor #5] previously worked at the Cedar River Clinics while a faculty member at the University of Washington.

[WA Doctor #6] is a former University of Washington resident who worked at the Cedar River Clinics and currently works at the Swedish Medical Center.

[WA Doctor #7] is a former University of Washington resident who worked at the Cedar River Clinics and currently works at Northwest Women's Healthcare.

[WA Doctor #8] is a faculty member at both the University of Washington and Northwestern University and owner and operator of All Women's Health-North.

[WA Doctor #9] is a physician who formerly worked at the Cedar River Clinics and now works at All Women's Health-North.

[WA Patient] was a patient at the Cedar River Clinics who filed a medical malpractice suit against [WA Doctor #2] for injuries alleged following an abortion performed at 25+ weeks.

[WA Doctor #10] is a former resident and current faculty member at the University of Washington who served as medical director of the Planned Parenthood of Greater Washington and North Idaho.

[WA Doctor #11] is a faculty member at the University of Washington and also works at the Planned Parenthood of Greater Washington and North Idaho.

[WA Research Doctor #1] is a faculty member at the University of Washington and the author of the university's Birth Defects Research Laboratory's NIH grant proposals.

[WA Research Doctor #2] is a research scientist at the University of Washington who has participated in fetal tissue research studies.

[WA Research Doctor #3] is a former resident at the University of Washington who has participated in fetal tissue research studies.

[WA Research Staff] is a technical operations manager at the University of Washington School of Medicine's WWAMI Institution for Simulation in Healthcare. He has participated in fetal tissue research studies.

[WA Administrator] is an administrator in the University of Washington's government relations office.

[PP Witness #1] is an abortion provider in Los Angeles, California, an executive with Planned Parenthood Federation of America (PPFA) who is in charge of the PPFA Manual of Medical Standard and Guidelines.

[PP Witness #2] is a manager of research projects at Planned Parenthood Gulf Coast (PPGC).

[PPFA Lawyer] is a legal official at PPFA.

[PPFA Medical Officer #1] is a PPFA official who was responsible for medical issues.

[PPFA Medical Officer #2] is a PPFA official who was responsible for medical issues.

[PPGC Abortion Doctor] is a doctor who performed abortions at PPGC.

[PPGC Staff] is a PPGC staff worker who assisted in the abortion clinic.

[UTMB Researcher # 1] is a researcher at the University of Texas Medical Branch who worked with PPGC on fetal tissue procurement.

[PPGC Abortion Services Official] is a manager of abortion services at PPGC.

[PPGC Executive] is the director of abortion services and medical director at PPGC.

[UTMB Researcher # 2] is a second researcher at the University of Texas Medical Branch who worked with PPGC on fetal tissue procurement.

[UTMB Staff] is a UTMB staff worker who administers contracts for researchers.

[BCM Researcher] is a researcher at the Baylor College of Medicine who worked with PPGC on fetal tissue procurement.

[BCM Staff] is a staff employee at the Baylor College of Medicine who worked with PPGC on fetal tissue procurement.

[BCM Contract Manager] is an employee of the Baylor College of Medicine who manages contracts.

[MO Doctor #1] is a faculty member of the Ob/Gyn department of the Washington University School of Medicine and also works at Planned Parenthood of the St. Louis Region and Southwest Missouri.

[MO Doctor #2] is Planned Parenthood of the St. Louis Region and Southwest Missouri's pathologist and the owner of Pathology Services, Inc.

[MO Doctor #3] is a faculty member of the Ob/Gyn department of the Washington University School of Medicine and also works at Planned Parenthood of the St. Louis Region and Southwest Missouri.

[MO Doctor #4] is a faculty member of the Ob/Gyn department of the Washington University School of Medicine and also works at Planned Parenthood of the St. Louis Region and Southwest Missouri.

[MO Doctor #5] is a faculty member of the Ob/Gyn department of the Washington University School of Medicine and also works at Planned Parenthood of the St. Louis Region and Southwest Missouri.

[MO Doctor #6] is or was a clinical fellow in the Ob/Gyn department of

the Washington University School of Medicine and also works at Planned Parenthood of the St. Louis Region and Southwest Missouri.

[WI Doctor #1] was an assistant professor of Ob/Gyn at the University of Wisconsin, School of Medicine and Public Health, while serving as the associate medical director of Planned Parenthood of Wisconsin.

[WI Doctor #2] is the director of the Ryan Fellowship and a member of the Ob/Gyn faculty at the University of Wisconsin, School of Medicine and Public Health, and also works at Planned Parenthood of Wisconsin.

[MI Doctor] is both an associate professor in University of Michigan's Ob/Gyn department and medical director for Planned Parenthood in Ann Arbor.

Chapter VII Redaction Key:

[Abortion Doctor #1] is an abortion provider in Nebraska and Maryland.

[Abortion Doctor #2] is an abortion provider in Colorado.

[Abortion Doctor #3] is an abortion provider in Texas.

[Dr. Administrator] is a faculty member at the University of New Mexico.

[Doctor #1] is an employee of Southwestern Women's Options and a faculty member of the University of New Mexico.

[Clinic B Staff #1] is an employee of a late-term abortion clinic in Maryland for [Abortion Doctor #1].

[Clinic B Staff #2] is an employee of a late-term abortion clinic in Maryland for [Abortion Doctor #1].

[Clinic B Staff #3] is an employee of a late-term abortion clinic in Maryland for [Abortion Doctor #1].

[Clinic B Staff #4] is an employee of a late-term abortion clinic in Maryland for [Abortion Doctor #1].

[Employee #1] is an employee of a late-term abortion clinic in Texas for [Abortion Doctor #3].

[Employee #2] is an employee of a late-term abortion clinic in Texas for [Abortion Doctor #3].

[Employee #3] is an employee of a late-term abortion clinic in Texas for [Abortion Doctor #3].

[Employee #4] is an employee of a late-term abortion clinic in Texas for [Abortion Doctor #3].

[Patient #1] is a former patient of [Abortion Doctor #3].

Chapter VIII Redaction Key:

[PP Witness #1] is an abortion provider in Los Angeles, California, an executive with Planned Parenthood Federation of America (PPFA) who is in charge of the PPFA Manual of Medical Standard and Guidelines.

[PP Witness #2] is a manager of research projects at Planned Parenthood Gulf Coast.

[PP Witness #3] is a university professor, an abortion provider and serves on the PPFA National Medical Committee.

[PP Witness #4] works for the Consortium of Abortion Provider Services at PPFA which provides technical assistance to PPFA affiliate clinics.

[PP Doctor #1] is an abortion provider in Los Angeles, California, who also works for the Medical Directors' Council.

[PPGC Abortion Services Official] is a manager of abortion services at PPGC.

[PPFA Executive] works for the Medical Standards Department at PPFA.

[PPFA Medical Officer #1] is a PPFA official who was responsible for medical issues

[PPFA Medical Officer #2] is a PPFA official who was responsible for medical issues

[PPFA Lawyer] is a legal official at PPFA.

[CRR lawyer] works for the Center for Reproductive Rights.

[ANSIRH lawyer] works for Advancing New Standards in Reproductive Health.

[NARAL executive] works for the Policy department at the National Abortion and Reproductive Rights Action League.

[StemExpress Founder and CEO] refers to the founder and CEO of StemExpress.

[Abortion Doctor] is any doctor who provides abortions.

[Researcher FT] refers to any person who is involved in fetal tissue transactions.

[Procurement Technician] refers to any person who procures fetal tissue.

Acknowledgments

The Chairman wishes to acknowledge important contributions made to the Panel's work. The General Accounting Office was very generous in providing a detailee, Pierre Kamga, a Senior Auditor who provided extraordinary guidance on all matters related to forensic accounting. Dr. David Prentice of the Charlotte Lozier Institute tutored the Members and Staff alike on the latest trends in biomedical research and helped us sharpen our thinking about the ethical issues associated with the use of abortive fetal tissue. Lastly, the Members of the Panel and their staffs performed beyond the normal, intense work-load of the House of Representatives.

I. Congress Establishes the Select Investigative Panel

A. Summary

David Daleiden, an investigative journalist, released undercover videos beginning in July 2015, recorded while posing as the head of a company interested in the fetal tissue procurement business. In numerous meetings with abortion providers and companies involved in the transfer of fetal tissue, Daleiden recorded doctors, executives, and staff-level employees discussing various aspects of the fetal tissue procurement industry. The videos and other materials that Daleiden acquired, detailed the relationship between fetal tissue procurement companies, such as Advanced Bioscience Resources, DaVinci Biologics, and StemExpress, and several abortion clinics.

The exposé followed an investigation Daleiden conducted through a not-for-profit group he founded, the Center for Medical Progress (CMP), identified on its website as "a group of citizen journalists dedicated to monitoring and reporting on medical ethics and advances."[1] CMP's first project, the "Human Capital" investigation, took almost three years—30 months. Working under the guise of a tissue procurement business in order to gain access to the top levels of the abortion giant Planned Parenthood, Daleiden, Susan Merritt, and other activists on the investigation recorded numerous videos documenting conversations in which Planned Parenthood executives discussed the procurement of fetal tissue (the body parts of aborted fetuses).[2]

The investigation culminated with the release of eleven videos documenting the practices of local abortion clinics and groups affiliated with the fetal tissue procurement industry. While most are familiar with the clips, Daleiden and his colleagues filmed hundreds of hours of meetings and conversations. According to the *Washington Post*, they filmed 500 hours of footage at two conferences alone.[3]

Multiple clips show abortion clinic doctors and executives admitting that their fetal tissue procurement agreements are profitable for clinics and help keep their bottom line healthy. Multiple clips also show them admitting that they sometimes changed the abortion procedure in order to obtain a more intact specimen,[4] including relying on the illegal partial-birth abortion procedure.[5] Planned Parenthood Federation of America (PPFA) also revealed that they intentionally had not set a policy about "remuneration" for fetal tissue because "the headlines

[1] Center for Medical Progress, About Us, http://www.centerformedicalprogress.org/about-us/.
[2] Center for Medical Progress, Human Capital, http://www.centerformedicalprogress.org/human-capital.
[3] Sandhya Somashekhar, *Meet the Millennial Who Infiltrated the Guarded World of Abortion Providers*, Wash. Post, Oct. 14, 2015, *available at* https://www.washingtonpost.com/national/meet-the-millennial-who-infiltrated-the-guarded-world-of-abortion-providers/2015/10/14/25aaf862-678b-11e5-9223-70cb36460919_story.html.
[4] Center for Medical Progress, Human Capital—Episode 3, http://www.centerformedicalprogress.org/blog/page/5/.
[5] Center for Medical Progress, CMP Reply to PPFA Cecile Richards Video Statement, http://www.centerformedicalprogress.org/blog/page/6/.

would be a disaster."[6] While the organization's executives told affiliates to "think, 'New York Times headline'" if this went badly,[7] at the end of the day, they thought "this is a good idea."[8]

Congress responded to the videos by holding hearings and initiating investigations. In particular, the Energy and Commerce Subcommittee on Oversight and Investigations initiated an investigation of fetal tissue transfers. The Committee on Oversight and Government Reform and the Judiciary Committee conducted hearings and also initiated investigations.

On October 7, 2015, Rep. Virginia Foxx (NC-5) managed the floor debate for H. Res. 461, a proposal for a centralized and comprehensive congressional investigation. During debate, Rep. Mimi Walters (CA-45) noted, "This resolution would create a select panel to investigate a number of claims related to Planned Parenthood's activities involving abortion and fetal tissue procurement. Like many Americans, I was horrified by the recent videos which depicted Planned Parenthood employees callously discussing the trafficking and sale of aborted babies' tissues and organs." Rep. Marsha Blackburn (TN-7) summarized:

> I want to clearly state this is about getting answers of how we treat and protect life in this country. The select panel will act to centralize the investigations that are at the Energy and Commerce Committee, Judiciary and Oversight Committees, and bring it all under one umbrella. Over the past several weeks, we have had lots of serious questions. They are troubling questions that have been asked. I think that the investigations we have had have raised a lot of those questions. It is imperative that we centralize these operations and bring it together under one umbrella.[9]

[6] Center for Medical Progress, Press Release, *Top Planned Parenthood Exec Agrees Baby Parts Sales "A Valid Exchange," Some Clinics "Generate a Fair Amount of Income Doing This,"* http://www.centerformedicalprogress.org/2015/09/top-planned-parenthood-exec-agrees-baby-parts-sales-a-valid-exchange-some-clinics-generate-a-fair-amount-of-income-doing-this/.

[7] Center for Medical Progress, Transcript, 13, (Feb. 27, 2015), http://www.centerformedicalprogress.org/wp-content/uploads/2015/05/PPCAPSDVDfinal.pdf.

[8] Center for Medical Progress, Transcript, 12-13, 15, (Mar. 18, 2015) http://www.centerformedicalprogress.org/wp-content/uploads/2015/05/PPCAPSDVDVRfinal.pdf.

[9] 161 Cong. Rec. H6869-6872 (daily ed. Oct. 7, 2015).

Congress passed H. Res 461 by a recorded vote of 242 yeas and 184 nays.[10] Rep. Blackburn was named Chairman of the Panel. The Panel's membership is as follows:

Select Investigative Panel

Marsha Blackburn (Tennessee - 07)
Chairman

Republican Members	**Democratic Members**
Joseph Pitts (Pennsylvania - 16)	Janice Schakowsky (Illinois - 09), Ranking Member
Diane Black (Tennessee - 06)	Jerrold Nadler (New York - 10)
Larry Bucshon (Indiana - 08)	Diana DeGette (Colorado - 01)
Sean Duffy (Wisconsin - 07)	Jackie Speier (California - 14)
Andy Harris (Maryland - 01)	Suzan DelBene (Washington - 01)
Vicky Hartzler (Missouri - 04)	Bonnie Watson Coleman (New Jersey - 12)
Mia Love (Utah - 04)	

B. Center for Medical Progress Videos Raise Serious Issues

The Panel did not design its investigation to prove or disprove the credibility of tapes released by the Center for Medical Progress (CMP). The CMP engaged in a multi-year series of investigations that involved journalists posing as persons interested in growing a fetal tissue procurement business. The journalists attended conferences, befriended numerous persons in the abortion industry, and obtained documents from existing companies involved in fetal tissue procurement. During much of this undercover activity, the journalists wore unseen video recording equipment. Beginning on July 14, 2015, the CMP began to release compilations of these videos to the public. The content was alarming and troubling to many. Some said the videos were "doctored" or "highly edited." The Panel viewed the videos as a series of serious claims made by a citizen advocacy group. Thus, the Panel obtained and viewed hours of unedited footage of the CMP videos and took notice of the issues they raised. Below are the Panel's summaries of eleven videos released by CMP. The titles of each video are the CMP title for the video.

1. "Planned Parenthood Orange County Changes Abortions to Harvest Intact Fetuses for Local Company's 'Fetal Products' sales"

The Panel took notice that this video raised the issue of infants born alive during late-term abortion procedures. The video showed a discussion between the medical director of Planned Parenthood of Orange and San Bernardino Counties and undercover journalists during which the medical director admitted that her affiliate does not use digoxin. This chemical is used to kill the fetus in later 2nd-trimester abortions *and prevent a live birth*. Middleman companies

[10] *Id.* at H6879.

such as Da Vinci Biologics, LLC (who gave large donations to this Planned Parenthood affiliate), can only harvest organs from fetuses who were aborted *without* digoxin because of the poisonous effect of the chemical on fetal cells. This video prompted us to investigate late-term abortion practices in the United States and what care is provided to infants who *are* born alive during late-term abortion procedures. See Chapter VII.

2. "Planned Parenthood Ally National Abortion Federation Suggests 'Group Purchasing Program' for Fetal Parts, Payments 'A Win-Win' for Clinics"

The Panel took notice that this video raised the issue of profiting from the sale of fetal parts, a violation of 42 U.S.C. § 289g-2. In this video, an employee of the National Abortion Federation (NAF), a network of abortion clinics, suggested a "group-purchasing program" for fetal tissue and that payments from middleman companies to NAF affiliated clinics would be a "win-win." This video prompted the Panel to seek accounting records from clinics and middleman companies in order to discover if the statute preventing profit needed further examination. See Chapter V.

3. "Planned Parenthood Houston Admits Accounting Gimmicks Hide Baby Parts Sales, Invoices Charge Thousands of Dollars"

The Panel took notice that this video again raised the issue of illegal profiting from the sale of fetal parts. In this video, the director of research at Planned Parenthood Gulf Coast tells undercover journalists about accounting gimmicks which can be used to hide the sale of fetal parts. The director of research even admitted that her department **"contributes so much to the bottom line of our organization here."** Again, this prompted the Panel to seek accounting records in order to analyze the transactions that were taking place between abortion clinics, middleman companies, and buyers—usually universities. See Chapter VI.

4. "Planned Parenthood TX Abortion Apprentice Taught Partial-Birth Abortions to 'Strive For' Intact Baby Brains"

The Panel took notice that this video raised the issue of changing abortion procedures in order to harvest the most intact fetal parts. Changing the timing or method of the abortion procedure is illegal under U.S.C. § 289g. A Planned Parenthood doctor, who admitted she was trained by PPFA's senior medical advisor, described using a partial-birth abortion technique to harvest fetal organs. She told undercover journalists that she will sometimes use ultrasound guidance to convert a 2nd-trimester fetus to a feet-first breech presentation: "That's what [PP Doctor] was telling us, was it really makes a difference for tissue collection at PPLA." This prompted the Panel to interview and depose abortion providers who it thought might be involved with fetal tissue collection, as well as subpoena and examine clinic manuals and procedure guides that relate to fetal tissue procurement methods. See Chapter VIII.

5. "Top Planned Parenthood Exec Agrees Baby Parts Sales 'A Valid Exchange,' Some Clinics 'Generate a Fair Amount of Income Doing This'"

The Panel took notice that this video again raised the issue of illegal profiting from the donation of fetal parts, as well as the apparent endorsement of these practices by senior Planned

Parenthood executives. In this video, the National Director for the Consortium of Abortion Providers (a key committee within PPFA that shapes abortion policy) referred to fetal tissue payments as "donation remuneration." She also admitted that she had been "talking to the executive director of the National Abortion Federation, we're trying to figure this out as an industry, about how we're going to manage remuneration, because the headlines would be a disaster." This prompted the Panel to interview top Planned Parenthood executives in order to ascertain their understanding of federal and state regulations, as well as their protocols of compliance surrounding the transfer of fetal tissue, in addition to seeking accounting information. See Chapter VIII.

6. "Planned Parenthood Baby Parts Vendor Advanced Bioscience Resources Pays Off Clinics, Intact Fetuses 'Just Fell Out'"

The Panel took notice that this video raised the issue of illegal profiting and born-alive infants. The former director of Planned Parenthood of the Pacific Southwest seems to affirm undercover journalists' offer to pay for tissue. When they say, "We return a portion of our fees to the clinics," the director responds eagerly, "**Right, get a toe in and make it, make a pro–alright.**" The video also featured the Procurement Manager at ABR, who described situations where enough dilation occurred to procure an intact fetus. "**I literally have had women come in and they'll go in the O.R. and they're back out in 3 minutes, and I'm going, 'What's going on?' Oh yeah, the fetus was already in the vaginal canal whenever we put her in the stirrups, it just fell out**." This prompted the Panel to investigate late-term abortion practices. See Chapters V and VII.

7. "Planned Parenthood Baby Parts Buyer StemExpress Wants 'Another 50 Livers/Weeks,' Financial Benefits for Abortion Clinics"

The Panel took notice that this video raised the issue of a callous tone and unethical behavior towards scientific research, late-term abortions, and fetal tissue procurement. CEO of StemExpress told undercover journalists about shipping aborted fetal cadavers to researchers after abortions and the reactions of scientists:

> …Tell the lab it's coming! So they don't open the box and go, "Oh God!" [laughter] So yeah, so many of the academic labs cannot fly like that, they're not capable…It's almost like they don't want to know where it comes from. I can see that. Where they're like, "We need limbs**, but no hands and feet need to be attached**." And you're like, ? Or they want long bones, and they want you to take it all off, like, make it so that we don't know what it is…But we know what it is. I mean, [laughter], but their lab… **And their lab techs freak out, and have meltdowns.**

The CEO was also asked what would "make her lab happy," to which she responded, "**Another 50 livers a week…We're working with almost like triple digit number clinics,**" she explains, "**and we still need more.**" She later noted, "**Planned Parenthood has volume, because they are a volume institution.**" She also suggested that abortion clinics profit from fetal tissue

donation. This prompted the Panel to examine the attitude towards fetal tissue donation. See Chapter V.

8. "Intact Fetuses 'Just a Matter of Line Items' for Planned Parenthood TX Mega-Center"

The Panel took notice that this video raised the issue of Planned Parenthood affiliate clinics breaking their own protocols in order to contract and conduct business with fetal tissue procurement companies. The director of research at Planned Parenthood Gulf Coast told undercover journalists: "**Where we probably have an edge over other organizations, our organization has been doing research for many many years.**" When researchers need a specific part from the aborted fetus, she says, "**We bake that into our contract, and our protocol, that we follow this, so we deviate from our standard in order to do that.**" She also admitted that some doctors change their procedure in order to procure the most intact specimen. This prompted the Panel to study the regulations around fetal tissue procurement and examine how closely those regulations are being followed. She also said of budgeting for fetal tissue, "**It's all just a matter of line items.**" This prompted the Panel to see how well Planned Parenthood executives understand the federal regulations surrounding fetal tissue. See Chapter VI.

9. "Planned Parenthood VP Says Fetuses May Come Out Intact, Agrees Payments Specific to the Specimen"

The Panel took notice that this video again raised the issue of born-alive infants because Planned Parenthood employees discussed delivering intact fetuses after an abortion. At Planned Parenthood of the Rocky Mountains, [Abortion Doctor] said, "**Sometimes, if we get, if someone delivers before we get to see them for a procedure, then we are intact.**" Again, because this affiliate does not use the feticide digoxin in 2nd trimester procedures, there is the potential that "intact deliveries" are born alive. This prompted the Panel to investigate late-term abortion procedures. She also said she would need to train doctors to change the abortion procedure in order to harvest the most intact brains if PPRM were to partner with the fake tissue procurement company. And finally, [Abortion Doctor] said, "**I think a per-item thing works a little better, just because we can see how much we can get out of it.**" This prompted the Panel to see if clinics were profiting from the transfer of fetal tissue, a violation of federal law. See Chapters VII and VIII.

10. "Second Planned Parenthood Senior Executive Haggles Over Baby Parts Prices, Changes Abortion Methods"

The Panel took notice that this video again raised the issue of illegal profit. Another Planned Parenthood executive, the President of the Medical Directors' Council, bargained with undercover journalists over the price of fetal tissue. **"You know, in negotiations whoever throws out the figure first is at a loss, right?"** She explains, "**I just don't want to lowball**." If Planned Parenthood loses money as they say they do by participating in fetal tissue programs, then "lowballing" wouldn't be a factor in contract negotiations. And even though she insists, "We're not in it for the money," she says, "**But it has to be big enough that it's worthwhile for me.**" This again prompted the Panel to seek accounting records and other records relating to Planned Parenthood's fetal tissue programs. See Chapter VIII.

11. "Planned Parenthood Uses Partial-Birth Abortions to Sell Baby Parts"

The Panel took notice that this video raised multiple issues: illegal profiting, changing the abortion procedure in order to procure a better specimen, the possible use of partial birth abortion, and the disregard of federal regulations. In the video, the Senior Medical Advisor to Planned Parenthood, discusses how she changes the abortion procedure to procure an intact calvarium (upper skull): **"We've been very good at getting heart, lung, liver, because we know that, so I'm not gonna crush that part, I'm gonna basically crush below, I'm gonna crush above, and I'm gonna see if I can get it all intact." "But I will tell you that behind closed doors these conversations are happening with the affiliates.** When asked about Planned Parenthood's position on fetal tissue procurement, she tells the journalists, "**behind closed doors these conversations are happening with the affiliates."** She stressed that Planned Parenthood is treading very carefully around the issue in order to "avoid headlines," a frequently repeated phrase in conversations among executives. This prompted the Panel to investigate late-term abortion practices to see if they were being modified to procure tissue, as well as to interview multiple Planned Parenthood executives. See Chapters VII and VIII.

C. The Panel Forms an Investigative Plan

On March 10, 1993, the House debated two competing amendments to H.R. 4, the National Institutes of Health Revitalization Act of 1993. The amendments, one offered by Rep. Bliley and one by Rep. Waxman, focused on safeguards governing the donation of fetal tissue for transplantation and for research. The House passed the Waxman Amendment to H.R. 4, the National Institutes of Health Revitalization Act of 1993. That Amendment includes the provisions codified as 42 U.S.C. §§ 289g-2(a) and (e)(3):

> **42 U.S.C. § 289g-2(a) states "It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce."**
>
> **42 U.S.C. § 289g-2(e)(3) "The term "valuable consideration" does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."**

During floor debate it was repeated over and over by supporters of the Waxman Amendment that "fetal tissue may not be sold."[11] Rep. Morella expressed her support for the legislation because "fetal tissue could not be sold."[12] Rep. Waxman himself said:

> This amendment that I am offering as a substitute would enact the most important safeguards, and those are the safeguards to prevent any sale of fetal tissue for any purpose, just not for the purpose of

[11] 139 Cong. Rec. H1099 (1993) (statement of Rep. John Edward Porter in support of the Waxman Amendment).
[12] *Id.* (statement of Rep. Connie Morella in support of H.R. 4 and the Waxman Amendment).

> research. It would be abhorrent to allow for a sale of fetal tissue and a market to be created for that sale.[13]

The floor debate corroborates the Committee Report language. The Report from the Committee on Energy and Commerce stated, "Section 498B prohibits the purchase of human fetal tissue as well as the solicitation or acceptance of directed fetal tissue donations."[14] The Committee prohibition on the sale of fetal tissue is described as making the transfer of fetal tissue parallel with donation of other organs under the Organ Procurement and Transplantation Act.[15] The Committee Report adds, however, "Indeed the Committee has dealt with fetal tissue more restrictively . . . ." [16] The Committee intent is to disallow payment for procurement of any organs.

The intent of the statute is best understood through a simple contrast between two modes of transferring fetal tissue from one entity to another. With the first, an abortion clinic or middleman Procurement Business transfers tissue to a researcher, and the researcher may reimburse the abortion clinic or Procurement Business for its reasonable costs incurred by the transportation, processing, preservation, and quality control of the tissue. With the second, the payment from the researcher exceeds those reasonable costs, enabling the abortion clinic or Procurement Business to make a profit, and thus violates the statute.

Not a violation of § 289g-2



Violation of § 289g-2



The congressional intent of the Waxman Amendment served as a guide for the Panel's investigative plan. The core question became the following: If fetal tissue is transferred from one entity to another, does the transfer violate the intent of § 289g-2? To answer this question, the panel identified four business. These are:

(1) *The Middleman Model.* This model comprises a middleman and tissue procurer who obtains tissue directly from a source such as an abortion clinic or hospital and then transfers the tissue to a customer, usually a university researcher.

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[13] *Id.* (statement of Rep. Waxman).
[14] H.R. Rep. No. 103-28 at 76 (1993).
[15] Pub. L. No. 98-507, 98 Stat. 2339 (1984).
[16] H.R. Rep. No. 103-28 at 76 (1993).

(2) *The University/Clinic Model*. This model comprises a particular university that has formed a close relationship with a nearby abortion clinic and regularly acquires tissue from that clinic for research purposes.

(3) *The Biotech Company/Clinic Model*. This model comprises a close relationship between a particular biotech company and one or more nearby clinics.

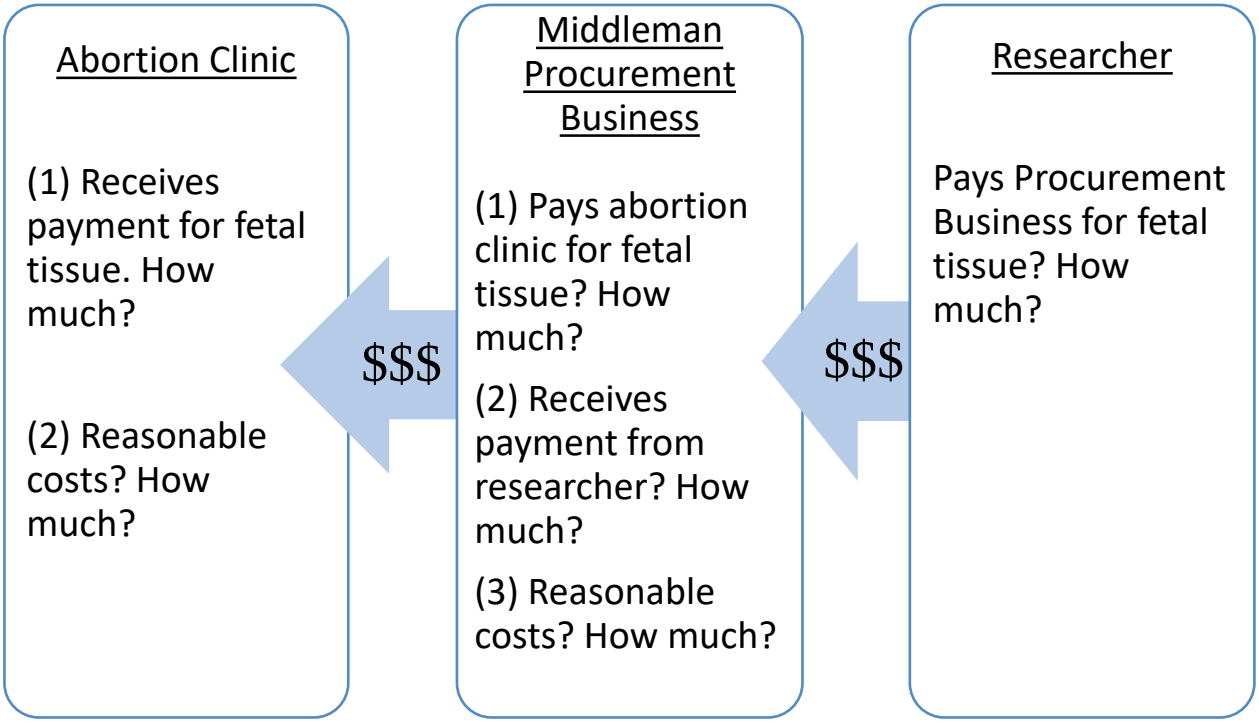
(4) *The Late-Term Clinic Model*. This model is of particular concern due to the intersection of late-term abortions, the potential for live births during the abortion procedure, and the transfer of tissues or whole cadavers from that clinic to research entities.

The Panel sought information from the following entities. Scientists from Harvard University and Pfizer provided bipartisan, off-the-record informational briefings for staff which gave a candid view into their view of fetal tissue research.

1. Advanced Bioscience Resources, Inc.
2. Albert Einstein College of Medicine
3. American Academy of Pediatrics
4. American Association for the Advancement of Science
5. American College of Obstetricians and Gynecologists
6. American Type Culture Collection
7. Anatomic Gift Foundation
8. Association of American Medical Colleges
9. Baylor
10. Bioarray Therapeutics
11. Buffalo Biosciences
12. Butler Medical Transport
13. Camelback Family Planning
14. Capital Biosciences
15. CEO StemExpress
16. Cedar River Clinics
17. Colorado State University
18. [Dr. Administrator] University of New Mexico
19. [MO Doctor #2]
20. [NM Research Doctor]
21. Dv Biologics
22. Family Planning Specialists Medical Group
23. Five Star Bancorp – StemExpress' bank
24. Germantown Reproductive Health Services
25. Harvard University – Provided Briefing
26. HHS
27. Holy Cross Germantown Hospital
28. InVivo Therapeutics
29. [Abortion Doctor #1] (Document Production and Deposition)
30. Life Technologies
31. Maryland Board of Physicians
32. Montgomery County Department of Fire and Rescue Services
33. Montgomery County Emergency Communications Center
34. Montgomery County Police Department
35. NAF
36. Neuralstem
37. NIH
38. Northland Family Planning
39. Novartis
40. Novogenix Labs
41. Oregon Health Sciences
42. Pfizer – Provided Briefing
43. Presidential Women's Center
44. Q Therapeutics
45. Saneron CCel Therapeutics, Inc.
46. Former Accountant StemExpress

47. SciKon
48. Scinto Group, LLP – StemExpress' accountant
49. Shady Grove Adventist Hospital
50. Southwestern Women's Options
51. Stem Cell Innovations
52. StemCells, Inc.
53. StemExpress
54. The Center for Medical Progress (CMP)
55. CEO and Chairman, AOL, Inc.
56. County of Orange, State of California
57. University of Colorado
58. University of Michigan
59. University of Minnesota
60. University of Texas
61. University of Wisconsin
62. University of California, San Diego
63. University of New Mexico
64. University of Washington Birth Defects Research Laboratory
65. U.S. Department of Justice
66. University of Southern California – Keck
67. Women's Health Specialists
68. Yale University

The Panel started its inquiry into the middleman or tissue broker model, the primary business model for the transfer of human fetal tissue. The statute raises several fundamental questions about this model as displayed by the graphic below.



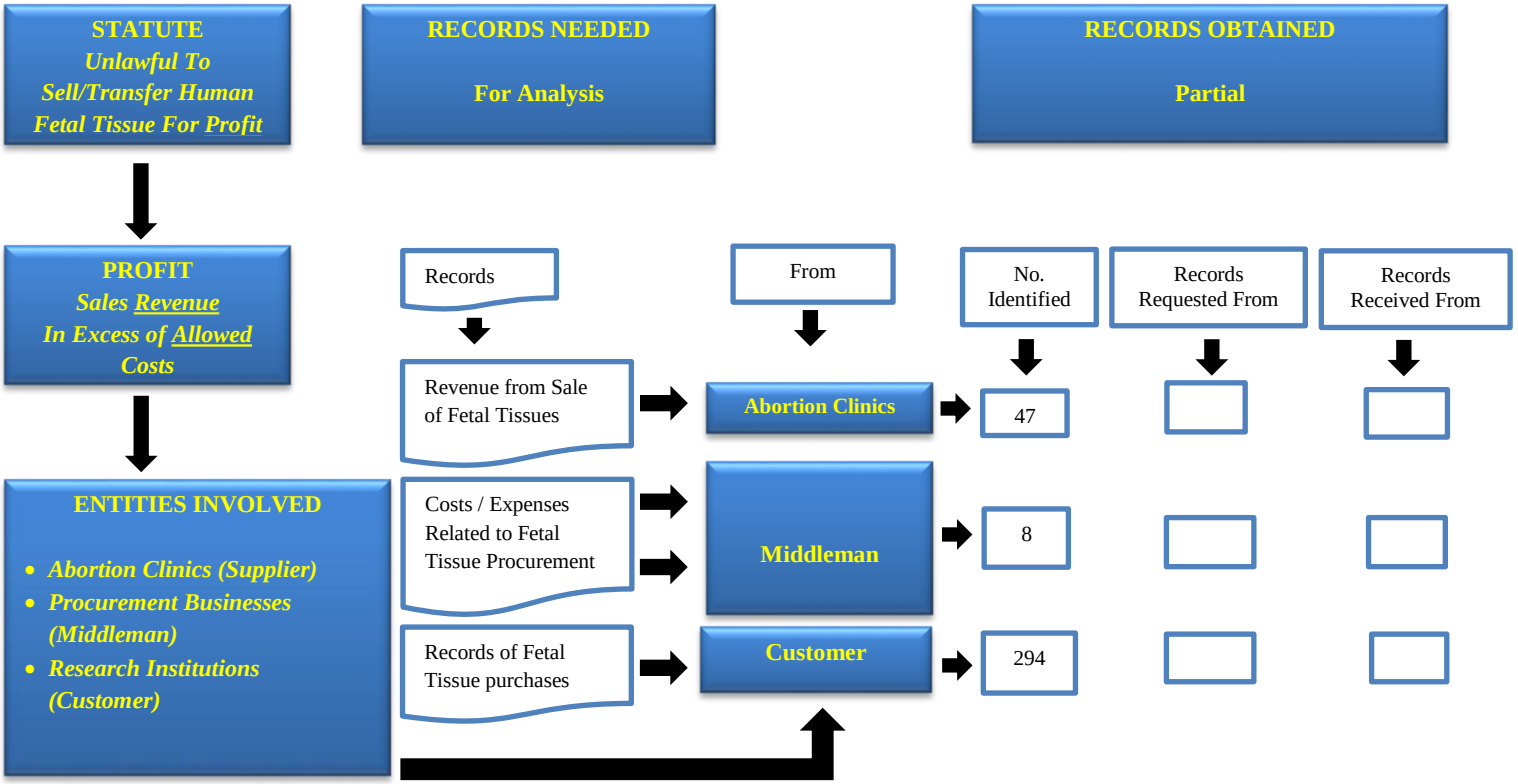
D. Middleman Investigative Work Plan Overview

The Panel relied upon the advice of a forensic accountant to formulate an investigative work plan. The statute (Section 289g-2) states that the term "valuable consideration" does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue. The Panel relied on generally accepted accounting standards, which defined payments made (including costs incurred) that are reflected as expenses, and payments received that are reflected as revenue (or income, from selling a product or service). Together these formed the Panel's basis for seeking accounting records of the business transactions of the fetal tissue procurement middleman companies, the abortion clinics from which they harvested fetal tissue, and the customers that purchased fetal tissue. The Panel sought to understand the transactional data, reflected on income statements and balance sheets. Also, the Panel relied upon the requirement that nonprofit entities comply with Internal Revenue Service (IRS) requirements to keep records that clearly show their income and expenses in order to substantiate deductions and claims made on their tax returns.

For the Panel to complete its review and determine the extent to which an entity did not receive valuable consideration allowed by the statute (or violated the statute), a thorough examination of the accounting records is necessary. Payments made and/or received as described in the preceding paragraph are embedded in accounting records. Each time a company makes a financial transaction, a paper trail is generated, also known as a source document. These source documents include but are not limited to cancelled checks, original invoices, sales receipts, bank transaction records, leases & contracts, purchase orders, etc. These source documents form the basis to substantiate any assertions made by an entity, through its financial or accounting records (including a trial balance report, an income statement or records of profit and loss, a statement of cash flow and a balance sheet). The Panel sought such documentation, but many entities refused to comply, even with lawful congressional subpoenas.

The Panel's document requests and subpoenas reflected these accounting standards: In order to do a forensic examination of accounting and financial records, those financial records have to be completely presented and handed over to the auditors, examiners, or investigators. The responsibility to substantiate entries, deductions, claims, or other assertions made on the financial records (arising through review of the records) is on the entity providing the documentation. Without sufficient and appropriate substantiation, accounting principles view such records as inaccurate, incomplete, invalid, or unreliable.

Thus, the Panel was able to reach partial conclusions about the sufficiency of the statute that governs fetal tissue transfers. The Panel has made criminal referrals to law enforcement agencies that have additional investigative tools. The graphic chart below illustrates the Panel's work plan for an examination of accounting documentation.


STATUTE
Unlawful To Sell/Transfer Human Fetal Tissue For Profit
RECORDS NEEDED
For Analysis
RECORDS OBTAINED
Partial
PROFIT
Sales Revenue In Excess of Allowed Costs
ENTITIES INVOLVED
Abortion Clinics (Supplier)
Procurement Businesses (Middleman)
Research Institutions (Customer)
Records
From
No. Identified
Records Requested From
Records Received From
Revenue from Sale of Fetal Tissues
Abortion Clinics
47
Costs / Expenses Related to Fetal Tissue Procurement
Middleman
8
Records of Fetal Tissue purchases
Customer
294

II. Applicable Laws, Regulations, and Commissions

Chapter II Redaction Key:

1. [PP Witness #1] is an abortion provider in Los Angeles, California, an executive with Planned Parenthood Federation of America (PPFA) who is in charge of the PPFA Manual of Medical Standards and Guidelines.

2. [PP Doctor #1] is an abortion provider in Los Angeles, California, who also works for the Medical Directors' Council.

Given the breadth of the Select Investigative Panel's authorization, the Panel examined numerous federal and state laws which can be grouped into four broad categories, with some overlap: (1) laws protecting human research subjects and patient privacy; (2) laws regulating anatomical gifts for transplantation, therapy, research, and education; (3) laws protecting late-term and born-alive infants; and (4) laws pertaining to public funding for fetal tissue research and abortion providers.

Laws protecting human research subjects and privacy are rooted in the principles set forth in the Belmont Report. Research subjects must be respected as autonomous persons, researchers must adhere to the Hippocratic ideal, and the benefits of research must outweigh the risks to human research subjects. The Panel heavily examined the legal and ethical importance of informed consent.

Laws regulating anatomical gifts are also heavily centered on the need for informed consent. Additionally, federal and many state laws explicitly prohibit the sale of human body parts. Laws protecting late-term unborn infants and infants born alive during abortion procedures recognize that the "right to an abortion" does not equal the right to a dead child. Federal laws prohibit a specific abortion procedure that occurs seconds before live birth and explicitly provide that infants born alive enjoy all of the constitutional rights available to other Americans.

Finally, laws pertaining to public funding for fetal tissue research and abortion providers need reforming. In particular, while federal law contains numerous restrictions on public funding for abortion, abortion providers receive millions of federal dollars ostensibly for other purposes. Government investigations and whistleblower testimonies have revealed that abortion providers often fail to separate public funding from abortion-related costs.

A. Laws Protecting Human Research Subjects and Patient Privacy

1. The Belmont Report

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created on July 12, 1974, with the passage of the National Research Act.[17] The Act was largely a response to the reprehensible Tuskegee Syphilis study, in which

[17] P.L. 93-348.

African-American men were asked to participate without informed consent. These men were not given adequate treatment for their disease, even after penicillin became the accepted drug for treating syphilis in 1947. In 1972, an advisory panel concluded that the Tuskegee Study was "ethically unjustified."[18]

The National Commission was tasked with identifying "the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects" and developing "guidelines which should be followed to assure that such research is conducted in accordance with those principles."[19] The Commission's work culminated in the issuance of the Belmont Report. This seminal report set forth three principles of biomedical research:

> (1) **Respect for persons**, with consideration given to individuals' autonomy. This principle underlies the requirement of obtaining a patient's informed consent.
>
> (2) **Beneficence**, reflecting the Hippocratic ideal of doing no harm.
>
> (3) **Justice**, with potential benefits of research balanced against the risks to subjects (*i.e.*, people).

The Belmont Report's relevance to the Panel's investigation was clear during the Panel's hearing on *Bioethics and Fetal Tissue*. Rep. Vicky Hartzler (MO-4) addressed an important statement in the Belmont Report regarding informed consent—that "inducements [to consent] that would ordinarily be acceptable may become undue influences if the [research] subject is especially vulnerable."[20] She asked an ethics expert if a form known to be widely used by abortion clinics to obtain a mother's consent to donate fetal tissue complied with "HHS's mandate against inducement."[21] The form stated that "[r]esearch using the blood from pregnant women and tissue that has been aborted has been used to treat **and find a cure** for such diseases as diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS."[22]

The witness agreed that this was an important question because the "idea of the promise of cures" found in the form was a "very powerful motivator."[23] The witness also

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[18] *See* The Tuskegee Timeline, CDC, http://www.cdc.gov/tuskegee/timeline.htm.
[19] *See* The Belmont Report, Office of the Sec., Ethical Principles and Guidelines for the Protection of Human Subjects of Research, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Summary (1979), http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/.
[20] The Belmont Report, Office of the Sec., Ethical Principles and Guidelines for the Protection of Human Subjects of Research, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979), http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/.
[21] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong. 77 (unedited transcript) (Mar. 2, 2016), http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-Transcript-20160302.pdf.
[22] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong. Majority exhibit A-3 (Mar. 2, 2016), http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-20160302-SD030.pdf (emphasis added).
[23] *Id.*

indicated that the "consent" form was deficient in other ways: "The concern I have is that the standards that we have typically for fetal tissue donation are just absent here. And so in addition to the voluntariness, there is just the thoroughness of the consent [that] seems to be missing in this form."[24]

A researcher invited by the Minority during the hearing agreed, stating that the form would not have "made it past" his IRB.[25] The testimony provided by witnesses invited by both the Majority and Minority raised concerns that the principles embodied in the Belmont Report, and later incorporated into federal regulations, are not being followed by abortion providers seeking consent for the donation of human fetal tissue.

During the hearing, Rep. Mia Love (UT-4) expressed deep concern with the issue of consent and minors. She stated: "So, imagine [a] 14-year-old going into a clinic to undergo a very invasive procedure without someone there that she trusts to walk her through, to make sure that she is not being taken advantage of, to make sure that she is making the right decision."[26] She asked, "How can anyone be sure that that minor, under difficult circumstances, fully understand[s] the long-term repercussions behind [her] decision when the current law wouldn't even allow that minor to get behind the wheel of a vehicle?"[27] Dr. G. Kevin Donovan, a witness, agreed that this presented a troubling problem.[28]

2. The Common Rule and IRB Regulations

In response to the Belmont Report, HHS and the FDA significantly revised their human subjects regulations in 1981.[29] The Common Rule[30] applies to research projects that receive funding from any one of 19 federal agencies. It requires three steps to be fulfilled before the research can take place: 1) the human subject must give informed consent; 2) an Institutional Review Board (IRB) must review the proposed research project; and 3) the institution conducting the research must file an assurance of compliance with the federal agency that is providing the funding. For fetal tissue, if the researchers would like access to the woman's medical information, then the HIPAA Privacy Rule applies, and she must give consent for that information to be shared.

The rule lists several criteria for IRB approval, including the requirement that researchers obtain the informed consent from their research subjects. There are eight basic elements of informed consent under the Common Rule that "shall be provided to each subject."[31] The HHS regulations also require an IRB to "prepare and maintain adequate documentation" of its activities.[32]

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[24] *Id.* (testimony of Paige Cunningham).
[25] *Id.* (testimony of Lawrence Goldstein).
[26] *Id.*
[27] *Id.*
[28] *Id.* (testimony of G. Kevin Donovan).
[29] 45 C.F.R. § 46; 21 C.F.R. § 50; *See* Erin D. Williams, Cong. Research Serv., RL32909, Federal Protection for Human Research Subjects: An Analysis of the Common Rule and its Interactions with FDA Regulations and the HIPAA Privacy Rule 78 (2005).
[30] 45 C.F.R. § 46.
[31] 45 C.F.R. § 116.
[32] 45 C.F.R. § 46.115(a).

The Panel's investigation revealed evidence that the IRB process used by some fetal tissue procurement companies is often grossly insufficient. For instance, on March 29, 2016, the Panel issued a subpoena to BioMed IRB which required it to produce documents sufficient to show BioMed IRB's ongoing oversight, within the definition of federal regulations, of any entity involved with fetal research or transplantation of fetal tissue for which it issued an IRB approval.[33] BioMed IRB's executive director informed the Panel on April 4, 2016, that, in regards to those records, "there are none."[34] This is an apparent direct violation of federal regulations.

3. Presidential Commissions

Since 1974, "public national bodies" have had a role in the national debate surrounding bioethics. These groups have grappled with topics ranging from human subject research to end-of-life care to stem cell research. Their studies have most frequently been conveyed through reports, policy proposals, and hearings. Furthermore, fetal tissue research has been a topic of their conversations since the first commission.

In addition to the Belmont Report, the first group published a report called *Research on the Fetus* (1975), in which they said their primary concern was "research on the fetus . . . before, during and after induced abortion." While they recommended "that use of the dead fetus, fetal tissue and fetal material for research purposes be permitted," several members of the commission (both for and against abortion) argued that research on fetuses past viability was unethical. They also recommended that the method of abortion should not be changed for research purposes and that no financial inducements "be offered to procure an abortion for research purposes."[35]

President Reagan's **Presidential Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research** (1978-1983) added an important voice to the discussion of euthanasia with their report *Defining Death*,[36] which served as the basis for the Uniform Determination of Death Act subsequently enacted by most states. Their report *Screening and Counseling for Genetic Conditions* (1983)[37] discussed in part the ethics of having abortions based on the knowledge of the sex or various disabilities of the fetus.

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[33] Subpoena from Select Investigative Panel to Biomedical Research Institute of America (Mar. 29, 2016).
[34] Email from Executive Director, Biomedical Research Institute of America, to Select Investigative Panel staff (Apr. 4, 2016).
[35] *See* Research on the Fetus, U.S. Dept. of Health, Ed., & Welfare, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1975), https://videocast.nih.gov/pdf/ohrp_research_on_fetus.pdf.
[36] *See* Defining Death: Medical, Legal, and Ethical Issues in the Determination of Death, President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1981), https://repository.library.georgetown.edu/bitstream/handle/10822/559345/defining_death.pdf?sequence=1&isAllowed=y.
[37] *See* Screening and Counseling for Genetic Conditions: The Ethical, Social and Legal Implications of Genetic Screening, Counseling, and Education Programs, President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1983), https://repository.library.georgetown.edu/bitstream/handle/10822/559349/geneticscreening.pdf?sequence=1&isAllowed=y.

The **Advisory Committee on Human Radiation Experiments** (1994-1995), created by President Clinton, investigated human radiation experiments conducted from 1944-1974, while his second commission, the **National Bioethics Advisory Commission**, set out in part to "familiarize professionals engaged in nonfederally-funded research with the ethical considerations associated with conducting research involving human subjects."[38]

President George W. Bush's **Presidential Council on Bioethics** (PCBE) is perhaps most renowned for the academic seriousness with which it approached bioethics. Guided by the belief that respect for human life and advancing biotechnology were compatible, President Bush appointed a diverse group of scientists and ethicists to the Council to advise him, particularly in regard to embryonic stem cell research. President Bush was especially concerned that research using embryonic stem cells, which he believed ended human lives, was unethical. He relied on policy recommendations from the PCBE to promote bills prohibiting biomedical practices he found morally objectionable. For example, the Fetus Farming Prohibition Act of 2006 was a response to the PCBE's report *Reproduction and Responsibility*, whose policy recommendations attempted to limit questionable practices, particularly by instituting (at least temporarily) moratoriums on those affecting reproduction.[39] The Fetus Farming bill made it a federal crime to be involved in interstate commerce to acquire "human fetal tissue knowing that a human pregnancy was deliberately initiated" to provide the tissue.[40]

The Panel's research found that—even with the material produced by these commissions—answers to many questions were out of date or nonexistent. Of particular concern are current practices in tissue and organ donation; research ethics and the revolution in biotechnology; the ability of the regulatory agencies to address misconduct; and the role of law enforcement. Many of the Panel's questions directed to the Federal Drug Administration and the National Institutes of Health could not be answered at all. The U.S. Department of Justice wrote to the Panel that it had never conducted training on the criminal statute that makes profiting from human fetal tissue sales a felony. The same letter could provide no example of attorney training or convictions under the statute.

4. HIPAA Privacy Rule

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule (Privacy Rule) protects all individually identifiable health information held or transmitted by a covered entity or its business associate and calls this information protected health information (PHI).[41] PHI identifies an individual, or can reasonably be believed to be useful in identifying an individual (*e.g.*, name, address, birth date, Social Security number), and includes demographic data relating to an individual's past, present, or future physical or mental health condition; the provision of health care to the individual; or the past, present, or future payment for the provision of health care to the individual.[42]

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[38] *See* Exec. Order No. 12975, "Protection of Human Research Subjects and Creation of National Bioethics Advisory Commission" (1995), https://bioethicsarchive.georgetown.edu/nbac/about/eo12975.htm.
[39] *See* Reproduction and Responsibility: The Regulation of New Biotechnologies, The President's Council on Bioethics (2004), https://bioethicsarchive.georgetown.edu/pcbe/reports/reproductionandresponsibility/.
[40] Pub. L. No. 109-242; 42 U.S.C. § 289g-2.
[41] 45 C.F.R. § 160.103.
[42] *Id.*

A covered entity may not use or disclose an individual's PHI except as the Privacy Rule permits or requires[43] or as the individual or their representative authorizes in writing. HHS may impose civil penalties on covered entities that fail to comply with the Privacy Rule. Further, both a covered entity that discloses and any person who knowingly obtains PHI in violation of the Privacy Rule can face criminal fines or imprisonment.[44]

The Panel's investigation uncovered a series of business contracts between StemExpress, a tissue procurement business (TPB), and several abortion clinics. These contracts included provisions for the payment of fees by StemExpress to the abortion clinics for fetal tissue and maternal blood. StemExpress then resold the fetal tissue and blood to researchers.

The Panel's investigation indicates that StemExpress and Planned Parenthood Mar Monte (PPMM), Planned Parenthood Shasta Pacific (PPSP), and Family Planning Specialists Medical Group (FPS) (the abortion clinics) committed systematic violations of the HIPAA Privacy Rule from about 2010 to 2015. These violations occurred when the abortion clinics disclosed patients' individually identifiable health information to StemExpress to facilitate the TPB's efforts to procure human fetal tissue for resale.

From about 2010 to 2015, the abortion clinics (covered entities under HIPAA) permitted employees of StemExpress (a non-covered entity) to enter their clinics and procure human fetal tissue from aborted infants, obtain PHI about their patients, interact with patients, and seek and obtain patient consent for tissue donation.[45] StemExpress did not have a medically valid reason to see, and the abortion clinics did not have a reason to provide, patients' PHI. Instead, the abortion clinics shared patients' PHI with StemExpress in furtherance of contractual agreements that financially benefited StemExpress and the clinics.[46]

The abortion clinics and StemExpress violated the HIPAA privacy rule because: (a) the disclosures of patients' PHI made by the abortion clinics and received by StemExpress were neither required nor permitted under HIPAA, and in particular did not meet the exceptions for cadaveric organ, eye or tissue transplantation or for research; (b) the consents for fetal tissue donation ostensibly obtained by StemExpress from the abortion clinics' patients did not constitute sufficient authorizations for the disclosure of PHI; (c) the disclosures of patients' PHI made by the abortion clinics to StemExpress were not the minimum necessary disclosures to facilitate the procurement of human fetal tissue from aborted infants; and (d) StemExpress is not a "business associate" of the abortion clinics under HIPAA.

The abortion clinics could have directly consented their patients for tissue donation and entered an agreement with StemExpress to provide a limited data set regarding the patients they were seeing on a particular day.[47] Instead, they violated the Privacy Rule by permitting StemExpress to view the most intimate information about their patients.

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[43] 45 C.F.R. § 164.502(a).
[44] Pub. L. No. 104-191; 42 U.S.C. §§ 1320d-5-1320d-6.
[45] *See* Clinic Procedures & Policies, produced by StemExpress, Exhibit 2.1.
[46] *See* Standard Operating Procedure, produced by StemExpress, Exhibit 2.2.
[47] *See* 45 C.F.R. § 164.514(e).

These disclosures made by the abortion clinics to StemExpress were intentional and purposeful.[48] StemExpress employees were handed a patient's medical chart by her healthcare provider in blatant violation of the HIPAA privacy rule.

B. Laws Regulating Anatomical Gifts for Transplantation, Therapy, Research, and Education

1. National Organ Transplant Act

The National Organ Transplant Act (NOTA)[49] was enacted in 1984, providing for the establishment of the Task Force on Organ Transplantation. The Act also authorized the Secretary of Health and Human Services to make grants for organ procurement organizations, created the Organ Procurement and Transplantation Network (OPTN), created the Scientific Registry of Transplant Recipients, and created an administrative unit within HHS to administer these activities. Importantly, NOTA included a criminal prohibition against the exchange of organs for transplantation for valuable consideration.[50]

NOTA provides that "[i]t shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. . . . Any person who violates [] this section shall be fined not more than $50,000 or imprisoned not more than five years, or both." The term "human organ" is defined to include fetal organs and subparts of organs.[51]

2. Uniform Anatomical Gift Act

The Uniform Anatomical Gift Act (UAGA), a model statute first available in 1968 and most recently amended in 2009, was written to facilitate organ donation for transplantation, therapy, research, and education by ensuring that state laws are consistent across the country.[52] The UAGA, adopted in every state in some form, includes stillborn babies and fetuses in the definition of "decedent" for purposes of obtaining consent from a relative before the deceased infant's body is donated for experimentation or transplantation. In the UAGA's official notes, the drafters explain that the inclusion of stillborn babies and fetuses ensures that they "receive the statutory protections conferred by this [act]; namely that their bodies or parts cannot be used for transplantation, therapy, research, or education without the *same appropriate consents* afforded other prospective donors."[53]

However, the notes also mention that states may choose to treat aborted fetuses

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[48] *See* 45 C.F.R. § 164.502(a)(1)(iii).
[49] 98 P.L. 507; 98 Stat. 2339.
[50] *See* U.S. Dept. of Health & Human Services, Selected Statutory and Regulatory History of Organ Transplantation, http://organdonor.gov/about-dot/laws/history.html.
[51] 42 U.S.C. § 274e.
[52] *See* Revised Uniform Anatomical Gift Act (2006) (Last Revised or Amended in 2009), drafted by the National Conference of Commissioners on Uniform State Laws, http://www.uniformlaws.org/shared/docs/anatomical_gift/uaga_final_aug09.pdf.
[53] *Id.*

differently, given the "complicated legal, scientific, moral, and ethical issues which may arise."[54] To date, eight states explicitly prohibit experimentation on aborted infants: Alabama, Arizona, Idaho, Indiana, North Dakota, Ohio, Oklahoma, and South Dakota. In other states, restrictions on the use of aborted infants' remains for research are implicit.

For instance, New Mexico's Jonathan Spradling Revised Uniform Anatomical Gift Act (Spradling Act)[55] is based on the UAGA.[56] The Spradling Act was enacted in 2007 to replace the State's existing Anatomical Gift Act[57] with provisions mirroring the UAGA.[58] In their new law, New Mexico decided to follow the suggestion in the UAGA to treat aborted fetuses differently: "'decedent' means a deceased individual whose body or part is or may be the source of an anatomical gift." It "includes a stillborn infant and . . . a fetus but [does] not includ[e] a fetus that is the subject of an induced abortion."[59]

Further, the Spradling Act provides that the Act "applies to an anatomical gift or amendment to, revocation of or refusal to make an anatomical gift, whenever made."[60] In other words, all anatomical gifts in the State of New Mexico must comply with this act, and the bodies or body parts of aborted infants cannot be anatomical gifts.

The Panel learned, however, that the University of New Mexico (UNM) and the late-term abortion clinic Southwestern Women's Options (SWWO) have an extensive history in which SWWO provided fetal tissue to UNM researchers. SWWO's provision and UNM's acquisition of and research using aborted infant remains appear to violate the Spradling Act. Any consents ostensibly obtained by SWWO from mothers of aborted infants do not validate the donation of their infants' remains for research, because under the Spradling Act the bodies or parts of aborted infants may not be anatomical gifts.

3. NIH Revitalization Act of 1993

Under the NIH Revitalization Act of 1993, the Secretary of the Department of Health and Human Services (HHS) is permitted "to conduct or support research on the transplantation of human fetal tissue for therapeutic purposes," including tissue from aborted infants. The law places numerous requirements on the acquisition of fetal tissue and on fetal tissue research, including a requirement that the infant's mother provide written consent. Further, when tissue is obtained from aborted infants, a mother's consent to donate her infant's remains must *follow* her consent to the abortion procedure. The law also prohibits the "alteration of the timing, method, or procedures used to terminate the pregnancy . . . solely for the purposes of obtaining the tissue," and requires abortion providers to perform the abortions in accordance with "applicable State law."[61]

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[54] *Id.*
[55] N.M. Stat. Ann. § 24-6B-1, *et seq*.
[56] Revised Uniform Anatomical Gift Act.
[57] N.M. Stat. Ann. § 24-6A-1 *et seq.*
[58] *See* Fiscal Impact Report, Revised Uniform Anatomical Gift Act 3 (Mar. 14, 2007), https://www.nmlegis.gov/Sessions/07%20Regular/firs/HB1276.pdf.
[59] N.M. Stat. Ann. § 24-6B-2 (emphasis added).
[60] N.M. Stat. Ann. § 24-6B-3.
[61] 42 U.S.C. § 289g-1.

Additionally, the Act provides that "[i]t shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce." Further, the solicitation or acceptance of tissue as directed donation for use in transplantation is prohibited. Persons or entities "involved or engaged in interstate commerce" may not "solicit or knowingly acquire, receive, or accept a donation of human fetal tissue knowing that a human pregnancy was deliberately initiated to provide such tissue." Violations of this law can result in a fine or imprisonment for up to 10 years. "Valuable consideration" is defined to exclude "reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."[62]

Laws regulating the donation of human organs, including human fetal organs, are relevant for the Panel's investigation, given the possibility that both tissue procurement businesses (TPBs) and abortion providers are profiting from fetal tissue procurement. During the Panel's April 20, 2016, hearing, *The Pricing of Fetal Tissue,* Panel members asked witnesses to examine evidence that payments paid by customers to a TPB for fetal tissue exceeded costs incurred by the business by a factor of 300 to 700 percent. Further, the evidence *did not* demonstrate that in many instances the "compensated" abortion clinics incurred any actual costs.[63]

Witness Brian Lennon, a former federal prosecutor, stated that he "didn't see [evidence] in any of the [hearing] exhibits" that abortion clinics had reasonable costs associated with fetal tissue donation.[64]

C. Laws Protecting Late-Term and Born-Alive Infants

House Resolution 461 provided the Panel with jurisdiction to review "[t]he practice of providers of second and third trimester abortions, including partial birth abortion procedures that may lead to a child born alive as a result of an attempted abortion," as well as "[m]edical procedures for the care of a child born alive as a result of an attempted abortion." The panel investigated these issues in the context of two federal laws—the Born-Alive Infants Protection Act and the Partial-Birth Abortion Ban Act.

1. Born-Alive Infants Protection Act (BAIPA)

President George W. Bush signed the Born-Alive Infants Protection Act (BAIPA)[65] in 2002, which passed by voice vote in the House of Representatives and with unanimous support in the Senate. BAIPA clarifies that for purposes of all federal laws, the terms "person," "human being," "child," and "individual" include every infant who is born alive, regardless of whether that birth is the result of labor, cesarean section, or induced abortion. BAIPA *does not* contain its own criminal penalties or any other enforcement mechanism to hold abortion providers accountable who fail to provide medical attention and care to infants born alive during an

[62] 42 U.S.C. § 289g-2.
[63] *See generally The Pricing of Fetal Tissue: Hearing Before the Select Investigative Panel, The Comm. on Energy and Commerce,* 114th Cong. (2016).
[64] *Id.* at 97.
[65] 1 U.S.C. § 8.

abortion or attempted abortion.

The "right to an abortion" does not equal the right to a dead child. Through the enactment of BAIPA, the United States Congress recognized that the right to abortion has limits, and is not an absolute, ever-expanding right. In particular, the right to abortion does not extend so far as to justify the denial of fundamental civil rights and protections to born, living human children.

During the Panel's investigation, staff reviewed tissue procurement notes, email exchanges among researchers, TPBs and abortion clinics, invoices, and more—all indicating that researchers want fetal tissue from late-gestation infants that has not been tainted by feticidal agents (*e.g.*, digoxin).[66] The Panel also learned that abortion providers may modify abortion procedures, in apparent violation of the law, to increase the odds of getting an intact infant cadaver (*e.g.*, increase the number of laminaria placed in a patient's cervix to achieve greater dilation).[67] Clearly, these factors increase the likelihood that unborn infants are born alive during late second trimester abortions, and raise the question whether these infants' civil rights are recognized by abortion providers.

[PP Witness #3] acknowledged that "a practitioner who does not intend to do an intact procedure could nonetheless have an intact delivery that was not intended."[68] Further, interviews with second-trimester abortion providers revealed that, while they deny delivering live infants during abortion procedures, they are inadequately prepared to care for an infant if a live birth were to occur. When asked what Planned Parenthood would do if an infant was born alive during an abortion procedure, [PP Witness #1] stated bluntly:

> I can tell you that none of our Health Centers provide obstetrics care. So they don't deliver babies. So they don't have anyone who can provide care, nor do they know what that care is. . . . We don't deliver babies at Planned Parenthood. . . . [O]ur affiliates don't provide obstetrical care. So therefore, they don't know how to manage a term infant or a premature infant.[69]

When Panel staff asked whether "the protocol [should] be to call an ambulance right away" if a premature infant were born alive during an abortion, [PP Witness #1] stated "[s]o there's no protocol for this. I'm not going to sit here and write a protocol."[70]

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[66] *See, e.g.*, Documents produced by the University of New Mexico: procurement notes stating "clinic now uses digoxin only at 20 weeks" [UNM 00049]; procurement notes lamenting that 25-week aborted infant "treated" with digoxin: "heart mushy; GI discolored +liver; skin loose; eyes discolored red" [UNM 00004]; heavily redacted email exchange, where UNM employee states that they will try to get later gestation lung; sometimes they can get up to 20-22 weeks, but unusual "these days" to get non-digoxin-exposed samples beyond 18 weeks [UNM 00910], Exhibit 2.3.

[67] *See generally Interview of [PP Witness #1], before the Select Investigative Panel, Comm. on Energy and Commerce*, 114th Cong. (unedited transcript) (Oct. 6, 2016).

[68] *Interview of* [PP Witness #3], *before the Select Investigative Panel, Comm. on Energy and Commerce*, 114th Cong. 46 (unedited transcript) (Nov. 1, 2016).

[69] *Interview of [PP Witness #1]*, at 223-24.

[70] *Interview of [PP Witness #1]*, at 225-27. At that time, [PP Witness #1]'s, attorney asked for a break. Upon returning, [PP Witness #1] stated that if an infant were born with signs of life, she "would call an ambulance and

2. Partial-Birth Abortion Ban Act (PBA)

President George W. Bush signed the **Partial-Birth Abortion Ban Act (PBA)** on November 5, 2003.[71] In 2007, the Act was upheld by the United States Supreme Court in *Gonzales v. Carhart*.[72] The PBA prohibits the abortion procedure known as "partial-birth abortion," or "intact dilation and extraction," described as when the abortion provider:

> (A) deliberately and intentionally vaginally delivers a living fetus until, in the case of a head-first presentation, the entire fetal head is outside the body of the mother, or, in the case of breech presentation, any part of the fetal trunk past the navel is outside the body of the mother, for the purpose of performing an overt act that the person knows will kill the partially delivered living fetus; and
>
> (B) performs the overt act, other than completion of delivery, that kills the partially delivered living fetus. . . .

At least 19 states have laws mirroring the federal PBA.[73] Because researchers desire to obtain intact fetal cadavers and organs, as discussed above, the Panel investigated whether abortion providers may be using the partial-birth abortion procedure in violation of federal and/or state law.

D. Laws Related to Public Funding of Fetal Tissue Research and Abortion Providers

1. NIH Grants

On October 4, 2000, the U.S. GAO reported that the National Institutes of Health (NIH) is the only federal agency under the Subcommittee on Labor, Health and Human Services, and Education jurisdiction that sponsors research using human fetal tissue.[74] NIH spent $76 million on human fetal tissue research in FY2014, and will spend approximately $76 million in FY2015 and $77 million in FY2016.[75] In addition to broader reporting requirements regarding "activities conducted or supported by the NIH, the Director of NIH is required to submit to Congress an annual report that describes how NIH and its agencies "store and track human tissue samples."[76] (For a detailed examination of NIH grants, please see Chapter IX.)

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give the fetus comfort care until the ambulance arrived if it was viable or looked like [sic] a periviable" or would "just give it comfort care and let it expire" if the infant were "nonviable."

[71] 18 U.S.C. § 1531.

[72] 550 U.S. 124 (2007).

[73] *See* Guttmacher Institute, *Bans on Specific Abortion Methods Used After the First Trimester* (Nov. 1, 2016), https://www.guttmacher.org/state-policy/explore/bans-specific-abortion-methods-used-after-first-trimester.

[74] GAO letter to Arlen Specter, Chairman, Subcomm. on Labor, Health and Human Services, and Education, Committee on Appropriations 2 (Oct. 4, 2000).

[75] Kristin Finklea, et al., Cong. Research Serv., R44129, Fetal Tissue Research: Frequently Asked Questions 1 (July 15, 2015) (based on search criteria entered at http://report.nih.gov/categorical_spending.aspx).

[76] PL 109-482.

2. Federal Funding for Abortion Providers

H. Res. 461 also gave the Panel jurisdiction to review federal funding and support for abortion providers. Congress has included restrictions on abortion funding in the HHS appropriations acts since fiscal year (FY) 1977. These restrictions, commonly known as the Hyde Amendment, prohibit the use of federal and state matching Medicaid funds[77] for most abortions. However, Congress permits abortion funding in specific circumstances that have changed periodically since enforcement began August 4, 1977, including when a pregnancy endangers a mother's life or health, and when the pregnancy resulted from rape or incest. In certain fiscal years, Congress required documentation and reporting to prove that a woman's circumstances fit the exceptions permitting abortion coverage. States may pay for abortions with state or local funds (*not* state matching Medicaid funds) allocated for health benefits or services.[78]

Other sources of federal funding may be used to pay for abortions; however, they are generally subject to restrictions mirroring the Hyde Amendment.[79] Hyde-like language exists "in the appropriations measures for foreign operations, the District of Columbia, the Treasury, and the Department of Justice."[80] Further, funds available to the Department of Defense (DOD) and the Indian Health Services (IHS) are limited by codified restrictions.[81]

While Congress has long limited the use of federal tax dollars to directly pay for abortions, abortion providers receive significant public funding ostensibly for other purposes. Sources of funding for "reproductive health services" include Medicaid (family planning), Title X of the Public Health Service Act, the Federal Health Center Program, The Ryan White HIV/AIDS program, the National Breast and Cervical Cancer Early Detection Program, Sexually Transmitted Diseases Prevention Grants, Title V Maternal and Child health Block Grant, Teen Pregnancy Prevention Program, and the Social Services Block Grant Program.[82] Additionally, many states and localities provide funding for reproductive health services.

a) Medicaid

Medicaid accounts for 75% of U.S. public expenditures for "family planning services"—up from 20% in 1980.[83] Medicaid reimburses providers for contraceptive items and procedures and related services, with the federal government paying 90% of the cost (versus 50% to 75% for

[77] "Medicaid provides health coverage to millions of Americans, including . . . pregnant women. . . . Medicaid is administered by states, according to federal requirements. The program is funded jointly by states and the federal government." Medicaid.gov, overview, https://www.medicaid.gov/medicaid-chip-program-information/medicaid-and-chip-program-information.html.
[78] *See generally* FY 2017 Moyer Material, Submitted by the Office of the Assistant Secretary for Financial Resources, U.S. Depart. of Health and Human Services, Addendum: Abortion-Related Reporting 1-8 (2016).
[79] *See generally* Elayne J. Heisler, et al., Cong. Research Serv., R44130, *Federal Support for Reproductive Health Services: Frequently Asked Questions* (Aug. 24, 2016).
[80] *Id.* at 2.
[81] *Id.*; 10 U.S.C. § 1093 (DOD) and 25 U.S.C. § 1676 (IHS).
[82] *See generally Federal Support for Reproductive Health Services: Frequently Asked Questions*.
[83] *See, e.g.*, Guttmacher Institute, *Publicly Funded Family Planning Services in the United States*, https://www.guttmacher.org/fact-sheet/publicly-funded-family-planning-services-united-states.

most other services) and states paying 10%, and with no out-of-pocket costs for beneficiaries.[84] Medicaid enrollees are permitted to receive family planning care from "qualified providers" of their choice, regardless of whether the providers are in their health plans' network. That family planning provider is then reimbursed by the state or by the plan.[85]

In FY 2010, federal and state[86] public expenditures for family planning services alone totaled $2.37 billion.[87] While not all recipients of this funding perform abortions,[88] the nation's largest abortion provider, Planned Parenthood, provides an excellent study of the impact of public funding on the abortion industry.[89] During fiscal year 2015, 43% of Planned Parenthood's revenue derived from "government health services grants & reimbursements," at a price tag of $553,700,000.[90]

Further, while abortion providers are not permitted to receive reimbursement *for abortion* from Medicaid, former employees of Planned Parenthood have testified that Planned Parenthood would separate out charges for services and products rendered in connection with abortions, such as office visits, ultrasounds, Rh factor tests, lab work, general counseling, and abortion aftercare, and submit those "fragmented" or "unbundled" charges as claims for Medicaid reimbursement.[91]

In fact, the Charlotte Lozier Institute and Alliance Defending Freedom have documented that—based on 51 known external audits or other reviews of Planned Parenthood affiliates' financial data and practices, and 61 federal audits of state family planning programs by HHS-OIG—Planned Parenthood affiliates have overbilled $132.4 million in Medicaid and other healthcare funding programs.[92] These audit results are troubling, given their limitations in scope,

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[84] *See, e.g., id.*; *Federal Support for Reproductive Health Services: Frequently Asked Questions.*
[85] *Federal Support for Reproductive Health Services: Frequently Asked Questions*.
[86] State funding accounted for 12 percent of the total. Guttmacher Institute, *Publicly Funded Family Planning Services in the United States*, https://www.guttmacher.org/fact-sheet/publicly-funded-family-planning-services-united-states.
[87] *Publicly Funded Family Planning Services in the United States*.
[88] *Publicly Funded Family Planning Services in the United States*. In 2010, subsidized family planning services were provided at 8,409 "safety-net health centers"—38% were federally qualified health centers; 29% were health department clinics; 16% were other clinics; 10% were Planned Parenthood centers; and 8% were hospital clinics.
[89] Planned Parenthood is the largest abortion provider in the U.S., performing more than 300,000 abortions per year, or approximately 1 in 3. Americans United for Life, *The New Leviathan: The Mega-Center Report—How Planned Parenthood has Become Abortion, Inc*. 4 (2015), http://www.aul.org/wp-content/uploads/2015/06/AUL-Mega-Center-Report-06-24-2015.pdf (citing PPH Annual Reports for 2012, 2013, and 2014 at Planned Parenthood of the Heartland, Publications, http://www.plannedparenthood.org/planned-parenthood-heartland/who-we-are/publications).
[90] Planned Parenthood Federation of America, Annual Report, 2014-2015, at 32-33, https://www.plannedparenthood.org/files/2114/5089/0863/2014-2015_PPFA_Annual_Report_.pdf.
[91] Americans United for Life, *The Planned Parenthood Exhibits: The continuing case for investigating the nation's largest abortion provider* Exhibit 17 (2012).
[92] Charlotte Lozier Institute and Alliance Defending Freedom, *Profit. No Matter What.* (Nov. 1, 2016). In addition to "fragmenting" and "unbundling" abortion services in violation of the Hyde Amendment, Planned Parenthood affiliates were found by audit: "Dispensing prescription drugs, including oral contraceptives, without an authorizing order by a physician or other approved healthcare practitioner; Dispensing prescription drugs, including oral contraceptives, to patients who have moved or have not been seen by the clinic for more than a year; Billing in excess of actual acquisition cost or other statutorily approved cost for contraceptive barrier products, oral contraceptives, and emergency contraceptive-Plan B (i.e., § 340B drugs) products; Billing for services that were not medically necessary, including services for men and for women who were already pregnant, sterilized, or

detail, and timeframe; in fact, of 57 U.S. Planned Parenthood affiliates, only 19 have been audited.[93]

Under federal law, healthcare providers participating in Medicaid are required to return overpayments within sixty days of identification.[94] State Medicaid agencies are also required to return overpayments and have up to a year to make collections before they are penalized by the federal government.[95]

The United States Supreme Court has held that it is permissible for a state to engage in unequal subsidization of abortion and other medical services to encourage alternative activity deemed in the public interest.[96] However, courts and the executive branch have largely thwarted efforts to prevent abortion providers from subsidizing abortion and other services with taxpayer funding.

The Obama Administration has denied or threatened to deny federal Medicaid funding to states that have attempted to withhold Medicaid reimbursement from abortion providers. Further, the Seventh and Ninth Circuits have interpreted Medicaid's "free choice of provider"[97] provision—guaranteeing Medicaid recipients' freedom to choose their family planning providers—as a legal impediment to prohibiting abortion providers from receiving federal Medicaid funding.[98]

However, in *Planned Parenthood v. Indiana*, the Seventh Circuit *upheld* Indiana's prohibition on abortion providers receiving funding through the federal Disease Intervention Services agency ("DIS"), for the diagnosis and monitoring of sexually transmitted diseases. The Seventh Circuit explained that the key difference between the provision upheld and the provision struck down was that the DIS program did *not* have a federal statutory limitation (similar to Medicaid's "free choice of provider" provision) on how states could determine eligibility.[99]

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postmenopausal; Billing for services that were not actually rendered; Duplicate billing for examinations and products, including billing products and services already billed as part of a service package, as fee for service; Incorrectly coding and billing services; Inadequate record-keeping, including lacking documentation to support the service billed and paid and not signing medical entries; and Failing to pay the bills for which an affiliate had already been reimbursed with taxpayer funds."

[93] *See id.*

[94] SSA Sec. 1128J(d).

[95] SSA Sec. 1903(d)(2).

[96] Further, the decision not to fund abortion places no governmental obstacle in the path of a woman who chooses to terminate her pregnancy. *See Rust v. Sullivan*, 500 U.S. 173, 201 (1991). The Court has repeatedly affirmed the constitutionality of federal and state restrictions on public funding for abortions. *See, e.g., Harris v. McRae*, 448 U.S. 297 (1980) (holding that the government may rationally distinguish between abortion and other medical procedures because "no other procedure involves the purposeful termination of a potential life").

[97] 42 U.S.C. § 1396a(a)(23)(B). A state may establish "reasonable standards relating to the qualifications of providers" and may exclude healthcare providers under certain circumstances: "[i]n addition to any other authority, a State may exclude an individual or entity . . . for any reason for which the Secretary [of HHS] could exclude the individual or entity from participation." 42 C.F.R. § 431.51(c)(2); 42 U.S.C. § 1396a(p)(1)).

[98] *Planned Parenthood v. Indiana*, 699 F.3d 962 (7th Cir. 2012) (invalidating an Indiana law); *Planned Parenthood v. Betlach*, 727 F.3d 960 (9th Cir. 2013) (invalidating an Arizona law).

[99] *Planned Parenthood v. Indiana*, 699 F.3d 962, 985 (7th Circ. 2012).

Legislative history demonstrates that states should have the power to exclude providers for *any reason/basis* under its state laws: "This provision is not intended to preclude a State from establishing, under State law, any other bases for excluding individuals or entities from its Medicaid program."[100] Also, the First Circuit held that the language of Medicaid's exclusion provision "was intended to permit a state to exclude an entity from its Medicaid program for *any* reason established by state law."[101]

b) Title X

Title X is the only federal grant program dedicated solely to providing family planning and related preventive care and is viewed as setting the standard for publicly funded family planning services. Priority is given to low-income families. Title X provides that "none of the funds appropriated … shall be used in programs where abortion is a method of family planning."[102] Public and private entities may obtain grants.

Ten percent of U.S. public expenditures for family planning client services are through Title X.[103] This is a 71% drop since 1980. Title X funding is valued because it provides more flexibility than Medicaid. The grants are used to maintain a network of "family planning Centers." The Reagan administration's strict regulations on Title X funding, designed to ensure the funds were not being used to subsidize abortion, were upheld by the Supreme Court in *Rust v. Sullivan*;[104] however, they are not in effect today.

Since 2011, numerous states have enacted laws requiring subrecipients of Title X funds to provide comprehensive healthcare to patients and/or refrain from performing abortions. In response, the federal government is actively circumventing the Title X prioritization laws in at least eight states by directly contracting with private entities such as Planned Parenthood.

Further, on Sept. 9, 2016, HHS issued a proposed rule stating that "[n]o recipient making sub awards for the provision of services as part of its Title X project may prohibit an entity from participating for reasons unrelated to its ability to provide services effectively."[105] In the proposed rule background, HHS states that "13 states have placed restrictions on or eliminated sub awards with specific types of providers. . . ."[106]

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[100] S. Rep. No. 100-109, at 20 (1987).
[101] *First Medical Health Plan v. Vega-Ramos*, 479 F.3d 46, 53 (1st Cir. 2007) (emphasis in original).
[102] 42 U.S.C. § 300a-6.
[103] *Publicly Funded Family Planning Services in the United States*. Other family planning funding: 75% - Medicaid; 12% - state-only sources; 3% - other federal sources.
[104] 500 U.S. 173 (1991).
[105] Compliance with Title X Requirements by Project Recipients in Selecting Subrecipients, 81 Fed. Reg. 173 (proposed Sept. 7, 2016) (to be codified at 42 C.F.R. pt. 59).
[106] *Id.*

III. Panel Hearings

The Panel held two public hearings to examine critical issues within its jurisdiction. In the first hearing on *Bioethics and Fetal Tissue*, the Panel noted that there have been several government-sponsored discussions on bioethics, but none directly on the transfer of fetal tissue since the 1980s. The hearing revealed substantial concern about the consent process for the donation of human fetal tissue used by abortion clinics and procurement businesses. Evidence revealed that self-interested staff, whose pay depends on the numbers of specimens donated, were assigned to obtain consent from patients. Additional evidence showed that tissue technicians and the abortion clinics violated the patient's privacy rights under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Still other evidence revealed that some middleman companies misrepresented that the consent forms and methods of tissue harvesting comply with federal regulations regarding Institutional Review Boards (IRBs). This evidence points toward conduct focused on profit and not on patient welfare.

The Panel's next hearing, *The Pricing of Fetal Tissue*, sought the judgment of seasoned federal prosecutors to compare the federal statute prohibiting profit from fetal tissue sales with the first tranche of materials from the investigation. Two former U.S. attorneys and a senior federal litigator agreed that based on the materials presented to them, they would open a case against a middleman company. The former prosecutors also suggested that accounting and bank records would be critical to understanding whether there was a violation of federal law. Minority witnesses agreed with this approach and urged the Panel to obtain such records.

A. Bioethics and Fetal Tissue

On March 2, 2016, the Panel held a hearing entitled *Bioethics and Fetal Tissue*. The hearing focused on ethical issues raised as a result of information recently made public about fetal tissue donations, transfer of fetal tissue, and use of fetal tissue by research institutions. The witnesses helped the Panel understand the ethical questions, both on theoretical and practical levels, which arise when fetal tissue is acquired and used in biomedical research.

Bioethics has its origins as a field of academic inquiry in the early 1960s due to extraordinary advances and development in American medical knowledge and practice. Organ transplantation, kidney dialysis, respirators, and intensive care units made possible medical procedures never before imagined. The first heart transplant raised ethical questions relating to the sources of organs for transplantation, how they would be allocated, and payment for these procedures.

Public debates took place and, in response, scholars and academics began to think and write about these issues, and scholars began to fuse theoretical ethics with applied or practical ethics. Since that time, continuing biomedical advances have presented bioethical questions that need to be confronted and addressed by societies.

Today's headlines are full of announcements and predictions that a few short years ago were the subject of speculative fiction. Organ reconstitution, three-parent children, personalized medicine, organ cloning, chimeras, gene therapy and editing, and bioinformatics are all recent

subjects discussed by professionals and the public. The current director of the National Institutes of Health has proposed compiling DNA information to help inform medical decisions and therapies. While these therapies further knowledge of biomedical and scientific information related to medical treatments and therapies, they also present broader ethical questions.

Paige Comstock Cunningham, Executive Director for The Center for Bioethics & Human Dignity, told the Panel that "you cannot take a life and then give away the body. Participants in elective abortion, including the mother, are morally disqualified from consenting to donating the body, organs, or tissue of the now dead fetus for research purposes."[107]

Dr. Patrick Lee, a professor at the Center for Bioethics at Franciscan University of Steubenville, spoke of his concern that "governmental funding of abortion providers and the use of fetal tissue from elective abortions involve profound dehumanization of unborn human beings and are grave injustices."[108]

During the hearing, Majority and Minority Members and witnesses discussed current bioethical questions regarding the use of fetal tissue in scientific research. One concern raised by the Minority Members of the Panel and the Minority witnesses was that stopping the use of fetal tissue in scientific research, such as developing a cure for the Zika virus, would delay the finding of a cure. Rep. Jan Schakowsky (IL-9) asked Dr. Lawrence Goldstein, a minority witness, "Would not having fetal tissue as a resource in this study potentially delay finding a cure?" Dr. Goldstein replied, "It would absolutely delay it."[109]

However, later in the hearing in an exchange with Dr. Goldstein, Rep. Andy Harris (MD-1), who is also a physician, emphasized that sometimes delays occur in order to ensure that research, especially research conducted on human subjects, is done ethically and safely. Addressing Dr. Goldstein, Rep. Harris stated, "[Y]ou have suggested that anything that slows this process down is a bad thing. You kind of suggested that. . . . How long does it take your IRB to approve, normally? Mine took months. I know exactly why you are laughing. It can take months or even a year, can't it?"[110] Rep. Harris summarized their discussion by stating that the United States has already decided "that it is all right to slow down life-saving research when it involves humans for ethical reasons because we have a national policy that you have to have an IRB."[111] Furthermore, the idea that not having access to fetal tissue would delay the discovery of a cure is mere speculation, especially since fresh fetal tissue has not been successful in curing diseases. Dr. Goldstein conceded Rep. Harris' point.

Also during the hearing, Members of the Panel expressed their deep concern regarding the issue of consent and minors. Rep. Mia Love (UT-4) stated: "So imagine [a] 14-year-old going into a clinic to undergo a very invasive procedure without someone there that she trusts to walk her through, to make sure that she is not being taken advantage of, to make sure that she is making the right decision."[112] Rep. Love asked, "How can anyone be sure that a minor, under

[107] *Bioethics and Fetal Tissue,* at 24 (Mar. 2, 2016) (unedited transcript).
[108] *Id.* at 98.
[109] *Id.* at 120.
[110] *Id.* at 138.
[111] *Id.* at 139.
[112] *Id.* at 86-87.

difficult circumstances, fully understand[s] the long-term repercussions behind [her] decision when the current law wouldn't even allow that minor to get behind the wheel of a vehicle?"[113] Dr. Gerald Kevin Donovan, a witness at the hearing, agreed that this presented a troubling problem.[114]

Dr. Kathleen Schmainda, a Professor at the Medical College of Wisconsin, told the Panel that "the repeated assurances that proper ethical guidelines are in place to avoid the connection between abortion and subsequent research are entirely inadequate."[115]

Members and witnesses came to a bipartisan agreement on several points:

Common Ground →	No one should profit from the sale of fetal tissue.[116] Inappropriate to get pregnant in order to donate fetal tissue for research.[117] A form used by an abortion clinic to obtain a woman's consent to donate fetal tissue contained inappropriate statements and should not have made it past an IRB.[118] No cures have been found that require fetal tissue.[119] Fetal tissue should not be used for cosmetics or taste testing.[120] It is a moral decision for a woman to decide whether to make the fetal tissue donation.[121]

[113] *Id.*
[114] *Id.*
[115] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong. 105 (Mar. 2, 2016) (unedited transcript).
[116] *Id.* at 161.
[117] *Id.* at 37-38.
[118] *Id.* at 149.
[119] *Id.*
[120] *Id.* at 37, 89, 136-37, 163 (Ms. Alta Charo, a minority witness, stated, "Well, using any tissue, fetal or adult, I find the cosmetic uses in Hollywood sometimes to be so frivolous, I would be perfectly happy to see us abandon them.").
[121] *Id.* at 140.

Amazing scientific and biomedical advances are continuously being discovered and developed. Congress, research institutions, and the medical community must continue to work together to promote medical advancements while simultaneously ensuring that laws and regulations on ethics remain up to date. Whenever biomedical research is conducted on human subjects, the work must be ethical and preserve the dignity of the human beings who made these advancements possible.

B. The Pricing of Fetal Tissue

On April 20, 2016, the Panel held a hearing on *The Pricing of Fetal Tissue*. During the hearing, the Panel examined documents revealing that abortion clinics and Tissue Procurement Businesses (TPBs) may have violated federal law by the payments they collected from the sale of fetal tissue. At the core of the Panel's investigation is a federal statute, 42 U.S.C. § 289g-2, which prohibits the transfer of any human fetal tissue for valuable consideration. The statute states that reasonable costs include transportation, implantation, processing, preservation, quality control, and storage—none of which it appears the abortion clinics did. Documents also show that payments made by the customer to the procurement business appear to exceed the costs incurred on the procurement business by a factor of 300 to 400 percent.[122]

Witnesses at the hearing were presented with a sample of the accounting records from StemExpress and several abortion clinics. The witnesses for the hearing included three former prosecutors who all agreed that the documents made the case that 42 USC § 289g-2 may have been violated and that further investigation was warranted. All witnesses at the hearing agreed that the Panel should review all bank and accounting records in order to gain a complete understanding.

When asked by Rep. Joe Pitts (PA-16) what communications or information should be sought to learn whether the intent of the procurement business and the abortion clinic was to profit from the sale of fetal tissue, former U.S. Attorney Kenneth Sukhia said, "I would also want to know what communications occurred between – other communications, email and so forth, back and forth between those people. We would seek those items as well, and of course the accounting records."[123]

Brian Lennon told the Panel that "a competent and ethical federal prosecutor could establish probable cause that both the abortion clinics and the procurement businesses [that the Panel was investigating] violated the statute, aided and abetted one another in violating the statute, and likely conspired together to violate the statute." Lennon went on to say "in my opinion, there is proof without a reasonable doubt."[124] He told the Panel that "a forensic accounting would be essential to breaking down the company's financials."[125]

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[122] *See generally The Pricing of Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong. (Apr. 20, 2016) (unedited transcript).
[123] *Id.* at 147.
[124] *Id.* at 52-53.
[125] *Id.* at 56-57.

Fay Clayton, a lead Democrat witness, said she'd "have them [StemExpress] come in, put them under oath . . . and ask them how did you come up with this charge?"[126] Clayton said she would "ask them, in each particular case, what aspect of the actual costs does a particular clinic incur? For example, does the clinic provide space? Does the clinic, as we have seen in your charts, provide the blood draws which requires a technician, perhaps a nurse, materials? Does the clinic have to do paperwork? And, if so, how much? And, therefore, how much of the actual reasonable cost is incurred by the clinic itself as opposed to by the procurement business?"[127]

Former U.S. Attorney Michael Norton told the Panel that he "would get forensic accounting."[128] "I would get all of the financial records. I would get the profit and loss statements, the income and expense statements, and I would get people under oath before a grand jury,"[129] Norton said.

Catherine Glenn Foster told the Panel that there were two things she would specifically seek among other documents:

> First of all, financial records. That is something that must be brought to light. And, second, women of every generation are unique human beings who can speak for themselves, but the baby body parts profiteers have created a market in which their profits rise if they pressure and coerce women into signing donation consent forms.[130]

Based on the consensus reached by witnesses at the hearing, the Panel has worked to acquire and further investigate the details of accounting records, accounts payable, and cash transfers of abortion businesses, fetal tissue procurement organizations, and related entities to determine whether or not someone made a profit.

[126] *Id.* at 144.
[127] *Id.* at 145.
[128] *Id.* at 146.
[129] *Id.*
[130] *Id.*

IV. Criminal and Regulatory Referrals

15 Criminal & Regulatory Referrals

The Select Investigative Panel has made numerous criminal and regulatory referrals and investigations are underway around the nation.

1) The Panel discovered that the University of New Mexico may have been violating its state's Anatomical Gift Act by receiving tissue from a late-term abortion clinic (Southwestern Women's Options). Referred to the Attorney General of New Mexico.

2 & 3) The Panel conducted a forensic accounting analysis of StemExpress' limited production and determined that it may have been profiting from the sale of baby body parts. Referral sent to El Dorado, California, District Attorney, and the U.S. Department of Justice.

4) The Panel learned that StemExpress and certain abortion clinics may have violated the HIPAA privacy rights of vulnerable women for the sole purpose of increasing the harvesting of fetal tissue to make money. Referred to the U.S. Department of Health and Human Services.

5) The Panel uncovered evidence showing that StemExpress may have violated federal regulations governing Institutional Review Boards (IRBs). Referred to the U.S. Department of Health and Human Services.

6) The Panel discovered that an abortion clinic in Arkansas may have violated the law when it sent tissue to StemExpress. Referred to the Attorney General of Arkansas.

7) The Panel discovered that DV Biologics, another tissue procurement company, may have been profiting from the sale of fetal tissue, and was not collecting California sales tax from purchasers of the baby body parts. The Orange County District Attorney has filed a lawsuit and the Panel sent a supplemental referral.

8) The Panel learned that Planned Parenthood Gulf Coast may have violated both Texas Law and U.S. Law when it sold fetal tissue to the University of Texas. Referred to the Texas Attorney General.

9) The Panel learned that Advanced Bioscience Resources appeared to have made a profit when it sold tissue to various universities. Referred to the District Attorney for Riverside County, California.

10) The Panel discovered that an abortion clinic in Florida, at least in part through its relationship with StemExpress, may have violated various provisions of federal and state law by profiting from the sale of fetal tissue. Referred to the Attorney General of Florida.

11 & 12) The Panel has uncovered evidence from former employees and a patient of a late-term abortionist in Texas alleging numerous violations of federal and state law at one or more of the

practitioner's clinics. The allegations include eyewitness accounts of the doctor killing infants who show signs of life both when partially outside the birth canal, in violation of the Partial-Birth Abortion Ban Act, and after they are completely outside the birth canal, in violation of the Born-Alive Infants Protection Act and Texas murder statutes. Referred to the Texas Attorney General, and the U.S. Department of Justice.

13) The Panel made a supplemental referral to the Attorney General of New Mexico based on information produced in document productions by the University of New Mexico (UNM) and Southwestern Women's Options (SWWO), deposition testimony by Doctor #5, and a complaint and affidavit with supporting documents submitted by a former patient at SWWO. It details the alleged failure of SWWO and UNM to provide informed consent to women prior to using tissue from abortions for research at the university.

14) The Panel has discovered information that StemExpress may have destroyed documents that were the subject of congressional inquiries, document request letters, and subpoenas, in violation of 18 U.S.C. § 1519. Referred to the U.S. Department of Justice.

15) Over the course of its investigation, the Panel has uncovered documents and received testimony from confidential informants indicating that several entities, including four Planned Parenthood clinics and Novogenix, may have violated federal law, specifically Title 42 U.S.C. § 289g-2, which forbids the transfer of fetal tissue for valuable consideration. Referred to the U.S. Department of Justice.

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
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Majority (202) 225–2927
Minority (202) 225–3641

June 23, 2016

VIA EMAIL

The Honorable Hector H. Balderas, Jr.
Attorney General of New Mexico
408 Galisteo Street
Villagra Building
Santa Fe, NM 87501

Dear Attorney General Balderas:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the "Panel") and empowered it to conduct a full and complete investigation regarding the medical practices of abortion providers and the practices of entities that procure and transfer fetal tissue. The Panel's work implicates 42 U.S.C. § 289g-2, which forbids the transfer of fetal tissue for valuable consideration.

Section 289g-2 requires that safeguards be in place, including a concern that too close a relationship might be formed between an abortion clinic and researchers. In the course of its inquiry, the Panel uncovered just such a relationship between the University of New Mexico ("UNM") and Southwestern Women's Options ("SWWO"), a clinic located one mile from UNM that provides abortions through all three trimesters of pregnancy. We understand that SWWO is the sole provider of fetal tissue to UNM.

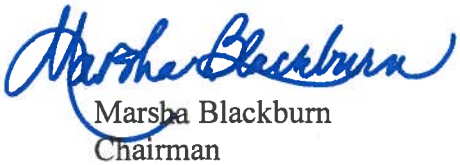
Through its investigation, the Panel has discovered that personnel within UNM's hospital and medical school have aggressively engaged in expanding abortion in New Mexico through the offices, personnel, and resources of UNM. In particular, leadership personnel at UNM: (1) expanded UNM's role in training new abortion doctors; (2) expanded UNM's referral for abortion services to outside clinics, including the clinic from which it obtained fetal tissue; (3) initiated the practice of sending UNM faculty and residents to an abortion clinic during its transition from one owner to another; (4) expanded the faculty of UNM by providing "volunteer faculty" status to local abortionists; (5) supplied residents and fellows to perform abortions for SWWO during the period that UNM was obtaining fetal tissue from that clinic; and (6) leveraged their status to organize UNM

employees and students for partisan political activities. UNM has stated that the fetal tissue transferred from SWWO is of great value to its research department.

Additionally, documentation obtained by the Panel in the course of its investigation reflects that the transfer of fetal tissue from SWWO to UNM for research purposes is a systematic violation of New Mexico's *Jonathan Spradling Revised Uniform Anatomical Gift Act* (*Spradling Act*). **These violations occurred as UNM personnel procured fetal tissue from patients at SWWO for research by UNM entities.**

A detailed report accompanying this letter describes the Panel's discovery that transfers of value to SWWO from UNM occurred within a context of aggressive abortion advocacy. We appreciate your swift attention to the serious and systematic violations of law committed by the University of New Mexico and Southwestern Women's Options. If you have any questions about this request, please contact Frank Scaturro, at (202) 225-2927, Frank.Scaturro@mail.house.gov, or Mary Harned, at (202) 480-7160, Mary.Harned@mail.house.gov.

Sincerely yours,



Marsha Blackburn
Chairman
Select Investigative Panel

Attachment(s)

cc: The Honorable Jan Schakowsky, Ranking Member
Select Investigative Panel

The Honorable Susana Martinez
Governor of New Mexico

The Honorable John A. Sanchez
Lieutenant Governor of New Mexico

The Honorable Steve Pearce
Second Congressional District, New Mexico

ONE HUNDRED FOURTEENTH CONGRESS
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November 2, 2016

VIA EMAIL AND FIRST CLASS MAIL

The Honorable Loretta Lynch
Attorney General
c/o Office of Legislative Affairs
U.S. Department of Justice
950 Pennsylvania Ave NW
Washington, DC 20530

Dear Attorney General Lynch:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the "Panel") and empowered it to conduct a full and complete investigation regarding the medical practices of abortion providers and the practices of entities that procure and transfer fetal tissue.

Over the course of our investigation, we have uncovered documents and received testimony from confidential informants indicating that StemExpress, LLC ("StemExpress"), a firm that procures fetal tissue from abortion clinics and transfers it to research customers, violated various provisions of federal and state law, including but not limited to 42 U.S.C. § 289g-2 and Cal. Penal Code § 367f, which forbid the transfer of fetal tissue for valuable consideration.

StemExpress' Business Model and Growth Strategy

StemExpress was founded in 2010 as a for-profit company and continues operations as StemExpress Foundation. Under its business plan, StemExpress recruited and screened clinics that were most likely to perform abortions that could produce saleable tissue to researchers.[1] The company sought information about the number of abortions the clinics performed each week, the gestational age of fetuses scheduled to be aborted, the days the abortions were done, whether

[1] StemExpress Website Recruitment Form for Abortion Clinics, attachment 1.

digoxin[2] was used (which would taint the tissue and, thus, render the baby useless for obtaining tissue), and, if so, at what age it was used. Researchers ordered tissue using StemExpress' website. The firm initially had a drop-down menu that allowed researchers to obtain various types of tissue.[3] It later switched to another web-based system.

In order to harvest the tissue, StemExpress embedded tissue technicians inside the abortion clinics. Evidence uncovered by the Panel indicates females were recruited as tissue technicians to facilitate the consent process. The technicians' typical work day went as follows:

- At the beginning of the day, the tissue technician received an email from StemExpress including the day's orders for certain baby body parts and the gestation period, letting her know what she needed to harvest that day, and where she would be assigned.

- Once she arrived at the clinic, the tissue technician checked in with the Abortion Clinic Assistant Manager and informed the staff what she would procure that day.

- Then the technician reviewed the private medical files of the patients for that day to learn their names and the gestational ages of their babies. She recorded the gestations on the gestation tracking log provided by StemExpress.

- Next the technician met with the patients waiting to be prepped for their abortions, after receiving their names from clinic staff. Then she convinced them to consent to donate by saying that the donation will help cure diabetes, Parkinson's, and heart disease.[4]

- After an abortion, the technician collected the baby's remains and procured the body parts that were ordered, using her own supplies.[5] The technician then packed the tissues or body parts, and shipped them directly to the customer via a courier or FedEx.

- She received an hourly wage and a bonus for each tissue, illustrated in the attached pay rate and bonus chart.[6]

StemExpress' stunning revenue growth five years after its formation belies the notion that the firm was not operating for profit. In 2010, its revenue was $156,312; during 2011, that figure more than doubled to $380,000; a year later, in 2012, StemExpress' revenue nearly tripled to $910,000; by 2013, its revenue was $2.20 million; then in 2014, the revenue had once again more than doubled to $4.50 million. Based on its three-year revenue growth of 1,315.9%, *Inc. Magazine* named StemExpress one of the fastest-growing privately held companies in the U.S.[7]

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[2] Digoxin is a heart medication that sometimes is injected into the amniotic fluid or fetus to cause fetal demise before surgical or induction abortion. *See* Abortion in California: A Medical-Legal Resource, *available at* http://californiaabortionlaw.com/wp/?page_id=135.

[3] StemExpress Drop-Down Ordering Menu, attachment 2.

[4] BioMed IRB Informed Consent to Participate in a Clinical Research Study, Sponsor: StemExpress, LLC, attachment 3.

[5] *See* Standard Operating Procedure, Jan. 24, 2011, at 1 ("The clinic staff will identify donors"), attachment 4.

[6] StemExpress Embedded Technician Pay Rates and Bonuses, attachment 5.

[7] *The 500: Get to know the 500 fastest-growing privately held companies in America*, INC., Sept. 2014, at 137.

This revenue growth accompanied an aggressive marketing strategy directed toward abortion clinics. StemExpress distributed its brochure at a conference hosted by the National Abortion Federation (NAF). The brochure promised clinics they would be "[f]inancially profitable" if they allowed StemExpress to procure tissue from the clinics. The brochure also said "By partnering with StemExpress" the clinics will not only help research "but [they] will also be contributing to the fiscal growth of [their] own clinic[s]."[8]

When StemExpress was formed, billing records show the firm was procuring fetal tissue from four clinics. By the end of 2014, the firm had "relationships with more than 30 procurement sites across the country."[9] However, many of those procurement sites had multiple clinics, making the actual number nearly 100. In 2015, StemExpress tried to execute a contract with NAF that would have given the firm potential access to nearly 200 additional clinics. Its overall strategy was to provide on-demand body parts to researchers. In order to do that, the firm needed a ready supply of fetal tissue. The only way to achieve that was to dramatically increase the number of abortion clinics from which it would obtain fetal tissue.

StemExpress' Profit and Loss

Attached is a sample of a StemExpress invoice to a customer.[10] According to the accounting records obtained by the Panel, StemExpress paid approximately $55 for each fetal tissue sample or Product of Conception (POC) it obtained from abortion clinics and transferred it to researchers for up to $595 to $890 per tissue or body part. The following charts summarize payments StemExpress made to abortion providers to obtain fetal tissue and those it received from its customers for such tissue.

Payments from StemExpress to Abortion Providers

CLINIC	DATE	ITEM	COST
Camelback Family Planning	2015	[not specified]	$600
Camelback Family Planning	2015	[not specified]	$600
			Total: $1,200
Cedar River Clinic	2015	Amniotic	$100.00
Cedar River Clinic	2013	Blood Samples	$960.00
Cedar River Clinic	2014	Blood Samples	$2,600.00
Cedar River Clinic	2014	Femur	$125.00
Cedar River Clinic	2015	Femur	$75.00
Cedar River Clinic	2014	Fetal Indications	$7,250.00
Cedar River Clinic	2015	Fetal Indications	$4,250.00
Cedar River Clinic	2014	Gift Cards	$10,650.00

[8] StemExpress Brochure Distributed at NAF Conference, attachment 6 (key text highlighted).
[9] Complaint at para. 17, StemExpress, LLC v. Center for Medical Progress, No. BC-589145 (L.A. Super. Ct. filed Jul. 27, 2015).
[10] Sample StemExpress Invoice to Customer, attachment 7.

Cedar River Clinic	2015	Gift Cards	$10,250.00
Cedar River Clinic	2015	Hotel	$92.00
Cedar River Clinic	2014	Kit	$625.00
Cedar River Clinic	2015	Liver	$125.00
Cedar River Clinic	2014	Maternal Blood	$1,400.00
Cedar River Clinic	2014	Maternal Blood	$350.00
Cedar River Clinic	2014	Maternal Blood	$28,675.00
Cedar River Clinic	2015	Maternal Blood	$8,700.00
Cedar River Clinic	2014	Maternal Blood	$650.00
Cedar River Clinic	2015	Maternal Blood	$100.00
Cedar River Clinic	2014	Maternal Blood/Tissue Kit	$35,550.00
Cedar River Clinic	2015	Maternal Blood/Tissue Kit	$39,225.00
Cedar River Clinic	2015	Maternal Bood	$250.00
Cedar River Clinic	2015	Peripheral Blood	$6,350.00
Cedar River Clinic	2015	Rental Car	$167.98
Cedar River Clinic	2015	Thymus	$75.00
Cedar River Clinic	2014	Tissue	$225.00
Cedar River Clinic	2014	Tissue	$75.00
Cedar River Clinic	2015	Tissue Brain	$75.00
Cedar River Clinic	2015	Tissue Liver	$250.00
Cedar River Clinic	2014	Tissue Only	$500.00
Cedar River Clinic	2015	Tissue Only	$75.00
Cedar River Clinic	2015	Tissue Pancreas	$75.00
Cedar River Clinic	2015	Triscomy credit	$200.00
Cedar River Clinic	2014	Whole Blood	$12,850.00
Cedar River Clinic	2015	Whole Blood	$8,400.00
			Total: $181,319.98
Family Planning Specialist	2011	Blood Draws	$1,090.00
Family Planning Specialist	2012	Blood Draws	$5,325.00
Family Planning Specialist	2011	Specimen	$440.00
Family Planning Specialist	2012	Specimen	$6600
			Total: $13,455.00
Mar Monte	2010	Blood	$1,700
Mar Monte	2011	Blood	$33,153
Mar Monte	2012	Blood	$31,380
Mar Monte	2013	Blood	$16,080
Mar Monte	2014	Blood	$14,640
Mar Monte	2015	Blood	$3,190
Mar Monte	2010	POC	$1,210
Mar Monte	2011	POC	$15,235

Mar Monte	2012	POC	$43,245
Mar Monte	2013	POC	$24,140
Mar Monte	2014	POC	$25,990
Mar Monte	2015	POC	$13,355
			Total: $223,318.00
Presidential Women's Center	2014	Blood	$6,450.00
Presidential Women's Center	2015	Blood	$4,455.00
Presidential Women's Center	2014	Tissue Liver	$1,425.00
Presidential Women's Center	2015	Tissue Liver	$675.00
Presidential Women's Center	2015	Tissue Villi	$75.00
Presidential Women's Center	2015	Tissue Villi	$150.00
Presidential Women's Center	2015	Tissue Villi	$525.00
Presidential Women's Center	2014	Tissue Villi	$75.00
Presidential Women's Center	2015	Tissue Villi	$1,800
Presidential Women's Center	2015	Tissue Villi Twin a	$75.00
Presidential Women's Center	2015	Tissue Villi Twin b	$75.00
			Total: $15,780.00
Shasta Pacific	2012	Blood	$650.0
Shasta Pacific	2013	Blood	$4,470.00
Shasta Pacific	2014	Blood	$2,530.00
Shasta Pacific	2015	Blood	$100.00
Shasta Pacific	2012	POC	$1,870.00
Shasta Pacific	2013	POC	$3,960.00
Shasta Pacific	2014	POC	$6,160.00
Shasta Pacific	2015	POC	$715.00
			Total: $20,455.00
			GRAND TOTAL: $455,527.98

Payments from Customers to StemExpress for Fetal Tissue

CUSTOMER	YEAR	TOTAL PAYMENTS
All Cells	2011	$4,040
Columbia University	2011	$540
Colorado State University	2011	$2,700
Dartmouth	2011	$3,240
Drexel University	2011	$3,510
Johns Hopkins	2011	$1,950
Ohio State University	2011	$235
Stanford University	2011	$28,650
University of California – Los Angeles	2011	$3,920
University of Connecticut	2011	$930
University of Massachusetts Medical School	2011	$43,115
Vanderbilt University Medical Center	2011	$2,700
Yale College of Medicine	2011	$390
Zyagen	2011	$3,910
All Cells	2012	$5,680
Baylor College of Medicine	2012	$2,500
Columbia University	2012	$2,925
Colorado State University	2012	$1,220
Dartmouth	2012	$4,160
George Washington University	2012	$435
Johns Hopkins	2012	$1,680
Massachusetts General Hospital	2012	$3,000
Stanford University	2012	$32,385
University of California – Los Angeles	2012	$9,370
University of Connecticut	2012	$1,110
University of Massachusetts Medical School	2012	$32,290
Vanderbilt University Medical Center	2012	$7,460
Yale College of Medicine	2012	$6,825
University of North Carolina	2012	$720
University of Illinois at Chicago	2012	$250
All Cells	2013	$3,920
Baylor College of Medicine	2013	$1,000
City of Hope	2013	$350
Columbia University	2013	$750
Colorado State University	2013	$2,250
Dartmouth	2013	$500
Ganogen, Inc.	2013	$6,825
Harvard	2013	$6,680
Massachusetts General Hospital	2013	$7,125
Rockefeller University	2013	$250

Stanford University	2013	$16,065
Thomas Jefferson University	2013	$500
University of California – Los Angeles	2013	$9,000
University of Connecticut	2013	$500
University of Illinois at Chicago	2013	$16,750
University of North Carolina	2013	$1,750
University of Pennsylvania	2013	$2,750
Vanderbilt University Medical Center	2013	$3,000
City of Hope	2014	$595
Ganogen, Inc.	2014	$795
Medical College of Wisconsin	2014	$2,380
Stanford University	2014	$42,535
University of Massachusetts Medical School	2014	$2,380
Vanderbilt University Medical Center	2014	$595
Children's Hospital of Philadelphia	2015	$1,190
City of Hope	2015	$595
Neurona Therapeutics	2015	$1,190
Stanford University	2015	$20,670
University of Massachusetts Medical School	2015	$595
Zyagen, Inc.	2015	$3,578

A more detailed breakdown of these tissue payments is attached hereto.[11]

Attorneys for StemExpress created several cost estimates that purport to show that StemExpress loses money each time it procures a fetal tissue sample and ships it to a customer, but the Panel's staff conducted an analysis of those estimates. A comparison of invoices, attorney-created accounting documents purporting to state costs, and productions from multiple StemExpress customers shows that the firm likely made a profit when procuring and transferring fetal tissue. Attached hereto[12] is a component of the Panel's analysis, which shows StemExpress overstated some of its labor costs and claimed as expenses shipping, supplies, and infectious disease screenings. These were costs charged to researchers.

Violation of Applicable Laws

Under 42 U.S.C. § 289g-2, it is unlawful for any person to "knowingly acquire, receive, or otherwise transfer any fetal tissue for valuable consideration if the transfer affects interstate commerce."[13] The term "'valuable consideration' does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."[14] Anyone who violates this law is subject to a fine "not less than

[11] List of StemExpress Fetal Tissue Sales by Customer, 2011-2015, attachment 8.
[12] Select Panel Analysis of StemExpress Statement of Costs, attachment 9.
[13] 42 U.S.C. § 289g-2(a).
[14] 42 U.S.C. § 289g-2(e)(3).

twice the amount of the valuable consideration received" and/or imprisonment for up to ten years.[15]

California state law includes a nearly identical prohibition. Under Cal. Health & Safety Code § 125320(a), a "person may not knowingly, for valuable consideration, purchase or sell embryonic or cadaveric fetal tissue for research purposes." The California statute's definition of "valuable consideration" is virtually identical to that of the federal statute.[16] Similar provisions in the California Penal Code § 367f(a) prohibit the acquisition, sale, or transfer of "any human organ, for purposes of transplantation, for valuable consideration," subject to a fine of up to $50,000 and imprisonment for up to five years.[17]

The foregoing analysis establishes with a high level of probability that StemExpress and the clinics and research institutions with which it contracted routinely violated 42 U.S.C. § 289g-2 and Cal. Health & Safety Code § 125320(a). This is established generally by the company's aggressive growth strategy, which explicitly included the goal of generating profit, and specifically by the transactions involving the transfer of fetal tissue to and from numerous entities for consideration that exceeded statutorily allowable costs. To the extent any of these transactions occurred for purposes of transplantation, StemExpress and any business partners so involved would additionally be in violation of California Penal Code § 367f(a).

The Panel's investigation additionally revealed indicates that StemExpress and Planned Parenthood Mar Monte (PPMM), Planned Parenthood Shasta Pacific (PPSP), and Family Planning Specialists Medical Group (FPS) committed systematic violations of the HIPAA Privacy Rule from about 2010 to 2015. During that time, the aforementioned clinics, which are "covered entities" under HIPAA, permitted employees of StemExpress, a noncovered entity, to enter their clinics and procure human fetal tissue from aborted infants, obtain PHI about their patients, interact with patients, and seek and obtain patient consent for tissue donation. StemExpress did not have a medically valid reason to see, and the abortion clinics did not have a reason to provide, patients' PHI. Instead, the clinics shared patients' PHI with StemExpress in furtherance of contractual agreements that financially benefited both sides of the respective contracts. StemExpress employees were routinely handed a patient's medical chart by her healthcare provider, in blatant violation of the HIPAA privacy rule.

These clinics and StemExpress violated the HIPAA privacy rule because: (a) the disclosures of patients' PHI made by the abortion clinics and received by StemExpress were neither required nor permitted under HIPAA, and in particular did not meet the exceptions for cadaveric organ, eye or tissue transplantation or for research; (b) the consents for fetal tissue donation ostensibly obtained by StemExpress from the abortion clinics' patients did not constitute sufficient authorizations for the disclosure of PHI; (c) the disclosures of patients' PHI made by the abortion clinics to StemExpress were not the minimum necessary disclosures to facilitate the procurement of human fetal tissue from aborted infants; and (d) StemExpress is not a business associate of the abortion clinics under HIPAA.

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[15] 42 U.S.C. § 289g-2(d).

[16] Such consideration "does not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of a part." Cal. Health & Safety Code § 125320(b).

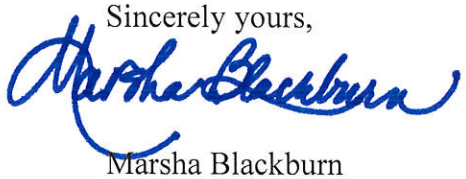
[17] Cal. Penal Code §§ 367f(a), (g).

The abortion clinics could have directly consented their patients for tissue donation and entered an agreement with StemExpress to provide a limited data set regarding the patients they were seeing on a particular day.[18] Instead, they violated the Privacy Rule by permitting StemExpress to view the most intimate information about their patients. These disclosures made by the abortion clinics to StemExpress were intentional and purposeful.[19] The Panel made a referral of each of these entities to the Department of Health and Human Services, and requested a swift and full investigation by the HHS Office of Civil Rights. A copy of this referral detailing the foregoing facts is attached hereto.[20]

Also relevant are the federal regulations governing consent prior to the acquisition of fetal tissue. Under 45 C.F.R. § 46, the Department of Health and Human Services requires investigators to obtain informed consent from each human being used as a research subject.[21] The rule lists several criteria for Institutional Review Board ("IRB") approval, including the requirement that researchers obtain the informed consent from their research subjects. As was demonstrated in the Panel's referral to the Secretary of Health and Human Services, attached hereto,[22] StemExpress' procurement of fetal tissue from abortion clinics and transfer thereof to research customers violated 45 C.F.R. § 46: The company devised the appearance of compliance with the regulations while fraudulently using invalid consent forms and misleading customers to believe it had a valid IRB approval.

Based on the facts outlined above and the supporting documentation, I urge your office to conduct a thorough investigation into whether StemExpress violated these statutes and regulations, and, if you agree that such violations occurred, to take all appropriate action. If you have any questions about this request, please contact Frank Scaturro, at (202) 225-2927, Frank.Scaturro@mail.house.gov, or Mary Harned, at (202) 480-7160, Mary.Harned@mail.house.gov.

Sincerely yours,



Marsha Blackburn
Chair
Select Investigative Panel

Attachment(s)

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[18] *See* 45 C.F.R. § 164.514(e).
[19] *See* 45 C.F.R. § 164.502(a)(1)(iii).
[20] Letter from Rep. Marsha Blackburn, Chair, Select Investigative Panel, to Jocelyn Samuels, Director, Centralized Case Management Operations, Department of Health and Human Services, June 1, 2016, attachment 10.
[21] 45 C.F.R. § 46.116.
[22] Letter from Rep. Marsha Blackburn, Chair, Select Investigative Panel, to Jerry Menikoff, Director, Office for Human Research Protections, Department of Health and Human Services, June 1, 2016, attachment 11.

cc: The Honorable Jan Schakowsky
Ranking Member
Select Investigative Panel

The Honorable Vern Pierson
El Dorado County District Attorney

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

VIA EMAIL

June 1, 2016

Ms. Jocelyn Samuels, Director
Centralized Case Management Operations
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Room 509F HHS Bldg.
Washington, D.C. 20201

Dear Director Samuels:

On October 7, 2015, the U. S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel and empowered it to conduct a full and complete investigation regarding the medical practices of abortion providers and the business practices of businesses who procure and resell fetal tissue.

The Panel's investigation uncovered a series of business contracts between StemExpress,[1] a tissue procurement business ("TPB"), and several abortion clinics. These contracts included provisions for the payment of fees by StemExpress to the abortion clinics for fetal tissue and maternal blood. StemExpress then resold the fetal tissue and blood to researchers.

These contracts produced a regime of cooperation between StemExpress and each clinic. In particular: (1) the day before scheduled abortions, StemExpress received a fax from a clinic with information about the abortions scheduled for the next day; (2) StemExpress employees were granted access to the medical files of individual patients; (3) The clinic's medical employees (doctors and nurses) directed the StemExpress employees to particular patients who were "good candidates" for fetal tissue donations; (4) the StemExpress employees had access to the "patient terminal" inside the abortion clinic; and (5) the StemExpress employees were permitted by the abortion clinic to interview the patients about personal information, including their dates of birth.

[1] StemExpress and Stem-Ex are the same company.

In particular, the Panel's investigation has uncovered information indicating that StemExpress and Planned Parenthood Mar Monte ("PPMM"), Planned Parenthood Shasta Pacific ("PPSP") and Family Planning Specialists Medical Group ("FPS") (hereinafter "the abortion clinics") committed systematic violations of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") privacy rule from about 2010 to 2015. **These violations occurred when the abortion clinics disclosed patients' *individually identifiable health information* to StemExpress to facilitate the TPB'S efforts to procure human fetal tissue for resale.** This complaint is against each of these entities, and we request a swift and full investigation by the Office of Civil Rights in the Department of Health and Human Services.

In addition to this letter, we are submitting a referral to the HHS Office for Human Research Protections indicating that StemExpress violated 45 CFR 46 by using invalid consent forms and failing to have valid Institutional Review Board ("IRB") approval.[2]

I. BACKGROUND

The abortion clinics are "covered entities" under HIPAA, while StemExpress is not.[3] StemExpress "procure[s] tissues and isolate[s] cells for researchers' individual needs in its own labs."[4]

From about 2010 to 2015, the abortion clinics permitted StemExpress employees to: enter their clinics and procure human fetal tissue from aborted infants; obtain *individually identifiable health information*, or *protected health information* ("PHI") about their patients; interact with patients; and seek and obtain patient consent for tissue donation.[5] StemExpress embedded tissue procurement technicians inside the abortion clinics whose **work sequence** followed a daily routine:

1. A researcher / customer placed an order for human fetal tissue using an online business portal provided by StemExpress. The web portal allowed the customer to request a particular gestational range for the fetal tissue.[6]

2. The abortion clinics from which StemExpress procured fetal tissue faxed the next day's schedule of potential patients directly to the StemExpress tissue procurement technician assigned to the clinic.[7]

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[2] *See* Attachment A.

[3] *See* 45 CFR Part 160.103 (Covered Entity means: (1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.) *See also* OCR Privacy Brief, Summary of the HIPAA Privacy Rule, *available at* http://www.hhs.gov/sites/default/files/privacysummary.pdf (last visited May 5, 2016) (used as reference throughout this complaint).

[4] Stemexpress, About Us, *available at* http://stemexpress.com/about/ (last visited Apr. 29, 2016).

[5] *See* Attachment B: Clinic Procedures & Policies.

[6] *See* Attachment C: Researcher Procurement Record.

[7] *See* Attachment D: Fax from The Alameda, San Jose [Planned Parenthood clinics] to StemExpress, Jan. 10, 2013.

3. The day the abortion procedures were scheduled, StemExpress posted the order on a website "task board" (order page) to be accessed by their procurement technician or communicated the order to the tissue technician via email.[8]

4. The StemExpress procurement technician informed the clinic what they wished to procure (*i.e.*, the type of tissue and gestational range) based on the order page, and the abortion clinic provided the medical files, including PHI, for the patients with abortions scheduled for that day.[9]

5. The StemExpress procurement technician then sought out particular patients by name and obtained their consent to donate fetal tissue while they were awaiting their procedures. The procurement technician was also permitted to interview patients and obtain their PHI.[10]

6. StemExpress procurement technicians were paid an hourly wage and a per tissue "bonus" for each item they procured from the order page.[11]

7. StemExpress paid the abortion clinic for each fetal tissue and each blood sample and then marked up the tissue four to six hundred percent for sale to the researcher.[12]

The work sequence, when combined with supporting documentation, reveals that StemExpress did not have a medically valid reason to see, and the abortion clinics did not have a reason to provide, patients' PHI. Instead, the abortion clinics shared patients' PHI with StemExpress in furtherance of contractual agreements that financially benefitted StemExpress and the clinics.[13]

II. THE HIPAA PRIVACY RULE

The HIPAA privacy rule ("Privacy Rule") protects all *individually identifiable health information* held or transmitted by a covered entity or its business associate, and calls this information *protected health information* ("PHI").[14] PHI identifies an individual, or can reasonably be believed to be useful in identifying an individual (*e.g.*, name, address, birth date, Social Security Number), and includes demographic data relating to: an individual's past, present, or future physical or mental health condition; the provision of health care to the individual; or the past, present, or future payment for the provision of health care to the individual.[15]

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[8] *See* Attachment E: Updated Task Assignment: Procurement Schedule Wednesday, 3/20/13 and Attachment F: Navigating The Task Board.
[9] *See* Attachment G: StemExpress Emails.
[10] *See* Attachment B, *supra*: Clinic Procedures and Policies and Attachment H: Consenting Patients.
[11] *See* Attachment I: Procurement Technician Compensation Policy for Tissue and Blood Procurement.
[12] See Attachment J: StemExpress Services Agreement with Planned Parenthood Shasta Pacific; StemExpress Services Agreement with Planned Parenthood of Santa Barbara, Ventura & San Luis Obispo Counties; Purchase Order No. 60856806; Purchase Order No. 3000014694; Purchase Order No. 60836838; Purchase Order No. 60858758; and StemExpress Invoice # 1439.
[13] *See* Attachment K: Standard Operating Procedure.
[14] 45 C.F.R. § 160.103.
[15] 45 C.F.R. § 160.103.

A covered entity may not use or disclose an individual's PHI except as the Privacy Rule permits or requires,[16] or as the individual or their representative authorizes in writing (see discussion below). HHS may impose civil money penalties on covered entities that fail to comply with the Privacy Rule. Further, both a covered entity that discloses, and any person who knowingly obtains, PHI in violation of the Privacy Rule can face criminal fines or imprisonment.[17]

III. THE CONTRACTS BETWEEN STEMEXPRESS AND THE ABORTION CLINICS

Particular language, contained within the four corners of the written contracts between StemExpress and the abortion clinics raises serious concerns that the parties violated the Privacy Rule.

The written contracts between StemExpress and the abortion clinics contain the following language:

> [a]ny information obtained from [the abortion clinics] patients' charts shall be privileged, and [Stem-Ex / StemExpress] will treat the information in order to preserve the confidentiality of the patients. [Stem-Ex / StemExpress] will not receive any information concerning identity of donors **except as necessary to obtain patients' consent** for use of POCs and maternal bloods (emphasis added).[18]

This admission, on the face of the contracts, that the abortion clinics granted StemExpress access to patients' PHI raises the question whether any HIPAA provision permits or requires such disclosure without patients' express authorization. This question is compounded by the contracts' admission that StemExpress reviewed PHI **prior to obtaining patients' consent to donate fetal tissue *or* patients' authorization to view their PHI.**

IV. VIOLATIONS OF THE HIPAA PRIVACY RULE BY STEMEXPRESS AND THE ABORTION CLINICS

This complaint argues that the agreements between StemExpress and the abortion clinics, on their face and in practice, are fundamentally flawed. A contractual agreement requiring StemExpress to "treat the information obtained from patients' charts in order to preserve the confidentiality of the patients" **cannot trump a law prohibiting the abortion clinics from permitting these disclosures in the first place.** As discussed below, the abortion clinics—covered entities under HIPAA—were not permitted to disclose or make available to StemExpress any patient's PHI without the patient's express authorization.

The abortion clinics and StemExpress violated the HIPAA privacy rule because: (A) The disclosures of patients' PHI made by the abortion clinics, and received by StemExpress, were

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[16] 45 C.F.R. §164.502(a).
[17] Pub. L. 104-191; 42 U.S.C. §§ 1320d-5 – 1320d-6.
[18] *See* Attachments L, M, and N.

neither required nor permitted under HIPAA, and in particular did not meet the exceptions for cadaveric organ, eye or tissue transplantation or for research; (B) The consents for fetal tissue donation ostensibly obtained by StemExpress from the abortion clinics' patients did not constitute sufficient authorizations for the disclosure of PHI; (C) The disclosures of patients' PHI made by the abortion clinics to StemExpress were not the minimum necessary disclosures to facilitate the procurement of human fetal tissue from aborted infants; and (D) StemExpress is not a *Business Associate* of the abortion clinics under HIPAA.

A. The disclosures of patients' PHI made by the abortion clinics, and received by StemExpress, were neither required nor permitted under HIPAA, and in particular did not meet the exceptions for cadaveric organ, eye or tissue transplantation or for research.

The disclosures of PHI that the abortion clinics made to StemExpress are neither required[19] nor permitted[20] by law. StemExpress was not involved in the treatment of patients, in the payment for treatment, or in clinic operations.[21] **Rather, StemExpress wanted patients' PHI to facilitate the procurement of human tissue from aborted infants for resale to researchers.**

1. Cadaveric organ, eye or tissue transplantation

Importantly, the disclosures to StemExpress do not fall under the provision in law permitting disclosure of PHI to aid organ transplantation. While the contracts reference the "National Organ Transplant Act," 42 U.S.C. 274e(c)(1), the abortion clinics were not facilitating the donation and *transplantation* of cadaveric organs, eyes, and tissue. **Instead, the clinics were facilitating the donation of human fetal tissue from aborted infants for *research,* which is not covered by the cadaveric organ, eye or tissue exception.**[22]

2. Research

Further, the disclosures to StemExpress do not meet the rigorous requirements applicable to PHI disclosures for research purposes. A covered entity is not permitted to disclose an individual's PHI for research purposes without the individual's authorization unless the covered entity (1) obtains verification of approval from an Institutional Review Board ("IRB") for disclosure without authorization; (2) the researcher represents that the use or disclosure of the PHI is solely to prepare research protocol and the PHI will not be removed from the covered entity, and that the PHI is necessary for the research; or (3) the research is on PHI of deceased individuals.[23]

3. Violations Preceding "Consent"

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[19] 45 C.F.R. § 164.502(a)(2) (The only "required" disclosures are to (1) an individual or their personal representative when they request access to, or an accounting of disclosures of, their protected health information; and (2) to HHS when it is undertaking compliance investigation or review or enforcement action).
[20] *See* 45 C.F.R. § 164.502(a)(1).
[21] *See* 45 C.F.R. § 164.506(c).
[22] *See* 45 C.F.R. § 164.512(h).
[23] 45 C.F.R. § 164.512(i).

Because StemExpress employees actually sought consent for tissue donation from patients, the abortion clinics permitted the employees to view patients' charts. Medical charts are filled with HIPAA-protected PHI, including names, addresses, past and present medical treatment, and more. **Each time that an abortion clinic employee shared a medical chart with a StemExpress employee, both violated the HIPAA privacy rule.**

No evidence suggests the abortion clinics' patients provided authorization for StemExpress staff to view their PHI *prior* to seeking their consent to donate tissue. Therefore, regardless of whether a patient *ultimately* consented to tissue donation and authorized disclosure of her PHI to StemExpress, her privacy was violated.

The abortion clinics could have directly consented their patients for tissue donation, and entered an agreement with StemExpress to provide a limited data set[24] regarding the patients they were seeing on a particular day. Instead, they violated the Privacy Rule by permitting StemExpress to view the most intimate information about their patients.

These disclosures made by the abortion clinics to StemExpress were inarguably direct and intentional—not incidental.[25] StemExpress employees did not merely overhear a patient's name while in the clinic—they were handed her medical chart by her healthcare provider in blatant violation of the HIPAA privacy rule.

B. The consent for fetal tissue donation obtained by StemExpress from the abortion clinics' patients did not constitute sufficient authorizations for the disclosure of PHI.

While StemExpress purportedly obtained consents from patients prior to procuring human fetal tissue from their aborted infants, the forms that they used were insufficient to authorize the disclosure of PHI under the HIPAA privacy rule.

The Privacy Rule requires a covered entity to obtain an individual's written authorization for any use or disclosure of PHI that is not permitted or required by law.[26] Such authorization must be in plain language and contain specific information regarding the information to be disclosed or used, the person(s) disclosing and receiving the information, expiration, right to revoke in writing, and other data.[27]

Neither the consent form provided by StemExpress ("SE form") nor the consent form provided by Planned Parenthood ("PP form") to obtain patient consent for the donation of human fetal tissue of aborted infants met these stringent requirements.[28] The statement in the SE form that a patient's "health information will be protected at all times" is ironic given that StemExpress's possession of the patient's PHI already placed the abortion clinics and StemExpress in violation of the HIPAA privacy rule.

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[24] *See* 45 C.F.R. § 164.514(e).
[25] *See* 45 C.F.R. §§ 164.502(a)(1)(iii).
[26] 45 C.F.R. § 164.508.
[27] 45 C.F.R. § 164.508(c).
[28] *See* Attachments O: StemExpress Consent Form and P: Planned Parenthood Consent Form.

The SE form also stated that "[i]n accordance with federal laws (HIPAA), your personal identifying information will be protected . . . health information . . . may be used or disclosed . . . [but] will NOT be connected to your name or any other personal identifier."[29]

Like the privacy provision in the contracts between Stem Express and the abortion clinics, this nod towards HIPAA requirements failed to meet the requirements of the HIPAA privacy rule. The SE form did not describe the specific patient information that will be disclosed or used, but rather provided a generic, nonexclusive list of information that *may* be disclosed. The SE form did not state who will disclose or use the patient's PHI. It also did not state when the patient's authorization will expire, or that the patient can withdraw her authorization for the use of her PHI (it mentioned that the patient cannot withdraw her consent to the tissue donation after she leaves the clinic).

The PP form, purportedly used to obtain patient consent for human fetal tissue donation at PPMM and PPSP,[30] was grossly insufficient. The form did not address privacy at all, with no information regarding: PHI that may be disclosed or used; the person(s) disclosing and receiving the PHI; any expiration on the availability of the patient's PHI to researchers or others; or the patient's right to revoke her authorization in writing.

C. The disclosures of patients' PHI made by the abortion clinics to StemExpress were not the minimum necessary disclosures to facilitate the procurement of human fetal tissue from aborted infants.

The abortion clinics and StemExpress violated a central aspect of the Privacy Rule by disclosing/obtaining more than the "minimum necessary" PHI to facilitate the procurement of human fetal tissue from aborted infants.[31] StemExpress employees did not need to know the names of patients, and they certainly did not need to directly obtain the patients' consent in order to procure fetal tissue. Instead, these deeply private activities could have been performed by the abortion clinics.

As addressed above, the abortion clinics could have established a relationship with StemExpress that did not require or result in the disclosure of any PHI. Instead, the Planned Parenthood affiliates permitted StemExpress to use PHI to directly encourage patients to donate human fetal tissue—tissue that would later be sold by StemExpress to researchers at a huge mark-up.

D. StemExpress is not a *Business Associate* of the abortion clinics under HIPAA.

A *Business Associate* under HIPAA is a person or organization, other than a member of a covered entity's workforce, that performs certain functions or activities on behalf of, or provides certain services to, a covered entity that involve the use or disclosure of individually identifiable health information. *Business Associates* are generally involved in claim processing, data analysis, utilization review, and billing. Their services are limited to legal, actuarial, accounting,

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[29] Attachment O, *supra*.
[30] Attachment P, *supra*.
[31] 45 C.F.R. §§ 164.502(b) and164.514(d).

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

VIA EMAIL

June 1, 2016

Mr. Jerry Menikoff
Director, Office for Human Research Protections
Department of Health and Human Services
Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Dear Director Menikoff:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel and empowered the panel to conduct a full and complete investigation regarding the medical practice of abortion providers and the business practices of firms that procure and resell fetal tissue.

During the course of our investigation, we have uncovered documents and received testimony from confidential informants indicating that StemExpress, LLC ("StemExpress"), a for-profit firm which procures fetal tissue from abortion clinics and transfers it to research customers, violated 45 CFR 46 by using the appearance of compliance with the regulations, while fraudulently using invalid consent forms, and misleading customers to believe it had a valid Institutional Review Board ("IRB") approval.

In addition to this letter, I have included as Attachment A another referral to the U.S. Department of Health and Human Services, Centralized Case Management Operations.

consulting, data aggregation, management, administrative, accreditation, or financial services, where the provision of the services involves the disclosure of PHI.[32]

Clearly, StemExpress did not perform one of these services for the abortion clinics, and is therefore not a *Business Associate* permitted to obtain the PHI of the abortion clinics' patients.

CONCLUSION

We appreciate your swift attention to the serious and systematic violations of the HIPAA privacy rule committed by StemExpress, Planned Parenthood Mar Monte, Planned Parenthood Shasta Pacific, and Family Planning Specialists Medical Group. If you have any questions about this request, please contact Mary Harned, Investigative Counsel at (202) 480-7160, or by email at Mary.Harned@mail.house.gov.

Sincerely yours,

Marsha Blackburn
Chair
Select Investigative Panel

Attachment(s)

cc: The Honorable Jan Schakowsky, Ranking Member
Select Panel on Infant Lives

[32] 45 C.F.R. § 160.103.

Background

StemExpress was founded in 2010 as a for-profit company and continues operations as StemExpress Foundation. Through its corporate existence, StemExpress' activities were obtaining contractual relationships with abortions clinics for the purpose of embedding a StemExpress company employee inside the clinic. The employees had access to confidential patient medical records, which they used to obtain consent and procure fetal tissue. StemExpress then resold that tissue to researchers. StemExpress pays the abortion clinic a per-specimen fee and then marks up the specimen four to six hundred percent for sale to a research institution.

Stem Express' tissue procurement technicians embedded inside the abortion clinics had the following daily **work sequence**:

- A researcher / customer placed an order for human fetal tissue using an online business portal provided by StemExpress. The web portal allowed the customer to request a particular gestational range for the fetal tissue. (See Attachment B, "Researcher Procurement Record.").

- When it first began operations, the abortion clinics from which StemExpress procured fetal tissue faxed the next day's schedule of potential patients directly to the StemExpress tissue procurement technician assigned to the clinic. (See Attachment C, "Fax from The Alameda, San Jose [Planned Parenthood clinics] to StemExpress, Jan. 10, 2013.").

- The day the abortion procedures were scheduled, StemExpress emailed the procurement schedule to its tissue technicians. (See Attachment D, "Updated Task Assignment: Procurement Schedule Wednesday, 3/30/13.").

- Emails produced by StemExpress demonstrate that its employees knew beforehand protected health information, including gestation periods of fetuses. For example: On January 6, 2015, a StemExpress employee emailed a customer that: "There are no patients that qualify for your request today. You will be on the schedule again for tomorrow, but the cases are all low gestation." On January 14, 2015, at 12:40 p.m., a StemExpress employee emailed a researcher: "Unfortunately, there is nothing within your gestational requirements today. There will be some potentials tomorrow, would you like to be on the schedule?" Hours later, the customer emailed: "Yes, please put me on the schedule for tomorrow." On April 14, 2015, a StemExpress employee emailed a researcher: We have a trisomy patient scheduled for this week and could try to procure a brain sample for you . . . ." (See Attachement E, "Emails.").

- As the firm became more computerized, tissue procurement technicians logged into a Website. (See Attachement F, "Navigating The Task Board.").

- The StemExpress procurement technician then sought out particular patients by name and obtained their consent to donate fetal tissue while they were awaiting their procedures. (See Attachment G, "Clinic Procedures and Policies.").

- StemExpress procurement technicians were paid an hourly wage and a per tissue "bonus" for each item they procured from the order page. (See Attachment H, "Procurement Technician Compensation Policy for Tissue and Blood Procurement.").

- StemExpress paid the abortion clinic a per tissue fee and then marked up the tissue four to six hundred percent for sale to the researcher. (See Attachment I, "StemExpress Services Agreement with Planned Parenthood Shasta Pacific," "StemExpress Services Agreement with Planned Parenthood of Santa Barbara, Ventura & San Luis Obispo Counties;" and Attachment J, "Purchase Order No. 60856806," "Purchase Order No. 3000014694," "Purchase Order No. 60836838," "Purchase Order No. 60858758," and "StemExpress Invoice # 1439.").

Documents produced to the Panel prove that StemExpress' tissue procurement technicians knew in advance of the abortion schedules, the clinics assisted them with obtaining consent, and the entire work flow was designed to maximize the firm's profits. For example instructions to the tissue procurement technicians (See Attachment K, "Standard Operating Procedure") states:

> The day before [the abortion] surgery: Check WebOffice [apparently an earlier version of the Task Board] for research requests; Determine your location for the next day; Call the clinic to verify how many surgeries are scheduled . . . .
>
> The clinic staff will identify donors. It is the procurement technician's responsibility to retrieve the tissue and package it appropriately for the given researcher. It is also the procurement technician's responsibility to update WebOffice so everyone is aware what tissue has been obtained and for whom.
>
> . . . On the day of the surgery, the following steps are taken to procure tissue from POC [Products Of Conception; i.e., fetal tissue] . . . Print a copy of the day's Procurement Schedule. Following along the chart flow so you know what gestations to expect.
>
> . . . Keep track of [the] time [of procurement], gestation [age], fetal foot size or sono[gram] report and date.
>
> . . . If you have an excellent sample with no researcher listed on today's schedule, please contact [redacted] Stem Express' President and CEO] immediately, and

they will work to call researchers who may be interested even though they are not currently scheduled.

The work sequence, when combined with the supporting documents reveals that StemExpress did not have a medically valid reason to see, and the abortion clinics did not have a reason to provide, patients' protected health information ("PHI"). Instead, the abortion clinics shared patients' PHI with StemExpress in furtherance of contractual agreements that financially benefitted StemExpress and the clinics.

Informed Consent

HHS requires investigators to obtain informed consent from each human being used as a research subject.[1] The "basic elements of informed consent" include the following information:

> (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental; . . . [and]
>
> (3) A description of any benefits to the subject or to others which may reasonably be expected from the research . . .[2]

Documents produced by StemExpress to the Select Panel indicate the firm did not follow those regulations. One of those documents is Attachment L, "A Form for Informed Consent To Participate In A Clinical Research Study, involving the donation of aborted pregnancy tissue for medical research, education, or treatment." It states:

> Research using donated tissue and blood is currently underway to uncover the causes of and ultimately find cures for things like: Heart Disease, Diabetes, Parkinson's Disease, Sickle Cell Anemia, Leukemia, Lymphoma, Cancer, Spinal Cord Disease, and more. . . .
>
> The benefits of consenting to donation today include furthering medical research in finding cures for disease like diabetes, leukemia, lymphoma, Parkinson's disease and more.

The Panel notes that the StemExpress consent form specifically does not conform to the General requirements for informed consent mandated under 45 CFR 46 §116. Witnesses at a recent Select Panel hearing agreed that forms similar to the one StemExpress used apparently do not conform to the HHS regulations on informed consent.[3]

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[1] 45 CFR 46 §116.

[2] *Id.*

[3] See generally House of Reps., Select Investigative Panel on Infant Lives, *Hearing on Bioethics and Human Tissue*, Mar. 2, 2016.

Coercion or Undue Influence

The requirements for informed consent further state that investigators "shall seek such consent only under circumstances that provide the prospective subject with . . . sufficient opportunity to consider whether or not to participate and that **minimize the possibility of coercion or undue influence.**" [emphasis added].[4]

The regulations further state: "When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as . . . pregnant women . . . additional safeguards" are included.[5] Documents produced by StemExpress indicate the firm only obtained fetal tissue from women who had undergone abortions at abortion clinics, and the company's employees were the ones obtaining consent. It is unclear whether such consent occurred before or after the procedures was conducted.

Additional documents produced by StemExpress demonstrate that tissue procurement technicians engaged in real-time email correspondence with researchers while abortions were taking place - presumably before they obtained informed consent to procure fetal tissue - and yet StemExpress employees already were promising to deliver products of conception. (See Attachment M, "Emails regarding PO # 60858758."). The emails reveal that a customer had placed an order for a skull and limbs.

On January 22, 2015, at 12:26 p.m., the customer emailed a StemExpress employee stating: "Just wanted to check in and see if there are any cases within our gestation range for today? Need to book some time on the equipment if so." Within minutes, at 12:30:11 p.m., the StemExpress employee replied: "There is one case currently in the room, I will let you know how the limbs and calvarium [skull] look to see if you are able to take them in about fifteen minutes." Less than two minutes later, the customer wrote: "Great thank you so much." At 1:20:32 p.m., the StemExpress employee informed the customer: "The calvarium is mostly intact, with a tear up the back of the suture line, but all pieces look to be there. The limbs, one upper and one lower, are totally intact, with one upper broken at the humerus, and one lower broken right above the knee. Please let me know if these are acceptable. I have set them aside and will await your reply." Approximately five minutes later, the customer replied: "That sounds great we would like both of them. Please send them our way. Thanks again . . ." The StemExpress employee responded: "Limbs and calvarium will be there between 3:30 and 4:00."

The fact that StemExpress was attempting to interest a customer in fetal body parts **before an abortion had taken place** raises serious concerns that there may have been coercion or undue influence upon the patient to consent to procurement. Both Members and witnesses at our recent hearing raised the same question.[6]

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[4] 45 CFR 46 §110(4) and (7)(b).

[5] *Id.*

[6] See generally House of Reps., Select Investigative Panel on Infant Lives, *Hearing on Bioethics and Human Tissue*, Mar. 2, 2016.

IRB

Documents produced by StemExpress violated 45 CFR 46 by misleading customers into believing it had a valid IRB approval. StemExpress obtained approval for its "study" from BioMed IRB (Seen Attachment N, "Informed Consent To Participate In A Clinical Research Study," and "BioMed IRB Continual Approval Notification.").

In fact, one of StemExpress' marketing materials advertises the firm provides clinics with "IRB Certified Consents," and that "Our IRB approved **protocols** and **consents** protect you as well as donor's privacy in accordance with HIPAA guidelines." (Attachment O, StemExpress marketing brochure.).

At our recent hearing, Dr. G. Kevin Donovan, the senior clinical scholar at the Kennedy Institute of Ethics at Georgetown University, and director of the Pellegrino Center for Clinical Bioethics at Georgetown University, said actions such as those undertaken by StemExpress "would never pass muster for an IRB."[7] Yet StemExpress purportedly had the approval of an IRB.

HHS regulations require IRBs to "prepare and maintain adequate documentation" of its activities, including:

> (1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
>
> (2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
>
> (3) Records of continuing review activities.
>
> (4) Copies of all correspondence between the IRB and the investigators . . . .[8]

On March 29, 2016, the Panel issued a subpoena to BioMed IRB which required it to produce documents sufficient to show BioMed IRB's ongoing oversight, within the definition of Title 45 Code of Federal Regulations Part 46, of any entity involved with fetal research or transplantation of fetal tissue for which it issued an IRB approval.[9]

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[7] House of Reps., Select Investigative Panel on Infant Lives, *Hearing on Bioethics and Human Tissue*, Mar. 2, 2016, at. P. 91.

[8] 45 CFR § 46.115 (a).

[9] House of Representatives, Select Investigative Panel on Infant Lives, Subpoena to Biomedical Research Institute of America, Mar. 29, 2016.

BioMed IRB's executive director informed the Panel on April 4, 2016 that, in regards to those records, "there are none."[10] This apparently is a direct violation of 45 CFR 46.

While regulation of IRBs does not fall under the auspices of OHRP, it may interest you to know that, in March of 2012, the Food and Drug Administration ("FDA") issued a warning letter to BioMed IRB, citing: A failure to fulfill membership requirements; failure to prepare, maintain, and follow adequate written procedures for conducting the review of research, including initial and continuing review; and keeping minutes that were not sufficient to show attendance at the meetings, actions taken by the IRB, the vote on these actions including the number of members voting for, against, and abstaining, the basis for requiring changes in or disapproving research, and a written summary of the discussion of controverted issues and their resolution. As a result, the FDA ruled it "will withhold approval of all new studies subject to 21 CFR Part 56 and reviewed by the IRB; and [n]o new subjects are to be enrolled in any ongoing studies subject to 21 CFR Part 56 and approved by the IRB."[11] That ban was lifted in January 2013.[12]

Given the facts outlined above, and the supporting documentation, I urge your office to conduct a thorough investigation into whether StemExpress violated 45 CFR 46, and, if OHRP agrees that such violations occurred, to take all appropriate actions.

Respectfully yours,

Marsha Blackburn
Chair, Select Investigative Panel

cc: Rep. Jan Schakowsky
Ranking Member

[10] Email from Fred Fox, Executive Director, Biomedical Research Institute of America, to Select Panel staff, Apr. 4, 2016.
[11] Letter from Mary A. Malarkey, Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, to Fred Fox, Executive Director, Biomedical Research Institute of America dba BioMed IRB, Mar. 29, 2012.
[12] Letter from Mary A. Malarkey, Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, to Fred Fox, Executive Director, Biomedical Research Institute of America dba BioMed IRB, Jan. 16, 2013.

Attachment A:

Letter to Ms. Jocelyn Samuels,

Director, Centralized Case Management Operations

U.S. Department of Health and Human Services

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6115

Majority (202) 225–2927

Minority (202) 225–3641

VIA EMAIL

June 1, 2016

Ms. Jocelyn Samuels, Director
Centralized Case Management Operations
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Room 509F HHS Bldg.
Washington, D.C. 20201

Dear Director Samuels:

On October 7, 2015, the U. S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel and empowered it to conduct a full and complete investigation regarding the medical practices of abortion providers and the business practices of businesses who procure and resell fetal tissue.

The Panel's investigation uncovered a series of business contracts between StemExpress,[1] a tissue procurement business ("TPB"), and several abortion clinics. These contracts included provisions for the payment of fees by StemExpress to the abortion clinics for fetal tissue and maternal blood. StemExpress then resold the fetal tissue and blood to researchers.

These contracts produced a regime of cooperation between StemExpress and each clinic. In particular: (1) the day before scheduled abortions, StemExpress received a fax from a clinic with information about the abortions scheduled for the next day; (2) StemExpress employees were granted access to the medical files of individual patients; (3) The clinic's medical employees (doctors and nurses) directed the StemExpress employees to particular patients who were "good candidates" for fetal tissue donations; (4) the StemExpress employees had access to the "patient terminal" inside the abortion clinic; and (5) the StemExpress employees were permitted by the abortion clinic to interview the patients about personal information, including their dates of birth.

[1] StemExpress and Stem-Ex are the same company.

In particular, the Panel's investigation has uncovered information indicating that StemExpress and Planned Parenthood Mar Monte ("PPMM"), Planned Parenthood Shasta Pacific ("PPSP") and Family Planning Specialists Medical Group ("FPS") (hereinafter "the abortion clinics") committed systematic violations of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") privacy rule from about 2010 to 2015. **These violations occurred when the abortion clinics disclosed patients' *individually identifiable health information* to StemExpress to facilitate the TPB'S efforts to procure human fetal tissue for resale.** This complaint is against each of these entities, and we request a swift and full investigation by the Office of Civil Rights in the Department of Health and Human Services.

In addition to this letter, we are submitting a referral to the HHS Office for Human Research Protections indicating that StemExpress violated 45 CFR 46 by using invalid consent forms and failing to have valid Institutional Review Board ("IRB") approval.[2]

I. BACKGROUND

The abortion clinics are "covered entities" under HIPAA, while StemExpress is not.[3] StemExpress "procure[s] tissues and isolate[s] cells for researchers' individual needs in its own labs."[4]

From about 2010 to 2015, the abortion clinics permitted StemExpress employees to: enter their clinics and procure human fetal tissue from aborted infants; obtain *individually identifiable health information*, or *protected health information* ("PHI") about their patients; interact with patients; and seek and obtain patient consent for tissue donation.[5] StemExpress embedded tissue procurement technicians inside the abortion clinics whose **work sequence** followed a daily routine:

1. A researcher / customer placed an order for human fetal tissue using an online business portal provided by StemExpress. The web portal allowed the customer to request a particular gestational range for the fetal tissue.[6]

2. The abortion clinics from which StemExpress procured fetal tissue faxed the next day's schedule of potential patients directly to the StemExpress tissue procurement technician assigned to the clinic.[7]

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[2] *See* Attachment A.

[3] *See* 45 CFR Part 160.103 (Covered Entity means: (1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.) *See also* OCR Privacy Brief, Summary of the HIPAA Privacy Rule, *available at* http://www.hhs.gov/sites/default/files/privacysummary.pdf (last visited May 5, 2016) (used as reference throughout this complaint).

[4] Stemexpress, About Us, *available at* http://stemexpress.com/about/ (last visited Apr. 29, 2016).

[5] *See* Attachment B: Clinic Procedures & Policies.

[6] *See* Attachment C: Researcher Procurement Record.

[7] *See* Attachment D: Fax from The Alameda, San Jose [Planned Parenthood clinics] to StemExpress, Jan. 10, 2013.

3. The day the abortion procedures were scheduled, StemExpress posted the order on a website "task board" (order page) to be accessed by their procurement technician or communicated the order to the tissue technician via email.[8]

4. The StemExpress procurement technician informed the clinic what they wished to procure (*i.e.*, the type of tissue and gestational range) based on the order page, and the abortion clinic provided the medical files, including PHI, for the patients with abortions scheduled for that day.[9]

5. The StemExpress procurement technician then sought out particular patients by name and obtained their consent to donate fetal tissue while they were awaiting their procedures. The procurement technician was also permitted to interview patients and obtain their PHI.[10]

6. StemExpress procurement technicians were paid an hourly wage and a per tissue "bonus" for each item they procured from the order page.[11]

7. StemExpress paid the abortion clinic for each fetal tissue and each blood sample and then marked up the tissue four to six hundred percent for sale to the researcher.[12]

The work sequence, when combined with supporting documentation, reveals that StemExpress did not have a medically valid reason to see, and the abortion clinics did not have a reason to provide, patients' PHI. Instead, the abortion clinics shared patients' PHI with StemExpress in furtherance of contractual agreements that financially benefitted StemExpress and the clinics.[13]

II. THE HIPAA PRIVACY RULE

The HIPAA privacy rule ("Privacy Rule") protects all *individually identifiable health information* held or transmitted by a covered entity or its business associate, and calls this information *protected health information* ("PHI").[14] PHI identifies an individual, or can reasonably be believed to be useful in identifying an individual (*e.g.*, name, address, birth date, Social Security Number), and includes demographic data relating to: an individual's past, present, or future physical or mental health condition; the provision of health care to the individual; or the past, present, or future payment for the provision of health care to the individual.[15]

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[8] *See* Attachment E: Updated Task Assignment: Procurement Schedule Wednesday, 3/20/13 and Attachment F: Navigating The Task Board.
[9] *See* Attachment G: StemExpress Emails.
[10] *See* Attachment B, *supra*: Clinic Procedures and Policies and Attachment H: Consenting Patients.
[11] *See* Attachment I: Procurement Technician Compensation Policy for Tissue and Blood Procurement.
[12] See Attachment J: StemExpress Services Agreement with Planned Parenthood Shasta Pacific; StemExpress Services Agreement with Planned Parenthood of Santa Barbara, Ventura & San Luis Obispo Counties; Purchase Order No. 60856806; Purchase Order No. 3000014694; Purchase Order No. 60836838; Purchase Order No. 60858758; and StemExpress Invoice # 1439.
[13] *See* Attachment K: Standard Operating Procedure.
[14] 45 C.F.R. § 160.103.
[15] 45 C.F.R. § 160.103.

A covered entity may not use or disclose an individual's PHI except as the Privacy Rule permits or requires,[16] or as the individual or their representative authorizes in writing (see discussion below). HHS may impose civil money penalties on covered entities that fail to comply with the Privacy Rule. Further, both a covered entity that discloses, and any person who knowingly obtains, PHI in violation of the Privacy Rule can face criminal fines or imprisonment.[17]

III. THE CONTRACTS BETWEEN STEMEXPRESS AND THE ABORTION CLINICS

Particular language, contained within the four corners of the written contracts between StemExpress and the abortion clinics raises serious concerns that the parties violated the Privacy Rule.

The written contracts between StemExpress and the abortion clinics contain the following language:

> [a]ny information obtained from [the abortion clinics] patients' charts shall be privileged, and [Stem-Ex / StemExpress] will treat the information in order to preserve the confidentiality of the patients. [Stem-Ex / StemExpress] will not receive any information concerning identity of donors **except as necessary to obtain patients' consent** for use of POCs and maternal bloods (emphasis added).[18]

This admission, on the face of the contracts, that the abortion clinics granted StemExpress access to patients' PHI raises the question whether any HIPAA provision permits or requires such disclosure without patients' express authorization. This question is compounded by the contracts' admission that StemExpress reviewed PHI **prior to obtaining patients' consent to donate fetal tissue *or* patients' authorization to view their PHI.**

IV. VIOLATIONS OF THE HIPAA PRIVACY RULE BY STEMEXPRESS AND THE ABORTION CLINICS

This complaint argues that the agreements between StemExpress and the abortion clinics, on their face and in practice, are fundamentally flawed. A contractual agreement requiring StemExpress to "treat the information obtained from patients' charts in order to preserve the confidentiality of the patients" **cannot trump a law prohibiting the abortion clinics from permitting these disclosures in the first place.** As discussed below, the abortion clinics—covered entities under HIPAA—were not permitted to disclose or make available to StemExpress any patient's PHI without the patient's express authorization.

The abortion clinics and StemExpress violated the HIPAA privacy rule because: (A) The disclosures of patients' PHI made by the abortion clinics, and received by StemExpress, were

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[16] 45 C.F.R. §164.502(a).
[17] Pub. L. 104-191; 42 U.S.C. §§ 1320d-5 – 1320d-6.
[18] *See* Attachments L, M, and N.

neither required nor permitted under HIPAA, and in particular did not meet the exceptions for cadaveric organ, eye or tissue transplantation or for research; (B) The consents for fetal tissue donation ostensibly obtained by StemExpress from the abortion clinics' patients did not constitute sufficient authorizations for the disclosure of PHI; (C) The disclosures of patients' PHI made by the abortion clinics to StemExpress were not the minimum necessary disclosures to facilitate the procurement of human fetal tissue from aborted infants; and (D) StemExpress is not a *Business Associate* of the abortion clinics under HIPAA.

A. The disclosures of patients' PHI made by the abortion clinics, and received by StemExpress, were neither required nor permitted under HIPAA, and in particular did not meet the exceptions for cadaveric organ, eye or tissue transplantation or for research.

The disclosures of PHI that the abortion clinics made to StemExpress are neither required[19] nor permitted[20] by law. StemExpress was not involved in the treatment of patients, in the payment for treatment, or in clinic operations.[21] **Rather, StemExpress wanted patients' PHI to facilitate the procurement of human tissue from aborted infants for resale to researchers.**

1. Cadaveric organ, eye or tissue transplantation

Importantly, the disclosures to StemExpress do not fall under the provision in law permitting disclosure of PHI to aid organ transplantation. While the contracts reference the "National Organ Transplant Act," 42 U.S.C. 274e(c)(1), the abortion clinics were not facilitating the donation and *transplantation* of cadaveric organs, eyes, and tissue. **Instead, the clinics were facilitating the donation of human fetal tissue from aborted infants for *research,* which is not covered by the cadaveric organ, eye or tissue exception.**[22]

2. Research

Further, the disclosures to StemExpress do not meet the rigorous requirements applicable to PHI disclosures for research purposes. A covered entity is not permitted to disclose an individual's PHI for research purposes without the individual's authorization unless the covered entity (1) obtains verification of approval from an Institutional Review Board ("IRB") for disclosure without authorization; (2) the researcher represents that the use or disclosure of the PHI is solely to prepare research protocol and the PHI will not be removed from the covered entity, and that the PHI is necessary for the research; or (3) the research is on PHI of deceased individuals.[23]

3. Violations Preceding "Consent"

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[19] 45 C.F.R. § 164.502(a)(2) (The only "required" disclosures are to (1) an individual or their personal representative when they request access to, or an accounting of disclosures of, their protected health information; and (2) to HHS when it is undertaking compliance investigation or review or enforcement action).
[20] *See* 45 C.F.R. § 164.502(a)(1).
[21] *See* 45 C.F.R. § 164.506(c).
[22] *See* 45 C.F.R. § 164.512(h).
[23] 45 C.F.R. § 164.512(i).

Because StemExpress employees actually sought consent for tissue donation from patients, the abortion clinics permitted the employees to view patients' charts. Medical charts are filled with HIPAA-protected PHI, including names, addresses, past and present medical treatment, and more. **Each time that an abortion clinic employee shared a medical chart with a StemExpress employee, both violated the HIPAA privacy rule.**

No evidence suggests the abortion clinics' patients provided authorization for StemExpress staff to view their PHI *prior* to seeking their consent to donate tissue. Therefore, regardless of whether a patient *ultimately* consented to tissue donation and authorized disclosure of her PHI to StemExpress, her privacy was violated.

The abortion clinics could have directly consented their patients for tissue donation, and entered an agreement with StemExpress to provide a limited data set[24] regarding the patients they were seeing on a particular day. Instead, they violated the Privacy Rule by permitting StemExpress to view the most intimate information about their patients.

These disclosures made by the abortion clinics to StemExpress were inarguably direct and intentional—not incidental.[25] StemExpress employees did not merely overhear a patient's name while in the clinic—they were handed her medical chart by her healthcare provider in blatant violation of the HIPAA privacy rule.

B. The consent for fetal tissue donation obtained by StemExpress from the abortion clinics' patients did not constitute sufficient authorizations for the disclosure of PHI.

While StemExpress purportedly obtained consents from patients prior to procuring human fetal tissue from their aborted infants, the forms that they used were insufficient to authorize the disclosure of PHI under the HIPAA privacy rule.

The Privacy Rule requires a covered entity to obtain an individual's written authorization for any use or disclosure of PHI that is not permitted or required by law.[26] Such authorization must be in plain language and contain specific information regarding the information to be disclosed or used, the person(s) disclosing and receiving the information, expiration, right to revoke in writing, and other data.[27]

Neither the consent form provided by StemExpress ("SE form") nor the consent form provided by Planned Parenthood ("PP form") to obtain patient consent for the donation of human fetal tissue of aborted infants met these stringent requirements.[28] The statement in the SE form that a patient's "health information will be protected at all times" is ironic given that StemExpress's possession of the patient's PHI already placed the abortion clinics and StemExpress in violation of the HIPAA privacy rule.

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[24] *See* 45 C.F.R. § 164.514(e).
[25] *See* 45 C.F.R. §§ 164.502(a)(1)(iii).
[26] 45 C.F.R. § 164.508.
[27] 45 C.F.R. § 164.508(c).
[28] *See* Attachments O: StemExpress Consent Form and P: Planned Parenthood Consent Form.

The SE form also stated that "[i]n accordance with federal laws (HIPAA), your personal identifying information will be protected . . . health information . . . may be used or disclosed . . . [but] will NOT be connected to your name or any other personal identifier."[29]

Like the privacy provision in the contracts between Stem Express and the abortion clinics, this nod towards HIPAA requirements failed to meet the requirements of the HIPAA privacy rule. The SE form did not describe the specific patient information that will be disclosed or used, but rather provided a generic, nonexclusive list of information that *may* be disclosed. The SE form did not state who will disclose or use the patient's PHI. It also did not state when the patient's authorization will expire, or that the patient can withdraw her authorization for the use of her PHI (it mentioned that the patient cannot withdraw her consent to the tissue donation after she leaves the clinic).

The PP form, purportedly used to obtain patient consent for human fetal tissue donation at PPMM and PPSP,[30] was grossly insufficient. The form did not address privacy at all, with no information regarding: PHI that may be disclosed or used; the person(s) disclosing and receiving the PHI; any expiration on the availability of the patient's PHI to researchers or others; or the patient's right to revoke her authorization in writing.

C. The disclosures of patients' PHI made by the abortion clinics to StemExpress were not the minimum necessary disclosures to facilitate the procurement of human fetal tissue from aborted infants.

The abortion clinics and StemExpress violated a central aspect of the Privacy Rule by disclosing/obtaining more than the "minimum necessary" PHI to facilitate the procurement of human fetal tissue from aborted infants.[31] StemExpress employees did not need to know the names of patients, and they certainly did not need to directly obtain the patients' consent in order to procure fetal tissue. Instead, these deeply private activities could have been performed by the abortion clinics.

As addressed above, the abortion clinics could have established a relationship with StemExpress that did not require or result in the disclosure of any PHI. Instead, the Planned Parenthood affiliates permitted StemExpress to use PHI to directly encourage patients to donate human fetal tissue—tissue that would later be sold by StemExpress to researchers at a huge mark-up.

D. StemExpress is not a *Business Associate* of the abortion clinics under HIPAA.

A *Business Associate* under HIPAA is a person or organization, other than a member of a covered entity's workforce, that performs certain functions or activities on behalf of, or provides certain services to, a covered entity that involve the use or disclosure of individually identifiable health information. *Business Associates* are generally involved in claim processing, data analysis, utilization review, and billing. Their services are limited to legal, actuarial, accounting,

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[29] Attachment O, *supra*.
[30] Attachment P, *supra*.
[31] 45 C.F.R. §§ 164.502(b) and164.514(d).

consulting, data aggregation, management, administrative, accreditation, or financial services, where the provision of the services involves the disclosure of PHI.[32]

Clearly, StemExpress did not perform one of these services for the abortion clinics, and is therefore not a *Business Associate* permitted to obtain the PHI of the abortion clinics' patients.

CONCLUSION

We appreciate your swift attention to the serious and systematic violations of the HIPAA privacy rule committed by StemExpress, Planned Parenthood Mar Monte, Planned Parenthood Shasta Pacific, and Family Planning Specialists Medical Group. If you have any questions about this request, please contact Mary Harned, Investigative Counsel at (202) 480-7160, or by email at Mary.Harned@mail.house.gov.

Sincerely yours,

Marsha Blackburn
Chair
Select Investigative Panel

Attachment(s)

cc: The Honorable Jan Schakowsky, Ranking Member
Select Panel on Infant Lives

[32] 45 C.F.R. § 160.103.

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

November 2, 2016

VIA EMAIL

The Honorable Leslie Carol Rutledge
Attorney General
State of Arkansas
323 Center Street, Suite 200
Little Rock AR 72201

Dear Attorney General Rutledge:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the "Panel") and empowered it to conduct a full and complete investigation regarding the medical practices of abortion providers and the practices of entities that procure and transfer fetal tissue.

Over the course of our investigation, we have uncovered documents and received testimony from confidential informants indicating that StemExpress, LLC ("StemExpress"), a firm that procures(d) fetal tissue from abortion clinics and transfers it to research customers,[1] violated state law, including but not limited to the Arkansas Anatomical Gift Act ("A.C.A.") § 120-17-802 (2)(c), which forbid the transfer of fetal tissue for valuable consideration.

Among the abortion clinics from which StemExpress sought to procure fetal tissue was Little Rock Family Planning Services,[2] which is located at [redacted].[3]

The A.C.A. makes it a five-year felony if a person "for valuable consideration, knowingly purchases or sells a part for transplantation or therapy if removal of a part from an individual is

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[1] *See* Select Investigative Panel of the H. Comm. on Energy and Commerce, Interim Update to the U.S. House of Representatives, Jul. 14, 2016, https://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/114/analysis/20160714Interim_Update.pdf.

[2] *See* Letter from [redacted], counsel for Little Rock Family Planning Services, to Matthew Tallmer, Investigator, Select Investigative Panel on Infant Lives [sic], Oct. 10, 2016.

[3] Little Rock Family Planning Services Website, https://lrfps.com/, last accessed Oct. 11, 2016.

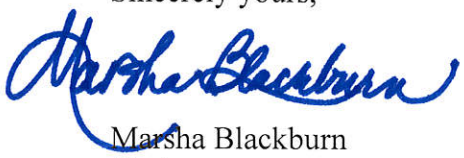
intended to occur after the individual's death . . ."[4] The A.C.A. goes on to state that an individual "may charge a reasonable amount for the removal, processing, preservation, quality control, storage, transportation, implantation, or disposal of a part."[5]

Another section of the A.C.A., however, states that: "A person shall not buy, sell, give, exchange, or barter or offer to buy, sell, give, exchange, or barter any fetus born dead as a result of a legal abortion or any organ, member, or tissue of fetal material resulting from a legal abortion."[6]

In a letter to the Panel, the counsel for Little Rock Family Planning Services ("LRFPS") wrote: "In 2015, LRFPS entered into a contract with StemExpress . . . . In June 2015, LRFPS collected two fetal tissue samples pursuant to appropriate written patient consents. Both samples were sent to StemExpress."[7]

Based on the facts outlined above and the supporting documentation, I urge your office to conduct a thorough investigation into whether StemExpress violated these statutes and regulations, and, if you agree that such violations occurred, to take all appropriate action. If you have any questions about this request, please contact T. March Bell at (202) 226-9027, March.Bell@mail.house.gov.

Sincerely yours,



Marsha Blackburn
Chair
Select Investigative Panel

Attachment

cc: The Honorable Jan Schakowsky
Ranking Member
Select Investigative Panel

[4] A.C.A. § 20-17-1216 (a).
[5] A.C.A. § 20-17-1216 (b).
[6] A.C.A. § 20-17-802(c)
[7] *Supra* note 2.

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

November 2, 2016

VIA EMAIL

The Honorable Tony Rackauckas
District Attorney, County of Orange
401 Civic Center Drive West
Santa Ana, California 92701

Dear District Attorney Rackauckas:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the "Panel") and empowered it to conduct a full and complete investigation regarding the medical practices of abortion providers and the practices of entities that procure and transfer fetal tissue.

Over the course of our investigation, we have uncovered documents that indicate DV Biologics, LLC ("DaVinci"), DaVinci Biosciences, LLC ("DVB"), two related firms that procured fetal tissue from a Planned Parenthood affiliate that performs abortions and transferred it to research customers, and Planned Parenthood Orange and San Bernardino Counties ("PPOSBC"), violated various provisions of state law, including but not limited to the California Sales and Use Tax Law.

History & Business Models of DaVinci & DVB

DaVinci Biosciences, LLC, was founded as a for-profit corporation. DaVinci filed its incorporation papers with the California Secretary of State on December 19, 2007.[1] It originally was located at [redacted].[2] As of this August 2016, however, it had moved to [redacted].[3] DVB was also founded as a for-profit

[1] California Secretary of State, Business Entity Detail, http://kepler.sos.ca.gov (last visited Oct. 21, 2016).
[2] *Id.*
[3] Letter from [redacted], Vice President of Operations, DaVinci Biosciences, LLC, to Panel staff, Aug. 10, 2016.

corporation and filed its incorporation papers with the California Secretary of State on March 16, 2009.[4] DVB was originally located at the same Yorba Linda location as DaVinci.[5] The counsel for both entities informed the Panel that "DVB is a subsidiary of DaVinci Biosciences, LLC."[6]

Both entities received aborted fetal tissue from the same source. The counsel for both told the Panel, "DVB received fetal tissue exclusively from its parent company, DaVinci. DaVinci itself received fetal tissue exclusively from Planned Parenthood of Orange and San Bernardino Counties. At this time, the Panel has not evidence that DaVinci paid money to Planned Parenthood for the donated tissue."[7]

Documents produced to the Panel from other firms in the fetal tissue industry pursuant to subpoenas demonstrate that the industry norm is for companies, be they for-profit or non-profit, to pay California-based abortion clinics for fetal tissue. For example, StemExpress, LLC, another for-profit tissue procurement firm, paid Planned Parenthood affiliates in California an average of $50 per-specimen obtained.[8] Advanced Bioscience Resources, Inc., a non-profit tissue procurement business, paid facility fees of $55 or $60 per month (depending upon the year) to the Planned Parenthood affiliates and clinics from which it obtained fetal tissue.[9] From 2010 through 2015, StemExpress paid a total of $135,880 to California-based Planned Parenthood affiliates for fetal tissue specimens.[10] Over the same time period, Advanced Biosciences Resources, Inc. paid a total of $328,225 to California-based Planned Parenthood affiliates for fetal tissue specimens.[11]

The contractual agreement between DVB and PPOSBC show that the firm provided PPOSBC "with a sterile container, including storage media, for each" fetal tissue specimen the Planned Parenthood affiliate obtained.[12] On each day DVB was scheduled to obtain fetal tissue, PPOSBC workers would, "following retrieval, store each [fetal tissue] Specimen in a separate container" and "notify DVB's "designated contact. . . that Specimen is ready for pick-up . . . ."[13]

Documents produced by DVB show that PPOSCB workers performed the following tasks:

- Discussed tissue donation with women awaiting abortions

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[4] California Secretary of State, Business Entity Detail, http://kepler.sos.ca.gov (last visited Oct. 21, 2016).
[5] *Id.*
[6] Letter from R. Joseph Burby, IV, Bryan Cave LLP, to Rep. Marsha Blackburn, Chair, Select Investigative Panel, Jan. 29, 2016, at 1 [hereinafter Burby letter].
[7] *Id.* at 3.
[8] *See* Services Agreement between StemExpress, LLC, and Planned Parenthood Mar Monte, Apr. 1, 2010, at 1 [STEM_HOUSE.SELECT_0167 – STEM_HOUSE.SELECT_0169]; Services Agreement between StemExpress, LLC, and Planned Parenthood Shasta Pacific, May 15, 2012, at 1 [STEM.HOUSE.SELECT_0170 – STEM.HOUSE.SELECT_0172]; Services Agreement between StemExpress, LLC, and Planned Parenthood of Santa Barbara, Ventura & San Luis Obispo Counties, Oct, 23, 2013, at 1.
[9] Advanced Bioscience Resources, Inc., "Statement of Facility Fees, Jan. 2010 – Oct. 2015."
[10] Panel analysis of invoices from Planned Parenthood Mar Monte and Planned Parenthood Shasta Pacific to Stem Express, LLC.
[11] Panel analysis of invoices from Planned Parenthood San Jose, Planned Parenthood Riverside, and Planned Parenthood to Advance Bioscience Resources, Inc.[date?]
[12] Specimen Donation Agreement between DaVinci Biosciences, LLC, and Planned Parenthood of Orange and San Bernardino Counties, Sep. 23, 2008, at 1, attachment # **TK** . [hereinafter DVB Agreement] [DVB_00001613].
[13] *Id.* at 2 [DVB-00001614].

- Obtained consent from the patients to donate human fetal tissue
- Procured fetal tissue of between a gestational period of 5-20 weeks
- Stored the signed consent forms
- Collected the fetal tissue samples, washed the samples, and transferred them to a sterile container with the gestational age written on the container, and
- Stored the samples on wet ice[14]

DaVinci and DVB sold the fetal tissue to researchers, educational institutions, and pharmaceutical companies. DaVinci "focused on the research and development of cell-based therapeutics targeting neurodegenerative and autoimmune diseases, while DVB supplied human biological tools to academic institutions and pharmaceutical companies for research purposes."[15]

DVB has an online catalog through which researchers can select from among 338 different types of cells and add the desired product to their "cart."[16] The prices range dramatically: bone marrow mononuclear cells sell online for $50;[17] cardiomyocytes for $850;[18] skeletal muscle progenitor cells for $900;[19] glioblastoma multiforme cell (uncultured) FFPE block for $1,200;[20] and synovial tissue FFPE block for $1,750.[21]

The DVB Website catalogue states that customers can "Order anytime, 24 hours a day, 365 days a year by email or fax. If your order arrives outside our normal business hours, it will be quickly processed at the beginning of the next business day."[22] All orders to North America "are shipped from DV Biologics headquarters in Southern California and freight is pre-paid and added to your invoice as a separate item unless customers references their own separate shipping account and vendor."[23] International orders are shipped from DV Biologics headquarters in Southern California every Monday unless specially requested to be shipped on another date.[24]

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[14] DaVinci Biosciences, LLC, "Characterization of Human Fetal Stem Cells and Determination of Research and Therapeutic Tool Potential," undated.
[15] *Id.*
[16] *See:* DV Biologics, LLC, "LIFEbank Products," http://www.dvbiologics.com/products (last visited Oct. 21, 2016).
[17] *Id.*
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] DV Biologics, LLC, Website, http://www.dvbiologics.com/ordering-information (last visited Oct. 25, 2016).
[23] *Id.*
[24] *Id.*

Potential Criminal Violations on the Part of DaVinci & DVB

California Revenue and Tax Code

A provision of the California Revenue and Tax Code states:

> [E]very retailer engaged in business in this state and making sales of tangible personal property for storage, use, or other consumption in this state, not exempted . . . shall, at the time of making the sales or, if the storage, use, or other consumption of the tangible personal property is not then taxable hereunder, at the time the storage, use, or other consumption becomes taxable, collect the tax from the purchaser and give to the purchaser a receipt therefor in the manner and form prescribed by the [California State Equalization Board].[25]

A publication put out by the State Board of Equalization ("SBE") states that provision applies to corporations, individuals, Limited Liability Companies, Limited Liability Partnerships, Limited Partnerships, partnerships, married co-owners, registered domestic partnerships, and organizations.[26]

The law defines a "retailer engaged in business in" California as "Any retailer maintaining, occupying, or using, permanently or temporarily, directly or indirectly, or through a subsidiary, or agent, by whatever name called, an office, place of distribution, sales or sample room or place, warehouse or storage place, or other place of business."[27]

There is an exemption for the sale of human blood and human body parts.[28] DVB is not a tissue or blood bank rather it sells fetal tissue cells, cell lines, and other products directly to customers. SBE recently collected nearly $82,000 for unpaid sales taxes for a non-profit organization that saves dogs, draws blood from those dogs, and sells the white blood cells, plasma, and red blood cells for transfusions into other canines.[29]

The statute defines tangible personal property as "personal property which may be seen, weighed, measured, felt, or touched, or which is in any other manner perceptible to the senses."[30] Thus, cells and cell lines are tangible personal property under the California Sales and Use Tax.

The SBE publication further states that California companies can pass along the amount of sales tax to customers, provided the business lists a separate amount for sales tax reimbursement on its receipts or invoices, or if the sales agreement "specifically calls for the addition of sales tax

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[25]Cal. Rev. & Tax Code § 6203.

[26] Cal. State Bd. of Equalization, "Your California Seller's Permit: Your Rights and Responsibilities under the Sales and Use Tax Law," Pub. 72, May 2014, at 1. [hereinafter Pub.. 72].

[27] Cal. State Bd. of Equalization, "Laws, Regulations & Annotations, Sales and Use Tax Law, Chapter 3. The Tax," https://www.boe.ca.gov/lawguides/business/current/btlg/vol1/sutl/6203.html (last visited Oct. 25, 2016).

[28] Cal. Rev. & Tax Code § 33 ("Human whole blood, plasma, blood products, and blood derivatives, or any human body parts held in a bank for medical purposes, shall be exempt from taxation for any purpose.").

[29] Chris Haire, "Greyhound Dog Rescue Hemopet Fights to Stay Open after $82,000 Tax Bill," *Orange County Register*, Oct. 10, 2016, http://www.ocregister.com/articles/blood-731674-hemopet-greyhounds.html (last visited Oct. 27, 2016).

[30] Cal. Rev. & Tax Code § 6016.

reimbursement."[31] If the business includes sales tax reimbursement in its prices, companies "must inform the buyer that tax is included" by making one of the following statements on a price tag or in an advertisement: "All prices of taxable items include sales tax reimbursement computed to the nearest mill," or "The price of this item includes sales tax reimbursement to the nearest mill."[32] Neither of those statements are on DVB's website.

Under the California Revenue and Tax Code,

> Internet sales are treated just like sales made at retail stores, by sales representatives, over the telephone, or by mail order. If your business is located in California, retail sales of tangible personal property that you make over the Internet to California customers are generally taxable unless the sales qualify for a specific tax exemption or exclusion . . . and you are required to register for a permit and report and pay tax to the same extent as any other retailer in California.[33]

As previously noted, DVB sold its products through the Internet. It should, therefore, have collected tax on sales made to California customers. Ten invoices produced by DVB show the firm did not charge tax to Applied StemCell, Inc., a California-based company ("Applied StemCell"). Applied StemCell filed its incorporation papers with the California Secretary of State on February 13, 2008.[34] Applied StemCell "is a leading stem cell and gene editing company . . ."[35] The invoices are listed in the chart below, and copies are attached to this letter.

DATE	INVOICE NUMBER	TOTAL COST	SALES TAX CHARGED
February 12, 2013	437	$ 82.00	$ 0.00
October 1, 2013	618	$ 450.00	$ 0.00
October 7, 2013	622	$1,570.00	$ 0.00
March 6, 2014	754	$4,016.99	$ 0.00
August 13, 2014	869	$ 592.99	$ 0.00
August 18, 2014	871	$ 856.99	$ 0.00
November 24, 2014	954	$ 410.00	$ 0.00
December 22, 2014	999	$ 82.00	$ 0.00
January 12, 2015	1021	$ 114.00	$ 0.00
February 24, 2015	1077	$1,250.00	$ 0.00

[31] Pub. 72 at 5.
[32] *Id.*
[33] Cal. State Bd. of Equalization, "Publication 109 Internet Sales," https://www.boe.ca.gov/formspubs/pub109/ (last visited Oct. 26, 2016).
[34] Online at http://kepler.sos.ca.gov/ (last visited Oct. 27, 2016).
[35] Applied StemCells, Inc. website, http://www.appliedstemcell.com/ (last visited Oct. 27, 2016).

Based on the facts outlined above and the supporting documentation, I urge your office to conduct a thorough investigation into whether DVB violated the statute, and, if you agree that such violations occurred, to take all appropriate action. If you have any questions about this request, please contact T. March Bell at (202) 226-907, March.Bell@mail.house.gov.

Sincerely yours,

Marsha Blackburn
Chair
Select Investigative Panel

Attachment(s)

cc: The Honorable Jan Schakowsky
Ranking Member
Select Investigative Panel

The Honorable Vern Pierson
El Dorado County District Attorney

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6115

Majority (202) 225–2927

Minority (202) 225–3641

December 1, 2016

VIA EMAIL

The Honorable Ken Paxton
Attorney General
State of Texas
300 W. 15th Street
Austin, TX 78701

Dear Attorney General Paxton:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the "Panel") and empowered it to conduct a full and complete investigation regarding the medical practices of abortion providers and the practices of entities that procure and transfer fetal tissue.

Over the course of our investigation, we have uncovered documents and received testimony that indicates that Planned Parenthood Gulf Coast ("PPGC"), an abortion facility that procured fetal tissue and transferred it to researchers,[1] allegedly violated state law, including but not limited to the Tex. Penal Code § 48.02, and Tex. Penal Code Title 8 § 37.08.

[1] *See* Select Investigative Panel of the H. Comm. on Energy and Commerce, Interim Update to the U.S. House of Representatives, Jul. 14, 2016, https://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/114/analysis/20160714Interim_Update.pdf.

Background on Planned Parenthood Gulf Coast

PPGC has a research department[2] that conducted studies for pharmaceutical companies,[3] the medical device industry,[4] and academic institutions, mostly in Texas.[5] PPGC procured fetal tissue for the University of Texas Medical Branch, Galveston.[6] PPGC bought its headquarters in 2010 largely because it met the needs of the research department.[7]

PPGC conducts in-house fetal tissue extraction, processing, storage, and shipping.[8] PPGC also ships tissue, but it requires the study sponsors to set up a FedEx account. PPGC prints the air bill, puts the air bill on the container, places the shipment on dry ice, and either has FedEx pick up the shipments or a PPGC staffer will drop it off.[9] PPGC bills customers for any sterile supplies needed for tissue procurement.[10]

Despite those costs incurred by PPGC, there are indications that PPGC made money from its sales of fetal tissue. [redacted], PPGC's director of research, stated "this research department generates more revenue than the entire OB GYN research program at Baylor [College of] Medicine. . . .multiple, multiple times more revenue."[11]

PPGC Interactions with University of Texas Medical Branch

From 2010 through 2011, PPGC procured fetal tissue for the University of Texas Medical Branch, Galveston ("UTMB").[12] While PPGC personnel generally obtained consent from patients to donate fetal tissue, and procured the tissue, emails produced by UTMB indicate that its personnel also obtained consent from patients and procured the fetal tissue.

October 20, 2010 email from [redacted]

In an October 10, 2010 email to [redacted] at UTMB, [redacted] wrote:

> We need to renegotiate the budget for both studies based on feedback from [PPGC staff] . . . . here is their proposal:
>
> $50 enrollment/consent process (consent per PPGC SOP, physician statements)[.]

---

[2] *See* Center for Medical Progress, "Transcript, Meeting with [redacted], Director of Research, Planned Parenthood Gulf Coast; [redacted], Ambulatory Surgery Director, Planned Parenthood Gulf Coast; [redacted], Physician, Planned Parenthood Gulf Coast; Medical Assistant, Planned Parenthood Gulf Coats; [and] Two Actors posing as fetal tissue procurement company," Apr. 9, 2015, attachment 1. [hereinafter CMP].
[3] *Id.* at 5.
[4] *Id.* at 6.
[5] *Id.* at 35.
[6] Documents produced by University of Texas Medical Branch.
[7] CMP at 96.
[8] *Id.* at 9, 14, 19-20, 29; 31, 40.
[9] *Id.* at 19-20.
[10] *Id.* at 90.
[11] *Id.*
[12] *Id.* at 7.

> $100 room set up/collection (strip machines, sterile equipment, rinse hosing with sterile water, biological sample collection) [.]
>
> $50 enrollment/consenting fee if tech leaves without tissue (staff performed the work and tech didn't/couldn't stay to collect sample).
>
> $2000 annual admin fee (new or retraining staff . . . and Research Mgmt oversight, consent storage, supply storage).
>
> It would also be preferable if we amended the contracts to provision $Xamount/yr for a spend-down grant. PPGC is paid in advance for a set number of samples/yr, and then you collect at will . . .. [13]

UTMB invoices and proposed amended contract

UTMB produced invoices to the Panel from PPGC that show PPGC billed UTMB a total of $21,424.98 in annual administrative fees, consent payments, staff training, and supplies.[14]

An unexecuted amended contract between PPGC and UTMB would have provided for the college to pay PPGC $150 for each executed informed consents of patients (up to 500 patients), plus $2,000 in annual administrative fees, and $1,500 for training UTMB staff.[15] Had the contract been executed as drafted, PPGC would have received $75,000 solely for consent forms signed by patients.

April 2011 Planned Parenthood Federation of America memo on fetal tissue donations

On April 4, 2011, Planned Parenthood Federation of America ("PPFA")'s senior director for public policy litigation and law sent a memorandum to affiliate chief executives, affiliate medical directors, and patient service directors, on federal regulations for participation in fetal tissue donation programs.[16] The memorandum notes that applicable federal laws "forbid the payment or receipt of valuable consideration for fetal tissue. However, they permit 'reasonable payments associated with the transportation, implantation, processing, perseveration, quality control, or storage' of fetal tissue."[17]

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[13] Email from [redacted] to [redacted], Re: Study, Oct. 1, 2010, attachment 2. [UTMB 321-322].
[14] Invoice from Planned Parenthood Gulf Coast to University of Texas Medical Branch, Nov. 11, 2010 [UTMB 328]; Invoice from Planned Parenthood Gulf Coast to University of Texas Medical Branch, Nov. 11, 2010 [UTMB 329]; Invoice from Planned Parenthood Gulf Coast to University of Texas Medical Branch, Jun. 11, 2011 [UTMB 344]; Invoice from Planned Parenthood Gulf Coast to University of Texas Medical Branch, Sep. 29, 2011 [UTMB 252], attachment 3.
[15] Tissue Supply and Biological Specimen Agreement, Amended No. 2, between Planned Parenthood Gulf Coast, Inc. and [redacted] of University of Texas Medical Branch, Jul. 26, 2011, attachment 4. [UTMB 299-301].
[16] Memorandum from [redacted], Public Policy Litigation and Law, Planned Parenthood Federation of America; [redacted] Acting Vice President for Medical Affairs, Planned Parenthood Federation of America; and [redacted], Vice President for Medical Services, Planned Parenthood Federation of America; to Affiliate Chief Executives, Affiliate Medical Directors, [and] Patient Service Directors, Re: Federal regulations for aborted pregnancy tissue donation programs, Apr. 4, 2001, attachment 5. [PPFA-HOU_E&C-000148 – 000150] [hereinafter [redacted] memo].
[17] [redacted] memo [PPFA-HOU_E&C-000149].

The memorandum states that PPFA affiliates "can chose one of two methods to comply with these laws."[18] The methods outlined in the memorandum are:

> One method would be to recover no costs associated with any aspect of participation in a fetal tissue donation program. This would mean that all staff time, clinic space, supplies, etc., would be donated by the affiliate, and the affiliate would receive no payments or in-kind services from the entity to whom the tissue is being donated.
>
> . . . The second method would be to employ an independent auditor to conduct a credible and good-faith analysis of the actual costs incurred by the affiliate in the transportation, implantation, processing, preservation, quality control, or storage of the fetal tissue and, if the research is supported by federal funds, for the removal of the fetal tissue. Under this method, affiliates must maintain careful records of actual tissue donations and of payments received from the researcher or the tissue-gathering entity. Affiliates must be able to demonstrate that the payments do not exceed the actual costs of the actual tissue donations.
>
> Sometimes tissue-gathering entities offer to pay rent for space occupied by one of their employees who would be on-site at a clinic on a regular basis. If an affiliate determines to enter into such an arrangement, then the independent auditor would also conduct a credible and good-faith computation of the actual cost of the space occupied by the tissue-gathering entity employee, in order to determine the amount of rent to be paid by that entity.[19]

The memorandum goes on to "remind affiliates that, in addition to the federal laws outlined above, there are laws in many states governing fetal tissue donation programs. Affiliates must take great care to assure compliance with those laws as well."[20]

January 2011 redistribution of PPFA memo on fetal tissue donation

The April 2001 memorandum was redistributed to PPFA affiliates in January 2011 under the signature of [redacted], then then senior PPFA director for clinical services.[21] The memorandum from [redacted] sought

> . . . to remind affiliates about the federal law relating to payment for participation in such programs. The attached memo was sent almost exactly 10 years ago (yikes!).

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[18] [redacted] memo [PPFA-HOU_E&C-000150].

[19] *Id.*

[20] *Id.*

[21] Memorandum from [redacted] Senior Director, Clinical Services, Planned Parenthood Federation of America; [and] [redacted] Director, Clinical Services, Planned Parenthood Federation of America; to Affiliate Medical Directors, [and] Patient Services Directors, Re: Aborted pregnancy tissue donation programs, Jan. 26. 2011, attachment 6 [PPFA-HOU_E&C-000146].

Given the time that has elapsed and that there has likely been staff turnover, we thought it would be helpful to resend it to assure continuing compliance with the statutes."[22]

PPFA affiliates, including PPGC, were, thus, twice put on notice about the steps they would have to undertake in order to participate in a fetal tissue donation program, and ensure that any reimbursable costs they received did not constitute valuable consideration under the applicable federal and state laws.

Despite that knowledge, the Panel has learned that the costs included in PPGC's contract and proposed contract with UTMB were based not on an independent auditor's credible and good-faith analysis of the actual costs it incurred to procure fetal tissue for UTMB. Rather it was based on back-of-the-envelope calculations by a single PPGC official. The fact that PPGC ignored the long-standing advice of PPFA's legal director when it drafted the UTMB contract and proposed amendment goes directly to PPGC's knowledge of the duty to comply with the applicable law and its willful decision to ignore the legal advice of its organization.

PPGC Interactions with Baylor College of Medicine

Documents produced by the Baylor College of Medicine ("BCM") show that for more than two years, from November 1, 2014 through November 4, 2015, PPGC entered into negotiations to procure fetal tissue for BCM.[23] Those documents show that PPGC assisted BCM with proposals that would be acceptable to the Institutional Review Board ("IRB") at BCM.

November 1, 2014 email from [redacted] of PPGC to [redacted] BCM, a copy of which was sent to [redacted], PPGC's medical director, and [redacted].

The email states [redacted] was "putting" [redacted] "in touch with our Medical Director [redacted], who oversees all research, as well as our Research Director [redacted] who will be your primary contact person during the IRB approval/coordination phase."[24]

March 24, 2014 email from [redacted] to [redacted]

[redacted] wrote: "Thank you for speaking with me today, and for your help with the IRB. Attached, please find my original [IRB] submission, the [PPFA] consent form draft, and the response from the IRB. . . .Please feel free to contact me any time with any questions you may have."[25] Later that same day, [redacted] replied, "Yes, we can do that."[26] [redacted] asked, "Would you have time to speak to me on Friday to discuss the IRB comments?"[27] [redacted] stated, "I can be available Monday."[28]

---

[22] *Id.*
[23] Documents produced by Baylor College of Medicine.
[24] Email from [redacted] to [redacted], cc: [redacted] RE: IRB Pediatrics BCM, Nov. 1, 2013, attachment 7.
[25] Email from [redacted] to [redacted], Subject RE: IRB pediatrics BCM, Mar. 2014, attachment 8.
[26] Email from [redacted] to [redacted], May 20, 2014, 4:51 PM, attachment 8.
[27] Email from [redacted] to [redacted], Subject: Re: IRB pediatrics BCM, Jun. 3, 2014, 6:38 PM, attachment 8.
[28] Email from [redacted] to [redacted], Jun. 6, 2014, 3:07 PM, attachment 8.

May 20, 2014 email from [redacted] to [redacted]

[redacted] sent an email to [redacted] on May 20, 2014 that stated, "I have received the following response to my IRB submission from BCM, and am wondering if you could comment on the bolded sections."[29]

October 20, 2014 email from [redacted] to [redacted]

In an October 20, 2014 email exchange, [redacted] an assistant to [redacted] emailed [redacted] in which she stated, "I want to follow up once more to see if it would be possible to set [up] a time to touch base over the phone sometime this week. I have spoken to our local IRB and need your approval/guidance before I proceed."[30]

October 20, 2014 email from [redacted] to [redacted]

[redacted] replied: "Yes, that would be fine. I have some this afternoon at 2pm. Would that work for you?"[31]

October 20, 2014 email from [redacted] to [redacted] regarding assigned tasks to assist IRB

On October 20, 2014, [redacted] again emailed [redacted]:

> Dear [redacted]
>
> Thank you so much for the productive phone call. I spoke with [redacted] after our phone call ended and she was really excited to know we had made so much progress. I have outlined some of her comments/feedback below in red:
>
> Key Discussion Items (Assigned party):
>
> • Check with PPFA if we can use the generic tissue procurement consent or do we need a site-specific IRB approved consent form [redacted] [sic] – Generic Information/Release/Acknowledgement form is acceptable. Please move forward with submission of the attached form to the IRS for approval. [sic]
>
> • Develop a budget/contract describing the scope of work and approximate time/effort it will take to execute the study. [redacted] will send us a sample contract she executed with UT Galveston. [redacted] [sic] – I can't provide this yet as the details of the project that need to be referenced in the contract are still being negotiated. We will need to make specific reference to the fact no remuneration for specimens will occur. Administrative costs only will be included in a budget. [sic]

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[29] Email from [redacted] to [redacted], Subject: Re: IRB pediatrics BCM, May 20, 2014, 11:12 AM, attachment 9.

[30] Email from [redacted] to [redacted], cc: [redacted], Subject: Pediatrics research proposal – [redacted] Baylor College of Medicine, Oct. 20, 2014, 8:34 AM, attachment 10.

[31] Email from [redacted] to [redacted], cc: [redacted], Subject: RE: Pediatrics research proposal – [redacted] Baylor College of Medicine, Oct. 20, 2014, 8:42 AM, attachment 10.

• [redacted] needs to provide a description of how the tissue should be collected, processed, stored, and transported.

1. RESPONSE [sic]: [redacted] would like the fetal cadaveric tissue transported on ice to our site. However, she would like to know if Planned Parenthood would be willing to separate out and send the brain, thymus, spleen and liver and how much would this process cost us? PPGC is unable to dissect the tissue per request. It is also important to understand PPGC performs D&E's so that there's disarticulation versus a whole fetus. [sic]

• Discuss the new gestational age calculation per TX state regulations with [redacted]. [redacted] will provide us with the new gestation age calculation formula. [redacted] The new state limit is 20 weeks post fertilization so 21.6wks LMP, which is how we calculate and our ultrasound machines are calibrated. Therefore, we could collect samples between 20-21.6wks [sic]
• [redacted] would like to have [redacted] and her team over for a meeting before the study is ready to get started. RESPONSE: [redacted] agrees with the idea. [sic][32]

Draft contract between PPGC and BCM

BCM produced copies of a draft contract with PPGC for the procurement of fetal tissue that were never executed to the Panel. Under the proposed terms, BCM would have been required to pay PPGC $5,700 for 25 executed informed consents, plus "$50 staff time expense involved in obtaining consent and relevant study documentation. This includes consents for which no sample is obtained. Planned Parenthood [Gulf Coast] will consent up to 500 patients,"[33]reimbursement of $100 per-informed consent for sterile procedure room set-up and sample collection, and annual administrative fees of $2,000 for "Surgical Services and Research Management oversight, consent storage, and supply storage. This list is not all inclusive."[34] Had the contract been executed, BCM would have paid PPGC up to $25,000 for 500 consents.

November 17, 2014 email from [redacted] to [redacted]

On November 17, 2014, [redacted] sent [redacted] an email, the subject of which was to "Pediatrics Research Proposal – [redacted] /Baylor College of Medicine – IRB Approval Obtained," that stated: "First, I would like to thank you for your support through our IRB review process . . .. Our IRB proposal for your outlining the study procedures/objectives is also attached for your reference. Lastly, I submitted the clinical consent you provided for tissue donation (attached) to BCM IRB and it was deemed acceptable for use."[35]

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[32] Email from [redacted] to [redacted]; [redacted], Subject: RE: Pediatrics research proposal – [redacted] /Baylor College of Medicine, Oct. 20, 2014, 3:10 PM, attachment 11. (emphasis and red highlights in original).
[33] Tissue Supply and Biological Specimen Agreement between Planned Parenthood Gulf Coast, Inc. and Baylor College of Medicine, attachment 12.
[34] *Id.*
[35] Email from [redacted] to [redacted], Subject: RE: Pediatrics research proposal – [redacted] /Baylor College of Medicine – IRB approval obtained, Nov. 17, 2014, 10:31 AM, attachment 13.

November 17, 2014 email from [redacted] to [redacted]

[redacted] replied "Thank you!"[36]

Emails demonstrating PPGC knew that BCM IRB approved the fetal tissue research proposal

Multiple email exchanges between [redacted] and persons at BCM show that PPGC knew the BCM IRB had approved the proposal. For example: On July 7, 2015, [redacted] sent an unknown document to [redacted];[37] [redacted] replied, "Just to clarify, you would like me to insert specifics on the experiments we plan to perform and replace the highlighted text with that corrected version of our experimental plans?"[38] [redacted] stated, "Yes, please insert any language that is pertinent to the project – this was meant to be a reference only."[39]

Center for Medical Progress videotapes

On July 14, 2015, the Center for Medical Progress ("CMP") began its release of videotapes obtained during the course of its 30-month long investigation into the sale of fetal tissue by PPFA affiliates to tissue procurement companies.[40] The release of the videos prompted several congressional investigations, and led to the Panel's creation by the U.S. House of Representatives.[41] The timing behind the start of CMP's release of its videotapes is relevant in light of how PPGC ended its negotiations with BCM.

October 13, 2015 email from [redacted] to [redacted]

On October 13, 2015, [redacted] sent [redacted] an email in which she stated:

> Hello [redacted], I hope that you are well and had a great weekend.
>
> In light of recent events, do we need to make a change to our contract?
>
> I still very much believe in the value of my NIH funded studies, and would very much like to proceed it this is possible.[42]

November 4, 2015 email from [redacted] to [redacted]

[redacted] did not reply until November 4, 2015, when she stated:

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[36] Email from [redacted] to [redacted], Nov. 17, 2014, 12:01 PM, attachment 13.
[37] Email from [redacted] to [redacted], Jul. 7, 2015, 4:32 PM, attachment 14.
[38] Email from [redacted] to [redacted], Subject: RE: Pediatrics research proposal – [redacted] Baylor College of Medicine – IRB approval obtained, Jul. 7, 2015, 4:40 PM, attachment 15.
[39] Email from [redacted], Jul. 7, 2015, 4:43 PM, attachment 15.
[40] *See* Center for Medical Progress website, http://www.centerformedicalprogress.org/human-capital/ (last visited Nov. 2, 2016).
[41] *Supra* note 1.
[42] Email from [redacted] to [redacted], Subject: RE: Pediatrics research proposal – [redacted] Baylor College of Medicine – IRB approval obtained, Oct. 13, 2015, 2:59 PM, attachment 16.

[redacted],

> To clarify: we do not have a valid contract, and I did not offer you a contract. I previously provided some exemplar language that should have been included in any contract regarding feta l tissue with the expectation that BCM Grants and Contracts or a BCM attorney would draft a complete contract for both parties to review.
>
> PPGC will not commit to engage in any fetal tissue research endeavors at this time.
>
> I encourage all academic researchers to escalate their need for donated fetal tissue to their department chair, IRB chairs, chancellors, etc. Academic institutions in Texas cannot remain publically silent regarding their need for donated feta l tissue in research, yet have expectations that research collaboration with Planned Parenthood will remain intact.[43]

October 22, 2015 visit by Texas law enforcement to PPGC

On October 22, 2015, nearly a year after PPGC learned that BCM's IRB had given its approval[44] and [redacted] sent her email to [redacted] in which she stated that PPGC would not commit to engage in any fetal tissue research endeavors at this time,[45] representatives of the Texas Department of Public Safety Texas Ranger Division, the House Police Department homicide division, and the Harris County district attorney's office visited PPGC headquarters to investigate allegations that PPGC may have violated Tex. Penal Code 48.02[46] The report refers to PPGC as GCPP.

During the course of this visit, PPGC's attorney introduced the law enforcement representatives to [redacted], who the attorney described as being a "Long time Baylor employee" who "had been instrumental in building the current research program."[47] The Texas Department of Public Safety Texas Ranger Division report stated that:

> [PPGC's attorney] advised that the last collected fetal tissue specimen collected by GCPP for a scientific study was on 07-26-2011, for the University of Texas Medical Branch. GCPP was recently approached by the Baylor College of Medicine and Rice University for fetal tissue studies. **The Institutional Review Board had not yet given approval for the Baylor or Rice studies.**[48]

The emails cited above demonstrate that [redacted] and potentially other PPGC officials knew that BCM's IRB had approved the research project, despite representations of PPGC's attorney to Texas law enforcement officials that no IRB approval had been obtained by BCM. In addition,

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[43] Email from [redacted] to [redacted], Subject: RE: Pediatrics research proposal – [redacted] Baylor College of Medicine – IRB approval obtained, Nov. 4, 2015, 2:59 PM, attachment 17.
[44] Attachments 14, 15, 16, 17.
[45] Attachment 17.
[46] *See* Tex. Dept. of Pub. Safety Tex. Ranger Div., Report of Investigation, attachment 18.
[47] *Id.*at 2, paragraph 3.5.
[48] *Id.*at 4, paragraph 3.17. (emphasis added).

the Panel has learned that the release of the CMP videotapes was the reason that [redacted] cancelled the negotiations with BCM, and sent her November 4, 2015 email.

Potential Violations of Texas Law

Prohibition of the Purchase and Sale of Human Organs

The Texas Penal Code makes it a misdemeanor if anyone "**knowingly or intentionally offers to buy, offers to sell, acquires, receives, sells, or otherwise transfers** any human organ for valuable consideration."[49] Under the statute, "valuable consideration" does not include "a fee paid to a physician or to other medical personnel for services rendered in the usual course of medical practice or a fee paid for hospital or other clinical services," "reimbursement of legal or medical expenses incurred for the benefit of the ultimate receiver of the organ;" or "reimbursement of expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ."[50]

The statute defines a human organ as "the human kidney, liver, heart, lung, pancreas, eye, bone, skin, **fetal tissue**, or any other human organ or tissue, but does not include hair or blood, blood components (including plasma), blood derivatives, or blood reagents."[51]

False Report to Peace Officer, Federal Special Investigator, or Law Enforcement Employee

The Texas Penal Code likewise makes it a misdemeanor for a person to lie to a law enforcement officer. The law states:

> A person commits an offense if, with intent to deceive, he knowingly makes a false statement that is material to a criminal investigation and makes the statement to: . . . a peace officer or federal special investigator conducting the investigation; or . . . any employee of a law enforcement agency that is authorized by the agency to conduct the investigation and that the actor knows is conducting the investigation.[52]

[49] Tex. Penal Code § 48.02(b). (emphasis added).
[50] Tex. Penal Code § 48.02(c).
[51] Tex. Penal Code § 48.02(a). (emphasis added).
[52] Tex. Penal Code Title 8, § 37.08.

Based on the facts outlined above and the supporting documentation, I urge your office to conduct a thorough investigation into whether PPGC violated these statutes, and, if you agree that such violations occurred, to take all appropriate action. If you have any questions about this request, please contact T. March Bell at (202) 226-9027, March.Bell@mail.house.gov.

Sincerely yours,

Marsha Blackburn
Chairman
Select Investigative Panel

Attachment

cc: The Honorable Jan Schakowsky
Ranking Member
Select Investigative Panel

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

November 30, 2016

VIA EMAIL

Mr. Michael Hestrin
District Attorney
County of Riverside
3960 Orange Street
Riverside, CA 92501

Dear District Attorney Hestrin:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the "Panel") and empowered it to conduct a full and complete investigation regarding the medical practices of abortion providers and the practices of entities that procure and transfer fetal tissue.

Over the course of our investigation, we have uncovered documents and received testimony from confidential informants indicating that Advanced Bioscience Resources (ABR) allegedly violated state law, including but not limited to the Cal. Health & Safety Code § 125320(a) and the California Penal Code § 367f(a), which forbid the transfer of fetal tissue for valuable consideration.

Among the abortion clinics from which ABR procured fetal tissue was Planned Parenthood of the Pacific Southwest,[1] located at [redacted], which has clinics throughout the region, including Planned Parenthood – Riverside Family Planning Center, located at [redacted].[2]

[1] Planned Parenthood Federation of America, Production to the Subcommittee on Oversight and Investigations of the US House of Representatives Energy and Commerce Committee, Aug. 20, 2015 (PPFA-HOU_E&C-000162).
[2] Planned Parenthood of the Pacific Southwest Website, https://www.plannedparenthood.org/planned-parenthood-pacific-southwest, last accessed Oct. 25, 2016.

Background on ABR

ABR, a non-profit organization, obtains fetal tissue from abortion clinics and offers it for resale to researchers. It pays the clinics "a flat fee for services on a product of conception (POC) basis, regardless of how many, or what type, of specimens are procured . . . ."[3] The fees range from $45 to $60, depending upon the year and the clinic.[4] The tissue is obtained by ABR tissue technicians who work in the abortion clinics; the technicians harvest, package, and ship the tissue to the researchers.[5] The abortion clinic staff obtains consent from the patients for fetal tissue donations.[6]

ABR's Interactions with Planned Parenthood Affiliates

ABR had contractual relationships with Planned Parenthood of San Diego and Riverside Counties (now called Planned Parenthood of the Pacific Southwest):

> Planned Parenthood of San Diego and Riverside Counties entered into an agreement with a TPO in June 1999 to facilitate fetal tissue donation by its patients. That affiliate changed its name to Planned Parenthood of the Pacific Southwest, and renewed the tissue donation agreement, in October 2010. The affiliate's participation in the program is ongoing. Planned Parenthood of San Diego and Riverside Counties also received approval for a research program involving fetal tissue donation in October 2008. That program is ongoing through Planned Parenthood of the Pacific Southwest as well.[7]

ABR Payments to the Abortion Clinics, Including Planned Parenthood Affiliates

During 2015, ABR made nearly $80,000 in payments to its top five abortion clinic sources from which it procured human fetal tissue. ABR claims that it paid the clinic for the "costs for clinical staff obtaining consents, maintaining records, transferring fetal tissue, clinical space, and utilities."[8]

ABR paid Planned Parenthood of Riverside $23,460 in 2015.[9] Furthermore, starting in January 2012, ABR paid Planned Parenthood Pacific Southwest for rented space two days a week for $1,000; if ABR only used the space for one day, it paid $500.[10]

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[3] Advanced Bioscience Resources, Inc., "ABR Overview: Key Points," at 5 (SP000752).
[4] Advanced Bioscience Resources, Inc., Production to the Subcommittee on Oversight and Investigations of the US House of Representatives Energy and Commerce Committee, Sept. 3, 2015 (HCEC000028 – 41).
[5] Advanced Bioscience Resources, at 7 (SP000754).
[6] Advanced Bioscience Resources, at 5 (SP000752).
[7] Planned Parenthood Federation of American (PPFA-HOU_E&C-000162). *See* Advanced Bioscience Resources, Inc., (HCEC000028 – 41).
[8] ABR Overview: Key Points, at 5 (SP000752).
[9] Advanced Bioscience Resources, Production to the Select Investigative Panel of the US House of Representatives Energy and Commerce Committee, June 7, 2016 (SP000817-826).
[10] Advanced Bioscience Resources (HCEC000039).

Potential Violations of Law

Under 42 U.S.C. § 289g-2, it is unlawful for any person to "knowingly acquire, receive, or otherwise transfer any fetal tissue for valuable consideration if the transfer affects interstate commerce." The term valuable consideration "does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue." Anyone who violates this law is subject to a fine "not less than twice the amount of the valuable consideration received" and/or imprisonment for up to ten years.

California state law includes a nearly identical prohibition. Under Cal. Health & Safety Code § 125320(a), a "person may not knowingly, for valuable consideration, purchase or sell embryonic or cadaveric fetal tissue for research purposes." Virtually identical to the abovementioned federal statute, the California statute states that "'valuable consideration' does not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of a part."[11]

Similar provisions in the California Penal Code § 367f(a) prohibit the acquisition, sale, or transfer of "any human organ, for purposes of transplantation, for valuable consideration," subject to a fine of up to $50,000 and imprisonment for up to five years.

To the extent any of payments to the Planned Parenthood affiliates or the other abortion clinics occurred for purposes of transplantation, ABR and any of its business partners so involved would additionally be in violation of California Penal Code § 367f(a).

Based on the facts outlined above and the supporting documentation, I urge your office to conduct a thorough investigation into whether Advanced Bioscience Resources violated these statutes and regulations, and, if you agree that such violations occurred, to take all appropriate action. If you have any questions about this request, please contact T. March Bell at (202) 226-9027, March.Bell@mail.house.gov

Sincerely yours,

Marsha Blackburn
Chair
Select Investigative Panel

Attachment(s)

cc: The Honorable Jan Schakowsky
Ranking Member
Select Investigative Panel

[11] Cal. Health & Safety Code § 125320(b).

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

November 30, 2016

Via Email

The Honorable Pam Bondi
Attorney General
Office of Attorney General
State of Florida
The Capitol PL-01
Tallahassee, FL 32399-1050

Dear Attorney General Bondi:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the "Panel") and empowered it to conduct a full and complete investigation regarding the medical practices of abortion businesses and the practices of entities that procure and transfer fetal tissue.

Over the course of our investigation, we have uncovered documents and received information indicating that Presidential Women's Center, Inc. ("PWC"), at least in part through its relationship with StemExpress, LLC ("StemExpress"), a firm that procures fetal tissue from abortion businesses and transfers it to research customers, violated various provisions of federal and state law, including but not limited to 42 U.S.C. § 289g-2 and Fla. Stat. § 873.05, which forbid the transfer of fetal tissue for valuable consideration.

StemExpress's Business Model and Growth Strategy

StemExpress was founded in 2010 as a for-profit company and continues operations as StemExpress Foundation. Under its business plan, StemExpress recruited and screened businesses that were most likely to perform abortions that could produce saleable tissue to researchers.[1] The company sought information about the number of abortions the businesses performed each week, the gestational age of fetuses scheduled to be aborted, the days the abortions were done, whether

[1] StemExpress Website Recruitment Form for Abortion Clinics, attachment 1.

digoxin[2] was used (which would taint the tissue and, thus, render the baby useless for obtaining tissue), and, if so, at what age it was used. Researchers ordered tissue using StemExpress's website. The firm initially had a drop-down menu that allowed researchers to obtain various types of tissue.[3] It later switched to another web-based system.

In order to harvest the tissue at PWC, a typical work day for PWC staff went as follows:

- At the beginning of the day, PWC staff logged into the StemExpress Daily Task Page website, which included the day's orders for certain baby body parts and the gestation period, letting PWC staff know what they needed to harvest that day.[4]

- Next PWC staff met with the patients waiting to be prepped for their abortions, and convinced them to consent to donate by saying that the donation will help cure diabetes, Parkinson's, and heart disease.[5]

- After an abortion, PWC staff collected the baby's remains and procured the body parts that were ordered.[6] PWC staff then packed the tissues or body parts, and shipped them directly to the customer via FedEx.[7]

- Throughout the day, PWC staff updated the StemExpress Daily Task Page website, informing both StemExpress and all other participating abortion businesses' staff of certain patient details via their responses to certain requests.[8]

- PWC staff further shared details from patients' private medical files with StemExpress via forms such as the StemExpress form "Patient and Sample Information Form for Research Study," which asks for the following patient information: name or kit ID, mother's date of birth, mother's ethnicity, date collected (i.e., date of abortion), and gestational age at time of blood draw.[9] The form admonishes, "Please fill out and return with the samples to ensure timely compensation!"[10] Other information appearing on StemExpress Researcher Procurement Forms includes patient height, patient weight, patient smoking history,[11] and

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[2] Digoxin is a heart medication that sometimes is injected into the amniotic fluid or fetus to cause fetal demise before surgical or induction abortion. *See* Abortion in California: A Medical-Legal Resource, *available at* http://californiaabortionlaw.com/wp/?page_id=135.

[3] StemExpress Drop-Down Ordering Menu, attachment 2.

[4] PWC00046, PWC00023-PWC00024.

[5] BioMed IRB Informed Consent to Participate in a Clinical Research Study, Sponsor: StemExpress, LLC, attachment 3; *see also* PWC00023.

[6] PWC00023-PWC00024, PWC00040-PWC00042, PWC00054-PWC00057.

[7] PWC00029-PWC00030, PWC00032-PWC00034, PWC00040-PWC00042, PWC00050-PWC00052. FedEx is the primary shipping method for StemExpress samples. FedEx pickups were scheduled every Tuesday and Thursday for Lab #1 specimens, and tissue samples were dropped off directly with FedEx. For each package, the weight was always listed as 4 lbs. *See* PWC00029-PWC00031, PWC00032. One document stated that the declared value should always be $1,250 per sample, PWC00030, and another form indicated that the declared value of blood specimens should be $500 and of tissue specimens, $750. PWC00033.

[8] PWC00046-PWC00048.

[9] PWC00026.

[10] PWC00026.

[11] PWC00027.

fetal sex.[12] PWC staff further disclosed information from patient data sheets with StemExpress.[13]

StemExpress's stunning revenue growth five years after its formation belies the notion that the firm was not operating for profit. In 2010, its revenue was $156,312; during 2011, that figure more than doubled to $380,000; a year later, in 2012, StemExpress's revenue nearly tripled to $910,000; by 2013, its revenue was $2.20 million; then in 2014, the revenue had once again more than doubled to $4.50 million. Based on its three-year revenue growth of 1,315.9%, *Inc. Magazine* named StemExpress one of the fastest-growing privately held companies in the U.S.[14]

This revenue growth accompanied an aggressive marketing strategy directed toward abortion businesses. StemExpress distributed its brochure at a conference hosted by the National Abortion Federation (NAF). The brochure promised businesses they would be "[f]inancially profitable" if they allowed StemExpress to procure tissue from the businesses. The brochure also said "By partnering with StemExpress" the businesses will not only help research "but [they] will also be contributing to the fiscal growth of [their] own clinic[s]."[15]

When StemExpress was formed, billing records show the firm was procuring fetal tissue from four businesses. By the end of 2014, the firm had "relationships with more than 30 procurement sites across the country."[16] However, many of those procurement sites had multiple locations, making the actual number nearly 100. In 2015, StemExpress tried to execute a contract with NAF that would have given the firm potential access to nearly 200 additional locations. Its overall strategy was to provide on-demand body parts to researchers. In order to do that, the firm needed a ready supply of fetal tissue. The only way to achieve that was to dramatically increase the number of abortion businesses from which it would obtain fetal tissue.

Presidential Women's Center, Inc.'s Contract with StemExpress

On February 14, 2014, PWC signed a contract with StemExpress providing:

> Presidential Women's Center will provide, and StemExpress will pay the reasonable costs for, services and facilities . . . associated with . . . the removal of fetal organs from POCs [(products of conception)]; the processing, preservation, quality control, and transportation of the fetal organs; appropriate space in which StemExpress representatives and employees may work; disposal services for non-used portions of cadaveric materials; obtaining maternal blood; seeking consent for donation of fetal organs and maternal blood from appropriate donors[;] and . . . maintaining records of such consents so that verification of consent can be supported.[17]

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[12] PWC00029.
[13] *See* PWC00029.
[14] *The 500: Get to know the 500 fastest-growing privately held companies in America*, INC., Sept. 2014, at 137.
[15] StemExpress Brochure Distributed at NAF Conference, attachment 6 (key text highlighted).
[16] Complaint at para. 17, StemExpress, LLC v. Center for Medical Progress, No. BC-589145 (L.A. Super. Ct. filed Jul. 27, 2015).
[17] PWC0001.

In return, StemExpress contracted to pay PWC $50.00 per 60ccs of maternal blood and $75.00 for the collection of fetal tissue, if the collection was handled solely by PWC staff. If StemExpress staff participated in the collection, these payments were reduced. PWC agreed to invoice StemExpress monthly by number of tissue and number of maternal bloods procured.[18]

PWC agreed to allow StemExpress access to patients' charts and identity of donors "as necessary to obtain patients' consent for use of POCs and maternal bloods."[19]

Presidential Women's Center, Inc.'s Profit

PWC billed StemExpress for the following amounts, and indicated that it was paid for the total amount, other than $300.00 related to the 1/5/2016 invoice. Based on both the invoices and the "Protocol for Stem Express Research,"[20] it appears that PWC provided only fetal livers and villi to StemExpress.[21]

[18] PWC0001.

[19] PWC0002: "StemExpress will not receive any information concerning identity of donors except as necessary to obtain patients' consent for use of POCs and maternal bloods."

[20] PWC00024.

[21] It may also have provided placenta at some point. *See* PWC00029.

INVOICE DATE	ITEM	COST PER ITEM	TOTAL INVOICE AMOUNT
4/25/2014	POC x3 (2 livers and 1 villi) Maternal blood x18	POC @ $75.00 each Maternal blood @ $50.00 each	$1,125.00
5/9/2014	POC x3 (3 livers) Maternal blood x16	POC @ $75.00 each Maternal blood @ $50.00 each	$1,025.00
5/23/2014	POC x3 (3 livers) Maternal blood x8	POC @ $75.00 each Maternal blood @ $50.00 each	$625.00
6/12/2014	POC x1 (1 liver) Maternal blood x6	POC @ $75.00 each Maternal blood @ $50.00 each	$375.00
6/20/2014	Maternal blood x6	Maternal blood @ $50.00 each	$300.00
7/19/2014	Maternal blood x14	Maternal blood @ $50.00 each	$700.00
8/1/2016	POC x2 (2 livers) Maternal blood x10	POC @ $75.00 each Maternal blood @ $50.00 each	$650.00
8/28/2014	Maternal blood x13	Maternal blood @ $50.00 each	$650.00
9/9/2014	POC x1 (1 liver) Maternal blood x11	POC @ $75.00 each Maternal blood @ $50.00 each	$625.00
10/31/2014	POC x6 (6 livers) Maternal blood x12	POC @ $75.00 each Maternal blood @ $50.00 each	$1,050.00
11/26/2014	POC x1 (1 liver) Maternal blood x14	POC @ $75.00 each Maternal blood @ $50.00 each	$775.00
1/13/2015	Maternal blood x10	Maternal blood @ $50.00 each	$500.00
1/31/2015	Maternal blood x15	Maternal blood @ $50.00 each	$750.00
3/5/2015	unknown[22]		$1,450.00
4/30/2015	POC x12 (4 livers and 8 villi) Maternal blood x18	POC @ $75.00 each Maternal blood @ $50.00 each	$1,800.00
7/3/2015	POC x16 (4 livers and 12 villi) Maternal blood x28	POC @ $75.00 each Maternal blood @ $50.00 each	$2,600.00
8/3/2015	POC 11 (1 liver and 10 villi) Maternal blood x14	POC @ $75.00 each Maternal blood @ $50.00 each	$1,525.00
9/2/2015	POC x12 (3 livers and 9 villi, including that from twins) Maternal blood x11	POC @ $75.00 each Maternal blood @ $50.00 each	$1,450.00
1/5/2016	unknown[23]		$2,625.00
TOTAL			**$20,600.00**

[22] PWC did not provide this invoice in response to the Panel's Request No. 2.
[23] PWC did not provide this invoice in response to the Panel's Request No. 2.

Unsurprisingly, PWC indicated that they "prefer patients consent to both" blood and tissue donation, though they indicate that they would accept consent for blood only.[24]

StemExpress's Profit and Loss

StemExpress paid $75.00 for each fetal tissue sample it obtained from abortion businesses, and then transferred them to researchers for $595 to $910 per tissue or body part.

Payments from Customers to StemExpress

Customer	Date	Item	Cost
Redacted by StemExpress	September 25, 2014	Human Fetal Tissue	$5,950.00
Redacted by StemExpress	September 25, 2014	Packaging- Gel Pack or Wet Ice	$150.00
Redacted by StemExpress	September 25, 2014	Local Delivery Flat Rate	$2,250.00
		Estimated Tax	$730.64
TOTAL:			**$9,080.64**
Redacted by StemExpress	November 14, 2014	Human Fetal Brains	$3,340.00
		Estimated Tax	$292.25
TOTAL:			**$3,632.25**
Redacted by StemExpress	December 16, 2014	Human Fetal Tissue (upper and lower limbs with hands and feet)	$890.00
Redacted by StemExpress	December 16, 2014	Human Fetal Tissue (calvarium matched to upper and lower limbs)	$595.00
		Estimated Tax	$129.95
TOTAL:			**$1,614.95**
Yale University	January 19, 2012	Fetal Brain Procurement	$2,860.00
Yale University	January 19, 2012	FedEx Priority Overnight	$85.00
Yale University	January 19, 2012	FedEx Priority Overnight	$85.00
Yale University	January 19, 2012	Fetal Brain Procurement	$2,145.00
Yale University	January 19, 2012	Credit for samples	-$2860.00
Yale University	January 19, 2012	Credit for FedEx	-$85.00

[24] PWC00023.

Customer	Date	Item	Cost
TOTAL:			**$2,230.00**

Attached is a sample of a StemExpress invoice to a customer.[25] A comparison of invoices, attorney-created accounting documents, and productions from multiple StemExpress customers shows that the firm may have made a profit when procuring and transferring fetal tissue, and passed a portion of that profit along to the businesses from which it obtained its tissue and blood specimens. The Panel's cost analysis shows StemExpress overstated some of its labor costs, and claimed as expenses shipping, supplies, and infectious disease screenings. These were costs charged to researchers.

[25] Sample StemExpress Invoice to Customer, attachment 7.

COMPARISON OF STEMEXPRESS COST ANALYSIS WITH GENERALLY ACCEPTED INDUSTRY STANDARDS FOR ONE UNIT OF FETAL TISSUE IN 2013

COST ITEMS AND ESTIMATE PRODUCED BY STEMEXPRESS

ADJUSTED BASED ON REASONABLE INDUSTRY STANDARDS

COSTS ALLOCATED TO MATERNAL BLOOD ESTIMATED AT 50%

Cost Item	Description	Estimated Time	Estimated Cost/Expense	Recalculated Time	Recalculated Cost/ Expenses	½ Costs for Maternal Blood
Procurement Management Labor	Receive and evaluate purchase order, enter into Computer system and task board, assign to clinics.	1 hour x $35	$25.00	.5 hour x $35	$12.50	**$ 6.25**
Packaging Supplies Labor	Packaging all supplies needed for procurement.	1 hour x $10	$10.00	.5 hour x $10	$5.00	**$2.50**
Shipping	Supplies to Clinic	N/A	$15.00		$15.00	**$7.00**
Mileage	Mileage paid to technician (.56/mile)	N/A	$75.00		$75.00	**$35.00**
Supply cost	Box, conical tube, media, petri dish, labels, biohazard bag, gel packs, etc.	N/A	$30.00		$30.00	**$15.00**
Technician Base Labor	Patient consent, procurement, paperwork packaging.	8 hour x $10	$80.00	1 hour x $10	$10.00	**$5.00**
Technician Supplemental Compensation	Technician Supplemental Compensation	N/A	$30.00		$0.00	**$0.00**
Clinic Reimbursement	Technician space, storage of supplies, blood draw chair usage, consent space	N/A	$55.00		$55.00	**$27.50**
Infectious Disease Draw	Supplies: tubes, labels, needle, biohazard bag, etc.	N/A	$15.00		$15.00	**$7.50**
Infectious Disease Screening	Screening for HIV, HepB, HepC, LCMV	N/A	$70.00		$70.00	**$35.00**
Shipping	Average Shipment cost to the Lab (blood and/or tissue)	N/A	$20.00		$20.00	**$10.00**
Procurement Management Labor	Review paperwork, communications with courier, communications with researcher	1 hour x $35	$35.00		$35.00	**$5.00**
Product Receipt	Receipt of product at front desk, check into Sage, check into log	1 hour x $15	$15.00	.25 hour x $15	$4.00	**$2.00**
Inventory & Supply Management	Prorated stores management	1 hour x $20	$20.00	.25 hour x $20	$5.00	**$2.50**
			$495.00		**$351.50**	**175.75**

Attorneys for StemExpress created several cost estimates (orange numbers) that purport to show that Stem Express loses money each time it procures a fetal tissue sample and ships it to a customer. Shown in orange, the cost estimates produced by the attorneys are inconsistent with accounting records produced by StemExpress itself. For example, StemExpress lists **Clinic Reimbursement** which the Panel found was **not** an actual payment made by StemExpress. Also, the costs associated with shipping and infectious disease are passed on to the customer and thus are **not** a cost to StemExpress. Finally, management labor costs at one hour per item ordered, which are counted twice, are dramatically inconsistent with the number of orders actually handled by StemExpress. Similarly, StemExpress estimates do **not** allocate any costs (such as mileage) to maternal blood which is harvested at the abortion business at the same time the human fetal tissue is harvested.

Sample review of a sale of fetal tissue to customer
Baylor per invoice #1940 of 1/12/2013
Sale price for Tissue $250.00
Disease screening charged to client $125.00
Shipping charged to client $85.00
Total Revenue obtained from this sale $460.00
Estimated cost of Tissue (per above) $175.75
Excess of revenue over cost $217.00

Sample review of a sale of fetal tissue to customer
Baylor per invoice #1940 of 1/12/2013
Sale price for Tissue $250.00
Disease screening charged to client $125.00
Shipping charged to client $85.00
Total Revenue obtained from this sale $460.00
Estimated cost of Tissue (per above) $351.00
Excess of revenue over cost $108.50

Violation of Applicable Laws

Under 42 U.S.C. § 289g-2, it is unlawful for any person to "knowingly acquire, receive, or otherwise transfer any fetal tissue for valuable consideration if the transfer affects interstate commerce."[26] The term "'valuable consideration' does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."[27] Anyone who violates this law is subject to a fine "not less than twice the amount of the valuable consideration received" and/or imprisonment for up to ten years.[28]

Florida state law includes a nearly identical prohibition. Under Fla. Stat. § 873.05, a "person may not knowingly advertise or offer to purchase or sell, or purchase, sell, or otherwise transfer, a human embryo for valuable consideration," and further, "may not advertise or offer to purchase, sell, donate, or transfer, or purchase, sell, donate, or transfer, fetal remains obtained from an abortion."

The Florida statute's definition of "valuable consideration" is virtually identical to that of the federal statute.[29] Fla. Stat. § 873.05(3) provides that this activity is a felony of the second degree, and is subject to a fine of up to $10,000 and/or imprisonment for up to 15 years for a first offense.[30]

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[26] 42 U.S.C. § 289g-2(a).
[27] 42 U.S.C. § 289g-2(e)(3).
[28] 42 U.S.C. § 289g-2(d).
[29] Such consideration "does not include the reasonable costs associated with the removal, storage, and transportation of a human embryo." Fla. Stat. § 873.05(1). It may include such costs as associated with a fetus, as well as the other activities for which StemExpress set a flat fee for payment to PWC.
[30] Fla. Stat. § 775.082-083; *see also* Fla. Stat. § 775.084 for sentencing of repeat offenders.

Similarly, Fla. Stat. § 873.01 provides that "no person shall knowingly offer to purchase or sell, or puchase sell, or otherwise transfer, any human organ or tissue for valuable consideration," and further, "no for-profit corporation or any employee thereof shall transfer or arrange for the transfer of any human body part for valuable consideration." The statute lists examples of human body parts that may not be purchased, sold, or transferred in that way, and livers are specifically named. Again, this activity is a felony of the second degree, and is subject to a fine of up to $10,000 and/or imprisonment for up to 15 years for a first offense.[31]

And Fla. Stat. § 390.0111(6) prohibits using "any live fetus or live, premature infant for any type of scientific, research, laboratory, or other kind of experimentation either prior to *or subsequent to any termination of pregnancy procedure* . . . ." (emphasis supplied).

The foregoing analysis establishes with a high level of probability that PWC, at least through its contract with StemExpress, routinely violated 42 U.S.C. § 289g-2 and Fla. Stat. § 873.05. This is established by the transactions involving the transfer of fetal tissue to numerous entities for consideration, via its contract with StemExpress, that exceeded statutorily allowable costs.

Finally, it appears that PWC may be in violation of HIPAA protected health information law, 42 U.S.C. § 1320d-6(a)(3), by disclosing individually identifiable health information to another person, which is usually punishable by a fine of up to $50,000 and/or imprisonment for up to 1 year, but when the personal health information was shared "for commercial advantage," as when PWC transferred protected health information in order to sell fetal tissue, the penalty is a fine of up to $250,000 and/or imprisonment for up to 10 years. In their contract, PWC and StemExpress agreed that HIPAA guidelines applied to patients' information and that the charts were "privileged" and merited "confidentiality,"[32] but based on the information requested on the StemExpress forms, such as "Patient and Sample Information Form for Research Study," described above, it seems that they did not adhere to the law or even to their own internal guidelines.[33] This form admonishes, "Please fill out and return with the samples to ensure timely compensation!,"[34] pressuring PWC to improperly share patient information in order to receive their checks. Less specific information than that on the form has been deemed protected health information in at least some states.[35]

Based on the facts outlined above and the supporting documentation, I urge your office to conduct a thorough investigation into whether Presidential Women's Center, Inc., violated these statutes and regulations, and, if you agree that such violations occurred, to take all appropriate action. If you have any questions about this request, please contact Frank Scaturro, at (202) 225-2927, Frank.Scaturro@mail.house.gov, or Mary Harned, at (202) 480-7160, Mary.Harned@mail.house.gov.

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[31] Fla. Stat. § 775.082-083; *see also* Fla. Stat. § 775.084 for sentencing of repeat offenders.

[32] PWC0002: "Any information obtained from [PWC] patients' charts shall be privileged, and StemExpress will treat the information in order to preserve the confidentiality of the patients. . . . This will always be done in accordance with HIPAA guidelines."

[33] PWC00026.

[34] PWC00026.

[35] *See, e.g., Planned Parenthood of the Great Northwest v. Bloedow*, 350 P.3d 660 (Wash. Ct. App. 2015).

Sincerely yours,



Marsha Blackburn
Chairman
Select Investigative Panel of
the Committee on Energy and Commerce

Attachment(s)

cc: The Honorable Jan Schakowsky
Ranking Member
Select Investigative Panel of
the Committee on Energy and Commerce

The Honorable Vern Pierson
El Dorado County District Attorney

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

December 7, 2016

VIA EMAIL

The Honorable Ken Paxton
Office of the Attorney General
300 W. 15th Street
Austin, TX 78711-2548

Dear Attorney General Paxton:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the "Panel") and empowered it to conduct a full and complete investigation regarding the medical practices of second- and third-trimester abortion providers and the practices of entities that procure and transfer fetal tissue. This includes investigation of partial-birth abortion and the standard of care for infants who survive the abortion procedure.

Over the course of our investigation, we have collected statements and video from former employees and a patient of [redacted] who allege numerous violations of law at one or more of his clinics, describing the practitioner as conducting himself with depraved indifference to infant life and committing acts of murder.

Allegations Against [redacted]

[redacted] is an abortion provider who has operated at three locations in Houston, Texas, including the Aaron Women's Clinic ("Aaron"), the Texas Ambulatory Surgery Center, and the Women's Pavilion; and at the Northpark Medical Group in Dallas. Several former employees who worked with him at one or more of the Houston locations have come forward alleging numerous violations of law.

According to several of his employees, including *Employee #1* and *Employee #2*, who were medical assistants, and *Employee #3*, who assisted with administrative tasks, numerous patients of [redacted] delivered infants alive prior to their demise, which the doctor himself brought about. Specifically, *Employee #1*, who assisted the doctor in the operating room at Aaron, estimated that "[d]uring a typical week with a full patient load, . . . [redacted] would perform

abortions at 20 or more weeks gestation, *i.e.*, later in the second trimester or in the third trimester, on approximately 40 patients."[1] Of that number, *Employee #1* asserted:

> approximately three or four infants would show signs of life. This typically happened when infants were extracted from the cervix in a breech position. At times, the infant would slide completely out because of the extent of the dilation caused by the laminaria administered to patients. In all such cases, [redacted] would terminate their lives. The signs of life they exhibited would include movement of the stomach as the infant breathed or movement of the toes or fingers.[2]

[redacted] would terminate the lives of these infants, *Employee #1* further alleges based on those incidents she witnessed, by any of several methods, including the following:

> snipping the infant's spinal cord with scissors; cutting the neck with Sopher forceps or similar instruments; twisting the infant's head; using forceps, other instruments, or his finger to crush the "soft spot" of the infant's head, or crushing it by the same means through its stomach; or inserting his finger down its throat. If the infant's cranium was coming out first, he would usually use his index finger to puncture its head, but if it was coming out feet first, he would instead insert an instrument in the back of the infant's head.[3]

Several of the same allegations were also made by *Employee #2*.[4]

Employee #3 was not in the treatment rooms when abortions took place, but she alleges she learned from her coworkers of numerous infants whose lives were terminated by [redacted] after showing signs of life following partial or full extraction from the uterus.[5] On one occasion, she stated that she learned from a coworker of an infant killed by the doctor after surviving an abortion; as he was preparing to put it into a bag for disposal, she maintained, the infant had "opened up his eyes and grabbed his hand."[6]

Employee #1 stated that "[o]f the three to four infants terminated in a typical week by [redacted] while showing signs of life, on average, approximately one or two would be put to death after they had left the birth canal entirely. The balance were terminated while they were partially out of the birth canal."[7] *Employee #1* added that she never observed [redacted] "make an attempt to keep alive or resuscitate any infant who showed any signs of life or to direct anyone else to do so," an observation consistent with *Employee* #3's understanding.[8]

[1] Affidavit of *Employee #1*, Dec. 5, 2016, ¶¶ 1-2, attachment 1 [hereinafter *Employee #1* Aff.].
[2] *Id.* ¶ 3.
[3] *Id.* ¶ 4.
[4] *See* Redacted video—see key, attachment 2 [hereinafter Redacted video] ("Sometimes he would go through the stomach as well. . . . He would like force it [the instrument] through the stomach . . . and he twists it.") ("he would put, like, his finger . . . through the throat") (statements of *Employee #2*).
[5] Affidavit of *Employee #3*, Dec. 6, 2016, ¶ 2, attachment 3 [hereinafter *Employee #3* Aff.].
[6] Redacted video.
[7] *Employee #1* Aff. ¶ 5.
[8] *Id.* ¶ 5; *Employee #3* Aff. ¶ 2.

Employee #1 also alleged that "[redacted] performed numerous abortions during the third trimester in cases that did not involve any serious threats to the mother's or the infant's health."[9] *Employee #2* asserted, "As long as the patients had the cash, he was going to do it past the 25 weeks."[10] Four photographs identified by *Employee #1* and *Employee #3* as taken in the sterilization room of the Women's Pavilion in 2012 depict the remains of infants clearly in their third trimester when they were allegedly terminated by [redacted].[11] According to *Employee #1*, the tears in the neck line visible in the photos are "inconsistent with" terminations done "while the infant[s were] entirely inside the uterus."[12] Thus, besides being late-term abortions, they were likely either partial-birth abortions or homicides committed after full delivery.

Employee #1 and two other employees at the clinic, *Employee #3* and *Employee #4*, additionally allege that the doctor regularly falsified sonogram results to misrepresent the gestational age of the fetus. Some sonograms, they maintain, would be falsified to "overstate the gestational age of the fetus in order to overbill customers."[13]

In other cases, according to *Employee #1* and *Employee #3*, "sonograms would be falsified to conceal the advanced gestational age of the fetus beyond the legal limit in Texas."[14] *Employee #1* claimed:

> I have witnessed this happen in cases involving fetuses as old as 28 weeks. [redacted] would typically tell his ultrasound technician in cases involving fetuses beyond a certain gestational age to allow him to perform the ultrasound himself; he would then bring the patient an ultrasound picture showing another fetus at the gestational age he was misrepresenting to the patient.[15]

An affidavit from a patient attached hereto alleges another specific case of manipulation: *Patient #1*, a woman who obtained an abortion in 2002 at "24 to 25 weeks" gestation, "worried that I was too far along. The girl doing my ultrasound told me that 'ultrasounds can be manipulated.' The clinic determined me to be 23 weeks."[16] "On two occasions that I witnessed," *Employee #1* also alleges that "[redacted] failed to inform a patient she was pregnant with twins."[17]

According to *Employee #1* and *Employee #3*, the doctor "would regularly make use of pre-drawn medicine," including Demerol and Nubain, "without properly logging or storing it." They added:

> This included improperly storing medicine in a food refrigerator. On one occasion, [redacted] concealed these practices during an inspection from the

[9] *Employee #1* Aff. ¶ 6.
[10] Redacted video.
[11] *Employee #1* Aff. ¶ 6; *Employee #3* Aff. ¶ 3. According to *Employee #3*, the photos were taken July 26, 2012. *Id.*
[12] *Employee #1* Aff. ¶ 6.
[13] *Id.* ¶ 7; *Employee #3* Aff. ¶ 4; Statement of *Employee #4*, Nov. 23, 2012, attachment 4, at 1.
[14] *Employee #1* Aff. ¶ 7; *Employee #3* Aff. ¶ 4.
[15] *Employee #1* Aff. ¶ 7.
[16] Affidavit of *Patient #1*, June 17, 2013, attachment 5.
[17] *Employee #1* Aff. ¶ 8.

> Harris County Public Health office by having a nurse put pre-drawn medicine in basins, which she hid in the trunk of her car while the inspector was present."[18]

Employee #1 and *Employee #3* also allege the doctor failed to keep a registered nurse on site in the recovery room at Aaron, which "left unqualified workers to draw and administer drugs."[19] *Employee #1* added that [redacted] concealed this deficiency from authorities by "hir[ing] a nurse from a temp agency for a few days at a time when a government inspection was scheduled."[20] *Employee #1* recorded examples of storage, recordkeeping, and personnel violations in an undercover video from 2011 attached hereto.[21]

Additionally, according to *Employee #1*:

> [redacted] would regularly fail to observe proper sterilization procedures. This included the doctor's habitual reuse of a bottle of Betadine, which is used for cleaning prior to the procedure, that was not cleaned or stored, and which he handled with his gloved hand for patient after patient when going inside the cervix. Additionally, after removing instruments such as Hawkins-Ambler's dilators and Bierer and Sopher forceps from sterile packages, he would place unused instruments back in the sterile package to use on other patients. He often would do so wearing gloves that he did not change between seeing one patient and another, or between trips to the restroom. . . . Instruments in [redacted]'s clinic were not regularly soaked in sterilizing solutions as they needed to be for specified periods of time in order to be sterile. The exception to this occurred prior to government inspections. The vast majority of the doctor's assistants in the sterilization room were uninformed on proper methods of sterilization. In order to reduce his costs, [redacted] also habitually disposed of biohazardous waste in standard garbage bags instead of sterile bags required for such waste.[22]

The same failure with respect to sterilization was also alleged by *Employee #2*, *Employee #3*, and *Employee #4*.[23]

Violations of Applicable Laws

Federal law makes clear that infants that are born, regardless of whether naturally or by extraction during an abortion, are entitled to the same protections given to every other person. Under the Born-Alive Infants Protection Act of 2002, "every infant member of the species homo sapiens who is born alive at any stage of development" is considered a person.[24] This is so

[18] *Id.* Aff. ¶ 9; *Employee #3* Aff. ¶ 5. *See also* Redacted video.
[19] *Employee #1* Aff. ¶ 10; *Employee #3* Aff. ¶ 6.
[20] *Employee #1* Aff. ¶ 10. For additional information regarding the deficiencies in [redacted] s nursing staff and other allegations regarding possible violations at his clinics, see Statement of *Employee #1* in support of Complaint against [redacted] D.O., Apr. 26, 2010, attachment 6.
[21] Aaron Women's Clinic video by *Employee #1*, attachment 7.
[22] *Employee #1* Aff. ¶¶ 11-12. See also Statement of *Employee #1* in support of Complaint against [redacted] D.O., Apr. 26, 2010, attachment 6, at 3.
[23] Redacted video; Statement of *Employee #4*, Nov. 23, 2012, attachment 4, at 1.
[24] 1 U.S.C. § 8(a).

whenever an infant undergoes "complete expulsion or extraction from his or her mother" and "has a beating heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, regardless of whether the umbilical cord has been cut, and regardless of whether the expulsion or extraction occurs as a result of natural or induced labor, cesarean section, or induced abortion."[25] The Partial-Birth Abortion Ban Act of 2003 makes clear that such protections apply even if the infant is only partially extracted from the mother's body at the time its life is ended. Specifically, a prohibited "partial-birth abortion" occurs when a person knowingly commits "an overt act . . . that kills the partially delivered living fetus" after the fetus is partially delivered with its entire head "outside the body of the mother, or, in the case of breech presentation, any part of the fetal trunk past the navel."[26] The only exceptions occur when such a procedure "is necessary to save the life of a mother whose life is endangered" by certain categories of physical conditions.[27] Violations of the 2003 act are punishable by fines, imprisonment for up to two years, or both.[28]

The foregoing allegations advance numerous federal violations against [redacted]—of the Partial-Birth Abortion Ban Act in those cases involving his terminations of partially delivered infants and of the Born-Alive Infants Protection Act in those cases where the infants have completely exited a mother's body. In at least the latter cases, they also amount to allegations that [redacted] violated Texas' criminal homicide statutes. First, the allegations constitute murder, defined by the Texas Penal Code as "intentionally or knowingly caus[ing] the death of an individual."[29] Second, the allegations against [redacted] constitute capital murder under Texas law in both of the following circumstances, either one of which is sufficient to establish that offense:

- "the person murders more than one person . . . during different criminal transactions but the murders are committed pursuant to the same scheme or course of conduct;"[30] and

- "the person murders an individual under 10 years of age . . . ."[31]

The murders alleged against [redacted] occurred on a repeated basis, and all occurred pursuant to his course of conduct as a provider of abortion who was alleged to have systematically killed any infant aborted while showing signs of life. The second circumstance is independently established by the obvious fact that every alleged victim was under 10 years of age.

[redacted]'s alleged conduct would also violate the gestational age limit established under Texas law. Former employees of the doctor allege he performed abortions as late as the third trimester.[32] Third trimester abortions are prohibited with narrow exceptions, inapplicable according to the allegations in the instant case, where "the abortion is necessary to prevent the death of the woman," the "unborn child has a severe, irreversible brain impairment; or . . . the woman is diagnosed with a significant likelihood of suffering imminent severe, irreversible brain

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[25] 1 U.S.C. § 8(b).
[26] 18 U.S.C. § 1531(b)(1).
[27] 18 U.S.C. § 1531(a).
[28] *Id.*
[29] Tex. Penal Code § 19.02(b)(1).
[30] Tex. Penal Code § 19.03(a)(7).
[31] Tex. Penal Code § 19.03(a)(8).
[32] *Employee #1* Aff. ¶ 6; *Employee #3* Aff. ¶ 2.

damage or . . . paralysis."[33] Since H.B. 2 became effective October 29, 2013, abortions additionally have been prohibited when "the probable post-fertilization age of the unborn child is 20 or more weeks."[34] [redacted]'s abortion practice is believed to continue to the present day, so it merits investigation whether he has violated both gestational limits.

The allegations that [redacted] regularly falsified sonogram results to misrepresent the gestational age of the fetus also potentially implicate both state and federal law. Regardless of whether the patient or another entity is responsible for payment, Texas law clearly prohibits fraudulent billing. Such conduct would constitute a form of theft[35] in addition to violating Texas' prohibition on insurance fraud.[36] In those cases in which patients were eligible for Medicaid coverage, such allegations would implicate numerous federal criminal prohibitions on false statements to federal agencies[37] and on false statements involving health care benefit programs,[38] as well as the prohibitions on health care fraud.[39] Such conduct would also violate the federal False Claims Act[40] and Texas' prohibition of Medicaid fraud.[41]

Other provisions of Texas law prohibit additional conduct alleged above on the part of [redacted], including the following:

- Misrepresentation of sonogram readings: In addition to violating the above-cited statutes prohibiting fraud, tampering and altering records containing patient data is prohibited under 25 Tex. Admin. Code § 135.9(d).

- Failure to properly store and log medication: The obligation to maintain and provide drugs safely and to properly log their use is set forth in detail under 22 Tex. Admin. Code § 291.76 and made applicable to ambulatory surgical centers under 25 Tex. Admin. Code § 135.12.

- Lack of adequate medical staff: 25 Tex. Admin. Code § 135.7 requires health care practitioners to meet numerous requirements that include necessary and appropriate training and to adhere to state law and "the standards and ethics of their professions." 25

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[33] Tex. Occ. Code § 164.052(a)(18). The Texas Health and Safety Code contains an additional prohibition of third-trimester abortions, under which such abortions are permitted only when they are "necessary to prevent the death or a substantial risk of serious impairment to the physical or mental health of the woman" or "the fetus has a severe and irreversible abnormality," in which case the physician is required to submit a written certification of the applicable conditions to the Department of State Health Services. Tex. Health & Safety Code §§ 170.002(b)-(c).

[34] Tex. Health & Safety Code §§ 171.044, 171.045. Exceptions apply when abortion is deemed necessary "to avert the woman's death or a serious risk of substantial and irreversible physical impairment of a major bodily function, other than a psychological condition." Tex. Health & Safety Code § 171.046. Note that these provisions of H.B. 2 were not challenged in *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016).

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[36] Tex. Penal Code § 35.02.

[37] 18 U.S.C. § 1001; 18 U.S.C. § 287. An accompanying prohibition on conspiracy in connection with such claims is established by 18 U.S.C. § 286.

[38] 18 U.S.C. § 1035.

[39] 18 U.S.C. § 1347; 42 U.S.C. § 1320a-7b(a). If fraud is proven to have been carried out by utilizing either the mails or other applicable interstate carriers or communications, the federal mail and wire fraud statutes would also be implicated. *See* 18 U.S.C. §§ 1341, 1343.

[40] 31 U.S.C. § 3729(a)(1).

[41] Tex. Penal Code § 35A.02.

Tex. Admin. Code § 135.15 specifies requirements for an organized nursing service under the direction of a qualified registered nurse and other personnel that must be present at the medical facility. [redacted]'s former employees' allegations amount to a violation of these sections. Additional investigation is warranted into whether clinic practices were in compliance with other requirements for adequate medical staff, including 25 Tex. Admin. Code § 135.10, which addresses additional facility requirements, and 25 Tex. Admin. Code § 135.11, which addresses anesthesia and surgical services.

- Failure to observe proper sterilization procedures and disposal practices: 25 Tex. Admin. Code § 135.11(b)(12) requires the development, implementation, and enforcement of such procedures, and 25 Tex. Admin. Code § 135.52(d)(14) requires sterilizing facilities to be included and properly maintained and utilized.

- Fraudulent concealment from government authorities of the foregoing alleged violations: The fabrication, alteration, and in applicable cases concealment involved in these allegations entail conduct proscribed by Tex. Penal Code § 37.09. It also subverts the state's right to inspect facilities containing controlled substances pursuant to Tex. Health & Safety Code § 481.181.

[redacted] was previously referred to the District Attorney of Harris County, but the investigation into the matter was deficient. In light of the gravity of the allegations outlined above and the supporting documentation, I urge your office to conduct a thorough investigation into whether [redacted] violated federal and state law, and, if you agree that such violations occurred, to take all appropriate action. If you have any questions about this request, please contact Frank Scaturro, at (202) 225-2927, Frank.Scaturro@mail.house.gov.

Sincerely yours,

Marsha Blackburn
Chair
Select Investigative Panel

Attachment(s)

cc: The Honorable Jan Schakowsky
Ranking Member
Select Investigative Panel

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

December 7, 2016

VIA EMAIL AND FIRST CLASS MAIL

The Honorable Loretta Lynch
Attorney General
c/o Office of Legislative Affairs
U.S. Department of Justice
950 Pennsylvania Ave., NW
Washington, DC 20530

Dear Attorney General Lynch:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the "Panel") and empowered it to conduct a full and complete investigation regarding the medical practices of second- and third-trimester abortion providers and the practices of entities that procure and transfer fetal tissue. This includes investigation of partial-birth abortion and the standard of care for infants who survive the abortion procedure.

Over the course of our investigation, we have collected statements and video from former employees and a patient of [redacted] who allege numerous violations of law at one or more of his clinics, describing the practitioner as conducting himself with depraved indifference to infant life and committing acts of murder.

Allegations Against [redacted]

[redacted] is an abortion provider who has operated at three locations in Houston, Texas, including the Aaron Women's Clinic ("Aaron"), the Texas Ambulatory Surgery Center, and the Women's Pavilion; and at the Northpark Medical Group in Dallas. Several former employees who worked with him at one or more of the Houston locations have come forward alleging numerous violations of law.

According to several of his employees, including *Employee #1* and *Employee #2*, who were medical assistants, and *Employee #3*, who assisted with administrative tasks, numerous patients of [redacted] delivered infants alive prior to their demise, which the doctor himself brought about. Specifically, *Employee #1*, who assisted the doctor in the operating room at Aaron, estimated that "[d]uring a typical week with a full patient load, . . . [redacted] would perform

abortions at 20 or more weeks gestation, *i.e.*, later in the second trimester or in the third trimester, on approximately 40 patients."[1] Of that number, *Employee #1* asserted:

> approximately three or four infants would show signs of life. This typically happened when infants were extracted from the cervix in a breech position. At times, the infant would slide completely out because of the extent of the dilation caused by the laminaria administered to patients. In all such cases, [redacted] would terminate their lives. The signs of life they exhibited would include movement of the stomach as the infant breathed or movement of the toes or fingers.[2]

[redacted] would terminate the lives of these infants, *Employee #1* further alleges based on those incidents she witnessed, by any of several methods, including the following:

> snipping the infant's spinal cord with scissors; cutting the neck with Sopher forceps or similar instruments; twisting the infant's head; using forceps, other instruments, or his finger to crush the "soft spot" of the infant's head, or crushing it by the same means through its stomach; or inserting his finger down its throat. If the infant's cranium was coming out first, he would usually use his index finger to puncture its head, but if it was coming out feet first, he would instead insert an instrument in the back of the infant's head.[3]

Several of the same allegations were also made by *Employee #2*.[4]

Employee #3 was not in the treatment rooms when abortions took place, but she alleges she learned from her coworkers of numerous infants whose lives were terminated by [redacted] after showing signs of life following partial or full extraction from the uterus.[5] On one occasion, she stated that she learned from a coworker of an infant killed by the doctor after surviving an abortion; as he was preparing to put it into a bag for disposal, she maintained, the infant had "opened up his eyes and grabbed his hand."[6]

Employee #1 stated that "[o]f the three to four infants terminated in a typical week by [redacted] while showing signs of life, on average, approximately one or two would be put to death after they had left the birth canal entirely. The balance were terminated while they were partially out of the birth canal."[7] *Employee #1* added that she never observed [redacted] "make an attempt to keep alive or resuscitate any infant who showed any signs of life or to direct anyone else to do so," an observation consistent with *Employee* #3's understanding.[8]

[1] Affidavit of *Employee #1*, Dec. 5, 2016, ¶¶ 1-2, attachment 1 [hereinafter *Employee #1* Aff.].
[2] *Id.* ¶ 3.
[3] *Id.* ¶ 4.
[4] *See* Redacted video—see key, attachment 2 [hereinafter Redacted video] ("Sometimes he would go through the stomach as well. . . . He would like force it [the instrument] through the stomach . . . and he twists it.") ("he would put, like, his finger . . . through the throat") (statements of *Employee #2*).
[5] Affidavit of *Employee #3*, Dec. 6, 2016, ¶ 2, attachment 3 [hereinafter *Employee #3* Aff.].
[6] Redacted video.
[7] *Employee #1* Aff. ¶ 5.
[8] *Id.* ¶ 5; *Employee #3* Aff. ¶ 2.

Employee #1 also alleged that "[redacted] performed numerous abortions during the third trimester in cases that did not involve any serious threats to the mother's or the infant's health."[9] *Employee #2* asserted, "As long as the patients had the cash, he was going to do it past the 25 weeks."[10] Four photographs identified by *Employee #1* and *Employee #3* as taken in the sterilization room of the Women's Pavilion in 2012 depict the remains of infants clearly in their third trimester when they were allegedly terminated by [redacted].[11] According to *Employee #1*, the tears in the neck line visible in the photos are "inconsistent with" terminations done "while the infant[s were] entirely inside the uterus."[12] Thus, besides being late-term abortions, they were likely either partial-birth abortions or homicides committed after full delivery.

Employee #1 and two other employees at the clinic, *Employee #3* and *Employee #4*, additionally allege that the doctor regularly falsified sonogram results to misrepresent the gestational age of the fetus. Some sonograms, they maintain, would be falsified to "overstate the gestational age of the fetus in order to overbill customers."[13]

In other cases, according to *Employee #1* and *Employee #3*, "sonograms would be falsified to conceal the advanced gestational age of the fetus beyond the legal limit in Texas."[14] *Employee #1* claimed:

> I have witnessed this happen in cases involving fetuses as old as 28 weeks. [redacted] would typically tell his ultrasound technician in cases involving fetuses beyond a certain gestational age to allow him to perform the ultrasound himself; he would then bring the patient an ultrasound picture showing another fetus at the gestational age he was misrepresenting to the patient.[15]

An affidavit from a patient attached hereto alleges another specific case of manipulation: *Patient #1*, a woman who obtained an abortion in 2002 at "24 to 25 weeks" gestation, "worried that I was too far along. The girl doing my ultrasound told me that 'ultrasounds can be manipulated.' The clinic determined me to be 23 weeks."[16] "On two occasions that I witnessed," *Employee #1* also alleges that "[redacted] failed to inform a patient she was pregnant with twins."[17]

According to *Employee #1* and *Employee #3*, the doctor "would regularly make use of pre-drawn medicine," including Demerol and Nubain, "without properly logging or storing it." They added:

> This included improperly storing medicine in a food refrigerator. On one occasion, [redacted] concealed these practices during an inspection from the

[9] *Employee #1* Aff. ¶ 6.
[10] Redacted video.
[11] *Employee #1* Aff. ¶ 6; *Employee #3* Aff. ¶ 3. According to *Employee #3*, the photos were taken July 26, 2012. *Id.*
[12] *Employee #1* Aff. ¶ 6.
[13] *Id.* ¶ 7; *Employee #3* Aff. ¶ 4; Statement of *Employee #4*, Nov. 23, 2012, attachment 4, at 1.
[14] *Employee #1* Aff. ¶ 7; *Employee #3* Aff. ¶ 4.
[15] *Employee #1* Aff. ¶ 7.
[16] Affidavit of *Patient #1*, June 17, 2013, attachment 5.
[17] *Employee #1* Aff. ¶ 8.

> Harris County Public Health office by having a nurse put pre-drawn medicine in basins, which she hid in the trunk of her car while the inspector was present."[18]

Employee #1 and *Employee #3* also allege the doctor failed to keep a registered nurse on site in the recovery room at Aaron, which "left unqualified workers to draw and administer drugs."[19] *Employee #1* added that [redacted] concealed this deficiency from authorities by "hir[ing] a nurse from a temp agency for a few days at a time when a government inspection was scheduled."[20] *Employee #1* recorded examples of storage, recordkeeping, and personnel violations in an undercover video from 2011 attached hereto.[21]

Additionally, according to *Employee #1*:

> [redacted] would regularly fail to observe proper sterilization procedures. This included the doctor's habitual reuse of a bottle of Betadine, which is used for cleaning prior to the procedure, that was not cleaned or stored, and which he handled with his gloved hand for patient after patient when going inside the cervix. Additionally, after removing instruments such as Hawkins-Ambler's dilators and Bierer and Sopher forceps from sterile packages, he would place unused instruments back in the sterile package to use on other patients. He often would do so wearing gloves that he did not change between seeing one patient and another, or between trips to the restroom. . . . Instruments in [redacted]'s clinic were not regularly soaked in sterilizing solutions as they needed to be for specified periods of time in order to be sterile. The exception to this occurred prior to government inspections. The vast majority of the doctor's assistants in the sterilization room were uninformed on proper methods of sterilization. In order to reduce his costs, [redacted] also habitually disposed of biohazardous waste in standard garbage bags instead of sterile bags required for such waste.[22]

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Federal law makes clear that infants that are born, regardless of whether naturally or by extraction during an abortion, are entitled to the same protections given to every other person. Under the Born-Alive Infants Protection Act of 2002, "every infant member of the species homo sapiens who is born alive at any stage of development" is considered a person.[24] This is so

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[39] 18 U.S.C. § 1347; 42 U.S.C. § 1320a-7b(a). If fraud is proven to have been carried out by utilizing either the mails or other applicable interstate carriers or communications, the federal mail and wire fraud statutes would also be implicated. *See* 18 U.S.C. §§ 1341, 1343.

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Sincerely yours,

Marsha Blackburn
Chair
Select Investigative Panel

Attachment(s)

cc: The Honorable Jan Schakowsky
Ranking Member
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ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

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COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

December 20, 2016

VIA EMAIL

The Honorable Hector H. Balderas, Jr.
Attorney General of New Mexico
408 Galisteo Street
Villagra Building
Santa Fe, NM 87501

Dear Attorney General Balderas:

On June 23, 2016, I sent you a criminal referral report pursuant to the investigation of the Select Investigative Panel (the "Panel") authorized by the U. S. House of Representatives under H. Res. 461. I now write to submit for your attention a supplementary referral concerning additional allegations regarding the University of New Mexico ("UNM") and Southwestern Women's Options ("SWWO"), the entities that were the subjects of our June referral report. This referral is based on information obtained in document productions by UNM and SWWO, deposition testimony by *Doctor #5*[1] of SWWO on May 6, 2016, and a complaint and affidavit with supporting documents submitted by a former patient at SWWO.

Allegations Against SWWO and UNM

As noted in the referral report and admitted by UNM, since 1995, SWWO has served as the only source of aborted infant tissue procured for the University of New Mexico Health and Sciences Center (UNMHSC) for research purposes.[2] From the Panel's investigation, it is apparent that there were several deficiencies in the consent process used to procure fetal tissue. Although SWWO provided the Panel a consent form that purported to give patients notice that tissue from their pregnancy would be donated to UNM,[3] there is evidence that this form was not used. While

[1] Names in this letter are redacted with the same pseudonyms used in the June 23 letter. *See* redaction key.
[2] UNM Document, UNM00560, attachment 1; UNM First Submission to House Select Panel, Jan. 29, 2016, p. 1, attachment 2; UNM Second Submission to House Select Panel, Feb. 16, 2016, p. 1, attachment 3; UNM Response to House Select Panel Subpoena, Mar. 3, 2016, p.1, attachment 4.
[3] Client Information for Informed Consent, Donation of Fetal Tissue for Medical Research, SWWO000524, attachment 5.

Doctor #5 testified that SWWO's practice was to provide women an opportunity to donate the tissue that resulted from their abortions and to obtain their consent to do so, she admitted she had never gotten a consent from a patient at SWWO to make a fetal tissue donation—and did not even recognize the consent form that SWWO produced to the Panel.[4] She also admitted she was unaware of whether consent was required prior to the donation of fetal tissue.[5]

Further evidence supports the inference that patients were not regularly given a fetal tissue donation consent form at SWWO. *Patient*, a patient who obtained an abortion from SWWO, has brought suit against the clinic and attested in an affidavit that she was never given a "consent to donate tissue that was separate from the consent for the [abortion] procedure."[6] Moreover, she alleges she was never informed by the doctors and staff at SWWO that her infant's remains were to be donated to UNM or another entity.[7] Neither, she alleged, was she informed of the nature and extent of any use of such remains, "which body parts were going to be used or donated," or what benefits could be expected from such use.[8] She added that she was not informed by SWWO doctors or staff that the doctor who treated her, *Doctor #6*, and the director of SWWO, *Doctor #3*, were volunteer faculty members at UNM, or that the clinic and the university had been collaborating on fetal tissue research since 1995.[9]

Even more problematically, the only semblance of consent SWWO allegedly sought from *Patient* for fetal tissue research was a phrase mentioning the use of "tissue and parts . . . in medical research" within a two-page consent form provided to her for the abortion procedure itself.[10] Thus, the only consent sought from her for fetal tissue donation came during what should have been a separate process of consent to the abortion procedure itself. A letter from *Patient* to SWWO dated December 2, 2015, requested "all information regarding the disposal, donation or sale of any medical waste," but she allegedly never received any records regarding the disposition of her infant's remains.[11] In September 2016, *Patient* read procurement notes dated October 17, 2012, that were attached to the Panel's referral of UNM and SWWO to the Attorney General of New Mexico that indicated brain tissue had been taken from one infant estimated at 11.5 weeks gestation and another at 12.7 weeks gestation.[12] Because *Patient's* ultrasound taken on October 5, 2012, stated she was 12 weeks and two days pregnant, and because she obtained her abortion five days later on October 10—when staff informed her she was between 12 and 13 weeks pregnant—she believed her "baby was one of the two babies given to the University of

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[4] Transcript of Deposition of *Doctor #5*, May 6, 2016 ("*Doctor #5* Tr.") at 162-63, 165-67, 188-89, 212-13. The consent form itself was marked twice during *Doctor #5*deposition, as Ex. 6 without a Bates number and as Ex. 12 with Bates number SWWO000524, the version the clinic produced to the Panel. *Id.* at 164-65, 212-13. *Doctor #5* maintained it was the job of a counselor rather than a doctor to obtain a consent. *Id.* at 190.

[5] *Doctor #5* Tr. at 273.

[6] Affidavit of *Patient*, Nov. 18, 2016 ("*Patient* Aff."), ¶ 30, attachment 6. *See also* Complaint ¶ 47, *Patient* v. *Doctor #3*, No. D-202-CV-2016-07498 (N.M. Dis. Ct. Bernalillo County Nov. 30, 2016) ("*Patient* Compl."), attachment 7. In an email dated Nov. 28, 2016, *Patient* gave permission to the Panel to disclose her identity publicly, but the Panel decided nonetheless to redact her name in the instant letter.

[7] *Patient* Aff. ¶ 10; *Patient* Compl. ¶ 32.

[8] *Patient* Aff. ¶¶ 21-22, 26; *Patient* Compl. ¶¶ 35-38.

[9] *Patient* Aff. ¶¶ 15, 18-20; *Patient* Compl. ¶ 32.

[10] *Patient* Aff. ¶ 8 & Ex. A, at 1; *Patient* Compl. ¶¶ 11-12 & Ex. A.

[11] *Patient* Aff. ¶¶ 32-33 & Ex. B; *Patient* Compl. ¶¶ 54-57.

[12] Compare *Patient* Aff. ¶¶ 35-36 and Procurement Notes, UNM00029. *See also Patient* Compl. ¶ 52.

New Mexico for their research."[13] This belief is consistent with SWWO's practice of storing fetal tissue in an on-site freezer until it is periodically picked up for transfer to UNM.[14] *Patient* attested, "If I had known my baby was going to be used for research I would have probably changed my mind about going through with the abortion," and added that the actions of SWWO and its doctors caused her "emotional distress and mental anguish."[15] *Patient* additionally alleged that she was advised by staff that she could apply for Medicaid funding for her abortion procedure and that the paperwork supporting such funding was prepared by a doctor she never saw, *Doctor #7*, and not her treating physician, *Doctor #6*.[16]

Violations of Applicable Laws

If true, *Patient's* allegation that the only informed consent to tissue donation sought from her was the cursory reference to the use of "tissue and parts . . . in medical research" in SWWO's abortion consent form amounts to violations of federal and state law by UNM and SWWO.

HHS regulations, which govern much of the human subject research conducted at UNM, requires in 45 C.F.R. § 46.116 a number of basic elements of informed consent:

> (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
>
> (2) A description of any reasonably foreseeable risks or discomforts to the subject;
>
> (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
>
> (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
>
> (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
>
> (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

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[13] *Patient* Aff. ¶¶ 7, 12-13, 37-38; *Patient* Compl. ¶¶ 49-53.
[14] SWWO letter responding to document request (Feb. 12, 2016), at 5; *Doctor #5* Tr. at 182-85. According to SWWO's Feb. 12 letter, pickup occurred weekly, but procurement notes record that pickup occurred an average of 39 times per year since 2010, 45 times in 2012.
[15] *Paitnet* Aff. ¶¶ 39, 42; *Patient* Compl. ¶¶ 60, 142.
[16] *Patient* Aff. ¶¶ 14-17; *Patient* Compl. ¶¶ 61-64, 110.

> (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
>
> (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.[17]

According to *Patient's* allegations, both SWWO and UNM failed to provide any of these elements of informed consent, in violation of 45 C.F.R. § 46.116, accompanied by a violation of 45 C.F.R. § 46.117 for failing to present such consent in writing.

To the extent the research of the fetal tissue acquired by UNM related to transplantation for therapeutic purposes, any violations by SWWO and UNM would include violation of 42 U.S.C. § 289g-1(b)(1), which requires written consent from the woman acknowledging the nature of the research, the lack of "restriction regarding the identity of individuals who may be the recipients of transplantation of the tissue," and that the woman was not informed of any such recipients' identities. Moreover, the use of a consent form that simultaneously seeks consent for abortion and for fetal tissue donation under the alleged circumstances would appear to violate 42 U.S.C. § 289g-1(b)(2)(A)(i), which requires the abortion consent to be "obtained prior to requesting or obtaining consent for a donation of the tissue . . . ."

UNM's own oversight policy provided as of 2015 that "appropriate informed consent by the mother" is required for "[t]he collection and storage of all fetal tissue for research."[18] The policy as revised April 11, 2016, further clarifies that UNMHSC

> will not acquire such fetal tissue from outside entities (a) without contractual and/or written assurance that the fetal tissue being acquired was collected in accordance with a process that separates the informed consent for the abortion procedure from the informed consent to donate such fetal tissue to the UNM HSC for Research, and (b) where there is contractual assurance that the terms of the acquisition complies fully with Section 112(a) of the NIH Act (42 U.S.C. § 289g-2(a)). In addition, the contractual assurance contemplated in Subsection 2 must indicate that there are no legal, ethical, or other restrictions against transferring the Research Tissues to the UNM HSC, nor against the UNM HSC's use of them.[19]

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[17] 45 C.F.R. § 46.116(a). These elements are the minimum required, subject to exceptions for public benefit or service programs under § 46.116(c) and potentially additional requirements under § 46.116(b).

[18] UNMHSC, Oversight of Human Tissue in Research, Policy # RC.05.002.PP (Sept. 16, 2015), UNM03420-UNM03428 at UNM03423.

[19] UNMHSC, Oversight of Human Tissue in Research, Policy # RC.05.002.PP (Apr. 11, 2016), at 3. This revised policy additionally reinforces the Panel's June 23, 2016, referral regarding violation of the Spradling Act by

UNM did not produce this revised policy to the Panel.

Despite SWWO's inclusion of a fetal tissue donation consent form in its production, *Patient's* allegation that it was never shown to her, combined with *Doctor #5* admission that she did not even recognize the form, raises a serious question as to whether SWWO and UNM systematically violated the law, not to mention UNM's own internal policy, by conducting fetal tissue donations without more than the perfunctory reference to tissue research in SWWO's abortion consent form.

The same alleged deficiencies in the consent process at SWWO would constitute a violation of New Mexico's state law. Regardless of whether government funding or transplantation research is involved, N.M. Stat. Ann. § 24-9A-5, which is part of the Maternal, Fetal and Infant Experimentation Act, prohibits any "clinical research activity involving fetuses, live-born infants or pregnant women" unless the woman

> has been fully informed of the following:
>
> > (1) a fair explanation of the procedures to be followed and their purposes, including identification of any procedures which are experimental;
> > (2) a description of any attendant discomforts and risks reasonably to be expected;
> > (3) a description of any benefits reasonably to be expected;
> > (4) a disclosure of any appropriate alternative procedures that might be advantageous for the subject;
> > (5) an offer to answer any inquiries concerning the procedure; and
> > (6) an instruction that the person who gave the consent is free to withdraw his consent and to discontinue participation in the project or activity at any time without prejudice to the subject.[20]

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requiring that fetal tissue for research be acquired "in accordance with the provisions of the" Spradling Act "and/or with contractual assurance that it was obtained in accordance with" that statute. *Id.* at 3-4.

[20] N.M. Stat. Ann. § 24-9A-5(C). As discussed above, the Spradling Act prohibits use of fetal tissue resulting from induced abortion, but this informed consent provision provides a basis for liability separate from the underlying use of such tissue. It additionally should be noted that the Maternal, Fetal and Infant Experimentation Act defines the term "clinical research" as follows:

> "clinical research" means any biomedical or behavioral research involving human subjects, including the unborn, conducted according to a formal procedure. The term is to be construed liberally to embrace research concerning all physiological processes in human beings and includes research involving human in vitro fertilization, but shall not include diagnostic testing, treatment, therapy or related procedures conducted by formal protocols deemed necessary for the care of the particular patient upon whom such activity is performed and shall not include human in vitro fertilization performed to treat infertility; provided that this procedure shall include provisions to ensure that each living fertilized ovum, zygote or embryo is implanted in a human female recipient, and no physician may stipulate that a woman must abort in the event the pregnancy should produce a child with a disability. Provided that emergency medical procedures necessary to

This statute is notably cited in the standard operating procedures of UNM's Office of the Institutional Review Board, but UNM failed to produce that document to the Panel.[21] Other sections of the Maternal, Fetal and Infant Experimentation Act make clear that neither a pregnant woman nor a fetus shall be involved as subjects in clinical research activity unless "the mother is legally competent and has given her informed consent,"[22] subject to penalties of imprisonment for less than one year and/or payment of a fine up to $1,000.[23]

I urge your office to conduct a thorough investigation into whether the University of New Mexico and Southwestern Women's Options violated federal and state law, and, if you conclude that such violations occurred, to take all appropriate action. If you have any questions about this request, please contact Frank Scaturro, at (202) 225-2927, Frank.Scaturro@mail.house.gov.

Sincerely yours,

Marsha Blackburn
Chairman
Select Investigative Panel

Attachment(s)

cc: The Honorable Jan Schakowsky, Ranking Member
Select Panel on Infant Lives

The Honorable Susana Martinez
Governor of New Mexico

The Honorable John A. Sanchez
Lieutenant Governor of New Mexico

The Honorable Steve Pearce
Second Congressional District, New Mexico

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preserve the life or health of the mother or the fetus shall not be considered to be clinical research . . . ."

N.M. Stat. Ann. § 24-9A-1(D).

[21] See UNM Office of the Institutional Review Board, Standard Operating Procedures, effective Mar. 1, 2016, at 1-2, http://irb.unm.edu/sites/default/files/511.0%20Compliance%20with%20Applicable%20Laws%20and%20Regulations.pdf, attachment 8.

[22] N.M. Stat. Ann. §§ 24-9A-2(B), 24-9A-3(B).

[23] N.M. Stat. Ann. § 24-9A-6.

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

December 20, 2016

VIA EMAIL

The Honorable Loretta Lynch
Attorney General
c/o Office of Legislative Affairs
U.S. Department of Justice
950 Pennsylvania Ave., NW
Washington, DC 20530

Dear Attorney General Lynch:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the "Panel") and empowered it to conduct a full and complete investigation regarding the medical practices of abortion providers and the practices of entities that procure and transfer fetal tissue.

The Panel investigation discovered information that StemExpress, LLC ("StemExpress"), a firm that procures fetal tissue from abortion clinics and transfers it to research customers, may have destroyed documents in violation of Title 18 U.S.C. § 1519. The transfer of fetal tissue for valuable consideration is a matter within the jurisdiction of the United States. Specifically, Title 42 U.S.C. § 289 (g) makes it a felony to receive valuable consideration for fetal tissue in excess of allowable costs.

From July 16, 2015 through the passage of H. Res. 461, the Senate Committee on the Judiciary ("Senate Judiciary"), the House Committee on Energy and Commerce ("Energy and Commerce"), and the House Committee on Oversight and Government Reform ("OGR") all conducted inquiries into the fetal tissue industry. The Senate Committee on the Judiciary's investigation still continues. During the course of those congressional inquiries, all of those committees sent document request letters to StemExpress.

Under 18 U.S.C. § 1519, "Whoever knowingly alters, destroys, mutilates, conceals, covers up, falsifies, or makes a false entry in any record, document, or tangible object with the intent to impede, obstruct, or influence the investigation or proper administration of any matter within the

jurisdiction of any department or agency of the United States"[1] commits a felony that is punishable by imprisonment for up to 20 years.[2]

The Panel has discovered a regime of StemExpress' potential destruction of documents that were the subject of congressional inquiries, document request letters, and subpoenas. This regime, which dates back to August 2015 and continues through the present, involves StemExpress' retention of a company that shreds documents for clients, and the production of accounting records that were created by StemExpress' counsel, which the counsel represented were produced by StemExpress itself.

A. Destruction of Documents

Senate Judiciary Committee

On July 16, 2015, Senate Judiciary sent StemExpress a document request letter for all records relating to StemExpress' communications with a senior official of Planned Parenthood, and with Planned Parenthood itself that related to "the centralization or coordination of StemExpress' acquisition of fetal tissue from Planned Parenthood's individual affiliates . . ."[3] On July 24, 2015, StemExpress produced only copies of its contract with Planned Parenthood affiliates.[4]

On August 13, 2015, StemExpress made its first payment to Shred-It-USA.[5] StemExpress bank records dating back to November 2012 reveal there were no payments made to Shred-It USA before August 13, 2015.[6] On August 19, 2016, StemExpress made a second production to Senate Judiciary.[7]

On August 25, 2015, StemExpress made its second payment to Shred-It-USA.[8] On September 17, 2015, Senate Judiciary sent its second document request letter to StemExpress.[9] On September 17, 2015, StemExpress produced documents to Senate Judiciary.[10] On September 24,

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[1] 18 U.S.C. § 1519.
[2] 18 U.S.C. § 1519.
[3] Letter from Sen. Charles E. Grassley, Chairman, Senate Committee on the Judiciary, to [redacted] Founder and CEO, Stem Express, (Jul. 16, 2015), at 2.
[4] *See* Letter from Stephen M. Ryan, McDermott Will & Emery, to Sen. Charles E. Grassley, Chairman, Senate Committee on the Judiciary, Re: StemExpress Response to Senate Judiciary Committee's July 16, 2015 Request for Information, (Jul. 24, 2015).
[5] Panel analysis of Five Star Bancorp production to Select Investigative Panel.
[6] Five Star Bank Production [5 Star 000001 – 5 Star 000511].
[7] *See* Letter from Stephen M. Ryan, McDermott Will & Emery, to Sen. Charles E. Grassley, Chairman, Senate Committee on the Judiciary, Re: StemExpress Second Response to Senate Judiciary Committee's July 16, 2015 Request for Information, (Aug. 19, 2015).
[8] Panel analysis of Five Star Bancorp production to Select Investigative Panel.
[9] *See* Letter from Stephen M. Ryan, McDermott, Will & Emery, to Sen. Charles E. Grassley, Chairman, Senate Committee on the Judiciary, Re: StemExpress Second Response to Senate Judiciary Committee's September 17, 2015 Request for Information, (Oct. 28, 2015). ("I am writing today on behalf of my client, StemExpress, in regard to the letter you sent to the company on September 17, seeking information related to StemExpress; 'acquisition and transfer of fetal tissue.'").
[10] Letter from Stephen M. Ryan, McDermott, Will & Emery, to Sen. Charles E. Grassley, Chairman, Senate Committee on the Judiciary, Re: StemExpress Second Response to Senate Judiciary Committee's September 17,

2015, StemExpress produced documents to Senate Judiciary.[11] On September 29, 2015, StemExpress made a payment to Shred-It-USA.[12] On October 28, 2015, StemExpress produced documents to Senate Judiciary.[13]

Energy and Commerce

On August 7, 2015, Energy and Commerce sent a letter to StemExpress that requested a briefing related to StemExpress' procurement, sale and donation of fetal tissue.[14] On August 13, 2015, StemExpress made its first payment to Shred-It-USA.[15] On August 21, 2015, StemExpress produced documents to Energy and Commerce.[16]

The briefing between StemExpress and Energy and Commerce staff was held on August 25, 2015. On August 24, 2015 StemExpress voluntarily produced documents to Energy and Commerce.[17] Congressional staff requested additional information and documents from StemExpress.[18] On August 25, 2015, StemExpress made its second payment to Shred-It-USA.[19] On September 11, 2015 StemExpress produced documents pursuant to the requests from the Majority and Minority.[20]

2015 Request for Information, (Oct. 28, 2015). ("StemExpress made an initial production in response to the September 17 letter shortly after receipt . . .").

[11] Letter from Stephen M. Ryan, McDermott Will & Emery, to Sen. Charles E. Grassley, Chairman, Senate Committee on the Judiciary, Re: StemExpress First Response to Senate Judiciary Committee's September 17, 2015 Request for Information, (Sep. 24, 2015).

[12] Panel analysis of Five Star Bancorp production to Select Investigative Panel.

[13] Letter from Stephen M. Ryan, McDermott, Will & Emery, to Sen. Charles E. Grassley, Chairman, Senate Committee on the Judiciary, Re: StemExpress Second Response to Senate Judiciary Committee's September 17, 2015 Request for Information, (Oct. 28, 2015).

[14] Letter from Stephen M. Ryan, McDermott Will & Emery, to Rep. Fred Upton, Chairman, House Energy & Commerce Committee, Re: StemExpress Response to House Energy and Commerce Committee's August 7, 2015 Request for a Briefing, (Aug. 21, 2015), at 1. ("I am writing today on behalf of my client, StemExpress, in regard to the letter you sent to the company on August 7, 2015, seeking a briefing related to StemExpress's 'practices regarding human fetal tissue collection, sale and/or donation.'").

[15] Panel analysis of Five Star Bancorp production to Select Investigative Panel.

[16] Letter from Stephen M. Ryan, McDermott Will & Emery, to Rep, Fred Upton, Chairman, House Energy & Commerce Committee Re: StemExpress Response to House Energy and Commerce Committee's August 7, 2015 Request for a Briefing, (Aug. 21, 2015).

[17] Letter from Stephen M. Ryan, McDermott Will & Emery, to Rep. Fred Upton, Chairman, House Energy & Commerce Committee, Re: StemExpress Response to House Energy and Commerce Committee's August 7, 2015 Request for a Briefing, (Aug. 24, 2015), at 1. ("In advance of our voluntary briefing to staff scheduled for August 25, we are voluntarily responding to the staff's request by producing several documents to facilitate our discussion.").

[18] Letter from Stephen M. Ryan, McDermott Will & Emery, to Rep. Fred Upton, Chairman, House Energy & Commerce Committee, (Sep. 11, 2015), at 1. ("As you know, StemExpress's CEO, [redacted] voluntarily agreed to provide a briefing to the Committee's staff on August 25. Following this briefing, both the Majority and Minority staff provided StemExpress with a list of 20 additional request.").

[19] Panel analysis of Five Star Bancorp production to Select Investigative Panel.

[20] Letter from Stephen M. Ryan, McDermott Will & Emery, to Rep. Fred Upton, Chairman, House Energy & Commerce Committee, Re: StemExpress Third Response to House Energy and Commerce Committee's August 7, 2015 Request for a Briefing (Follow-Up Requests), (Sep. 11, 2015), at 1.

OGR

On September 9, 2015, OGR sent a document request letter to StemExpress.[21] StemExpress produced documents to OGR on September 2, 2015 and September 23, 2015.[22] On September 29, 2015, StemExpress made a payment to Shred-It-USA.[23] On October 9, 2015, StemExpress produced more documents to OGR.[24]

The Panel

The Panel was created on October 7, 2016. On November 10, 2015 StemExpress made a payment to Shred-It-USA.[25] On December 10, 2015, StemExpress made another payment to Shred-It-USA. [26] During that time period, StemExpress was under investigation by Senate Judiciary and OGR.

On December 17, 2015, the Panel sent StemExpress a document request letter.[27] On December 18, 2015, congressional staff had a telephone conference with counsel for StemExpress to discuss the document request. On December 22, 2015, StemExpress produced documents to the Panel.[28]

On January 12, 2015, StemExpress made a payment to Shred-It-USA.[29] On January 15, 2015, StemExpress produced documents to the Panel.[30] On January 27, 2015, StemExpress made a

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[21] Letter from Amandeep S. Sidhu, McDermott Will & Emery, to Rep. Jason Chafettz, Chairman, House Committee on Oversight and Government Reform, Re: StemExpress First Response to House Committee on Oversight and Government Reform's September 9, 2015 Request for Information, (Sep. 23, 2015), at 1. ("I am writing today on behalf of my client, StemExpress, in regard to the letter you sent to the company on September 9, 2015, seeking documents and information regarding 'the process whereby StemExpress obtained fetal tissue from Planned Parenthood Federation of America . . .'").

[22] Letter from Amandeep S. Sidhu, McDermott Will & Emery, to Rep. Jason Chafettz, Chairman, House Committee on Oversight and Government Reform, Re: StemExpress First Response to House Committee on Oversight and Government Reform's September 9, 2015 Request for Information, (Sep. 23, 2015), at 1. ("As an initial matter, StemExpress voluntarily produced several documents to the Committee's staff on September 2, 2015. Accordingly, today's production represents StemExpress's second voluntary response to the Committee's inquiries . . .").

[23] Panel analysis of Five Star Bancorp production to Select Investigative Panel.

[24] Letter from Amandeep S. Sidhu, McDermott Will & Emery, to Rep. Jason Chaffetz, Chairman, House Committee on Oversight and Government Reform, Re: StemExpress Second Response to House Committee on Oversight and Government Reform's September 9, 2015 Request for Information, (Oct. 9, 2015).

[25] Panel analysis of Five Star Bancorp production to Select Investigative Panel.

[26] Panel analysis of Five Star Bancorp production to Select Investigative Panel.

[27] Letter from Rep. Marsha Blackburn, Chairman, House Select Investigative Panel, to [redacted] Founder and CEO, StemExpress, LLC (Dec. 17, 2015). The letter sought, among other items, asking for, among other items, a list of all entities from which it procured fetal tissue, a list of all entities to which it sold or donated fetal tissue, an organization chart, all communications that direct its employees to procure fetal tissue, a list of all federal funds the firm received, accounting records, and all StemExpress banking records related to the procurement, sale, donation, or distribution or shipment of fetal tissue.

[28] Letter from Stephen M. Ryan, McDermott Will & Emery, to Rep. Marsha Blackburn, Chair, Select Panel on Infant Lives , Re: StemExpress Response to House "Select Panel on Infant Lives" December 17, 2015 Request for Documents, (Dec. 22, 2015).

[29] Panel analysis of Five Star Bancorp production to Select Investigative Panel.

[30] Letter from Amandeep S. Sidhu, McDermott Will & Emery, to Rep. Marshal Blackburn, Chair, Select Panel on Infant Lives, Re: StemExpress LLC Second Production in Response to House "Select Panel on Infant Lives" December 17, 2015 Request for Documents, (Jan. 15, 2016).

payment to Shred-It-USA.[31] On February 1, 2016, StemExpress produced documents to the Panel.[32]

On February 12, 2016, the Panel issued a subpoena to StemExpress.[33] The subpoena to StemExpress instructed that: "No records, documents, data or information called for by this

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[31] Panel analysis of Five Star Bancorp production to Select Investigative Panel.

[32] Letter from Amandeep S. Sidhu, McDermott Will & Emery, to Rep. Marsha Blackburn, Chair, Select Panel on Infant Lives, Re: StemExpress LLC Third Production to House "Select Panel on Infant Lives" December 17, 2015 Request for Documents, (Feb. 1, 2016).

[33] Subpoena to StemExpress, LLC, (Feb. 12, 2016). The subpoena demanded the following:

> 1) Documents sufficient to show (a) all entities from which StemExpress procured fetal tissue, and (b) all entities to which StemExpress transported, sold, donated, moved, or shipped fetal tissue. Should StemExpress wish to produce a list of such entities referenced in (a) and (b) in lieu of documents, it may do so.
>
> 2) Documents sufficient to show the name and title of all StemExpress current and former employees whose responsibilities included procuring, researching, storing, packaging for donation, sale, transport, or disposal of fetal tissue, and the identity, of any supervisory personnel under whom such individuals worked.
>
> 3) All communications and documents relating to StemExpress employee compensation resulting from or relating to fetal tissue samples procured by current and former StemExpress personnel or other persons or entities that transact business with StemExpress.
>
> 4) All communications and documents that identify any federal, state, or local government funds received, directly or indirectly, by StemExpress.
>
> 5) All communications referring or relating to abortion or fetal tissue between StemExpress and any federal, state, or local government officials or employees.
>
> 6) All communications and documents regarding any direction to StemExpress current or former personnel with respect to the procurement or disposal of fetal tissue.
>
> 7) All communications and documents that StemExpress utilizes to obtain patient consent for fetal tissue at any clinic.
>
> . . . 8) All communications and documents, including but not limited to accounting memoranda, referring or relating to the cost and pricing of fetal tissue by StemExpress.
>
> 9) All communications and documents, sorted by customer, referring or relating to requests or orders made to StemExpress regarding fetal tissue and the amount paid by each customer to StemExpress.
>
> 10) All communications and documents referring or relating to the purchase, ownership, or rental by StemExpress of equipment for the storage, disposal, modification, or research of fetal tissue, including equipment price, purchase date, maintenance costs, and records of the depreciation treatment under the tax code of any such equipment.
>
> 11) All StemExpress banking and accounting documents, sorted by any source of fetal tissue and any customer of StemExpress, that reflect accounts payable and/or funds received that in any way refer or relate to the procurement, sale, donation, or distribution or shipment of fetal tissue.

request shall be destroyed, modified, removed, transferred or otherwise made inaccessible to the Select Panel."[34] On March 21, 2016, StemExpress made a payment to Shred-It-USA.[35] On March 28, 2016, StemExpress produced documents to the Panel pursuant to the subpoena.[36]

On April 26, 2015, StemExpress made a payment to Shred-It-USA.[37] On May 10, 2016, StemExpress produced documents to the Panel pursuant to the February 2016 subpoena.[38]

b. Intent to Obstruct

Documents produced to Congress and testimony before congressional inquiries strongly suggest StemExpress' intent to potentially subvert congressional investigations. The investigations involve matters within the jurisdiction of the United States. An attempt to obstruct such an investigation would violate Title 18 § 1519.

In productions to Senate Judiciary, OGR, and the Panel, StemExpress refused to provide congress with a list of all the entities from which it obtained fetal tissue.[39] StemExpress refused to produce to the Panel requested accounting documents, StemExpress represented that it had lost money on fetal tissue procured from Planned Parenthood affiliates.[40]

> 12) Documents sufficient to show any known litigation in which StemExpress is named as a party, including any threatened or anticipated litigation. Should StemExpress wish to produce a list of such litigation, including appropriate docket information, in lieu of documents, it may do so.

Subpoena to StemExpress, LLC (Feb. 12, 2016) (Schedule).

[34] Subpoena to StemExpress, LLC, at Instruction Item 5, (Feb. 12, 2016).

[35] Panel analysis of Five Star Bancorp production to Select Investigative Panel.

[36] Letter to Rep. Marsha Blackburn, Chair, Select Panel on Infant Lives, Re: Fourth Production in Response to February 12, 2016 subpoena Issued to StemExpress LLC, (Mar. 28, 2016).

[37] Panel analysis of Five Star Bancorp production to Select Investigative Panel.

[38] StemExpress Sixth Response to House Select Panel Subpoena Produced on May 10, 2016. [STEM.HOUSE.SELECT_0908 – STEM.HOUSE.SELECT_0913].

[39] *See* StemExpress Second Response to Senate Judiciary Committee September 17 Letter, undated. ("StemExpress has obtained fetal tissue from two Planned Parenthood affiliates . . . . StemExpress has also obtained fetal tissue from five independent (non-Planned Parenthood) clinics. StemExpress agrees to identify the states where it has agreements with independent clinics, but will not be providing the names of these clinics . . ."). [STEM.JUD000000024; STEM.HOUSE.SELECT_0057]. StemExpress Response to House Committee on Oversight and Government Reform, (Dec. 22, 2015). ("StemExpress has obtained fetal tissue from two Planned Parenthood affiliates . . . and from independent (non-Planned Parenthood) clinics. StemExpress agrees to identify the states where it has agreements with independent clinics, but will not be providing the names of these clinics . . .") [STEM.HOUSE.ORG_000018 / STEM.HOUSE.SELECT_0184]. StemExpress First Response to House Select Panel Document Requests (Jan. 15, 2016), at 2. (". . . many of the company's contracts are subject to non-disclosure agreements and, therefore, cannot be voluntarily produced.") [STEM.HOUSE.SELECT_0228].

[40] StemExpress First Response to House Select Panel Document Requests (Jan. 15, 2016), at 6. (". . . unaltered fetal tissue procured from Planned Parenthood affiliates generated approximately $50,000 in gross (pre-tax) revenue against expenses in excess of $75,000. StemExpress charged researchers a fee of roughly $500 to $600 for unaltered tissues, but incurred directly associated expenses of approximately $750 to $1,000 for each procurement. Other costs included compensation paid to StemExpress' tissue procurement personnel and costs associated with training, packaging and ordering supplies, overnight shipping charges, infectious disease screening. . ."). [STEM.HOUSE.SELECT_0232]. StemExpress invoices produced to the Panel show that StemExpress charged its customers the costs of infectious disease screening, overnight shipping charges, and some supplies. Those charges cannot have been incurred by both StemExpress and its customers.

In response to the Panel's February 12, 2016, subpoena StemExpress produced communications that spanned only two years instead of the five required by the subpoena and these were so replete with redactions as to render them unusable.[41] StemExpress produced only "roll-up" accounting summaries, not the required primary source accounting records.[42]

In response to Specification 4, which required the production of communications and documents that identify any federal, state, or local government funds received, directly or indirectly, by the firm, StemExpress responded that it had nothing responsive to produce. ("StemExpress has confirmed that there are no communications or documents responsive to this . . ."). [43] Despite that representation, the Panel discovered that StemExpress received more than $9,000 in a small business loan from the U.S. Small Business Administration.[44]

[redacted] refused to produce any documents to the Congress pursuant to the Panel's March 29, 2016 subpoena to her.[45] [redacted] supplied the name of the Scinto Group, LLP ("Scinto"), an outside accounting firm that provided services to StemExpress, and suggested that the Panel seek the information it required from Scinto or from [redacted] a former employee of StemExpress. [46] Attorneys for [redacted] offered summary documents of revenue and costs but no accounting records.[47]

[redacted] offer of [redacted] as a source of accounting records proved hollow. [redacted] and StemExpress' counsel, who also represented former employee [redacted] explained that [redacted] had only W-2's and related tax information. In a teleconference with Congressional staff, [redacted] stated that she had no documents and that if the Panel contacted her again she would call the police.[48]

On April 29, 2016, the Panel issued a subpoena to Scinto.[49] Scinto refused to comply with the Panel's subpoena and produced no documents. Scinto told the Panel that StemExpress objected

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[41] [41] *See* StemExpress, Third Response to House Select Investigative Panel Subpoena, Apr. 11, 2016. [STEM.HOUSE.SELECT_0667].

[42] *See* Letter from Amandeep S. Sidhu, McDermott Will & Emery, to T. March Bell, Chief Counsel and Staff Director, House Select Investigative Panel (Mar. 18, 2016), at 1; Letter from Amandeep S. Sidhu, McDermott Will & Emery, to Rep. Blackburn, Chairman, House Select Investigative Panel (May 6, 2016), at 2.

[43] *See* StemExpress, Third Response to House Select Investigative Panel Subpoena, Apr. 11, 2016. [STEM.HOUSE.SELECT_0667].

[44] Center for Effective Government website, www.FedSpending.org.

[45] "StemExpress First Response to House Select Panel's March 29, 2016 Subpoena," at 2-3.

[46] "StemExpress First Response to House Select Panel's March 29, 2016 Subpoena," at 2-3.

[47] "StemExpress First Response to House Select Panel's March 29, 2016 Subpoena," at 1-2.

[48] Memorandum from House Select Investigative Panel Counsel to Majority Members of the House Select Investigative Panel, Mar. 7, 2016.

[49] Subpoena to Scinto Group, LLP, (Apr. 29, 2016). The subpoena required the production of:

> 1) All communications and documents referring or relating to StemExpress, LLC, or StemExpress Foundation (collectively known as "StemExpress").
>
> 2) Documents sufficient to show all institutions or entities to which StemExpress donated or provided fetal tissues for the following years: 2010, 2011, 2012, 2013, 2014 and 2015.

to Scinto's compliance with the Panel's subpoena on the grounds of several privileges.[50] The Panel informed Scinto its objections based upon the asserted privileges, were inapplicable and do

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. . . 3) Copies of all invoices (by month and year), reflecting the billing that StemExpress issued to all institutions or entities to which StemExpress donated or provided fetal tissues for the following years: 2010, 2011, 2012, 2013, 2014 and 2015.

4) Documents sufficient to show all institutions or entities from which StemExpress obtained fetal tissues for the following years: 2010, 2011, 2012, 2013, 2014 and 2015.

. . . 5) Copies of all invoices (by month and year) reflecting the billing or payment of funds for fetal tissues obtained by StemExpress for the following years: 2010, 2011, 2012, 2013, 2014 and 2015.

6) A copy of any chart of accounts for StemExpress, including but not limited to account descriptions from any financial recording system relating to StemExpress.

7) StemExpress' end of year trial balance report and trial balance details for the following years: 2010, 2011, 2012, 2013, 2014 and 2015.

8) All documents reflecting StemExpress' statement of revenues (i.e., a breakdown by product categories) for the following years: 2010, 2011, 2012, 2013, 2014 and 2015.

9) All documents reflecting StemExpress' record of costs and expenses (i.e., a breakdown by operations, including fetal tissue acquisition) for administrative costs and expenses as well as compensation and benefits, for the following years: 2010, 2011, 2012, 2013, 2014 and 2015. Where applicable, records should include identification of vendors and descriptions of expenses.

10) StemExpress' balance sheets for the following years: 2010, 2011, 2012, 2013, 2014 and 2015. Audited statements should be provided, if available.

11) StemExpress' income statements, including but not limited to any profit and loss statements, statements of operations and statements of activities for the following years: 2010, 2011, 2012, 2013, 2014 and 2015. Audited statements should be provided, if available.

12) Copies of Stem Express' filed tax returns for the following years: 2010, 2011, 2012, 2013, 2014 and 2015.

13) All StemExpress bank statements from any financial institution where StemExpress has maintained an account for the following years: 2010, 2011, 2012, 2013, 2014 and 2015.

14) Documents sufficient to show how StemExpress calculates the cost of a fetal tissue and all factors applied in determining pricing of fetal tissue. In lieu of these documents, you may provide a written explanation.

15) Documents sufficient to show StemExpress' cost of production and revenue from the following products: CD34+StemlProgenitor Cells; CD36+ Erythroid Progenitor; CD 133+ Stem/ Progenitor Cells; Fetal Fiver Mononuclear Cells. (Schedule).

[50] *See* email from Kevin Murphy, counsel for Scinto Group LLP, to House Select Investigative Congressional staff (Jun. 15, 2016) ("StemExpress has now told me definitively that it does not waive any available and applicable privileges or confidentiality rights in regard to the records related to StemExpress that are in the possession of my client, Scinto, and that StemExpress holds Scinto accountable to observe and protect those privileges and confidentiality rights. As you know, because Scinto is a CPA firm and tax preparer for StemExpress, there are potentially applicable privileges and confidentiality statutes, under the Internal Revenue Code and related provisions, under the California Business & Professions Code and Tax Code, and under professional standards. I understand that you probably do not agree that any of those laws or provisions would ultimately be found by a court to be applicable, but from our reading of the laws and provisions, we believe that the privilege and confidentiality

not impair the legal requirement to comply with a congressional subpoena.[51] Despite these efforts, Scinto refused to comply with this Panel's subpoena.[52]

In documents produced by an entity from which StemExpress procured fetal tissue, the Panel discovered that StemExpress had an account at Five Star Bancorp. On April 29, 2016, the Panel issued a subpoena to Five Star Bancorp. [53] During a telephone conference with congressional staff, counsel for Five Star Bancorp stated that StemExpress had threatened litigation against his client if it complied with the Panel's subpoena.[54]

On August 23, 2016, the Panel was informed by McDermott Will & Emery, the law firm previously representing StemExpress and [redacted] throughout the course of the investigation, that StemExpress was no longer their client.[55] StemExpress' former attorney supplied the Panel with contact information for the new lawyer.[56] On September 8, 2016, Chairman Blackburn sent a letter to Mr. Frank Radoslovich, the new counsel for StemExpress and [redacted] outlining a

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laws/provisions could be found applicable. I have also reviewed correspondence and a memorandum from the Democratic members of the Select Investigative Panel which assert that the subpoena (and others) was issued in violation of House rules. I have also reviewed articles (including the comprehensive articles by the Congressional Research Service) and court cases regarding enforcement of subpoenas from a House committee or subcommittee or investigative committee. My conclusion, based upon a reading of all these materials, and in light of the position conveyed to me by StemExpress, is that Scinto has an obligation to object to the subpoena.").

[51] *See* T. March Bell, Chief Counsel and Staff Director, House Select Investigative Panel, to Kevin Murphy, counsel for Scinto Group, LLP (Sept. 8, 2016).

[52] *See* Letter from Kevin Murphy, counsel for Scinto Group, LLP, to T. March Bell, Chief Counsel and Staff Director, House Select Investigative Panel (Sept. 16, 2016) ("First, let me reiterate that, if not for the potential application of the privilege and/or confidentiality laws, Scinto Group LLP would be willing and able to comply with a valid subpoena from the Select Investigative Panel. However, in light of the potential application of those laws, under the current circumstances, Scinto Group is not in a position to unilaterally respond to the subpoena with the requested documents, absent client consent.").

[53] *See* Subpoena to Five Star Bancorp (Apr. 29, 2016). that required the production of:

> For the period January 1, 2010, through the present, all documents relating to any Five Star Bank account(s) held by or in the name of Stem Express, LLC, and all documents relating in any way to account number 0032068931.
>
> This request encompasses, but is not limited to, all:
>
> 1) Monthly account statements;
>
> 2) Credit card transaction receipts;
>
> 3) Documents reflecting payments related to the account(s), including, but not limited to, checks (front and back), debit memos, cash in tickets, and wire transfers; and
>
> 4) Correspondence related to the account(s).

(Schedule).

[54] Telephone conference between David R. Gabor, Weintraub Tobin Chediak Coleman Grodin, and congressional staff (May 26, 2016).

[55] Email from Amandeep S. Sidhu, McDermott Will & Emery, to House Select Investigative Panel staff (Aug. 23, 2016).

[56] Email from Amandeep S. Sidhu, McDermott Will & Emery, to House Select Investigative Panel staff (Aug. 23, 2016).

brief history of the Panel's interactions with StemExpress, and the Panel's unsuccessful attempts to reach an accommodation with StemExpress.[57] The letter concluded:

> Since StemExpress has been unwilling to comply with the Panel's subpoenas and having exhausted all its efforts to obtain compliance from the subpoena recipients, the Chairman of the Select Investigative Panel will recommend that StemExpress and [redacted] be held in contempt for their willful failure to fully comply with the Panel's subpoena issued to them . . . .[58]

The Chairman provided one last offer to StemExpress and [redacted] to comply with the subpoenas.[59] After receiving no substantive reply from StemExpress' new counsel, the Panel, on September 21, 2016, voted to recommend that the House of Representatives hold StemExpress and [redacted] in contempt of Congress.[60]

Based on the facts outlined above and the supporting documentation, I request that the Department of Justice conduct a thorough investigation into whether StemExpress committed any violation of federal law during its evasive interactions with Congress. If you have any questions about this request, please contact T. March Bell, Chief Counsel and Staff Director, at (202) 226-9027, March.Bell@mail.house.gov.

Sincerely yours,

Marsha Blackburn
Chair
Select Investigative Panel

Attachment(s)

cc: The Honorable Jan Schakowsky
Ranking Member

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[57] Letter from Rep. Marsha Blackburn, Chairman, House Select Investigative Panel, to Frank Radoslovich, counsel for StemExpress (Sept. 8, 2016).
[58] Letter from Rep. Marsha Blackburn, Chairman, House Select Investigative Panel, to Frank Radoslovich, counsel for StemExpress (Sept. 8, 2016) at 4.
[59] Letter from Rep. Marsha Blackburn, Chairman, House Select Investigative Panel, to Frank Radoslovich, counsel for StemExpress (Sept. 8, 2016) at 4.
[60] *See* Select Investigative Panel of the H. Comm. on Energy and Commerce, Business Meeting, unedited transcript, Sep. 21, 2016.

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

December 21, 2016

VIA EMAIL

The Honorable Loretta Lynch
Attorney General
c/o Office of Legislative Affairs
U.S. Department of Justice
950 Pennsylvania Ave NW
Washington, DC 20530

Dear Attorney General Lynch:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the "Panel") and empowered it to conduct a full and complete investigation regarding the medical practices of abortion providers and the practices of entities that procure and transfer fetal tissue.

Over the course of our investigation, the Panel investigators have uncovered documents and received testimony from confidential informants indicating that several entities may have violated federal law, specifically Title 42 U.S.C. § 289g-2, which forbids the transfer of fetal tissue for valuable consideration. These entities are as follows:

Planned Parenthood Mar Monte
Planned Parenthood Shasta Pacific (Northern California)
Planned Parenthood Los Angeles
Planned Parenthood Pacific Southwest
Novogenix

For your review and careful study, I have attached herewith [redacted] that present facts and supporting documentation of possible criminal misconduct by the entities listed above. I urge your office to conduct a thorough investigation into possible violations of federal law and, if you agree that such violations occurred, to take all

appropriate action. If you have any questions about this request, please contact T. March Bell at (202) 226-9027, March.Bell@mail.house.gov.

Sincerely yours,

Marsha Blackburn
Chairman
Select Investigative Panel

Attachment(s)

cc: The Honorable Jan Schakowsky
Ranking Member
Select Investigative Panel

V. Case Studies of the Fetal Tissue Industry – The Middleman Model

Chapter V Redaction Key:

StemExpress, LLC

1. [PP Witness #1] is an abortion provider in Los Angeles, California, an executive with Planned Parenthood Federation of America (PPFA), and is charge of the PPFA Manual of Medical Standards and Guidelines.

2. [PP Doctor #1] is an abortion provider in Los Angeles, California, who also works for the Medical Directors' Council.

3. [the Founder and CEO] is the founder and CEO of StemExpress, LLC (StemExpress)

4. [ABR's Procurement Manager] is the procurement manager at Advanced Bioscience Resources, Inc.

5. [FDA Consumer Safety Officer # 1] is a consumer safety officer at the U.S. Food and Drug Administration.

6. [FDA Consumer Safety Officer # 2] is a consumer safety officer at the U.S. Food and Drug Administration.

Novogenix Laboratories, LLC

1. [PP Witness # 1] is an abortion provider in Los Angeles, California, an executive with Planned Parenthood Federation of America (PPFA), and is charge of the PPFA Manual of Medical Standards and Guidelines.

2. [PP Doctor #1] is an abortion provider in Los Angeles, California, who also works for the Medical Directors' Council.

3. [Founder and Executive Director] is the founder and executive director of Novogenix Laboratories, LLC (Novogenix).

4. [Supervisor Consumer Safety Officer] is a supervisor consumer safety officer at the U.S. Food and Drug Administration.

5. [Consumer Safety Officer] is a consumer safety officer at the U.S. Food and Drug Administration.

DaVinci Biosciences, LLC/DaVinci Biologics, LLC

1. [DVB Executives] are the owners and managers of DaVinci Biosciences, LLC (DaVinci) and DaVinci Biologics, LLC (DVB).

2. [DVB Executive # 1] is the president of DaVinci and DVB.

3. [DVB Executives # 2 and 3] are founding members and officers of DaVinci and DVB.

Human Fetal Tissue Repository

1. [Einstein Executive Dean] is a senior official at the Albert Einstein College of Medicine.

2. [Einstein Vice-President, Government and Community Relations] is an official who handles government relations at the Albert Einstein College of Medicine.

3. [Einstein Vice-President, External Affairs] is an official who handles external relations at the Albert Einstein College of Medicine.

A. StemExpress, LLC: A Case Study

1. Summary

The Panel conducted an investigation of StemExpress, LLC (StemExpress) that uncovered evidence that StemExpress may have violated 18 § 1519, 42 § 289g-2, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), provisions of the California Health and Safety Law, the California Tax Revenue and Tax Code, and regulations promulgated by the U.S. Department of Health and Human Services (HHS).

a) Background of StemExpress

StemExpress was founded as a for-profit corporation with the California Secretary of State on March 4, 2010, by [the Founder and CEO].[131] On December 2, 2015, [the Founder & CEO] filed papers with the California Secretary of State that created the StemExpress Foundation, which is located at the same address as StemExpress.[132] It is unclear whether the Foundation is for-profit or non-profit, because its tax forms are not yet publicly available.

Before [the Founder and CEO] began StemExpress, she worked for Advanced Bioscience Resources, Inc. (ABR) another tissue procurement company that is established as a non-profit.[133]

[131] California Secretary of State, Business Entity Detail, http://kepler.sos.ca.gov.
[132] *Id.*
[133] For more details on ABR, see subsection B below.

ABR executives express a low opinion of the Founder & CEO. On an unedited Center for Medical Progress (CMP) videotape viewed by Panel Staff, [ABR's procurement manager] stated that [the Founder and CEO] ". . . is totally unethical, she worked for us, she went into our office one night, looked around, and took everything we had, and started her own business, and quit the next day. I will tell you that."[134]

The U.S. Food and Drug Administration (FDA) had planned in 2014 to conduct an inspection of StemExpress based on the FDA's "priorities list."[135] The FDA only has jurisdiction over fetal tissue that is intended for transplantation into human subjects. The inspection was dropped after an FDA consumer safety officer determined that StemExpress:

> . . . essentially collected blood and tissue products including stem cells, whole blood, leukocytes, etc . . . from a human donor. . . . The company advertises for, collects from (on-site), and maintains, [a] potential donor database . . . . Their products are **not** intended for transplant, implant or transfer into a human recipient.[136]

The FDA consumer safety officer stated: "I plan to tell StemExpress that they do not have to register as a human tissue establishment [and thus are not under FDA jurisdiction] because they do not sell [a] product that is intended for transfer into a human recipient."[137]

b) History of the Panel's Interactions with StemExpress

On December 17, 2015, the Panel sent StemExpress a document request letter that requested a list of all entities from which it procured fetal tissue, a list of all entities to which it sold or donated fetal tissue, an organization chart, all communications that direct its employees to procure fetal tissue, a list of all federal funds the firm received, accounting records, and all StemExpress banking records related to the procurement, sale, donation, distribution or shipment of fetal tissue.[138]

StemExpress only produced the names of abortion clinics to the Panel from which it had procured fetal tissue that also had been previously produced to investigations into the fetal tissue industry conducted by the Senate Committee on the Judiciary and the House Committee on Energy and Commerce.[139] StemExpress refused to produce voluntarily the names of all of the clinics from which it procured fetal tissue.[140] Due to this lack of cooperation, on February 12, 2016, the Panel issued a subpoena to StemExpress. The subpoena demanded copies of the

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[134] Center for Medical Progress videotape produced to the Committee on Oversight and Government Reform, FNND0569_ 20140406173620.
[135] Email from [Consumer Safety Officer # 1], U.S. Food and Drug Administration, to [Consumer Safety Officer # 2], U.S. Food and Drug Administration (Aug. 15, 2014).
[136] *Id.* (emphasis in original).
[137] *Id.*
[138] Letter from Rep. Marsha Blackburn, Chairman, House Select Investigative Panel, to [Founder and CEO, StemExpress, LLC] (Dec. 17, 2015), Exhibit 5.1.1
[139] StemExpress Second Response to Senate Judiciary Committee. [STEM.JUD00000024; STEM.HOUSE SELECT 0057] Exhibit 5.1.
[140] StemExpress First Response to House Select Panel Document Requests (Jan. 15, 2016) Exhibit 5.2.

documents first requested in the December 17, 2015 letter, including the communications with its employees, accounting documents, and all banking records.[141]

StemExpress produced communications to the Panel that spanned only two years instead of the five required by the subpoena, and these were so replete with redactions as to render them unusable.[142] StemExpress produced only "roll-up" accounting summaries, not the required primary source accounting records.[143] To date, the Panel has not received a single accounting record from StemExpress.

The Panel, in a February 12, 2016, subpoena to StemExpress (which is discussed below), requested all communications and documents that identify any federal, state, or local government funds that StemExpress received either directly or indirectly.[144] StemExpress responded that it had nothing responsive to produce. ("StemExpress has confirmed that there are no communications or documents responsive to this . . . .")[145] Despite that representation, the Panel discovered that StemExpress received more than $9,000 in a small business loan from the U.S. Small Business Administration.[146]

StemExpress refused to produce any of its banking records as required by the subpoena. However, in a production from another entity, the Panel discovered the name of StemExpress' bank and its account number and issued a subpoena to that bank.[147] Due to StemExpress' refusal to comply with repeated subpoenas, on September 21, 2016, the Panel unanimously recommended that the House of Representatives hold StemExpress in contempt of Congress (for more details on this, see subsection 7: The Select Panel Recommends that the House Find StemExpress in Contempt of Congress).[148]

As Rep. Duffy (WI-7) noted during the meeting at which the contempt recommendation was voted:

> This committee nine months ago sent out a request for documents to StemExpress. And they failed to comply completely with that subpoena. Now, we have sent other subpoenas to tissue procurement businesses and they have complied. They had no problem sharing their information with this committee. But StemExpress, however, failed to fully comply. And we are not talking about really sensitive information. We are talking about their banking records, their accounting records. That is what we have asked for. What is in the

[141] Subpoena to StemExpress, LLP, (Feb. 12, 2016), Exhibit 5.3.
[142] StemExpress, Third Response to House Select Investigative Panel Subpoena (Apr. 11, 2016) [STEM.HOUSE.SELECT0064 – STEM.HOUSE.SELECT_0670], Exhibit 5.4.
[143] *See* Letter from Amandeep S. Sidhu, McDermott Will & Emery, to T. March Bell, Chief Counsel and Staff Director, House Select Investigative Panel 1 (Mar. 18, 2016) (emphasis in original); *See* Letter from Amandeep S. Sidhu, McDermott Will & Emery, to Rep. Blackburn, Chairman, House Select Investigative Panel 2 (May 6, 2016).
[144] Subpoena to StemExpress, Exhibit 5.3.
[145] *Id*., Exhibit 5.3
[146] *See* Center for Effective Government website, www.FedSpending.org.
[147] *See* Subpoena to Five Star Bancorp (Apr. 29, 2016).
[148] *See* Select Investigative Panel of the H. Comm. on Energy and Commerce, Business Meeting, unedited transcript (Sept. 21, 2016).

> banking and accounting records that is so secretive that they won't comply with a congressional lawful subpoena? That is the question that we have to ask ourselves. What don't they want us to know?[149]

The Panel had reason to ask the questions posed by Rep. Duffy. An examination by Panel staff of StemExpress' bank records found payments to Shred-It USA that, for the most part, corresponded with dates of document demand letters from congressional investigations of the fetal tissue industry, subpoenas from the Panel, and StemExpress productions to the Panel and other congressional inquiries. StemExpress bank records dating back to November 2012 revealed there were no payments made to Shred-It USA prior to the first congressional investigations into the fetal tissue industry.[150] The chart below shows those payments:

Congressional Action	**Payment to Shred-It-USA**	**StemExpress Action**
July 16, 2015 – Senate Judiciary Committee document request	August 13, 2015	August 19, 2015 – StemExpress production to Senate Judiciary Committee
August 7, 2015 – Energy & Commerce Committee document request	August 13, 2015	August 21, 2015 – StemExpress production to Energy & Commerce Committee
August 25, 2015 – Energy & Commerce Committee document request	August 25, 2015	September 11, 2015 – StemExpress production to Energy & Commerce Committee in response to questions from briefing
September 9, 2015 – Oversight & Government Reform Committee document request	September 29, 2015	October 9, 2015 – StemExpress production to Oversight & Government Reform Committee
September 17, 2015 – Senate Judiciary		September 24, 2015 – StemExpress production to Senate Judiciary Committee

[149] *Id.* at 27.
[150] Panel staff analysis of StemExpress, LLC, payments to Shred-It-USA drawn from documents produced by Five Star Bancorp to the Panel.

Committee document request letter		
December 17, 2015 – Select Investigative Panel document request	January 12, 2016	January 15, 206 – StemExpress production to Select Investigative Panel
	January 27, 2016	February 1, 2016 – StemExpress production to Select Investigative Panel
February 12, 2016 – Select Investigative Panel subpoena	March 12, 2016	March 28, 2016 – StemExpress production to the Select Investigative Panel
	April 26, 2016	May 10, 2016 – StemExpress production to Select Investigative Panel

2. StemExpress Business Model

StemExpress' business model was to obtain fresh fetal tissue from a large number of abortion clinics and provide on-demand fetal tissue to researchers around the world. In order to do that, the firm needed a ready supply of fetal tissue. The only way to achieve that was to dramatically increase the number of abortion clinics from which it obtained fetal tissue. In order to provide fetal tissue to the largest number of customers, StemExpress had to increase the number of abortion clinics from which it procured fetal tissue. A profile of [the Founder and CEO] published in July 2015, noted: "[StemExpress was] opening a branch in Washington, D.C., in the next three months and is looking at the possibility of a site in Europe as well."[151]

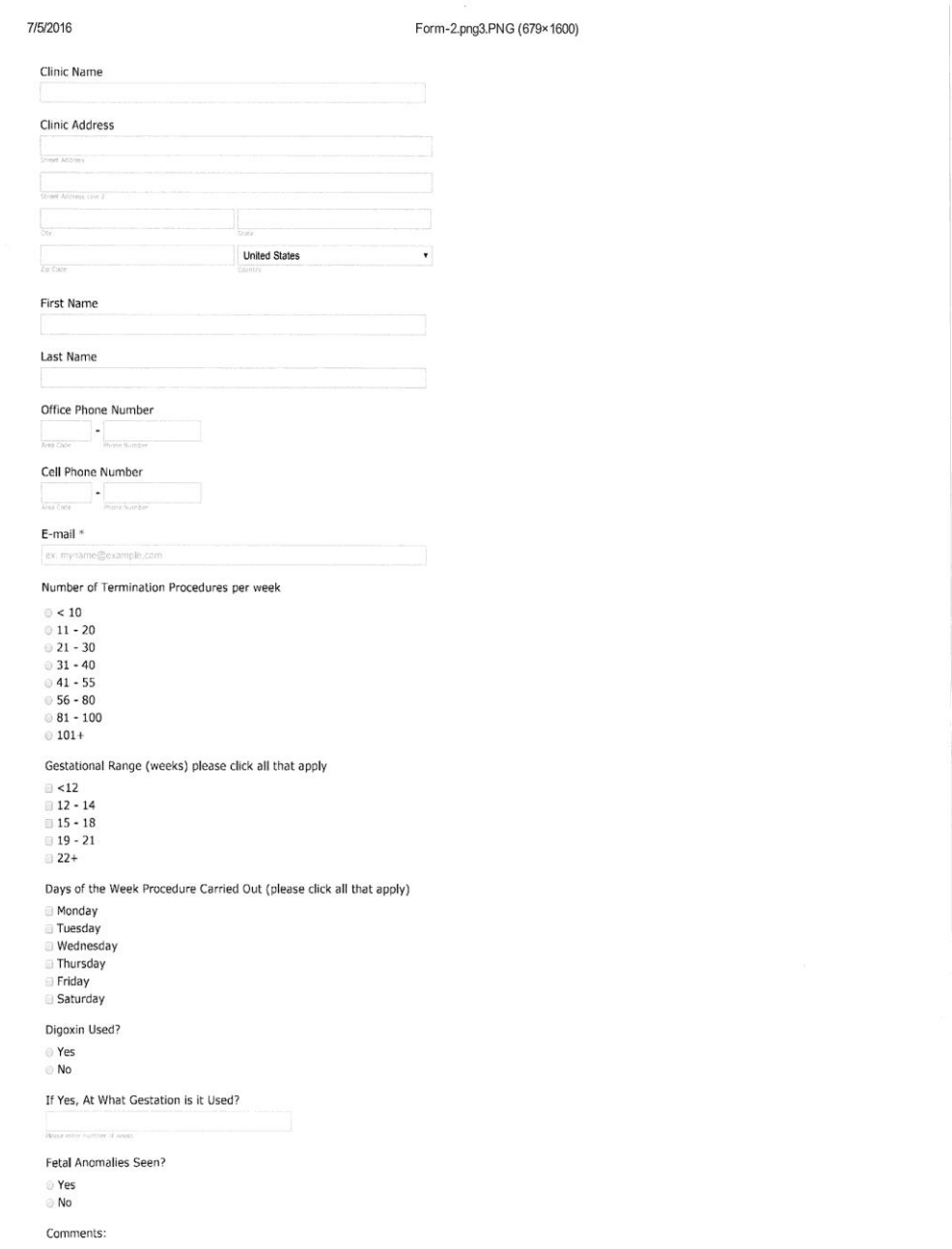
The Panel notes that StemExpress' entry into the tissue procurement business coincided with an increase in federal government grants for research using fetal tissue. The average amount of time for a researcher to obtain a grant for fetal tissue research from the National Institutes of Health (NIH) is three years. The Panel reviewed all grants that involved fetal tissue (see Chapter IX). That review found the number of grants using fetal tissue declined from fiscal years 2009 through 2012, but, starting in fiscal year 2013, there was an upsurge.

a) Marketing Activities

StemExpress recruited and screened abortion clinics from which it could procure saleable tissue for researchers.[152] The company sought information about the number of abortions the

[151] "2015 Women Who Mean Business: [Founder and CEO and StemExpress] founder and CEO, Stem Express [sic]," Sacramento Business Journal," June 19, 2015.
[152] StemExpress Website Recruitment Form for Abortion Clinics. See following page.

clinics performed each week, the gestational ages of fetuses scheduled to be aborted, the days the abortions were done, whether digoxin[153] was used (which would taint the tissue and thus render the tissue useless for research), and, if so, at what gestation digoxin was used. A copy of the Website Recruitment Form for abortion clinics follows:



7/5/2016 Form-2.png3.PNG (679×1600)

Clinic Name

Clinic Address

Street Address

Street Address Line 2

City State

Zip Code United States Country

First Name

Last Name

Office Phone Number

Area Code Phone Number

Cell Phone Number

Area Code Phone Number

E-mail *

ex: myname@example.com

Number of Termination Procedures per week

- < 10
- 11 - 20
- 21 - 30
- 31 - 40
- 41 - 55
- 56 - 80
- 81 - 100
- 101+

Gestational Range (weeks) please click all that apply

- <12
- 12 - 14
- 15 - 18
- 19 - 21
- 22+

Days of the Week Procedure Carried Out (please click all that apply)

- Monday
- Tuesday
- Wednesday
- Thursday
- Friday
- Saturday

Digoxin Used?

- Yes
- No

If Yes, At What Gestation is it Used?

Please enter number of weeks

Fetal Anomalies Seen?

- Yes
- No

Comments:

[153] Digoxin is a heart medication that sometimes is injected into the amniotic fluid or fetus to cause fetal demise before surgical or induction abortion. *See* Abortion in California: A Medical-Legal Resource, http://californiaabortionlaw.com/wp/?page_id=135.

The firm developed an aggressive marketing strategy directed toward abortion clinics. StemExpress had booths at both the 2014 and 2015 annual meetings of the National Abortion Federation (NAF). StemExpress was a silver-level sponsor at the NAF meeting: StemExpress paid NAF $5,000 for that status in 2014 and $10,000 in 2015.[154] StemExpress had a half-page advertisement in the program for both the 2014 and 2015 NAF meetings.[155] At the conferences, StemExpress distributed a brochure to NAF members that promised abortion clinics they would be "[f]inancially profitable" if they allowed StemExpress to procure tissue from the clinics. The brochure stated: "By partnering with StemExpress" the clinics will not only help research "but [they] will also be contributing to the fiscal growth of [their] own clinic[s]."[156] The full brochure and the two half-page ads follow.



[154] Email from name redacted, Vice President, Corporate Development, StemExpress, LLC, to name redacted, Subject: Partnership Agreement – StemExpress (Mar. 25, 2015) [NAF-000045]; Partnership Agreement between StemExpress, LLC, and the National Abortion Federation (Mar. 25, 2015) [NAF-000046 – NAF-000053], Exhibit 5.5.

[155] NAF 2014 and 2015 advertisements. *See* Exhibit 5.1.9.

[156] StemExpress, LLC, brochure distributed at National Abortion Federation Meeting, undated [NAF-000001 – NAF-000004]. NAF produced to the Panel a black-and-white version of the brochure. A color copy that is identical, with the exception of a StemExpress employee's business card, that the Panel found on the Internet is reprinted in the Report.



stem express

About StemExpress

StemExpress is a California-based biomedical company that provides qualified research laboratories with human cells, fluids, blood and tissue products for the pursuit of disease detection and cure. We procure, preserve, isolate and deliver cell lines exclusively to research facilities across the world. StemExpress products are not available for patient care. Stem Express is accredited by an independent biomedical Institutional Review Board.

"Our partnership with StemExpress is beneficial in a number of ways. First, it allows us to contribute to life-saving research that is advancing diagnostic and medical care. Second, StemExpress has a Plug-in Solution that allows us to add additional clinics quickly. Lastly, I feel confident that our patient's anonymity is secure through their strict protocols and practices."
[redacted] Planned Parenthood Mar Monte

Advancing BioMedical Research Together

Join the StemExpress partner program that fiscally rewards clinics for contributing to the advancement of life-saving research — with a solution that is easy to incorporate into your clinic practices. StemExpress is a California-based biomedical company that provides human tissue products ranging from fetal to adult tissues and healthy to diseased samples to many of the leading research institutions in the world. Our IRB approved protocols and consents protect you as well as donor's privacy in accordance with HIPAA guidelines.

Partnering with Obstetrical-Care Clinics

Cell-free fetal DNA circulates in maternal blood throughout pregnancy. Noninvasive, stem cell free methods to obtain fetal DNA are being used for earlier detection of genetic diseases as well as reproductive decision-making. Research pioneers who develop noninvasive diagnostic technologies rely on the blood samples that are collected from hospitals and clinics throughout the United States.



Easy to Implement Program + Financial Profits

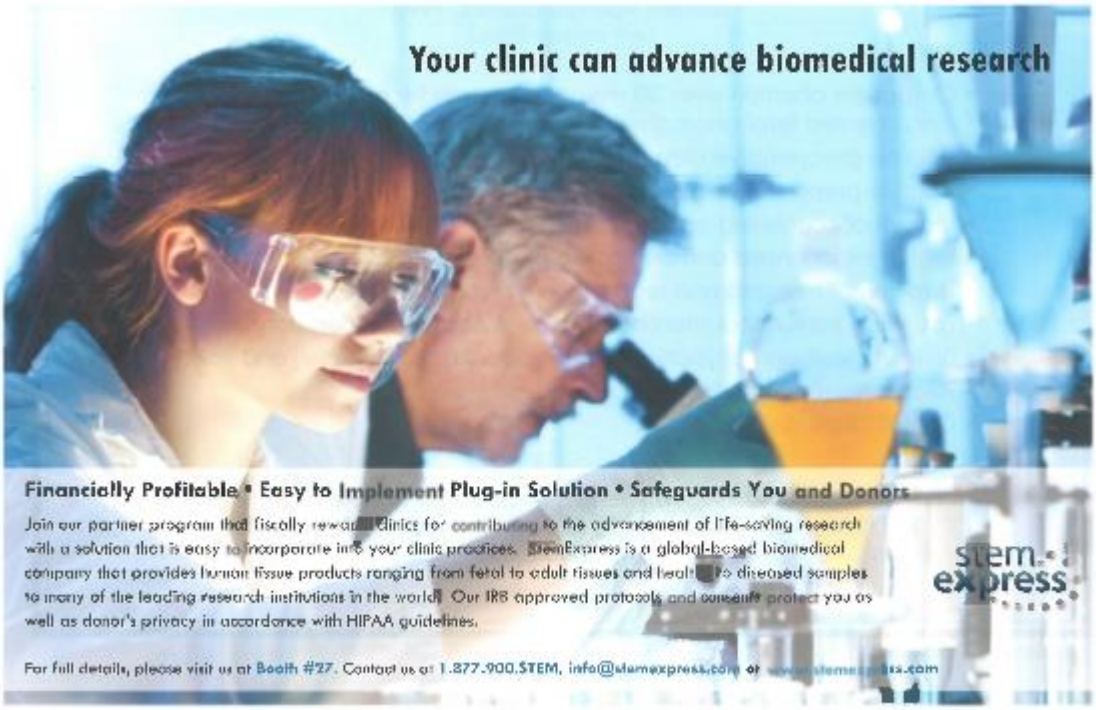
StemExpress promotes global biomedical research while also providing a financial benefit to your clinic. By partnering with StemExpress, not only are you offering a way for your clients to participate in the unique opportunity to facilitate life-saving research, but you will also be contributing to the fiscal growth of your own clinic. The stem cell rich blood and raw materials that are usually discarded during obstetrical procedures can, instead, be expedited through StemExpress to research laboratories with complete professionalism and source anonymity.



[redacted]

NAF 2014 Conference




Your clinic can advance biomedical research
Financially Profitable • Easy to Implement Plug-in Solution • Safeguards You and Donors
Join our partner program that fiscally rewards clinics for contributing to the advancement of life-saving research with a solution that is easy to incorporate into your clinic practices. StemExpress is a global-based biomedical company that provides human tissue products ranging from fetal to adult tissues and healthy to diseased samples to many of the leading research institutions in the world. Our IRB approved protocols and consents protect you as well as donor's privacy in accordance with HIPAA guidelines.
For full details, please visit us at Booth #27. Contact us at 1.877.900.STEM, info@stemexpress.com or
stem express

b) StemExpress Seeks a Nationwide Network of Abortion Clinics

During the timeframe of StemExpress' conference marketing scheme, it sought a contractual relationship with NAF, a national association of independent abortion clinics. Documents produced by NAF to the Panel reveal that, for at least a year, StemExpress and NAF actively negotiated a "Group Purchasing" contract. This effort revealed StemExpress' strategy to increase the number of abortion clinics from which it obtained fetal tissue, thereby enabling StemExpress to both promise customers a quick response *and* achieve higher revenues.

The Panel sought to understand the proposed NAF-StemExpress relationship. The proposed partnership agreement raises questions of whether StemExpress and NAF both saw the proposed contract as a means to increase their respective revenue streams.

An email NAF produced to the Panel shows that the negotiations with StemExpress date back to at least February 2014. On February 20, 2014, NAF's Group Purchasing Manager sent an email that stated:

> I spoke with [name redacted] from Stem Express [sic] today regarding them becoming a Group Purchasing vendor in the program. As [name redacted] and I discussed yesterday theirs is a unique service that would not fall under the 3% administrative fee realm. From my conversation today I feel it is even more unique than I initially anticipated.
>
> Here is a summarization of the process as [named redacted] described it:
>
> 1. Stem Express collects the maternal blood from the patient and/or the fetal tissue after the procedure.
> 2. Either a Stem Express employee located at the clinic or a clinic employee gathers and stores the collection.
> 3. The collection (product) is sent to the lab and cells are isolated for research.
> 4. The participating clinic is paid by Stem Express a fee per collection.
>
> The fact that Stem Express is the payer and our member is the payee changes the fee structure. Perhaps we can access a fee or value for each member that participates or base it on financial payouts to the member. For instance, when a member is paid up to $500, Stem Cell [sic] would owe X amount to NAF or a flat yearly fee based on the number of participating members.

> I know the final decision would be [name redacted]'s regarding payment terms however I wanted to have a concrete suggestion to put forth. What are your thoughts?[157]

An unidentified person at NAF responded on February 20, 2014: "I like the idea of setting benchmarks and NAF getting fees based on usage."[158] StemExpress and NAF actively and repeatedly discussed the proposed draft contract in email exchanges.

In August 2014, StemExpress' accounting manager told a person within the company whose name was redacted: "This [proposed contract with NAF] looks like it aligns better with us."[159] On October 24, 2014, an unknown person at NAF emailed StemExpress: "Just checking in to see how the vendor agreement is coming."[160] In January 2015, [the Founder and CEO] sent an email to an unidentified person at NAF in which she explained that the StemExpress official charged with negotiating the NAF agreement "is no longer with the company and I wanted to make sure the vendor agreement doesn't get put on back burner so could you please resend this agreement and we will get it turned around to you."[161] An unidentified person at NAF responded:

> Well that explains her lack of response. I am glad you are still interested.
>
> I have attached an initial draft of an agreement. As I explained to [name redacted] this is unique as it is not a product therefore the standard admin[istrative] fee process does not apply.
>
> Please review the attached and fill in the blanks. Let me know if we need to [set up] a call to discuss.
>
> On another note, we are gearing up for our Annual Meeting in Baltimore. I will have a prospectus in the next week or so.[162]

On January 15, 2015, [the Founder and CEO] sent an email to NAF in which she stated:

> Attached is the draft agreement with marked up comments. It might be best to set up a conference call next week to discuss this in further detail as a lot of this agreement had language in it that looked like it was for a professional liability insurance company, which we clearly

[157] Email from Group Purchasing Manager, National Abortion Federation, to [redacted], Subject: RE: Stem Express [sic] GP Vendor (Feb. 20, 2014) [NAF-000016] (spacing in original), Exhibit 5.6.
[158] Email from [redacted] to [redacted], Subject: RE: Stem Express [sic] GP Vendor (Feb. 20, 2014) [NAF-000016], Exhibit 5.6.
[159] Email from [redacted], Accounting Department Manager, StemExpress, LLC, to [redacted], StemExpress, LLC, Subject: RE: NAF GP membership (Aug. 8, 2014) [NAF-000034], Exhibit 5.7.
[160] Email from [redacted], National Abortion Federation, to [redacted], StemExpress, LLC, Subject: RE: NAF GP membership (Oct. 24, 2014) [NAF-000034], Exhibit 5.7.
[161] Email from [redacted], CEO and Founder, StemExpress, LLC, to [redacted], Subject: RE: NAF GP membership (Jan. 6, 2015) [NAF-000033], Exhibit 5.8.
[162] Email from [redacted], National Abortion Federation, to [redacted] (Jan. 8, 2015) [NAF-000033], Exhibit 5.8.

> aren't, so I just wanted to make sure that we were on the same page about what should be included in this agreement.[163]

On February 18, 2015, [the Founder and CEO] wrote NAF: "I haven't forgotten to send this I have just been buried . . . I have been in the process of updating a few contracts here at the beginning of the year. The clinic contract is one of them. We should have it to you in the next two weeks."[164] NAF replied on February 27, 2015, "I have attached a revised agreement. Please submit any changes and contact me with any questions."[165]

In March 2015, StemExpress' vice president for corporate development sent NAF the firm's revised version of the partnership agreement:

> Please find a draft Partnership Agreement for your consideration. I've taken the liberty of reformatting a bit of it to follow our more-routine contract structure (no real change to the substantive contract). I removed the language pertaining to alternative donations ($5K and $10K) since we elected to go with $10K and participate in the upcoming NAF meeting . . . There will appear to be a lot of redlining in the Appendix, but this is largely an artifact of changing the content to reflect StemExpress business . . .
>
> If the agreement with changes are acceptable to you, please 'accept changes,' sign and return to me at your earliest convenience. If you need to make changes, please reply with your redline as soon as possible and I'll get the document turned around promptly.[166]

Below are excerpts of the March 25, 2015, draft partnership agreement between StemExpress and NAF:

> Services and Donation:
>
> (a) NAF commits to performing the services outlined in this document under Appendix A.
> (b) StemExpress agrees to make a donation to the NAF in the amount of US $10,000 and undertake the activities listed in Appendix B . . .

[163] Email from [redacted], CEO and Founder, StemExpress, LLC, to [redacted], Subject: RE: NAF GP membership (Jan. 15, 2015) [NAF-000023]; Purchase Agreement between NAF and StemExpress, LLC (Jan. 10, 2015) [NAF-000024 – NAF-000032], Exhibit 5.9.
[164] Email from [redacted], CEO and Founder, StemExpress, LLC, to [redacted], Subject: FWD: NAF GP membership (Feb. 18, 2015) [NAF-000036], Exhibit 5.10.
[165] Email from [redacted], to [redacted], StemExpress, LLC, Subject: RE: NAF revised agreement (Feb. 27, 2015). [NAF-000036]; Partnership Agreement between the National Abortion Federation and Stem Express [sic], undated [NAF-000037 –NAF-000044], Exhibit 5.10.
[166] Email from [redacted], Vice President, Corporate Development, StemExpress, LLC, to [redacted], Subject: Partnership Agreement – StemExpress (Mar. 25, 2015). [NAF-000045]; Partnership Agreement between StemExpress, LLC, and the National Abortion Federation (Mar. 25, 2015) [NAF-000046 – NAF-000053], Exhibit 5.11.

Appendix A

NAF's Commitment

For the aforementioned sum mentioned in the section marked "Payment for Services," NAF commits to performing the following for one year to assist StemExpress in presenting its collection program to NAF members:

- Create and disseminate to NAF members correspondence from NAF's Group Purchasing Manager about StemExpress and the collection program twice yearly at the request of StemExpress.
- . . . Provide a cover letter for NAF's President and CEO pertaining to the StemExpress collection program which StemExpress can use to accompany marketing materials for NAF members.
- . . . Provide mailing list for StemExpress to send out marketing materials to NAF members regarding the background of StemExpress, its collection program, and benefits of member participation in the program.
- Provide assistance to StemExpress in gathering testimonials from existing program participants from among NAF members.
- . . . Supply StemExpress with a quarterly updated list of members.

Appendix B

StemExpress' Commitment

StemExpress commits to performing the following for one year to market its collection services to NAF members:

- . . . Create and produce marketing "slicks" on the background of StemExpress, its capabilities, and highlight participation benefits.
- Provide, at no charge to NAF, informative sessions or meetings that present the collection program.
- Develop client success stories on how StemExpress brought a value added service to participating members. This will help to inform members about StemExpress' offerings.
- Commit to attending NAF's Annual Meeting in April of each year.
- Pursue all leads from NAF, introducing StemExpress and what StemExpress' capabilities are.[167]

[167] *See* StemExpress, Third Response to House Select Investigative Panel Subpoena (Apr. 11, 2016) [STEM.HOUSE.SELECT0064 – STEM.HOUSE.SELECT_0670], Exhibit 5.4.

In April 2015, NAF replied:

> My apologies as my promise to respond by COB today comes with a delay. There is cause for concern regarding the added text under the Assignment section. It denotes, "StemExpress may assign this Agreement to an acquirer without notice . . . pursuant to an acquisition or merger of StemExpress involving greater than 50% of the company, provided further, that any respective successor or permitted assign shall thereby assume all of such StemExpress' rights, and shall be subject to all of such StemExpress' duties and obligations, hereunder.
>
> That clause takes away a discretion that is essential to the prescreen process and creates [a] privacy concern that we go to great lengths to protect. Although I agree there is no other changes that impact the substantive content, [name redacted], our general counsel, is giving it a quick read. I did think however that in the interest of time, you could respond to the deletion request noted above.[168]

NAF produced no further communications about its proposed partnership agreement with StemExpress. However, NAF's counsel told Panel staff that, during the timeframe when the Center for Medical Progress videos were made public, the organization's leadership had significant concerns about being involved with a tissue procurement business.

The Panel determined that StemExpress' brochure aimed at abortion clinics nationwide, and its attempted partnership agreement with NAF belies StemExpress' contention that it was losing money. Rather, those facts show StemExpress had a business model based on expansion of its market share.

c) StemExpress Seeks Partnership Agreement with Planned Parenthood Federation of America

Just as StemExpress sought a relationship with NAF, it also sought a contract with Planned Parenthood Federation of America (PPFA) and its affiliates. If the proposed relationships with PPFA and NAF had been successful, StemExpress would have had access to virtually every abortion clinic in the nation. [PP Witness #1] stated:

> So, we tried to do this, and at the national office we have a Litigation and Law Department that just really doesn't want us to be the middle people for this issue, right now. Because we were actually approached by StemExpress to do the same thing. One of the California affiliates said, "We're working with these people, we love it, we think every affiliate should work with them." And so we had a conversation, and we said, you know, what if we go out and

[168] Email from [redacted], National Abortion Federation, to [redacted], StemExpress, LLC, (Apr. 9, 2015) [NAF-00063], Exhibit 5.11.

> find everyone who is doing this and present everybody with a menu, and at the end of the day they just decided that right now, it's just too touchy an issue for us to be an official middleman.[169]

In a conversation with a CMP journalist, [PPFA Witness #3] confirmed that one of the major reasons that held PPFA back from a partnership agreement with a tissue procurement organization was because "we have [the] potential for a huge PR issue on doing this."[170] Despite PPFA's hesitancy due to public relations, StemExpress already had contracts with a number of PPFA affiliates.

d) StemExpress' Contracts with Abortion Clinics

StemExpress had contracts to procure fetal tissue from the following PPFA affiliates:

- Planned Parenthood Mar Monte (PPMM)
- Planned Parenthood Shasta Pacific (PPSP); and
- Planned Parenthood of Santa Barbara, Ventura & San Luis Obispo Counties (PPSB).[171]

StemExpress also had contracts with the following five independent abortion clinics:

- Camelback Family Planning (CFP)
- Cedar River Clinics (CRC)
- Presidential Women's Center (PWC)
- Women's Health Specialists (WHS)
- Family Specialists Medical Group (FPS)
- Little Rock Family Planning Services (LRFPS).[172]

Documents show that StemExpress never procured fetal tissue from Planned Parenthood San Bernardino, Women's Health Specialists, or Little Rock Family Planning Services.[173]

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[169] Center for Medical Progress, Transcript of Meeting with [PP Witness #1] 28-29 (July 25, 2014).

[170] Center for Medical Progress video FNND0569_ 20150226165708 (Feb. 26, 2015) produced to the Committee on Oversight and Government Reform.

[171] Exhibit 5.4; Services Agreement between StemExpress, LLC, and Planned Parenthood Mar Monte (Apr. 1, 2010) [STEM.HOUSE.SELECT_0167 – STEM.HOUSE.SELECT_0189], Services Agreement between StemExpress, LLC, and Planned Parenthood Shasta Pacific (May 5, 2012) [STEM.HOUSE.SELECT_0170 – STEM.HOUSE.SELECT_0172], Services Agreement between StemExpress, LLC, and Planned Parenthood of Santa Barbara, Ventura & San Luis Obispo Counties (Oct. 23, 2013) [STEM.HOUSE.SELECT_0181 – STEM.HOUSE.SELECT_0183], Exhibit 5.12.

[172] StemExpress, LLC, produced to the Panel invoices covering numerous years from Planned Parenthood Mar Monte, and Planned Parenthood Shasta Pacific. Camelback Family Planning, Cedar River Clinics, Presidential Women's Center, and Family Specialists Medical Group produced to the Panel invoices to StemExpress, LLC. *See* Letter from Mark Merin, counsel to Women's Health Specialists, to Panel staff 2-3 (Apr. 11, 2016); Letter from Bettina E. Brownstein, counsel for Little Rock Family Planning Services 1 (Oct. 10, 2016).

[173] Services Agreement between StemExpress, LLC, and Camelback Family Planning, undated [CFP000002 – CFP000006], Services Agreement between StemExpress, LLC, and Cedar River Clinics (Nov. 15, 2013) [CRC001 – CRC 006], Services Agreement between StemExpress, LLC, and Presidential Women's Center (Feb. 14, 2014) [PWC-0001 – PWC0003], Exhibit 5.13; Letter from Mark Merin, counsel to Women's Health Specialists, to Panel staff (Apr. 11, 2016); Letter from Bettina E. Brownstein, counsel for Little Rock Family Planning Services 1 (Oct. 10, 2016)

Under the terms of its contracts:

- StemExpress paid Planned Parenthood Mar Monte $55 for each fetal tissue specimen and $10 for each maternal blood sample.[174]

- StemExpress paid Planned Parenthood Shasta Pacific $55 for each fetal tissue specimen and $10 for each maternal blood sample.[175]

- StemExpress had a two-tier payment plan with Planned Parenthood San Bernardino: $75 for fetal tissue samples and $50 for maternal blood, if it was "collected solely" by Planned Parenthood San Bernardino staff; if StemExpress staff collected the samples, "then there would be a cost adjustment . . ."[176]

- StemExpress paid Camelback Family Planning $200 for 5cc or more of liver tissue and three tubes of maternal blood; $250 for 5cc of liver and thymus of the same fetus and three tubes of maternal blood; and $75 for other fetal tissue "as requested by StemExpress" with three tubes of maternal blood.[177]

- StemExpress paid Cedar River Clinics $50 for maternal blood; $75 for each fetal tissue specimen; $125 for fetal tissue with an IDS blood sample; $125 for maternal blood and tissue kits; between $100 - $400 for fetal blood samples; $50 for blood; $75 for each fetal tissue specimen; and face value ($25) for gift cards distributed to "blood donors," if Cedar River Clinics staff collected the blood and tissue.[178]

- StemExpress paid Presidential Women's Center $50 per 60cc of maternal blood, and $75 for each fetal tissue specimen, if collected solely by clinic staff:[179] "If StemExpress staff is onsite to physically collect the sample, then there would be a cost adjustment for the collection of the sample."[180] StemExpress paid Family Specialists Medical Group $55 for each tissue sample, and $10 for maternal blood.[181]

[174] Exhibit 5.12. H. Res. 461 did not mention maternal blood; thus, the Panel did not examine StemExpress' role in the procurement or sales of maternal blood. StemExpress' practices when it came to the procurement and sale of maternal blood are indicative of its profit-driven business model, and will be discussed in the Revenue Growth section below.
[175] *Id.*
[176] *Id.*
[177] Services Agreement between StemExpress, LLC, and Camelback Family Planning, undated [CFP000002 – CFP000006], Exhibit 5.13.
[178] Services Agreement between StemExpress, LLC, and Cedar River Clinics (Nov. 15, 2013) [CRC001 –CRC 006], Exhibit 5.13.
[179] Services Agreement between StemExpress, LLC, and Presidential Women's Center (Feb. 14, 2014) [PWC-0001 – PWC0003], Exhibit 5.13.
[180] *Id.*
[181] *Id.*

- StemExpress paid Women's Health Specialists $50 per 60 ccs of maternal blood and $75 "for the collection of fetal tissue, including each tissue organ/component (e.g., 1 heart, 1 liver, 1 brain = 3 component[]s X $75 each = $225) . . ."[182]

e) Impact of StemExpress Contracts on Clinical Practices

The Panel sought to determine whether the clinics changed their clinical practices in order to increase the amount of tissue samples StemExpress could obtain and thereby generate more revenue to the clinics. Through its review of the unedited CMP videotapes, the Panel learned that Cedar River Clinics (CRC), by its own admission, changed its clinical practices. [Clinic Executive #1] had the following exchange with a CMP journalist:

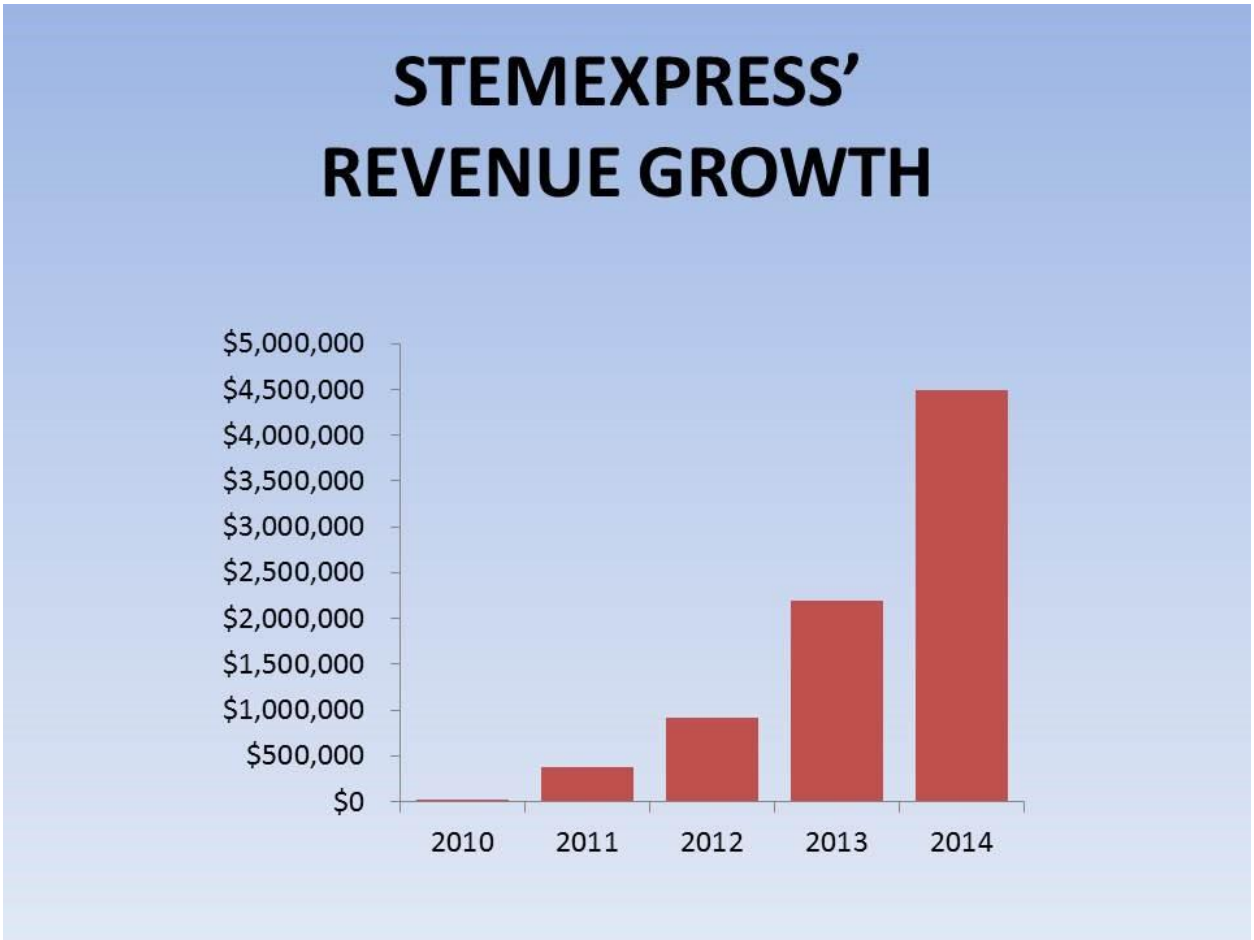
> CMP Journalist: [C]ould we just get a certain number of liver from you.
>
> [Clinic Executive #1]: Liver's a big thing right now. We just actually increased our gestation for dig[oxin], so that we could be able to get more liver, bigger liver.[183]

[PP Witness #1] testified that she changed abortion procedures to procure specific orders for fetal tissue (see Chapter VIII). [PP Witness #1] made similar statements on a Center for Medical Progress videotape.

3. StemExpress Revenue Grows from $156,312 to $4.5 Million

Between 2010 and 2014, StemExpress experienced tremendous revenue growth. In 2010, its revenue was $156,312. During 2011, that figure more than doubled to $380,000, and a year later, in 2012, StemExpress' revenue nearly tripled to $910,000. By 2013, its revenue was $2.20 million, and in 2014, the revenue had once again more than doubled to $4.50 million.

[182] Letter from Mark Merin, counsel to Women's Health Specialists, to Panel staff (Apr. 11, 2016), Exhibit 5.13.
[183] Center for Medical Progress videotape FNND0569_20140407161401 (Apr. 7, 2014) produced to the Committee on Oversight and Government Reform.



A profile of [the Founder and CEO] noted:

> She started StemExpress with just $9,000, running the business out of her Placerville home. She quickly found that there was indeed a demand for the company's products. Several new clients contacted her each week, without any active marketing, as word about StemExpress spread along the scientific grapevine.
>
> The company ranked No. 363 [in 2014] on the lnc. 500 list of fastest growing private companies, with 1,315 percent growth over three years and revenue of $2.2 million in 2013, and it ranked No. 35 on lnc.'s list of the fastest growing women-led companies in the country.[184]

The Panel sought to determine an accurate picture of StemExpress' revenues and costs associated with fetal tissue procurement. StemExpress presented conflicting accounts. For

[184] "2015 Women Who Mean Business: [Redacted], founder and CEO, StemExpress," Sacramento Business Journal, June 19, 2015.

example, [the Founder and CEO] stated to the Committee on Energy and Commerce: "StemExpress believes that it is losing money [on fetal tissue]."[185] StemExpress produced a list to the Panel of its estimated costs and expenses associated with fetal tissue procurement which purported to show that StemExpress lost money on fetal tissue.[186] StemExpress' counsel represented that the reports "were generated by StemExpress personnel directly from the company's accounting and software systems."[187] When she was asked to document StemExpress' costs to obtain fetal tissue, [the Founder and CEO] stated that "StemExpress doesn't have a spreadsheet or matrix for all of its costs," and acknowledged that the firm's estimated costs and expenses were produced by the firm's lawyers.[188] These conflicting statements redoubled the Panel's efforts to obtain accounting records.

a) StemExpress' Estimated Costs and Expenses Indicates That It May Have Made a Profit

A comparison of invoices, attorney-created accounting documents, and productions from multiple StemExpress customers shows that the firm may have made a profit when procuring and transferring fetal tissue. The Panel's cost analysis shows StemExpress overstated some of its labor costs, and claimed shipping, supplies, and infectious disease screenings as expenses. These costs were charged to researchers and thus cannot be costs that StemExpress can count against its revenue. StemExpress has consistently refused to produce subpoenaed accounting documents that the Panel requires to complete its analysis.

Attorneys for StemExpress created several cost estimates (orange numbers) that purport to show that StemExpress loses money each time it procures a fetal tissue sample and ships it to a customer. Shown in orange, the cost estimates produced by the attorneys are inconsistent with accounting records produced by StemExpress itself. For example, the Panel determined there was a discrepancy among the firm's cost items, StemExpress' contracts with the abortion clinics at which it procured fetal tissue, and invoices from abortion clinics to StemExpress. The firm contended that $55 for clinic reimbursement consisted of technician space, storage of supplies, blood draw chair usage, and consent space. Both the contracts with the abortion clinics and the invoices from the abortion clinics to StemExpress show the firm paid $55 per fetal tissue sample. In another example, the management labor costs at one hour per item ordered, which are counted twice, are dramatically inconsistent with the number of orders actually handled by StemExpress. Similarly, StemExpress estimates do not allocate any costs (such as mileage) to maternal blood which is harvested at the abortion clinic at the same time the human fetal tissue is harvested.

[185] StemExpress Briefing Notes, Committee on Energy and Commerce (Aug. 25, 2015), Exhibit 5.14.
[186] StemExpress, LLC, StemExpress Estimated Costs and Expenses Associated with Fetal Tissue Procurement (2011-2016) (May 10, 2016) [STEM.HOUSE.SELECT_0915], Exhibit 5.15.
[187] StemExpress, LLC, StemExpress Sixth Response to House Select Panel Subpoenas (May 10, 2016) [STEMHOUSE.SELECT_0908], Exhibit 5.16.
[188] StemExpress Briefing Notes, Exhibit 5.14.

COMPARISON OF STEMEXPRESS COST ANALYSIS WITH GENERALLY ACCEPTED INDUSTRY STANDARDS FOR ONE UNIT OF FETAL TISSUE IN 2013

COST ITEMS AND ESTIMATE PRODUCED BY STEMEXPRESS

ADJUSTED BASED ON REASONABLE INDUSTRY STANDARDS

COSTS ALLOCATED TO MATERNAL BLOOD ESTIMATED AT 50%

Cost Item	Description	Estimated Time	Estimated Cost/Expense	Recalculated Time	Recalculated Cost/ Expenses	½ Costs for Maternal Blood
Procurement Management Labor	Receive and evaluate purchase order, enter into Computer system and task board, assign to clinics.	1 hour x $35	**$25.00**	.5 hour x $35	$12.50	**$ 6.25**
Packaging Supplies Labor	Packaging all supplies needed for procurement.	1 hour x $10	**$10.00**	.5 hour x $10	$5.00	**$2.50**
Shipping	Supplies to Clinic	N/A	**$15.00**		$15.00	**$7.00**
Mileage	Mileage paid to technician (.56/mile)	N/A	**$75.00**		$75.00	**$35.00**
Supply cost	Box, conical tube, media, petri dish, labels, biohazard bag, gel packs, etc.	N/A	**$30.00**		$30.00	**$15.00**
Technician Base Labor	Patient consent, procurement, paperwork packaging.	8 hour x $10	**$80.00**	1 hour x $10	$10.00	**$5.00**
Technician Supplemental Compensation	Technician Supplemental Compensation	N/A	**$30.00**		$0.00	**$0.00**
Clinic Reimbursement	Technician space, storage of supplies, blood draw chair usage, consent space	N/A	**$55.00**		$55.00	**$27.50**
Infectious Disease Draw	Supplies: tubes, labels, needle, biohazard bag, etc.	N/A	**$15.00**		$15.00	**$7.50**
Infectious Disease Screening	Screening for HIV, HepB, HepC, LCMV	N/A	**$70.00**		$70.00	**$35.00**

Shipping	Average Shipment cost to the Lab (blood and/or tissue)	N/A	**$20.00**		$20.00	**$10.00**
Procurement Management Labor	Review paperwork, communications with courier, communications with researcher	1 hour x $35	**$35.00**		$35.00	**$5.00**
Product Receipt	Receipt of product at front desk, check into Sage, check into log	1 hour x $15	**$15.00**	.25 hour x $15	$4.00	**$2.00**
Inventory & Supply Management	Prorated stores management	1 hour x $20	**$20.00**	.25 hour x $20	$5.00	**$2.50**
			$495.00		**$351.50**	**175.75**

Sample review of a sale of maternal blood to customer Baylor per invoice #1940 of 1/12/2013

Sale price for Tissue $250.00

Disease screening charged to client $125.00

Shipping charged to client $85.00

Total Revenue obtained from this sale $460.00

Estimated cost of Tissue (per above) $175.75

Sample review of a sale of fetal tissue to customer Baylor per invoice #1940 of 1/12/2013

Sale price for Tissue $250.00

Disease screening charged to client $125.00

Shipping charged to client $85.00

Total Revenue obtained from this sale $460.00

Estimated cost of Tissue (per above) $351.00

b) StemExpress Used Deceptive Trade Practices to Obtain Maternal Blood at Zero Cost

The Panel's investigation revealed that, while StemExpress paid market prices for maternal blood in some settings, it obtained blood from abortion clinic patients without payment to the women.

While blood donations and sales are not covered by 42 U.S.C. § 289g-2, StemExpress' procurement and sales of maternal blood is indicative of how profit drove the company. StemExpress paid abortion clinics between $10 and $75 for maternal blood. StemExpress paid nothing to the blood donors at the clinics, with the sole exception of Cedar River Clinics, where it provided $25 gift cards to patients who donated blood. Outside of abortion clinics, however, StemExpress directly paid donors. The Panel obtained a photograph that demonstrates that StemExpress offered women the opportunity to "Donate your blood and Get $25."[189] The photograph of a company booth, has a sign on it which states: "Need Cash: $25 . . . per [blood] donation . . ."[190] For example, a brochure that sought blood donations produced by StemExpress to the Panel shows that the firm paid women outside of abortion clinics: "All of our donors receive a gift card for their donation ranging from $25-$250. . . . In 2014 StemExpress gave out over $140,000 in gift cards to donors . . ."[191]

StemExpress' website shows it sold (and continues to do so) maternal blood for between $340 and $510;[192] peripheral blood for between $115 and $2,464;[193] and umbilical cord blood for between $76 and $10,885.[194] StemExpress' collection of blood shows that the firm's focus is on profits, not on informing patients in abortion clinics who donate their blood that they have the opportunity to be paid for their blood elsewhere.

The Panel sought to determine the attitude of StemExpress' contractors, PPFA and its affiliates, toward StemExpress' practice of how it obtained blood. The PPFA executive responsible for the organization's medical guidelines and practices was asked repeatedly by the Panel whether she was troubled by StemExpress' remuneration for women's blood outside of abortion clinics, while it paid nothing for the blood of vulnerable women who were about to undergo an abortion. Despite repeated questions, the senior PPFA executive declined to answer.[195]

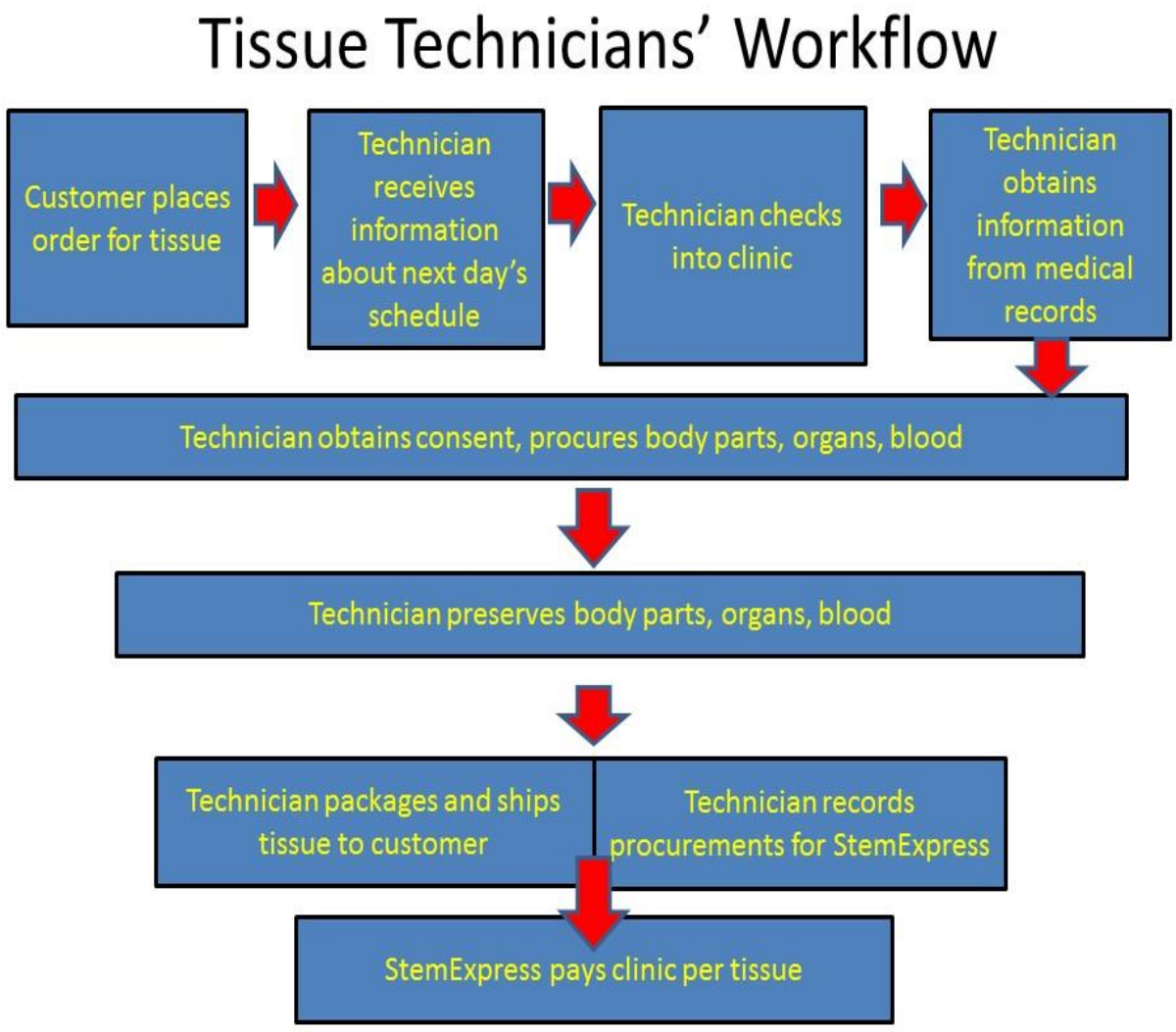
StemExpress made up to $10,875 in profit for sale of an individual blood product. While there is no law that bars a firm from valuable consideration for the sale of maternal or umbilical blood, the fact that StemExpress had such a large profit margin on its blood is key to understanding the firm.

---

[189] Photograph of StemExpress, LLC, blood donation booth, Exhibit 5.17.
[190] Transcribed Interview of [PP Witness #1](Oct. 6, 2016) at 20.
[191] StemExpress, LLC, Donate Blood and Bone Marrow with StemExpress, undated 2 [STEM.HOUSE.SELEC_0192 – STEM.HOUSE.SELECT_0195], Exhibit 5.18.
[192] StemExpress website, Maternal Blood, http://stemexpress.com/product-category/maternal-blood/
[193] StemExpress website, Peripheral Blood, http://stemexpress.com/product-category/peripheral-blood/.
[194] StemExpress website, Umbilical Cord Blood, http://stemexpress.com/product-category/umbilical-cord-blood/.
[195] *See* Transcribed Interview of [PP Witness #1] (Nov. 1, 2016).

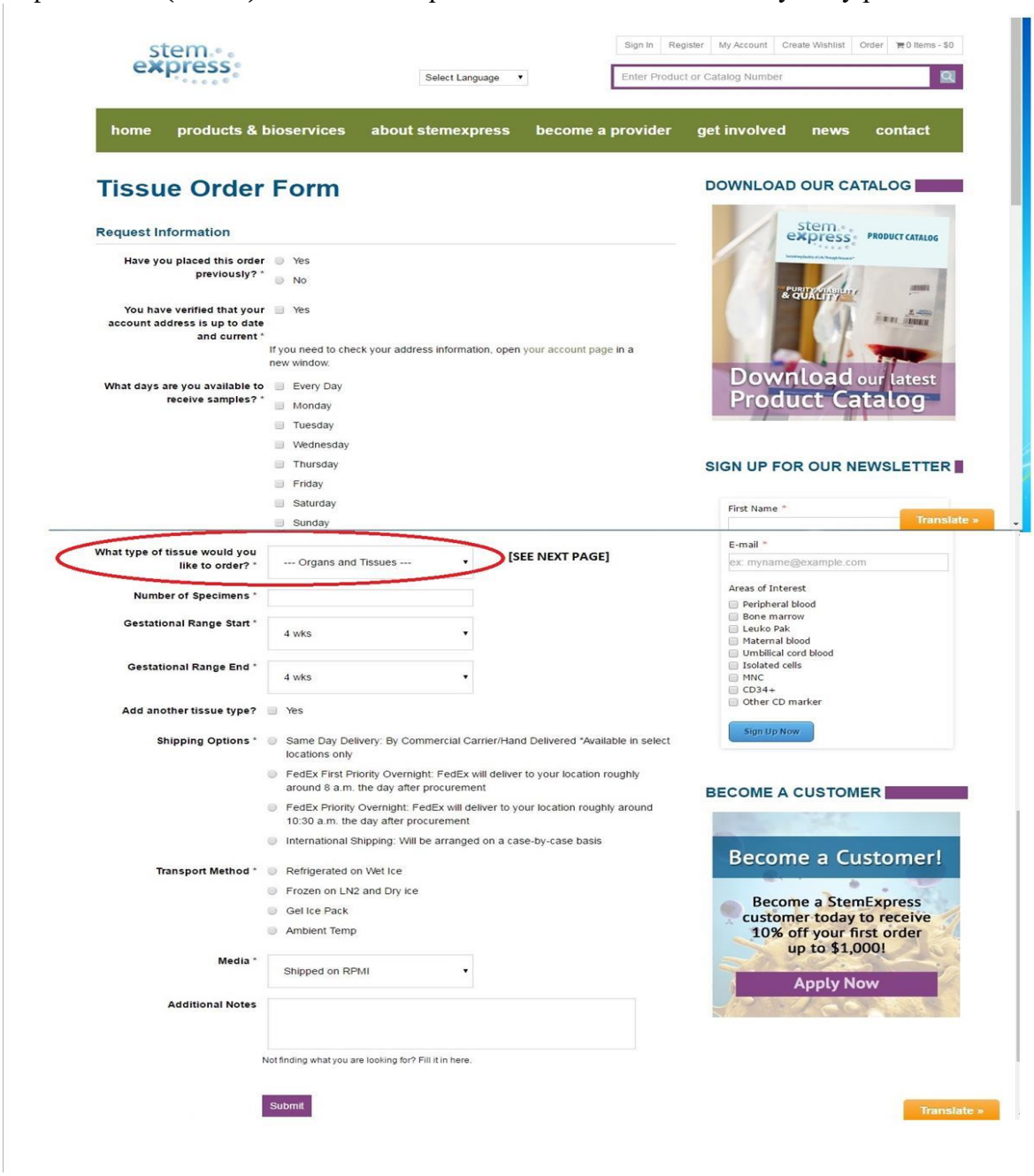
4. StemExpress Tissue Technicians Embedded in Planned Parenthood Affiliates: A Typical Day

The Panel sought to determine whether the PPFA affiliates that had contracts with StemExpress had any allowable costs under 42 U.S.C. § 289g. Documents produced by StemExpress show the clinics did not. StemExpress had tissue technicians embedded in the PPFA affiliates. The technicians obtained consent to donate fetal tissue from women scheduled to undergo abortion. They procured the fetal tissue, packaged it, and shipped it directly to StemExpress' customers. The chart below depicts the typical day of a StemExpress embedded tissue technician:

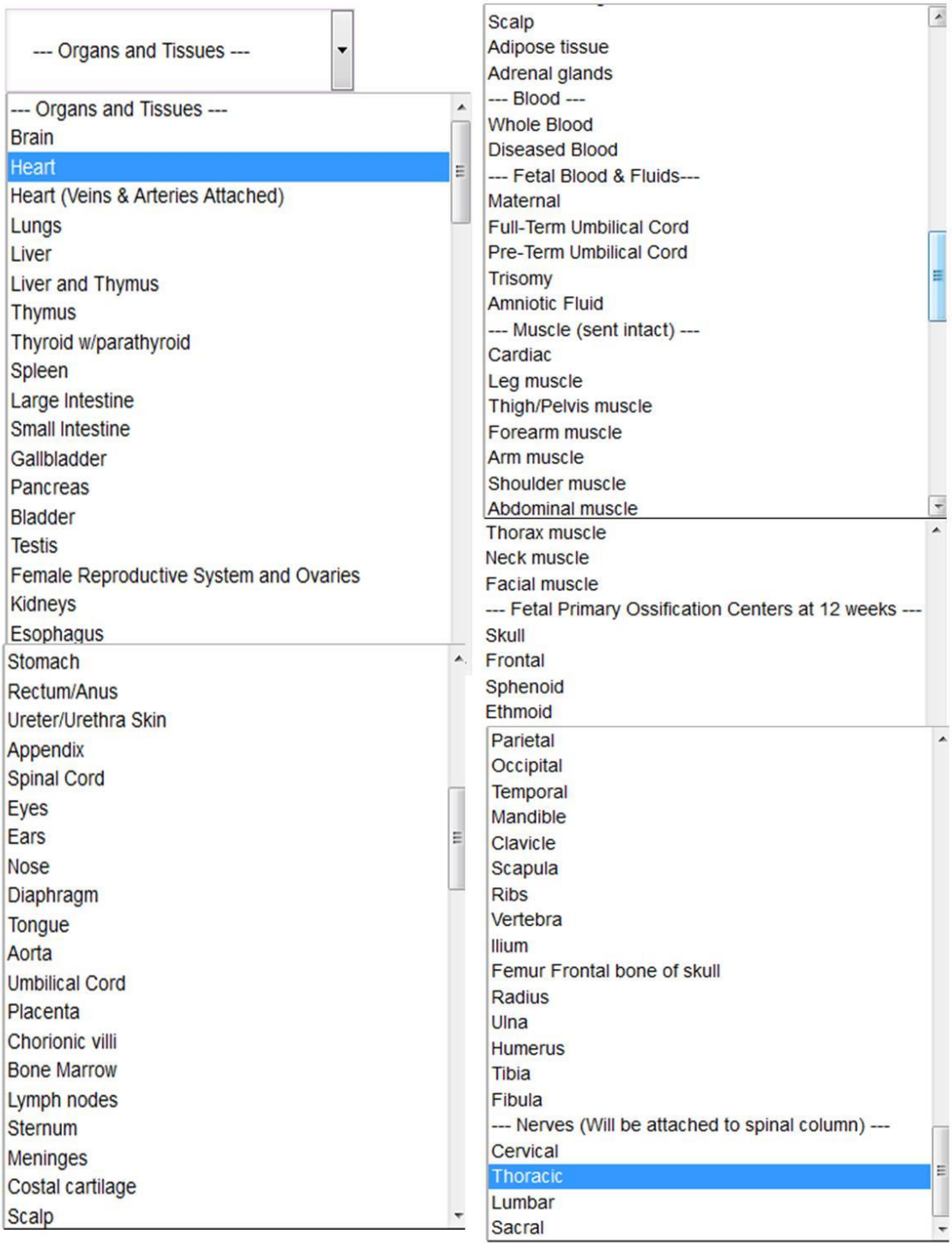


a) How Researchers Placed an Order

Customers placed orders through an on-line catalogue, a copy of which is shown below (Panel staff inserted the red circle). Based upon the web page, both Rep. Diane Black (TN-6) and Rep. Joe Pitts (PA-16) called StemExpress "the Amazon.com of baby body parts."[196]



[196] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel of the H. Comm. on Energy and Commerce*, 114th Cong., Mar. 6, 2016 (unedited transcript 55); *The Pricing of Fetal Tissue: Hearing Before the Select Investigative Panel of the H. Comm. on Energy and Commerce*, 114th Cong. 77 (unedited transcript) (Apr. 20, 2016).


--- Organs and Tissues ---
--- Organs and Tissues ---
Brain
Heart
Heart (Veins & Arteries Attached)
Lungs
Liver
Liver and Thymus
Thymus
Thyroid w/parathyroid
Spleen
Large Intestine
Small Intestine
Gallbladder
Pancreas
Bladder
Testis
Female Reproductive System and Ovaries
Kidneys
Esophagus
Stomach
Rectum/Anus
Ureter/Urethra Skin
Appendix
Spinal Cord
Eyes
Ears
Nose
Diaphragm
Tongue
Aorta
Umbilical Cord
Placenta
Chorionic villi
Bone Marrow
Lymph nodes
Sternum
Meninges
Costal cartilage
Scalp
Scalp
Adipose tissue
Adrenal glands
--- Blood ---
Whole Blood
Diseased Blood
--- Fetal Blood & Fluids---
Maternal
Full-Term Umbilical Cord
Pre-Term Umbilical Cord
Trisomy
Amniotic Fluid
--- Muscle (sent intact) ---
Cardiac
Leg muscle
Thigh/Pelvis muscle
Forearm muscle
Arm muscle
Shoulder muscle
Abdominal muscle
Thorax muscle
Neck muscle
Facial muscle
--- Fetal Primary Ossification Centers at 12 weeks ---
Skull
Frontal
Sphenoid
Ethmoid
Parietal
Occipital
Temporal
Mandible
Clavicle
Scapula
Ribs
Vertebra
Ilium
Femur Frontal bone of skull
Radius
Ulna
Humerus
Tibia
Fibula
--- Nerves (Will be attached to spinal column) ---
Cervical
Thoracic
Lumbar
Sacral

b) Embedded Tissue Technicians Learn of Next Day's Scheduled Abortions

The Panel sought to determine whether StemExpress employees had prior knowledge of the abortions scheduled at PPFA clinics. The Panel determined that, at the beginning of each workday, StemExpress sent an email to its tissue technicians that informed them of the scheduled abortions at the clinic to which they were assigned, listed the customer orders for fetal tissue or body parts (including the gestation requested), and described what specific tissues or parts the technicians were expected to harvest.

A document produced by StemExpress to the Panel shows that, "[t]he day before the surgery," tissue technicians were required to check the company's web-based system "for researcher requests; Determine your location for the next day; [and] Call the clinic to verify how many surgeries are scheduled."[197] The morning of the abortions, StemExpress emailed the tissue technicians the daily customer orders, including a list of the specific organs that were ordered, the desired gestational age of the organs, and other information.[198]

c) Clinic Personnel Gave Tissue Technicians Access to Patients' Private Medical Information

The Panel sought to determine whether StemExpress employees assigned to PPFA abortion clinics had access to patients' medical information that is protected under HIPAA. Testimony shows that clinic personnel provided StemExpress' embedded tissue technicians with patients' private medical records and other personally identifiable information.[199]

After StemExpress' tissue technicians arrived at their assigned sites, clinic personnel, including doctors and nurses, allowed StemExpress' tissue technicians to review the medical files of individual patients that were in files attached to the examining room doors, so they could determine whether women seeking abortions met their order specifications.[200] A person with intimate knowledge of StemExpress' operations stated on a CMP video that, often, "the head nurse gives the [tissue technicians] a sheet with a list of everyone who is coming in for that day with the types of procedures. The [tissue technicians] walk around the clinic and consent the patients, either in the waiting room or in a patient room."[201]

If, due to the large volume of patients, StemExpress tissue technicians could not review the patient files hanging on the examining room doors, clinic personnel allowed them to access clinic computer terminals that contained confidential patient medical information.[202] Doctors

[197] StemExpress, LLC, Tissue Procurement for Non-Therapeutic Research, Standard Operating Procedure (Jan. 24, 2011), Exhibit 5.19.
[198] Email from [name and title redacted], StemExpress, LLC, to [names redacted], Subject: Updated Task Assignment: Procurement Schedule Wednesday 3/20/13 (Mar. 20, 2013), Exhibit 5.20.
[199] Testimony from a confidential witness.
[200] Testimony from a confidential witness.
[201] Center for Medical Progress videotape MVI_0064 produced to the Committee on Oversight and Government Reform.
[202] Testimony from a confidential witness.

and nurses at the clinics also directed the StemExpress tissue technicians to particular patients who were good candidates for fetal tissue donations.[203]

d) Embedded Tissue Technicians Obtained Consent from Women to Donate Fetal Tissue

The Panel sought to determine whether StemExpress employees obtained consent to donate fetal tissue from women at PPFA clinics who were scheduled to undergo abortions. By her own admission to the Committee on Energy and Commerce [the Founder and CEO] stated that StemExpress employees did consent PPFA patients:

> StemExpress employee[s] can obtain consent. Once it is already determined that the patient is having an abortion, they are moved to a different waiting room, at that point [StemExpress] staff meets with the patient. If she agrees, they go over the paperwork and she signs. There are times that PPFA does the consent.[204]

Documents produced by StemExpress to the Panel show that StemExpress employees obtained consent to procure fetal tissue from patients scheduled to undergo abortions.[205] A person with intimate knowledge of StemExpress' operations stated on a CMP videotape that some StemExpress tissue technicians would procure fetal tissue specimens "without consenting patients."[206]

Unlike California PPFA clinics that had contracts with StemExpress, [PP Witness #2] testified that she would never have allowed such an arrangement at her facility. When Panel staff asked the witness whether she would have agreed to have employees of an outside vendor obtain informed consent to donate fetal tissue from PPGC patients, she testified:

> I would not agree to have outside staff come in and obtain a crucial element as the informed consent from our patient population.
>
> Q: Okay. And what is it about that that troubles you?
>
> A: I would like for only our staff to do it, because in that way we have control over their training. We have control over who is there day to day obtaining informed consents. We have control to ensure that it's done correctly, and we have the authority to follow up in the event that our procedures and our processes regarding informed consent are not followed. I would not permit a third party to come in and obtain informed consent from our patient population.[207]

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[203] Testimony from a confidential witness.
[204] *See* StemExpress Briefing Notes, Exhibit 5.14.
[205] StemExpress, LLC, Consenting Patients, undated, Exhibit 5.21.
[206] Center for Medical Progress videotape MVI_0064 produced to the Committee on Oversight and Government Reform.
[207] Transcribed interview of [PP Witness #2] at 97 (Oct. 19, 2016).

i) When it obtained consent from PPFA Affiliates, StemExpress used PPFA's consent form

The Panel sought to determine the specific form that StemExpress used to obtain consent from women scheduled to undergo abortions at PPFA affiliates. The firm produced two forms to the Panel, one that was created by PPFA, the other by StemExpress. [The Founder and CEO] told the Committee on Energy and Commerce that, when collecting fetal tissue at PPFA affiliates, StemExpress used "a PPFA consent form, which is different than the consent form at non-PPFA facilities."[208] The PPFA consent form stated, "Research using . . . tissue that has been aborted has been used to treat and find a cure for such diseases as diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS."[209]

When [PP Witness #1] was asked by the Panel whether the inclusion in the consent form of the statement that fetal tissue had been used to find a cure for incurable diseases could be construed as being coercive, the PPFA official testified: "I can understand your concern that perhaps this may make someone think about donating fetal tissue because of this potential."[210] The PPFA official testified that the wording of the PPFA consent form may make patients more likely to want to donate fetal tissue.[211]

ii) StemExpress used its own consent form when it obtained consent from patients at independent women's clinics

StemExpress had another consent form that it used at independent women's clinics. That form purported to be approved by "an institutional review board" (IRB),[212] BioMed IRB.[213] The Panel sought to determine whether BioMed IRB was a legitimate IRB. The Panel determined that it was not. In March of 2012, the FDA issued a warning letter to BioMed IRB for multiple violations of agency rules. As a result, the FDA ruled it "will withhold approval of all new studies" approved by BioMed IRB, "and [n]o new subjects are to be enrolled in any ongoing [BioMed IRB] studies . . ."[214] That ban was lifted in January 2013.[215]

Prior to the FDA suspension, the House Committee on Energy and Commerce had investigated BioMed IRB as part of an investigation into the ability of IRBs to protect human

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[208] StemExpress Briefing Notes, Exhibit 5.14.
[209] Planned Parenthood Federation of America, PPFA Manual of Medical Standards and Guidelines, Client Information and Informed Consent, Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research, Education, or Treatment," Revised June 2011 [PPGC-HOU-E&C-000006], Exhibit 5.22.
[210] Transcribed interview of [PP Witness #1] (Oct. 6, 2016), at 131-132.
[211] *Id.* at 132.
[212] StemExpress Briefing Notes, Committee on Energy and Commerce (Aug. 25, 2016).
[213] BioMed IRB Informed Consent to Participate in a Clinical Research Study, Sponsor: StemExpress, LLC (Jan. 24, 2011) [STEM.HOUSE.SELECT_0680 – STEM.HOUSE.SELECT_0681], Exhibit 5.23.
[214] *See* Letter from [Compliance Official], U.S. Food and Drug Administration, to [Executive], Biomedical Research Institute of America dba BioMed IRB (Mar. 29, 2012), http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm298607.htm.
[215] *Id.*

subjects in biomedical research.[216] That investigation "led the Committee to believe that the IRB application approval process is essentially perfunctory, lacking vigorous oversight and controls, and thus raising the risk of some IRBs not adequately protecting the safety of human subjects."[217]

On March 29, 2016, the Panel issued a subpoena to BioMed IRB which required it to produce documents sufficient to show BioMed IRB's ongoing oversight, within the definition of 45 C.F.R. 46, of any entity involved with fetal tissue research or transplantation of fetal tissue for which it issued an IRB approval.[218] The BioMed IRB [Executive] informed the Panel on April 4, 2016, that, regarding StemExpress IRB records, "there are none."[219] After he refused to comply with the Panel's subpoena, [Executive] told the Panel: "Please schedule the contempt process at the earliest possible date."[220] The Panel still has yet to receive any documents from BioMed IRB.

e) StemExpress Tissue Technicians Procured the Fetal Tissue

The Panel sought to determine whether StemExpress' embedded tissue technicians or PPFA procured fetal tissue after abortions. [The Founder and CEO] told the Committee on Energy and Commerce that "StemExpress staff are the only ones procuring tissue at PPFA facilities."[221]

StemExpress produced documents about its procurement kit to the Panel that provided explicit instructions to its tissue technicians on the method to procure fetal tissue.[222] The kit included directions on the method to obtain consent from patients, to harvest body parts and fetal tissue, and to package and ship the "products" once obtained.[223] At independent abortion clinics, StemExpress tissue technicians were required to "procure the specimen(s) on the petri dish [that were included in the technicians' packages. . . ."[224]

In contracts with the PPFA affiliates with which StemExpress had contracts, [PP Witness #2] testified that she would never have allowed such an arrangement at her facility:

> A: From my ancillary knowledge of our abortion services area, it appears highly regulated. And just like the informed consent for researchers, I can't see that we would allow staff that are not or people in general that are not Planned Parenthood staff to go into the

[216] *See* Letter from Rep. John D. Dingell, Chairman, H. Comm. on Energy and Commerce, to [Executive], Biomedical Research Institute of America, et al. (Dec. 13, 2007).
[217] *See* Memorandum from Committee staff to Members and Staff Subcomm. on Oversight and Investigations (Mar. 23, 2009).
[218] *See* Subpoena to Biomedical Research Institute of America dba BioMed IRB (Mar. 29, 2016).
[219] *See* Email from [Executive], Biomedical Research Institute of America, to Panel staff (Apr. 4, 2016).
[220] *Id.*
[221] StemExpress Briefing Notes, Exhibit 5.14.
[222] StemExpress, LLC, Work Instruction, StemExpress Procurement Kit 1 (Mar. 12, 2015) [STEM.SELECT.HOUSE_0266 – STEM.HOUSE.SELECT_0272], Exhibit 5.24.
[223] *Id.*
[224] Tissue Procurement for Non-Therapeutic Research, Standard Operating Procedure, Exhibit 5.19.

> facility and be involved in the setup of the room where abortions are obtained.
>
> Q: So all of the little daily things that can go on, let's go back to consent. All the manner, the manners, the time, the thoughtfulness, understanding what you call the supplemental consent, the IRB consent, because these are staff that work directly for the clinic, you can manage them and tweak even the smallest of behaviors or practices, migrate the whole process in a direction that's under the management of you and others; is that right?
>
> A: That would be my personal preference, yes.[225]

The Panel sought to determine whether StemExpress' procurement practices were driven by a desire to assist medical researchers find potential cures for diseases or by a profit motive. StemExpress' standard operating instructions that were used at non-Planned Parenthood abortion clinics indicate it was profit. StemExpress instructed its tissue technicians:

> If you have an excellent [fetal tissue] sample with no researcher listed on today's schedule, please contact [Founder & CEO] immediately, and they will work to call researchers who may be interested even though they are not currently scheduled.[226]

i) After they procured the body parts and tissue, StemExpress employees packaged and shipped them directly to StemExpress customers

Documents produced by StemExpress to the Panel show that, along with being responsible for consent and procurement, the firm's tissue technicians also packaged and shipped the fetal tissue.

StemExpress' procurement kit provided detailed instructions on the method tissue technicians should use to package fetal tissue:

> The items of the kit should be reassembled in the same placement as they were when the kit was received.
>
> Place the specimens inside of the plastic bag liner
>
> One sealed biohazard bag with the 50ml conical tube (containing RPMI and the liver specimen) [along with] One sealed biohazard bag with 3 tubes of maternal blood (two 10ml EDTA one 5ml Z serum sep. [sic] clot activator blood collection tube) [and] 2 chilled gel packs

[225] Transcribed interview of [PP Witness #2] (Oct. 19, 2016) at 98.
[226] Tissue Procurement for Non-Therapeutic Research, Standard Operating Procedure, Exhibit 5.19.

> Seal the plastic bag liner by tying it in a knot
>
> Place the tied plastic bag inside of the Styrofoam box
>
> Place the Styrofoam lid on the Styrofoam box
>
> Adhere a biohazard sticker on opposite sides of the Styrofoam box so they seal the top of the box to the bottom.
>
> Place Styrofoam box inside the cardboard box
>
> Place completed Procurement Form on top of the Styrofoam box
>
> Tape the cardboard box shut
>
> Adhere the FedEx shipping label to the top of the cardboard box
>
> Once the package is ready for shipment call FedEx . . . to schedule a pick up or drop the package off at the nearest FedEx location by 16:30 on the day of procurement.[227]

The firm also issued its tissue technicians a four-page document on how to package and ship tissue samples.[228] StemExpress' standard operating procedure stated:

> Packaging the specimens and blood [samples] for shipment once all specimens have a number. Be sure to place them on ice or cold packs . . . . For delivery: If the specimen is local courier, be sure to call the courier once you know you have obtained an appropriate specimen. If the specimen is going by FedEx, be sure to know the local cut-off times for your closest FedEx office. Each FedEx location is listed under "contacts" in [StemExpress' web-based system].[229]

ii) StemExpress' tissue technicians had a financial incentive to procure the most body parts and fetal tissue possible

Documents StemExpress produced to the Panel indicated the tissue technicians did have such a potential conflict of interest. PPGC's research director testified that she had similar concerns.[230]

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[227] Work Instruction, StemExpress Procurement Kit 1, Exhibit 5.24.
[228] StemExpress, LLC, Packaging Blood and Tissue Samples (Jan. 16, 2014) [STEM.HOUSE.SELECT_0257 – STEM.HOUSE.SELECT_0260], Exhibit 5.25.
[229] Tissue Procurement for Non-Therapeutic Research, Standard Operating Procedure, Exhibit 5.19.
[230] Transcribed interview of [PP Witness #2] (Oct. 19, 2016) at 162-164.

StemExpress' tissue technicians were "compensated at a rate of $10 per hour plus a per tissue or blood bonus" that varied depending upon the type of tissues and the amount they procured. The document produced by StemExpress is below.[231]

stem express

Procurement Technician Compensation Policy for Tissue and Blood Procurement Effective 01/01/2013

Procurement Fees

- Procurement Technicians are compensated at a rate of $10.00 per hour plus a per tissue or blood bonus as outlined in the table below:

Tissue Bonus Structure			
# Specimens	Category A*	Category B*	Category C
1-10 Specimens	$35/Tissue	$15/Tissue	$10/Blood
11-20 Specimens	$45/Tissue	$20/Tissue	$15/Blood
21-30 Specimens	$55/Tissue	$25/Tissue	$20/Blood
31-40 Specimens	$65/Tissue	$30/Tissue	$25/Blood
41-50 Specimens	$75/Tissue	$35/Tissue	$30/Blood

*Blood Samples may be obtained with these specimens in which case Category C bonus does not apply.

Please refer to the Procurable Specimens by Category dated 01/01/2013 for a detailed listing of Tissues.

Two or More Procurement Technicians working in Unison

- Procurement Technicians often work in unison so procurements are split equality between the technicians.

For example, if two technicians are working together at the same clinic, and two maternal bloods are procured, each technician would receive $5 for the Blood Procurement.

778 Pacific Street / Placerville CA 95667
T: 530-626-7000 F: 530-26-7900 / info@stemexpress.com / www.stemexpress.com

HIGHLY CONFIDENTIAL INFORMATION / NOT FOR PUBLIC RELEASE STEM.HOUSE.SELECT_ 0672

[231] StemExpress, LLC, Procurement Technician Compensation Policy for Tissue and Blood Procurement Effective 01/01/2013 [STEM.HOUSE.SELECT_0672 – STEM.HOUSE.SELECT_0674].

Procurable Specimens by Category
Effective 01/01/2013

Category A*
Brain
Heart
Lungs
Liver
Thymus
Thyroid w/parathyroid
Liver
Spleen
Large Intestine
Small Intestine
Gallbladder
Pancreas
Bladder
Testis
Ovaries
Esophagus
Stomach
Rectum/Anus
Ureter/Urethra
Appendix
Spinal Cord
Spinal Column
Eyes
Diaphragm
Lymph nodes
Sternum
Adipose tissue
Lymph nodes
All Muscle tissue
All Bone structures

Category B*
Kidneys
Adrenal glands
Ear
Decidua
Chorionic Villi
Umbilical Cord
Placenta
Amniotic Fluid
Large Intestine
Small Intestine
Skin
Nose
Tongue
Scalp

Category C
Maternal Blood
Post Surgery Blood
Umbilical Cord Blood
Trisomy Blood

*Note: Blood Samples may be obtained with these specimens in which case Category C bonus does not apply

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T: 530-626-7000 F: 530-26-7900 / info@stemexpress.com / www.stemexpress.com

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The Panel sought to determine whether StemExpress' payment rate was standard practice at abortion clinics which participated in fetal tissue donation programs. The Panel found it was not. When [PP Witness #2] was asked whether she would allow tissue technicians employed by an outside firm, who were reimbursed by the outside firm based on the amount of tissue they procured, into her facility, she testified, "That's not something I would initiate in our organization, no."[232]

The Panel determined that the PPFA affiliates at which StemExpress procured fetal tissue had no allowable costs under 42 U.S.C. § 289g. StemExpress' embedded tissue technicians obtained consent to donate fetal tissue from women scheduled to undergo abortion, procured the fetal tissue, packaged it, and shipped it directly to StemExpress' customers. Thus, the Panel determined the PPFA affiliates had no allowable costs.

5. StemExpress' Due Diligence

The Panel sought to evaluate StemExpress' level of due diligence before entering into contracts with the independent abortion clinics at which it procured fetal tissue. The Panel discovered StemExpress failed to examine the disciplinary records of officials and doctors at those independent clinics.

The director of one clinic, and doctors at others, were disciplined multiple times by state regulators. In addition, multiple clinic doctors settled malpractice suits. Panel staff found these issues through simple online searches, which raises the question of whether StemExpress did any background checks on the clinics or doctors with which it did business.

At Camelback Family Planning, the clinic official who signed the contract with StemExpress had multiple disciplinary proceedings for substance abuse, two of which occurred before she signed the StemExpress signed contract. Even though she performed abortions, the doctor was not an Ob/Gyn. The doctor surrendered her license to practice medicine.

The Presidential Women's Specialists clinic settled four malpractice suits, including one that involved a woman who died five days after an abortion surgical instruments were left inside her body. Three of the clinic's doctors have either been disciplined by the state department of health, including performing an abortion on a 12-year-old girl (which is below the age of consent in the state), destroying evidence related to that case, and not informing law enforcement of child abuse. The state charged the same doctor with gross or repeated malpractice involving another patient.

One doctor who performs abortions at Cedar River Clinics has been disciplined by the state, and another settled a malpractice suit that alleged that he had to perform an emergency hysterectomy after he perforated the patient's uterus during an abortion.

[232] Transcribed interview of [PP Witness #2] at 114-15 (Oct. 19, 2016).

6. Payments Received by Clinics

Between 2010 and the middle of 2015, StemExpress paid the clinics from which it procured fetal tissue a total of $152,460. Between 2010 and the middle of 2015, StemExpress paid the clinics a total of $366,443 for both blood and fetal tissue.[233] StemExpress produced over a hundred monthly invoices from PP affiliate clinics. Stem refused to produce invoices for other clinics from which it procured fetal tissue. The Panel sought those invoices directly from those clinics. StemExpress paid the following amounts for fetal tissue. These numerical sums are calculated by the Panel's forensic accountant from these invoices:

- $123,175 to Planned Parenthood Mar Monte
- $12,705 to Planned Parenthood Shasta Pacific
- $8,130 to Family Planning Services
- $4,875 to Presidential Women's Center
- $2,375 to Cedar River Clinics
- $1,200 to Camelback Family Planning.

Over the same time period (2010 through the middle of 2015), StemExpress paid the clinics a total of $213,983 for blood draws. StemExpress produced over a hundred monthly invoices from Planned Parenthod affiliate clinics. StemExpress refused to produce invoices for other clinics from which it procured fetal tissue. The Panel sought those invoices directly from those clinics. These numerical sums are calculated by the Panel's forensic accountant from these invoices.

StemExpress paid:

- $100,143 to Planned Parenthood Mar Monte
- $88,625 to Cedar River Clinics
- $10,905 to Presidential Women's Center
- $7,750 to Planned Parenthood Shasta Pacific
- $6,415 to Family Planning Services for blood.

[233] Planned Parenthood Mar Monte, Planned Parenthood Shasta Pacific, Planned Parenthood of Santa Barbara, Ventura & San Luis Obisbo Counties, Camelback Family Planning, Cedar Rivers Clinics, Family Planning Specialists Medical Group. Presidential Women's Center, and Women's Health Specialists produced to the Panel documents that reflected payments the entities had received from StemExpress, LLC. Panel staff conducted a forensic accounting analysis of those payments to determine the total amounts to the entities.

During the course of its investigation, the Panel sought to determine the motive of clinic executives when they entered into their contracts with StemExpress. In at least one instance, an executive from a clinic at which StemExpress procured fetal tissue indicated that profit may have been a motive. [Clinic Executive #1] stated to CMP journalists that the clinic made approximately $250,000 a year from fetal tissue and blood donations:

> [Clinic Executive #1]: [Laughter] Well, I just—we've been into this, and it's been very good. And now we've gone through our first year—
> CMP journalist: Yeah.
> [Clinic Executive #1]: I mean, I was looking at numbers of, you know, $250,000 a year. And now—
> CMP journalist: I'm sorry, say that again?
> [Clinic Executive # 1]: I mean, originally, we were looking at numbers of about $250,000 a year. Last year I did $100,000.[234]

The Panel notes that, in most instances, the clinics had little or no allowable reimbursable costs as permitted under § 289g-2.

7. Payments Received by StemExpress for Its Resale of Fetal Tissue

StemExpress produced invoices that it sent to customers. The numerical sums listed below are calculated by the Panel's forensic accountant from these invoices. Invoices produced to the Panel by StemExpress show that, between 2011 and 2016, StemExpress received a total of $593,152 in payments from its customers. The invoices show the total payments from customers included $59,300 in payments for disease screening and $53,110 for the shipment or delivery of fetal tissue products.

The Panel notes that, in addition to fresh fetal tissue and body parts, StemExpress sold products derived from fetal tissue. The invoices produced by StemExpress to the Panel do not reflect the sale of products derived from fetal tissue.

Below is a chart of StemExpress' customers, and the amounts the customers paid the firm (all amounts are in U.S. dollars).

[234] Center for Medical Progress, videotape FNND0569_ 20150419153726 (Apr. 7, 2014) produced to the Committee on Oversight and Government Reform.

CLIENT	2011	2012	2013	2014	2015	2016	GRAND TOTAL
AllCells, LLC.	73,045	7,720	4,880				85,645
Baylor College of Medicine		5,785	1,630				7,415
Beckman Research Institute City of Hope			545	760			$2,065
Children's Hospital of Philadelphia					695	695	1,390
Columbia University Medical Center	615	3,715	995				5,325
Colorado State University	3,835	1,645	2,930				8,410
Dartmouth University	3,920	5,010	585				9,515
Drexel University College of Medicine	3,680						3,680
Ganogen, Inc.			6,535	805			7,340
George Washington University		350					350
Harvard University			8,610				8,610
Howard Hughes Medical Institute	340	695					1,035

Johns Hopkins Hospital	1,950	1,680					3,630
Massachusetts General Hospital		4,560	10,705				15,265
Medical College of Wisconsin				2,740			2,740
Neurona Therapeutics					1,830		1,830
Ohio State University	490						490
Rockefeller University			855				855
Stanford University	37,940	42,739	18,050	57,070	27,190		182,989
Thomas Jefferson University			500				500
University of California. Los Angeles	3,920	8,920	9,000				21,840
University of Connecticut Health Center	780	1,700	500				2,980
University of Illinois at Chicago		335	820				1,155
University of Massachusetts Medical School	62,275	62,195	23,705	2,159	491		150,825

University of Minnesota				3,235			
University of North Carolina, Chapel Hill		720	1,835				2,555
University of Pennsylvania			4,790				4,790
Vanderbilt University Medical Center	11,955	9,665	5,640	845		-125	
Yale University School of Medicine	515	12,065					12,580
Zyagen	5,080				3,570		8,659
TOTAL ALL CUSTOMERS							**$593,152**

8. The Select Panel Recommends that the House Find StemExpress in Contempt of Congress

For nearly a year, the Panel sought documents, including accounting documents, from StemExpress.[235] In its first response to the Panel's document request, StemExpress provided very limited information. StemExpress produced a general accounting summary that stated: "[F]etal tissue procured from Planned Parenthood Affiliates generated approximately $50,000 in gross (pre-tax) revenue against expenses in excess of $75,000."[236]

As a result of StemExpress' limited compliance with the Panel's document request letter, the Chairman, over a three-month period, issued two subpoenas to StemExpress,[237] one to the founder & CEO,[238] and another to StemExpress' outside accountant, Scinto Group, LLP (Scinto).[239]

[235] Letter from Rep. Marsha Blackburn, Chairman, House Select Investigative Panel, to [Founder and CEO, StemExpress, LLC] (Dec. 17, 2015), Exhibit 5.1.1.
[236] StemExpress First Response to House Select Panel Document Requests (Jan. 15, 2016), Exhibit 5.2.
[237] Subpoena to StemExpress, LLP, (Feb. 12, 2016), Exhibit 5.3.
[238] *See* Subpoena to [Founder & CEO] (Mar. 29, 2016).
[239] *See* Subpoena to Scinto Group, LLP (Apr. 29, 2016)

[The Founder and CEO] refused to comply with the Panel's March 29, 2016, subpoena.[240] Like the Panel's February 12, 2016, subpoena to StemExpress, the subpoena issued to [the Founder and CEO] requested the names of StemExpress accounting personnel and documents showing accounts payable and receivable.[241] [The Founder and CEO] refused to provide any of the information demanded by the Panel's subpoena.

In addition, she suggested that the Panel seek the information it required from Scinto or from [Former StemExpress Employee]. Once again, attorneys for [the Founder and CEO] offered summary documents of revenue and costs, but no accounting records.[242] [The Founder & CEO]'s and StemExpress' counsel, who also represented [Former StemExpress Employee], explained that [Former StemExpress Employee] had only W-2's and related tax information. For her part, [Former StemExpress Employee] told Panel staff that she had no documents and that if the Panel contacted her again she would consider it harassment.[243]

Scinto refused to comply with the Panel's subpoena and to date has provided no accounting documents. Scinto told the Panel that StemExpress objected to Scinto's compliance with the Panel's subpoena on the grounds of several privileges.[244] The Panel informed Scinto that its objections based upon the asserted privileges were inapplicable and do not impair the legal requirement to comply with a congressional subpoena.[245] Despite these efforts, Scinto refused to comply with the Panel's subpoena.[246]

On August 23, 2016, McDermott Will & Emery, the law firm previously representing StemExpress and [the Founder and CEO] throughout the course of the investigation, informed the Panel that StemExpress was no longer their client.[247] StemExpress' former attorney supplied the Panel with contact information for the new lawyer.[248] On September 8, 2016, Chairman Blackburn sent a letter to Mr. Frank Radoslovich, the new counsel for StemExpress, and [the Founder and CEO], outlining a brief history of the Panel's interactions with StemExpress, and

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[240] StemExpress First Response to House Select Panel's March 29, 2016 Subpoena [STEM.HOUSE.SELECT_0713 – STEM.HOUSE.SELECT_0715], Exhibit 5.26.
[241] *See* Subpoena to [Founder & CEO] (Mar. 29, 2016).
[242] StemExpress First Response to House Select Panel's March 29, 2016 Subpoena [STEM.HOUSE.SELECT_0713 – STEM.HOUSE.SELECT_0715], Exhibit 5.26.
[243] *See* Memorandum from House Select Investigative Panel Counsel to Majority Members of the House Select Investigative Panel (Mar. 7, 2016).
[244] Letter from Kevin Murphy, Carr Maloney LLP, to T. March Bell, Chief Counsel and Staff Director, Select Investigative Panel on Infant Lives [sic] (Sept, 16, 2016), Exhibit 5.1.6.
[245] *See* T. March Bell, Chief Counsel and Staff Director, House Select Investigative Panel, to Kevin Murphy, Carr Maloney LLP (Sept. 8, 2016), Exhibit 5.1.5
[246] Letter from Kevin Murphy, Carr Maloney LLP, to T. March Bell, Chief Counsel and Staff Director, Select Investigative Panel on Infant Lives [sic] (Sept., 16, 2016), Exhibit 5.1.6 (" . . . if not for the potential application of the privilege and/or confidentiality laws, Scinto Group LLP would be willing and able to comply with a valid subpoena from the Select Investigative Panel. However, in light of the potential application of those laws, under the current circumstances, Scinto Group is not in a position to unilaterally respond to the subpoena with the requested documents, absent client consent.").
[247] *See* Email from Amandeep S. Sidhu, McDermott Will & Emery, to Panel Staff (Aug. 23, 2016).
[248] *Id.*

the Panel's unsuccessful attempts to reach an accommodation with StemExpress.[249] The letter concluded:

> Since StemExpress has been unwilling to comply with the Panel's subpoenas and having exhausted all its efforts to obtain compliance from the subpoena recipients, the Chairman of the Select Investigative Panel will recommend that StemExpress and [StemExpress Founder and CEO] be held in contempt for their willful failure to fully comply with the Panel's subpoena issued to them . . . .[250]

The Chairman provided one last opportunity for StemExpress and [the Founder and CEO] to comply with the subpoenas.[251] In April 2016, the Panel wrote a letter to [the Founder and CEO] that included a chart of the missing items in an attempt to secure compliance with the congressional subpoenas.[252] In a response letter, former counsel for StemExpress and [the Founder and CEO] disputed the Panel's attempt to clarify what was missing.[253] After receiving no substantive reply from StemExpress' new counsel, the Panel, on September 21, 2016, voted unanimously to recommend that the House of Representatives hold StemExpress and [the Founder and CEO] in contempt of Congress.[254]

9. StemExpress May Have Violated Federal Laws and Regulations

H. Res. 461 required the Panel to undertake an investigation into "medical procedures and business practices used by entities involved in fetal tissue procurement . . . and any changes in law or, regulation necessary resulting from" its investigation.[255]

The Panel, acting pursuant to H. Res. 461, determined that StemExpress may have violated applicable federal and state laws, and regulations promulgated by the Department of Health and Human Services. The Panel referred StemExpress' apparent violations of laws to appropriate federal and state law enforcement and violations of regulations to the appropriate agency. (See Chapter IV for a discussion of the criminal referrals made by the Panel.)

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[249] *See* Letter from Rep. Marsha Blackburn, Chairman, Select Investigative Panel, to Frank Radoslovich, counsel for StemExpress (Sept. 8, 2016), Exhibit 5.1.7.
[250] *Id.*
[251] *Id.*
[252] *See* Letter from Rep. Marsha Blackburn, Chairman, Select Investigative Panel, to [Founder and CEO], StemExpress, LLC (Apr.28, 2016), Exhibit 5.1.8.
[253] *See* Letter from Amandeep S. Sidhu, McDermott Will & Emery, to Rep. Marsha Blackburn, Chairman, House Select Investigative Panel (May 6, 2016), Exhibit 5.1.9
[254] *See* Select Investigative Panel of the H. Comm. on Energy and Commerce, Business Meeting, unedited transcript, Sept. 21, 2016.
[255] H. Res. 461 (Oct. 7. 2015).

d) 18 U.S.C. § 1519

18 U.S.C. § 1519 makes it a 20-year felony for "Whoever knowingly alters, destroys, mutilates, conceals, covers up, falsifies, or makes a false entry in any record, document, or tangible object with the intent to impede, obstruct, or influence the investigation or proper administration of any matter within the jurisdiction of any department or agency of the United States . . . ."[256]

The Panel determined that StemExpress may have violated 18 U.S.C. § 1519 by potentially destroying documents pertinent to congressional investigations into the fetal tissue industry, including documents that were covered by the Panel's subpoenas. The Panel's two subpoenas to StemExpress direct that "No records, documents, data or information called for by this request shall be destroyed, modified, removed, transferred or otherwise made inaccessible to the Select Panel."[257]

StemExpress' bank produced to the Panel banking records that show StemExpress payments to Shred-It USA that, for the most part, correspond with dates of document demand letters from congressional investigations of the fetal tissue industry, subpoenas from the Panel, and StemExpress productions to the Panel and other congressional inquiries. StemExpress bank records dating back to November 2012 reveal there were no payments made to Shred-It USA prior to the first congressional investigations into the fetal tissue industry. Since the first congressional inquiries began, and continuing through the Panel's investigation, StemExpress made payments to Shred-It USA.

The Panel cannot determine what specific documents StemExpress shredded, but the timing raises the question of whether StemExpress knowingly and willfully attempted to avoid productions to a congressional inquiry.

e) 42 U.S.C. § 289g-2

42 U.S.C. § 289g-2(a) states, "It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce." Under that law, "the term 'valuable consideration' does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."[258] Human fetal tissue is defined broadly to include any "tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth."[259]

[256] 18 U.S.C. § 1519.
[257] Subpoena to StemExpress, LLP, (Feb. 12, 2016), Exhibit 5.3; Instructions Item 5 (Mar. 29, 2016).
[258] 42 U.S.C. § 289g-2(e)(3).
[259] 42 U.S.C. § 289g-l(g).

f) California Health and Safety Code Section 125320

The California Health and Safety Code contains virtually identical language as 42 U.S.C. § 289g-2. That law states that:

> (a) A person may not knowingly, for valuable consideration, purchase or sell embryonic or cadaveric fetal tissue for research purposes pursuant to this chapter.
>
> (b) For purposes of this section, "valuable consideration" does not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of a part.
>
> (c) Embryonic or cadaveric fetal tissue may be donated for research purposes pursuant to this chapter.[260]

As with § 289g, another provision of the California Health and Safety Code broadly defines tissue to "mean a human cell, group of cells, including the cornea, sclera, or vitreous humor and other segments of, or the whole eye, bones, skin, arteries, sperm, blood, other fluids, and any other portion of a human body . . ."[261]

The Panel determined that StemExpress may have violated 42 U.S.C. § 289g-2 and Cal. Health & Safety Code § 125320(a). This can be seen generally by the company's aggressive growth strategy, which explicitly included the goal of generating profit, and specifically by the transactions involving the transfer of fetal tissue to and from numerous entities for consideration that exceeded statutorily allowable costs.

g) HIPAA

The HIPAA privacy rule is described in detail in Chapter II. The Panel determined that StemExpress may have committed systematic violations of the HIPAA Privacy Rule from about 2010 to 2015. StemExpress did not have a medically valid reason to see patients' PHI. StemExpress' contracts with PPFA affiliates contend that the tissue procurement firm was a business associate. That statement does not comport with HIPAA or with CRS' interpretation of the statute.

h) HHS Regulations on Informed Consent

The Department of Human Service regulations that require researchers to obtain informed consent from each human being used as a research subject, and that outline the elements of informed consent that shall be provided to each subject are described in detail in Chapter III: Panel Hearings.

[260] Cal. Health & Safety Code § 125320.
[261] Cal. Health & Safety Code § 1635(c).

The Panel has determined that StemExpress may have violated the HHS regulations on informed consent. When it obtained informed consent from patients at PPFA affiliates, StemExpress used the PPFA consent form, which states that fetal tissue has been used to cure diseases. For example, the PPFA consent form used by Planned Parenthood Los Angeles states, "Research using . . . tissue that has been aborted has been used to treat and find a cure for such diseases as diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS."[262]

Numerous witnesses, including senior PPFA officials, testified before the Panel that the PPFA consent form is misleading and unethical due to its contention that fetal tissue has been used to find a cure for diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS. [PP Witness #1] testified that the PPFA consent form contained inaccurate statements, and that she, the person who oversees the production of the PPFA manual that contains the consent form, was not happy that an inaccurate document was in the manual:

> Q: Have we found a cure for cancer?
> A: If we had found a cure, we wouldn't be asking for tissue donations to try to find a cure.
> Q: Have we found a cure for AIDS?
> A: Not that I'm aware of, not yet.[263]
>
> [A:] . . . To my knowledge there is no cure for AIDS. So that is probably an inaccurate statement . . . . a consent form should not have an incorrect statement [on it].[264]

i) HHS Regulations on Coercion

The HHS regulations further state: "When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as . . . pregnant women . . . additional safeguards" are included.[265]

The Panel sought to determine whether StemExpress coerced women who underwent abortions. The Panel determined that such coercion on the part of StemExpress may have occurred. For example, emails produced by StemExpress to the Panel show that its tissue procurement technicians engaged in real-time email correspondence with researchers while abortions were taking place—presumably before they obtained informed consent to procure fetal tissue—and yet StemExpress employees already were promising to deliver fetal tissue.

On January 22, 2015, at 12:26 p.m., a customer emailed a StemExpress employee stating: "Just wanted to check in and see if there are any cases within our gestation range for today?

[262] Planned Parenthood Consent Form, Exhibit 5.22.
[263] Unedited transcribed interview of [PP Witness #1] at 130 (Oct. 6, 2016).
[264] Unedited transcribed interview of [PP Witness #1] at 131 (Oct. 6, 2016).
[265] 45 C.F.R. § 46.111(7)(b).

Need to book some time on the equipment if so."[266] Within minutes, at 12:30:11 p.m., the StemExpress employee replied: "There is one case currently in the room, I will let you know how the limbs and calvarium [skull] look to see if you are able to take them in about fifteen minutes."[267] Less than two minutes later, the customer wrote: "Great thank you so much."[268] At 1:20:32 p.m., the StemExpress employee informed the customer:

> The calvarium is mostly intact, with a tear up the back of the suture line, but all pieces look to be there. The limbs, one upper and one lower, are totally intact, with one upper broken at the humerus, and one lower broken right above the knee. Please let me know if these are acceptable. I have set them aside and will await your reply.[269]

Approximately five minutes later, the customer replied: "That sounds great we would like both of them. Please send them our way. Thanks again . . ."[270] The StemExpress employee responded: "Limbs and calvarium will be there between 3:30 and 4:00."[271]

[PP Witness #1] testified before the Panel that the PPFA consent form used by Novogenix may coerce women to donate fetal tissue. When she was asked whether the "incorrect statement" that fetal tissue has found a cure for various diseases "could be viewed as coercive or . . . more likely to induce somebody to want to donate fetal tissue," the PPFA executive testified: "I can understand your concern that perhaps this may make someone think about donating fetal tissue because of this potential."[272]

j) HHS Regulations on Institutional Review Boards

HHS regulations require IRBs to "prepare and maintain adequate documentation" of their activities, including copies of all research proposals reviewed, scientific evaluations of those proposals, minutes of IRB meetings, records of continuing review activities, and copies of all correspondence between the IRB and the investigators.[273] The HHS IRB regulations only cover investigations of products regulated by the Food and Drug Administration.[274]

The Panel sought to determine whether any of the fetal tissue procured by StemExpress and resold to researchers was used in any product regulated by the FDA. The Panel could not make such a determination due to the lack of documentation provided by StemExpress.

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[266] StemExpress, LLC, purchase order and emails [STEM.HOUSE.SELECT_0369 – STEM.HOUSE.SELECT_0382], Exhibit 5.27.
[267] *Id.*.
[268] *Id.*
[269] *Id.*
[270] *Id.*
[271] *Id.*
[272] Unedited transcribed interview of [PP Witness # 1] at 131-32 (Oct. 6, 2016).
[273] 45 C.F.R. § 46.115(a).
[274] 21 C.F.R. § 56.101(a).

The Panel sought to determine whether BioMed IRB, which StemExpress represented approved its research, complied with 45 C.F.R. 46. By its own admission, BioMed IRB violated the HHS regulations by it representation to the Panel that it had no records that related to StemExpress.

The Panel, as a result, determined that StemExpress may have violated 45 C.F.R. 46 through statements that the firm provided abortion clinics with IRB Certified Consents, and that "Our IRB approved protocols and consents protect you as well as donor's privacy in accordance with HIPAA guidelines." Those representations appeared on brochure distributed at the NAF meetings.

k) California Revenue and Tax Code

A provision of the California Revenue and Tax Code states:

> [E]very retailer engaged in business in this state and making sales of tangible personal property for storage, use, or other consumption in this state, not exempted . . . shall, at the time of making the sales or, if the storage, use, or other consumption of the tangible personal property is not then taxable hereunder, at the time the storage, use, or other consumption becomes taxable, collect the tax from the purchaser and give to the purchaser a receipt therefore in the manner and form prescribed by the [California State Equalization Board].[275]

The law defines a "retailer engaged in business in" California as "Any retailer maintaining, occupying, or using, permanently or temporarily, directly or indirectly, or through a subsidiary, or agent, by whatever name called, an office, place of distribution, sales or sample room or place, warehouse or storage place, or other place of business."[276]

There is an exemption for the sale of human blood and human body parts.[277] StemExpress is not a tissue or blood bank; rather, it sells fetal tissue cells, cell lines, and other products directly to customers. The California State Board of Equalization (SBE) recently collected nearly $82,000 for unpaid sales taxes for a non-profit organization that saves dogs, draws blood from those dogs, and sells the white blood cells, plasma, and red blood cells for transfusions into other canines.[278]

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[275] Cal. Rev. & Tax Code § 6203. A publication put out by the State Board of Equalization ("SBE") states that provision applies to corporations, individuals, Limited Liability Companies, Limited Liability Partnerships, Limited Partnerships, partnerships, married co-owners, registered domestic partnerships, and organizations. *See* Cal. State Bd. of Equalization, "Your California Seller's Permit: Your Rights and Responsibilities under the Sales and Use Tax Law," Pub. 72, at 1 (May 2014).

[276] Cal. State Bd. of Equalization, "Laws, Regulations & Annotations, Sales and Use Tax Law, Chapter 3. The Tax," https://www.boe.ca.gov/lawguides/business/current/btlg/vol1/sutl/6203.html.

[277] Cal. Rev. & Tax Code § 33 ("Human whole blood, plasma, blood products, and blood derivatives, or any human body parts held in a bank for medical purposes, shall be exempt from taxation for any purpose.").

[278] Chris Haire, "Greyhound Dog Rescue Hemopet Fights to Stay Open after $82,000 Tax Bill," *Orange County Register*, Oct. 10, 2016, http://www.ocregister.com/articles/blood-731674-hemopet-greyhounds.html.

The statute defines tangible personal property as "personal property which may be seen, weighed, measured, felt, or touched, or which is in any other manner perceptible to the senses."[279] Thus, cells and cell lines are tangible personal property under the California Sales and Use Tax.

An SBE publication states that California companies can pass along the amount of sales tax to customers, provided the business lists a separate amount for sales tax reimbursement on its receipts or invoices, or if the sales agreement "specifically calls for the addition of sales tax reimbursement."[280] If the business includes sales tax reimbursement in its prices, companies "must inform the buyer that tax is included" by making one of the following statements on a price tag or in an advertisement: "All prices of taxable items include sales tax reimbursement computed to the nearest mill," or "The price of this item includes sales tax reimbursement to the nearest mill."[281] Neither of those statements are on StemExpress' website, nor in any advertisements or brochures produced to the Panel.

Under the California Revenue and Tax Code:

> Internet sales are treated just like sales made at retail stores, by sales representatives, over the telephone, or by mail order. If your business is located in California, retail sales of tangible personal property that you make over the Internet to California customers are generally taxable unless the sales qualify for a specific tax exemption or exclusion . . . and you are required to register for a permit and report and pay tax to the same extent as any other retailer in California.[282]

The Panel sought to determine whether StemExpress complied with the California Revenue and Tax Code. The Panel has determined StemExpress may have violated that statute because it did not charge the legally required sales tax to its California-based clients.

10. The Panel Makes Criminal Referrals Based on StemExpress' Apparent Violations of Law and Federal Regulations

The Panel sent criminal referrals that allege StemExpress may have violated applicable federal and state laws, and federal regulations to the following authorities:

- The U.S. Attorney General related to potential violations by StemExpress of 18 U.S.C. § 1519 and 42 §289g-2.

[279] Cal. Rev. & Tax Code § 6016.
[280] Cal. State Bd. of Equalization, "Your California Seller's Permit: Your Rights and Responsibilities under the Sales and Use Tax Law," Pub. 72, at 5 (May 2014).
[281] *See id.*
[282] Cal. State Bd. of Equalization, "Publication 109 Internet Sales" 5, https://www.boe.ca.gov/formspubs/pub109/.

- The El Dorado County, California, District Attorney related to potential violations by StemExpress of the California Health and Safety Law, and the California Tax Revenue and Tax Code.

- The U.S. Department of Health and Human Services related to potential violations of the Health Insurance Portability and Accountability Act of 1996.

- The U.S. Department of Health and Human Services related to potential violations 45 C.F.R. 46.

B. DaVinci Biosciences, LLC/DaVinci Biologics, LLC: A Case Study

7. Summary

Documents obtained by the Panel and a lawsuit filed by the Orange County, California District Attorney[283] suggest that DaVinci Biosciences, LLC (DaVinci), and DaVinci Biologics, LLC (DVB) were driven by one motive: profit. Documents cited in the District Attorney's lawsuit show that DaVinci and DVB charged considerably more for fetal tissue and cell lines derived from that tissue than the costs it incurred. The firms' business and marketing plans show that officers and directors pushed their employees to sell more and more tissue, and thus increased DaVinci and DVB's bottom line. The company's sole source of fetal tissue was at Planned Parenthood of Orange and San Bernardino Counties.

The Panel has uncovered evidence that DaVinci and DVB may have violated 42 U.S.C. § 289g-2 and provisions of the California Health and Safety Law and the California Tax Revenue and Tax Code.

c) Background of DaVinci and DVB

DaVinci was founded as a for-profit corporation with the California Secretary of State on December 19, 2007.[284] DVB was also founded as a for-profit corporation and filed its incorporation papers with the California Secretary of State on March 16, 2009.[285] DVB was and remains located at the same physical location as DaVinci.[286] The California Franchise Tax Board revoked DaVinci's powers, rights, and privileges on July 28, 2015.[287] It took the same action against DVB on November 3, 2014.[288]

Such revocations occur when an entity fails to do the following: File a tax return; Pay taxes or penalties (including any to the Secretary of State penalty); Pay fees (such as collection,

[283] Complaint, People v. DV Biologics, LLC, et al., 201600880665, (Cal. Super. Ct., Orange County, Oct. 11, 2016), Exhibit 5.28.
[284] California Secretary of State, Business Entity Detail, http://kepler.sos.ca.gov.
[285] *Id.*
[286] Complaint, People v. DV Biologics, LLC, et al., 201600880665, (Cal. Super. Ct., Orange County, Oct. 11, 2016), Exhibit 5.28.
[287] *Id.*
[288] *Id.*

filing enforcement, lien, sheriff, or exempt fees); or Interest. "Suspended business entities lose their rights, powers, and privileges to conduct business in California."[289] The Orange County District Attorney alleged the Franchise Tax Board revoked DaVinci and DVB's ability to conduct business in California because the firms failed to pay all the required taxes or fees.[290] Documents produced by DVB show that, despite its revocation, the firm continued to conduct business through October 16, 2015.[291]

The counsel for both entities informed the Panel that "DVB is a subsidiary of DaVinci Biosciences, LLC."[292] DaVinci is jointly owned and managed by [DVB Executives].[293] [DVB Executive #1] is a founding member of both DaVinci and DVB.[294] The other founders of both DaVinci and DVB are [DVB Executives #2 and #3].[295] All are related.[296]

d) History of the Panel's Interactions with DaVinci and DVB

The Panel sent a December 18, 2015 document request letter to DVB that asked for, among other items, a list of all entities from which it procured fetal tissue and to which is sold or donated fetal tissue, an organization chart, all communications that direct DVB personnel to procure fetal tissue, and all accounting and banking records.[297]

DVB responded in a January 29, 2016 letter in which it produced only information about where it procured fetal tissue, a list of entities to which it sold or donated fetal tissue, and an organization chart.[298] DVB in that same letter agreed to produce on a rolling basis all communications that direct its personnel to procure fetal tissue, all accounting records, all specific requests for fetal tissue made by any entity (including order lists, billing records, and payment records), documents related to equipment (including maintenance costs and depreciation), an inventory of all fetal tissue procured or sold, and its banking records.[299]

On May 5, 2016, the Panel issued a subpoena to DVB that required the production by May 23, 2016, of all the documents requested in the December 18, 2015, letter, as well as detailed accounting records, copies of invoices that related to the sale of fetal tissues or cell lines derived therefrom, and communications or documents related to Institutional Review Board

[289] State of California Franchise Tax Board website, https://www.ftb.ca.gov/businesses/faq/742.shtml.
[290] Complaint, People v. DV Biologics, LLC, et al., 201600880665, (Cal. Super. Ct., Orange County, Oct. 11, 2016), Exhibit 5.28.
[291] Invoices produced to the Panel by DaVinci Biologics, LLC (May 27, 2016).
[292] *See* Letter from R. Joseph Burby, IV, Bryan Cave LLP, to Rep. Marsha Blackburn, Chair, Select Investigative Panel (Jan. 29, 2016).
[293] Complaint, People v. DV Biologics, LLC, et al., 201600880665, (Cal. Super. Ct., Orange County, Oct. 11, 2016), Exhibit 5.28.
[294] *Id.*
[295] *Id.*
[296] *Id.*
[297] *See* Letter from Rep. Marsha Blackburn, Chair, Select Investigative Panel, to Juan Jose Duran, Vice President for Operations, DaVinci Biologics, LLC (Dec. 18, 2015).
[298] *See* Letter from R. Joseph Burby, IV, Bryan Cave LLP, to Rep. Marsha Blackburn, Chair, Select Investigative Panel (Jan. 29, 2016).
[299] *See id.*

approvals.[300] The subpoena did not demand the production of charitable contributions made by DVB, its officers, or executives.[301]

During a May 13, 2016, telephone conference with Panel staff, DVB offered to produce various accounting documents, with the provision that the Panel's forensic accountant would review the documents. [302] If the Panel determined that the documents were inadequate, the Panel could request more detailed records.[303] On May 18, 2016, DVB produced cost analysis and other financial documents that it contended showed the firm lost money on fetal tissue production and sales.[304] After a forensic accounting analysis of the proposed production, the Panel found that the documents were insufficient to determine the adequacy of the applicable federal statute.

On May 27, 2016, DVB produced to the Panel 1,711 invoices that counsel for the firm represented covered all orders for fetal tissue.[305] DVB still has not produced all communications related to the procurement or sale of fetal tissue, accounting memoranda, chart of accounts, tax returns, bank statements, orders for fetal tissue, and communications and documents that relate or refer to Institutional Review Board approvals.

In late May 2016, the Panel discovered an online copy of the Planned Parenthood Orange and San Bernardino Counties' (PPOSBC) 2008-2009 program report which listed DaVinci as having donated between $1,000 and $2,499 to the Planned Parenthood affiliate.[306] Panel staff held a May 26, 2016, telephone conference with DVB counsel to request information on DVB's charitable contributions to PPOSBC from January 1, 2010, through May 26, 2016. In a June 7, 2016, email to staff, DVB's counsel represented that DVB:

> only made two donations to PPOSBC during this time period, which together totaled only $380. The donations were made by purchasing a ticket (at a price of $190) to attend PPOSBC's annual fundraising luncheon. We trust you'll find that these donations were nominal and hardly represented some sort of effort by DV Biologics to covertly pay PPOSBC for fetal tissue donations it received.[307]

Panel staff and DVB counsel exchanged emails on June 7, 2016, in which the Panel requested additional information and documentation.[308] In a June 9, 2016 email to the Panel, DVB counsel produced records that show DVB officials donated a total of $3,030 to PPOSBC,

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[300] Subpoena to DV Biologics, LLC (May 5, 2016), Exhibit 5.29.
[301] *Id.*
[302] Telephone conference between Panel staff and R. Joseph Burby, IV, Bryan Cave LLP (May 13, 2016).
[303] *See* Letter from R. Joseph Burby, IV, Bryan Cave LLP, to Rep. Marsha Blackburn, Chair, Select Investigative Panel (Jan. 29, 2016). Telephone conference between Panel staff and R. Joseph Burby, IV, Bryan Cave LLP (May 13, 2016).
[304] *See* Letter from Michael R. Tein, co-counsel to DVB, to Panel staff (May 16, 2016).
[305] *See* Email from Matthew Simmons, Lewis Tein PL, to Panel staff (May 27, 2016).
[306] *See* Planned Parenthood of Orange and San Bernardino Counties, "Program Report 2008-2009: I Am Building Healthy Communities," at 12.
[307] *See* Email from R. Joseph Burby, IV, Bryan Cave LLP, to Panel staff (June 7, 2016).
[308] *See* Email from Panel staff to R. Joseph Burby, IV, Bryan Cave LLP (June 7, 2016, 5:09 p.m.); Email from R. Joseph Burby, IV, Bryan Cave, LLP, to Panel staff (June 7, 2016, 5:44 p.m).

not the $380 he had earlier represented.[309] In his email, DVB counsel acknowledged "these records are outside the scope of the Committee's [sic] subpoena, but our client has nevertheless elected to voluntarily provide them to you."[310] On August 10, 2016, DVB's vice president for operations sent a letter to Panel staff changing the amount that DVB, its officers, directors, and employees donated to PPOSBC from $3,030 to $3,620.[311]

On October 11, 2016, the Orange County, California District Attorney filed a lawsuit against DaVinci, DVB, and their corporate officers that alleged the entities violated 42 § 289g-2, and Section 125320 of the California Health and Safety Code that likewise bars the sale of fetal tissue for valuable consideration.[312] The lawsuit alleged that DaVinci and DVB "obtained aborted fetus donations from Planned Parenthood [Orange and San Bernardino Counties] and turned those donations into a profit-driven business," through which the companies wound up "earning hundreds of thousands of dollars in revenue."[313]

8. Business Model of DaVinci and DVB

a) Marketing Activities

DVB began commercial operations in May 2009, without a market strategy. A few months later, the firm launched its first marketing campaign,[314] which stated:

> The marketing challenge for [2009-2010] will be to introduce our products in a politically conscious way given that the material is both human and in some cases pre-natal derived . . . . The challenge will be to form a sales tactic team, infiltrate markets . . . to change existing buyer's outlook and purchasing behaviors . . . [and to make] human cell-derived products well understood and appear worthy of any additional cost to purchase."[315]

Both DaVinci and DVB hired an outside marketing consultant to develop marketing materials, including a catalog, to support their sales effort. The 2010 catalog was posted on the company's website and was sent to various sales leads in an effort to drive sales. The catalogue advertised numerous fetal tissue "products," as part of DVB's LIFEbank brand. The fetal tissues and cells that were listed for sale on the first catalogue included heart, brain, lungs, kidneys, liver, large, intestines, small intestines, skin, skeletal muscle, and bones.[316]

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[309] *See* Email from Joseph R. Burby, IV, Bryan Cave LLP, to Panel staff (June 9, 2016).
[310] *See* Email from Joseph R. Burby, IV, Bryan Cave, to Panel staff (June 9, 2016).
[311] *See* Letter from [DVB Vice President of Operations] to Panel staff (Aug. 10, 2016).
[312] Complaint, People v. DV Biologics, LLC, et al., 201600880665, (Cal. Super. Ct., Orange County, Oct. 11, 2016), Exhibit 5.28.
[313] *Id.*.
[314] *Id.*
[315] *Id.*
[316] *Id.*

The first online catalogue advertised prices in a range as low as $40/vial for Total RNA cells from several fetal parts to as high as $1,100/vial for fetal brain cells. Most products were priced somewhere in the middle of this range ($300-$375/vial for fetal lung cells; $300-$450/vial for fetal kidney cells; $500-$700/vial for fetal heart cells; and $250-$700/vial for fetal liver cells).[317] The current DVB online catalog allows researchers to select from among 338 different types of cells and add the desired product to their "cart."[318] As with the original catalogue, the prices vary dramatically.[319]

DVB's current website catalogue states that customers can "[O]rder anytime, 24 hours a day, 365 days a year by email or fax. If your order arrives outside our normal business hours, it will be quickly processed at the beginning of the next business day."[320] All orders to North America "are shipped from DV Biologics headquarters in Southern California and freight is pre-paid and added to your invoice as a separate item unless customers references their own separate shipping account and vendor."[321] International orders are shipped from DV Biologics headquarters in Southern California every Monday unless specially requested to be shipped on another date.[322]

In late 2011, DaVinci and DVB created a business and marketing plan for the next three years. The plan laid out DaVinci and DVB's three-year goals: "to infiltrate the cell-based market, be a major competitor in the cell-based therapies and tools market for improving health and quality of life, and provide a healthy and conservative balance sheet."[323] The plan's "objective" was to develop the "business units" of DaVinci and DVB "into revenue and value generating subsidiaries."[324] To achieve that, the plan called for "hiring a commercial representative" or "a dedicated sales/marketing person," increasing "the amount of marketing" and the "number of distributors throughout the world and tak[ing] advantage of the internet, distributors, newsletters, educational presentations, and direct marketing/sales."[325]

The plan also called for "penetrating the local American market" by securing a United States distributorship agreement.[326] The business and marketing plan required DVB to "market no less than 10 new products yearly."[327] The driving force behind the business and marketing plan was "to increase sales yearly by no less than 30% each year for the next 3 years . . ."[328]

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[317] Complaint, People v. DV Biologics, LLC, et al., 201600880665, (Cal. Super. Ct., Orange County, Oct. 11, 2016), Exhibit 5.28.
[318] DV Biologics, LLC, LIFEbank Products, http://www.dvbiologics.com/products, Exhibit 5.30.
[319] *Id.*
[320] DV Biologics, LLC, Website, http://www.dvbiologics.com/ordering-information, Exhibit 5.31.
[321] *Id.*
[322] *Id.*
[323] Complaint, People v. DV Biologics, LLC, et al., 201600880665, (Cal. Super. Ct., Orange County, Oct. 11, 2016), Exhibit 5.28.
[324] *Id.*
[325] *Id.*
[326] *Id.*
[327] *Id.*
[328] *Id.*

After a regional sales manager was hired in early 2013, DaVinci and DVB started a 2013 Sales Launch Plan to further increase sales. "The primary objective of [the] plan" was to "help" DVB "meet or exceed its bottom-line goals & objectives," including a goal to "[g]enerate $550,000 in gross revenue by the end of 2013."[329]

The 2013 sales plan also called for improved "selling techniques," the retention of two additional sales managers, and a focus on the sales of "the hottest selling products," which included, among others, the firms' fetal tissue cell lines. In addition, the sales plan expected that the "sales team will go 'above & beyond' what is generally expected," by "heavy prospecting" to generate "leads" and secure sales.[330]

The Orange County District Attorney alleged that, starting in 2012 and for years after under updated marketing and sales plans, both DaVinci and DVB management consistently pushed staff to sell more "product."[331]

As part of its marketing and sales efforts, DVB offered customer discounts.[332] The Orange County District Attorney lawsuit noted DaVinci and DVB "offered numerous discounts, including distributor discounts (20-30%); first time buyer discounts (10-15%); and bulk purchase discounts (sometimes as high as 50%). The company also regularly offered 'sales' pricing promotions, including, for example, a '25% off' summer sale' and '25% off' fall promotion in 2013.[333]

Documents DVB produced to the Panel demonstrate that the District Attorney was correct: Customers who sought a discount had to submit a credit application, that included business references.[334] A DVB operations assistant then contacted the business references and asked them how long the customer has been doing business with the reference, what was their credit line, and whether they always paid on time.[335] If the customer or distributor had three favorable references, they received up a $5,000 maximum credit line upon approval of DVB's vice president for operations. The vice presidents of operations and sales could provide larger unspecified credit lines.[336] If a customer who received a discount paid within 10 days of the invoice date, they could receive an additional early payment discount of 1.5%.[337]

In addition, a tradeshow ad produced by DVB to the Panel shows that attendees of the University of California Riverside Biotechnology Vendor Showcase received a 20% discount

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[329] *Id.*
[330] *Id.*
[331] *Id.*
[332] DV Biologics, LLC, Guidelines for Payments and Discounts, (Feb. 12, 2015) [DVB_00000014–00000018], Exhibit 5.32.
[333] Complaint, People v. DV Biologics, LLC, et al., 201600880665, (Cal. Super. Ct., Orange County, Oct. 11, 2016), Exhibit 5.28.
[334] DV Biologics, LLC, Guidelines for Payments and Discounts, (Feb. 12, 2015) [DVB_00000014–00000018], Exhibit 5.32.
[335] *Id.*
[336] *Id.*
[337] *Id.*

"off their first order! [sic]"[338] DVB also offered customers 10% of their next order if they referred a colleague to DVB.[339] Invoices produced by DVB to the Panel show the firm also offered, in several instances, discounts of 50%, significant "special discounts," complimentary evaluation samples, lower prices for distributors, a 25% holiday discount, and a 15% discount off first orders.[340]

b) DaVinci and DVB's Relationship with Planned Parenthood of Orange and San Bernardino Counties

Both entities received aborted fetal tissue from the same source: Counsel for DaVinci and DVB told the Panel, "DVB received fetal tissue exclusively from its parent company, DaVinci. DaVinci itself received fetal tissue exclusively from Planned Parenthood of Orange and San Bernardino Counties [PPOSBC]." DaVinci claimed it did not pay any money to Planned Parenthood for the donated tissue."[341]

Planned Parenthood Federation of America ("PPFA) told investigators from the Energy and Commerce Committee that PPOSBC "entered into an agreement [with DVB] in September 2008 to facilitate fetal tissue donation by its patients. The affiliate last facilitated tissue donation on June 5, 2015. The program was suspended because [DVB]'s laboratory was undergoing renovations."[342] PPFA also revealed to an earlier investigation that PPOSBC was the only Planned Parenthood affiliate that "has facilitated tissue donation directly to a biosciences company."[343]

A September 23, 2008, contractual agreement between DVB and PPOSBC shows that the firm provided PPOSBC "with a sterile container, including storage media, for each" fetal tissue specimen the Planned Parenthood affiliate obtained.[344] On each day DVB was scheduled to obtain fetal tissue, PPOSBC workers would, "following retrieval, store each [fetal tissue] Specimen in a separate container" and notify DVB's "designated contact . . . that Specimen is ready for pick-up . . . ."[345]

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[338] DV Biologics, LLC, Biotechnology Tradeshow Ad, undated [DVB_00000289], Exhibit 5.33.
[339] DV Biologics, LLC, Customer Referral Program, Sept. 5, 2014, at 6 [DVB_00000254], Exhibit 5.34.
[340] *See* Invoices produced to the Panel by DaVinci Biologics, LLC (May 27, 2016).
[341] *See* Letter from Joseph R. Burby, IV, Bryan Cave LLP, to Rep. Marsha Blackburn, Chair, Select Investigative Panel 3 (Jan. 29, 2016).
[342] Planned Parenthood Federation of America, "Follow-up Questions Dated August 20, 2015: U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Oversight and Investigations," at 2 [PPFA-HOU_E&C-0000162 – PPFA-HOU_E&C-000169], Exhibit 5.35.
[343] Planned Parenthood Federation of America, "Follow-up Questions Dated August 20, 2015: U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Oversight and Investigations" [PPFA-HOU_E&C-0000259 – PPFA-HOU_E&C-000262], Exhibit 5.36.
[344] Specimen Donation Agreement between DaVinci Biosciences, LLC, and Planned Parenthood of Orange and San Bernardino Counties (Sept. 23, 2008) [DVB_00001613 – DVB00001622], Exhibit 5.37.
[345] Planned Parenthood Federation of America, "Follow-up Questions Dated August 20, 2015: U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Oversight and Investigations" [PPFA-HOU_E&C-0000259 – PPFA-HOU_E&C-000262], Exhibit 5.36.

The 2008-2009 program report of PPOSBC listed DaVinci as having donated between $1,000 and $2,499 to the Planned Parenthood affiliate.[346] DVB's contract with PPOSBC is dated September 23, 2008.[347] Documents produced by DVB to the Panel show officials with the firm donated $2,190 to PPOSBC during 2008 alone, including four separate $500 "charitable donation[s]" on April 24, 2008.[348] That date is significant because it not only predates by nearly five months DVB's contract with PPOSBC, but also because invoices produced by DVB to the Panel show that less than one year later, on April 1, 2009, the firm first transferred human fetal tissue to a customer.[349] In 2009, DVB donated another $500 to PPBOSBC.[350]

DVB's attorney represented that "the individuals responsible for these donations have not worked at DV Biologics since approximately 2011. The company underwent a significant change in management at that time."[351] [DVB Executive #1], who contributed $2,500 to PPOSBC before the PPOSBC contract was signed, was named by the Orange County District Attorney as DaVinci's manager and chief executive officer.[352] However, in 2012, DVB donated $380 more in two separate $190 donations to PPBOSCB.[353] It is unclear why DVB made the two donations if the individuals responsible for the earlier donations had left, along with key management officials.

Documents produced by other firms in the fetal tissue industry to the Panel pursuant to subpoenas demonstrate that the industry norm is for companies, both for-profit or non-profit, to pay California-based abortion clinics for fetal tissue. For example, StemExpress, LLC, another for-profit tissue procurement firm, paid Planned Parenthood affiliates in California an average of $50 per-specimen obtained.[354] Advanced Bioscience Resources, Inc., a non-profit tissue procurement business, paid facility fees of $55 or $60 per month (depending upon the year) to the Planned Parenthood affiliates and clinics from which it obtained fetal tissue.[355] From 2010 through 2015, StemExpress paid a total of $135,880 to California-based Planned Parenthood affiliates for fetal tissue specimens.[356] Over the same time period, Advanced Biosciences

[346] See Planned Parenthood of Orange and San Bernardino Counties, "Program Report 2008-2009: I Am Building Healthy Communities," 12.
[347] Specimen Donation Agreement between DaVinci Biosciences, LLC, and Planned Parenthood of Orange and San Bernardino Counties (Sept. 23, 2008) [DVB_00001613–DVB00001622], Exhibit 5.37.
[348] DV Biologics, LLC, "Transactions Detail by Account, January 1, 2007 through September 28, 2015."
[349] DV Biologics, LLC, Invoice Number 1, Apr. 1, 2009.
[350] DV Biologics, LLC, "Transactions Detail by Account, January 1, 2007 through September 28, 2015."
[351] Email from R. Joseph Bury, IV, Bryan Cave LLP, to Panel staff, June 9, 2016.
[352] Complaint, People v. DV Biologics, LLC, et al., 201600880665, (Cal. Super. Ct., Orange County, Oct. 11, 2016), Exhibit 5.28.
[353] DV Biologics, LLC, "Transactions Detail by Account, January 1, 2007 through September 29, 2015."
[354] *See* Services Agreement between StemExpress, LLC, and Planned Parenthood Mar Monte, Apr. 1, 2010, at 1 [STEM_HOUSE.SELECT_0167–STEM_HOUSE.SELECT_0169]; Services Agreement between StemExpress, LLC, and Planned Parenthood Shasta Pacific (May 15, 2012) 1 [STEM.HOUSE.SELECT_0170–STEM.HOUSE.SELECT_0172]; Services Agreement between StemExpress, LLC, and Planned Parenthood of Santa Barbara, Ventura & San Luis Obispo Counties 1 (Oct, 23, 2013).
[355] Advanced Bioscience Resources, Inc., "Statement of Facility Fees, Jan. 2010 – Oct. 2015."
[356] Panel analysis of invoices from Planned Parenthood Mar Monte and Planned Parenthood Shasta Pacific to Stem Express, LLC.

Resources, Inc. paid a total of $328,225 to California-based Planned Parenthood affiliates for fetal tissue specimens.[357]

c) Revenue Growth

When DVB began its commercial operations in May 2009, the company had "minimal product inventory and no marketing or sales."[358] Between 2009 and 2011, sales revenues nearly tripled.[359] By 2012, DaVinci and DVB's products were "valued at much greater than $4.4 million."[360] An undated audit of DaVinci and DVB stated the value of the firms' inventory could be as high as $10 million.[361]

The Orange County District Attorney alleged that DVB's goal in 2013 was to generate $555,000 in revenue by the end of the year.[362] Those goals were slightly high: In both 2013 and 2014, the company grossed in excess of $400,000 in revenue—double that of 2012. In 2015, the firms continued their upward momentum and exceeded $550,000 in gross revenues.[363] The District Attorney alleged, "When subtracting the cost of goods sold, DV produced a gross profit on sales every year, except 2012."[364]

9. Consent & Procurement During the Abortion Procedure

Documents produced by DVB to the Panel show that PPOSCB workers performed the following tasks:

- Discussed tissue donation with women awaiting abortions;
- Obtained consent from the patients to donate human fetal tissue;
- Procured fetal tissue of between a gestational period of 5-20 weeks;
- Stored the signed consent forms;
- Collected the fetal tissue samples, washed the samples, and transferred them to a sterile container with the gestational age written on the container; and,

[357] Panel analysis of invoices from Planned Parenthood San Jose, Planned Parenthood Riverside, and Planned Parenthood to Advanced Bioscience Resources, Inc.
[358] Complaint, People v. DV Biologics, LLC, et al., 201600880665, (Cal. Super. Ct., Orange County, Oct. 11, 2016), Exhibit 5.28.
[359] *Id.*
[360] *Id.*
[361] *Id.*
[362] *Id.*
[363] *Id.*
[364] *Id.*

- Stored the samples on wet ice, which were transported by DVB employee(s).[365]

10. Post-Procedure Practices

DV employees received the fetal tissue, noting the harvest date, the pickup time, the arrival time, the organ/tissue, gender, which employee picked up the tissue, whether the tissue was discarded, and if so, why.[366] Once the tissue was logged in, DVB employees then processed the fetal tissue, checked it in, "[i]dentified fetal organs" "mechanically minced and enzymatically digested" the organs, cultured the isolated cells, and, in some instances "cryopreserved" the cells or cell lines at DVB.[367]

11. Customers that Received Fetal Tissue from DaVinci and DVB

DaVinci and DVB sold the fetal tissue to researchers, educational institutions, and pharmaceutical companies. DaVinci "focused on the research and development of cell-based therapeutics targeting neurodegenerative and autoimmune diseases, while DVB supplied human biological tools to academic institutions and pharmaceutical companies for research purposes."[368]

Roughly half of all DVB's customers were foreign entities.[369] DVB's domestic customers were, in chronological order:

- The University of Utah Cell Therapy Facility
- VA Health Center - Long Beach
- University of Connecticut Health Center
- Cedars-Sinai Medical Center
- University of Texas San Antonio
- University of California Irvine Department of Radiation
- Life Technologies
- Cleveland Clinic

[365] DaVinci Biosciences, LLC, Characterization of Human Fetal Stem Cells and Determination of Research and Therapeutic Tool Potential, undated [DVB_00001611-0000612], Exhibit 5.38.
[366] DaVinci Biosciences, LLC, Form 101, Prenatal Receiving, undated [DVB_00000062], Exhibit 5.39.
[367] DaVinci Biosciences, LLC, Characterization of Human Fetal Stem Cells and Determination of Research and Therapeutic Tool Potential, undated [DVB_00001611-0000612], Exhibit 5.38.
[368] *See* Letter from R. Joseph Burby, IV, Bryan Cave LLP, to Rep. Marsha Blackburn, Chair, Select Investigative Panel (Jan. 29, 2016).
[369] Panel analysis of invoices produced by DaVinci Biologics, LLC.

- City of Hope
- Cellular Dynamics International
- SA Biosciences Corporation
- StemCell Technologies, Inc.
- Omeros Corporation
- University of Wisconsin Medical College
- University California Merced
- Procter & Gamble (Miami Valley Innovation)
- Stanford University
- Fisher Scientific
- UNIVSION USA
- B-Bridge International Inc.
- iPierian, Inc.
- AgenSys
- Aloecorp, Inc.
- Santa Cruz Biotechnology, Inc.
- Zyagen
- Trim-edcine
- WuXi App Tech, Inc.
- Tufts University
- Royspec
- J. David Gladstone Institutes

- Applied StemCell, Inc.
- Gentech
- Creative Biolabs, Inc.
- Baylor College of Medicine
- RaNa Therapeutics, Inc.
- MatTek Corporation
- New York Medical Center
- Tufts University Department of Biomedical Research
- University of Washington
- Organovo
- Amira Pharmaceuticals Inc.
- New York University Langone Center
- University of Texas Medical Branch
- National Institutes of Health
- Brigham & Women's Hospital
- Abbvie, Inc.
- Quorum Innovations
- Earth Science Tech.[370]

[370] Invoices produced by DaVinci Biologics, LLC, to the Panel.

12. Potential Violations of Law

c) Applicable Laws

l) 42 U.S.C. § 289g-2

The applicable federal law on fetal tissue is 42 U.S.C. § 289g-2(a), which states "It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce." Under that law, "The term 'valuable consideration' does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."[371] Human fetal tissue is defined broadly to include any "tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth."[372]

ii) California Health and Safety Code Section 125320

The California Health and Safety Code contains virtually identical language as 42 U.S.C. § 289g-2. That law states that:

> (d) A person may not knowingly, for valuable consideration, purchase or sell embryonic or cadaveric fetal tissue for research purposes pursuant to this chapter.
>
> (e) For purposes of this section, "valuable consideration" does not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of a part.
>
> (f) Embryonic or cadaveric fetal tissue may be donated for research purposes pursuant to this chapter.[373]

As with 42 U.S.C. § 289g-l(g), another provision of the California Health and Safety Code also broadly defines tissue to "mean a human cell, group of cells, including the cornea, sclera, or vitreous humor and other segments of, or the whole eye, bones, skin, arteries, sperm, blood, other fluids, and any other portion of a human body . . . ."[374]

iii) California Revenue and Tax Code

A provision of the California Revenue and Tax Code states that:

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[371] 42 U.S.C. § 289g-2(e)(3)
[372] 42 U.S.C. § 289g-l(g).
[373] Cal. Health & Safety Code § 125320.
[374] Cal. Health & Safety Code § 1635(c).

> [E]very retailer engaged in business in this state and making sales of tangible personal property for storage, use, or other consumption in this state, not exempted . . . shall, at the time of making the sales or, if the storage, use, or other consumption of the tangible personal property is not then taxable hereunder, at the time the storage, use, or other consumption becomes taxable, collect the tax from the purchaser and give to the purchaser a receipt therefor in the manner and form prescribed by the [California State Equalization Board].[375]

The law defines a "retailer engaged in business in" California as "Any retailer maintaining, occupying, or using, permanently or temporarily, directly or indirectly, or through a subsidiary, or agent, by whatever name called, an office, place of distribution, sales or sample room or place, warehouse or storage place, or other place of business."[376]

There is an exemption for the sale of human blood and human body parts.[377] DVB is not a tissue or blood bank. Rather it sells fetal tissue cells, cell lines, and other products directly to customers. The California State Board of Equalization ("SBE") recently collected nearly $82,000 for unpaid sales taxes for a non-profit organization that saves dogs, draws blood from those dogs, and sells the white blood cells, plasma, and red blood cells for transfusions into other canines.[378]

The statute defines tangible personal property as "personal property which may be seen, weighed, measured, felt, or touched, or which is in any other manner perceptible to the senses."[379] Thus, cells and cell lines are tangible personal property under the California Sales and Use Tax.

An SBE publication states that California companies can pass along the amount of sales tax to customers, provided the business lists a separate amount for sales tax reimbursement on its receipts or invoices, or if the sales agreement "specifically calls for the addition of sales tax reimbursement."[380] If the business includes sales tax reimbursement in its prices, companies "must inform the buyer that tax is included" by making one of the following statements on a price tag or in an advertisement: "All prices of taxable items include sales tax reimbursement computed to the nearest mill," or "The price of this item includes sales tax reimbursement to the

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[375]Cal. Rev. & Tax Code § 6203. A publication put out by the State Board of Equalization ("SBE") states that provision applies to corporations, individuals, Limited Liability Companies, Limited Liability Partnerships, Limited Partnerships, partnerships, married co-owners, registered domestic partnerships, and organizations. Cal. State Bd. of Equalization, "Your California Seller's Permit: Your Rights and Responsibilities under the Sales and Use Tax Law," Pub. 72, May 2014, at 1.

[376] Cal. State Bd. of Equalization, "Laws, Regulations & Annotations, Sales and Use Tax Law, Chapter 3. The Tax," https://www.boe.ca.gov/lawguides/business/current/btlg/vol1/sutl/6203.html.

[377] Cal. Rev. & Tax Code § 33 ("Human whole blood, plasma, blood products, and blood derivatives, or any human body parts held in a bank for medical purposes, shall be exempt from taxation for any purpose.").

[378] Chris Haire, "Greyhound Dog Rescue Hemopet Fights to Stay Open after $82,000 Tax Bill," *Orange County Register*, Oct. 10, 2016, http://www.ocregister.com/articles/blood-731674-hemopet-greyhounds.html.

[379] Cal. Rev. & Tax Code § 6016.

[380] Cal. State Bd. of Equalization, "Your California Seller's Permit: Your Rights and Responsibilities under the Sales and Use Tax Law," Pub. 72, May 2014, at 5.

nearest mill."[381] Neither of those statements are on DVB's website or in the advertisement produced to the Panel by DVB.[382]

Under the California Revenue and Tax Code,

> Internet sales are treated just like sales made at retail stores, by sales representatives, over the telephone, or by mail order. If your business is located in California, retail sales of tangible personal property that you make over the Internet to California customers are generally taxable unless the sales qualify for a specific tax exemption or exclusion . . . and you are required to register for a permit and report and pay tax to the same extent as any other retailer in California.[383]

d) Findings

j) 42 U.S.C. § 289g-2 & California Health and Safety Code Section 125320

The Orange County District Attorney alleged that DaVinci and DVB's costs to process fetal tissue were minimal: a limited number of labor hours (2-9 hours per product) and that it cost the firms an average of less than $20/vial.[384]

Internal company documents cited in the District Attorney's lawsuit show that DaVinci and DVB sold fetal tissue for valuable consideration. Human Cardiomyocytes cells derived from fetal tissue were produced at a cost including labor of $25.92 per vial; DaVinci and DVB sold it for between $350-per vial and $700-per vial, which amounted to between $324.08 and $674.08 in profit for each vial sold (not including any profits earned on packaging and handling or other fees).[385]

Human Cardiac Progenitor cells, also derived from fetal tissue, were produced at a total cost of $62.31 per vial; the product sold for between $455 and $650-per vial, which amounted to between $392.69 and $587.69 profit for each vial.[386] Another product derived from fetal tissue, Human Whole Liver Cells cost $18.46 per vial to produce; the vials sold for between $125 and $200 a vial, which meant the companies made profits of between $106.54 and $181.54 for each vial.[387] Human CD34 Positive Cells, also derived from fetal liver tissue donations, cost $126.17

[381] *See* Cal. State Bd. of Equalization, "Your California Seller's Permit: Your Rights and Responsibilities under the Sales and Use Tax Law," Pub. 72, May 2014.
[382] DVB Advertisement, Exhibit 5.33.
[383] Cal. State Bd. of Equalization, "Publication 109 Internet Sales," https://www.boe.ca.gov/formspubs/pub109/.
[384] Complaint, People v. DV Biologics, LLC, et al., 201600880665, (Cal. Super. Ct., Orange County, Oct. 11, 2016), Exhibit 5.28.
[385] *Id.*
[386] *Id.*
[387] *Id.*

per vial to produce; it sold for between $225 and $360 for each vial—a profit of between $98.83 and $233.83 per vial.[388]

Stomach cells, also derived from fetal tissue, sold for between $210 and $240 per vial. It cost DaVinci and DVB $18.46 to produce ten vials. Thus, the firms earned a profit of between $191.54 and $221.54 per vial.[389] Two other products that came from fetal tissue, Human Small Intestine Cells (uncultured) and Human Large Intestine Cells were produced in ten-vial lots at a total cost of $18.46 per vial—a profit of between $191.54 and $281.54 per vial.[390]
Another product derived from fetal tissue, Human Small Intestine Epithelial Cells, were manufactured in 10 vials at a cost of $35.91 per vial; DaVinci and DVB sold it for between $297.50 and $700 a vial, which amounted to a per-vial profit of between $261.59 and $664.09.[391]

ii) California Revenue and Tax Code

As previously noted, DVB sold its products through the Internet. It should, therefore, have collected tax on sales made to California customers. Seventeen invoices produced by DVB show the firm did not charge tax to California-based clients.[392] The invoices are listed in the chart below:

CUSTOMER	**DATE**	**INVOICE NUMBER**	**AMOUNT OF SALE**	**SALES TAX CHARGED**
Life Technologies	Feb. 9, 2010	017	$1,500	0
Life Technologies	Jun. 29, 2010	042	$2,425	0
Life Technologies	Jun. 29, 2010	043	$2,390	0
Life Technologies	Aug. 3, 2010	053	$ 631	0
Life Technologies	Sep. 7, 2010	064	$2,415	0

[388] *Id.*
[389] *Id.*
[390] *Id.*
[391] *Id.*
[392] Invoices from DV Biologics, LLC, to Life Technologies, Exhibit 5.40.

Life Technologies	Oct. 6, 2010	073	$1,078	0
Applied StemCell, Inc.	Oct. 31, 2012	387	$ 450	0
Applied StemCell, Inc.	May 16, 2013	504	$1,214	0
Applied StemCell, Inc.	Jun. 4, 2013	517	$ 152.99	0
Applied StemCell, Inc.	Sep. 9, 2013	600	$ 82	0
Applied StemCell, Inc.	Oct. 1, 2013	618	$ 450	0
Applied StemCell, Inc.	Oct. 7, 2013	622	$1,570	0
Applied StemCell, Inc.	Mar. 6, 2014	754	$4,016.99	0
Applied StemCell, Inc.	Jun. 30, 2014	837	$ 218	0
Applied StemCell, Inc.	Aug. 13, 2014	869	$ 592.99	0
Applied StemCell, Inc.	Aug. 18, 2014	871	$ 856.99	0
Applied StemCell, Inc.	Feb. 24, 2015	1077	$1,250	0

13. Conclusion

The Panel referred DVB's potential violations of the California Revenue and Tax Code to the Orange County District Attorney. The Panel referred DVB's potential violation of Title U.S.C. § 289g-2 to the United States Department of Justice.

C. Novogenix Laboratories, LLC: A Case Study

10. Summary

The Panel has uncovered evidence that Novogenix Laboratories, LLC (Novogenix) may have violated laws, including 42 §289g-2, Cal. Health & Safety Code § 125320(a), provisions of the California Tax Revenue and Tax Code, and regulations promulgated by the U.S. Department of Health and Human Services.

a) Background of Novogenix

Novogenix was founded as a for-profit corporation with the California Secretary of State on February 24, 2010, by [Founder and Executive Director].[393] As of October 2015, Novogenix went out of business.[394] Documents produced by the U.S. Food and Drug Administration (FDA) to the Panel show that Novogenix may not have registered with the FDA.[395] Novogenix claimed its work with fetal tissue and stem cells derived from fetal tissue "was exclusively for the purposes of scientific research, and was not used for therapeutic or transplantation purposes."[396] If true, Novogenix was not regulated by the FDA. [Founder and Executive Director], owner of the company told the investigators from the Committee on Energy and Commerce inquiry into the fetal industry that, during the time Novogenix was operating 70%-80% of its business was selling services related to fetal tissue.[397] Those services included the procurement of fetal tissue, the creation of stem cells from fetal tissue, and the shipment of those fetal tissues and stem cells to scientists engaged in research.[398]

b) History of the Panel's Interactions with Novogenix

On December 17, 2015, the Panel sent Novogenix a document request letter requesting a list of all entities from which it procured fetal tissue, a list of all entities to which it sold or donated fetal tissue, an organization chart, all communications that direct its employees to procure fetal tissue, accounting records, and all Novogenix banking records related to the procurement, sale, donation, or distribution or shipment of fetal tissue.[399]

Citing its productions to preliminary congressional investigations into the fetal tissue industry, and that the firm had stopped doing business, Novogenix initially refused to provide

[393] California Secretary of State, Business Entity Detail, http://kepler.sos.ca.gov.
[394] *See* Letter from Joshua A. Levy, Cunningham Levy LLP, to Rep. Fred Upton, Chairman, Committee on Energy and Commerce 1 (Oct. 6, 2015); Letter from Joshua A. Levy, Cunningham Levy LLP, to Panel staff (Dec. 22, 2015); California Secretary of State, Business Entity Detail, http://kepler.sos.ca.gov.
[395] Email from [Supervisor Consumer Safety Officer], U.S. Food and Drug Administration, to [Consumer Safety Officer], U.S. Food and Drug Administration (Sept. 14, 2014).
[396] *See* Letter from Joshua A. Levy, Cunningham Levy LLP, to Charles Ingbertson, Chief Counsel, Committee on Energy and Commerce 2 (Sept. 2, 2015), Exhibit 5.4.1.
[397] [Founder and Executive Director] Novogenix, briefing before Committee on Energy and Commerce (Sept. 3, 2015), Exhibit 5.42
[398] *Id.*
[399] *See* Letter from Rep. Marsha Blackburn, Chairman, House Select Investigative Panel, to [Founder and Executive Director] Novogenix Laboratories, LLC (Dec. 17, 2015), Exhibit 5.4.2

any responsive documents.[400] Novogenix refused to provide the names of the research institutions to whom it supplied fetal tissue "not only out of consideration for the well being [sic] of the people working at these entities, but also out of respect for [Novogenix's] non-disclosure agreements" with its customers.[401] Novogenix said it was "working with dispatch to reach out to" its former customers "in order to determine whether any of them would consent to our disclosure of their names to the Select Panel."[402] Over the next month, Novogenix produced to the Panel the names of some of its customers.[403]

After Novogenix provided only some customers names, on April 29, 2016, the Panel authorized a subpoena that required production of the documents first requested in the December 17, 2015, letter, including the communications with its employees, accounting documents, and all banking records.[404] Following a telephone conference with Novogenix counsel, the Panel agreed not to serve the subpoena, if Novogenix provided the names of all its former customers by May 31, 2016.[405] Novogenix produced the names of entities that "have received over 99% of the fetal tissue that Novogenix has donated."[406]

To date, the Panel has not received any communications that relate to fetal tissue, as well as any accounting or banking records. Senior law enforcement attorneys and other witnesses who testified at the Panel's April 20, 2016, hearing, "The Pricing of Fetal Tissue," stated accounting and banking documents were critical to any analysis of § 289g-2.[407]

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[400] *See* Letter from Joshua A. Levy, Cunningham Levy Muse LLP, to Panel staff 1 (Dec. 22, 2015), Exhibit 5.4.3.
[401] *See* Letter from Joshua A. Levy, Cunningham Levy Muse LLP, to Panel staff 1 (Feb. 16, 2016), Exhibit 5.4.4.
[402] *Id.*
[403] *See* Letter from Joshua A. Levy, Cunningham Levy Muse, LLP, to Panel staff, Feb. 24, 2015; Letter from Joshua A. Levy, Cunningham Levy Muse, LLP, to Panel staff (Feb. 26, 2015); Letter from Joshua A. Levy, Cunningham Levy Muse, LLP, to Panel staff (Mar. 2, 2015); Letter from Joshua A. Levy, Cunningham Levy Muse, LLP, to Panel staff (Mar. 21, 2015).
[404] Subpoena to Novogenix Laboratories, LLP, (April 29, 2016), Exhibit 5.4.5.
[405] Telephone conference between Joshua A. Levy, Cunningham Levy Muse LLP, and Panel staff (May 3, 2016); Email from Joshua A. Levy, Cunningham Levy Muse LLP, to Panel staff (May 6, 2016); Email from Joshua A. Levy, Cunningham Levy Muse LLP, to Panel staff (May 19, 2016).
[406] *See* Letter from Joshua A. Levy, Cunningham Levy Muse LLP, to March Bell, Staff Director and Chief Counsel, Select Investigative Panel 2 (May 31, 2016), Exhibit 5.4.6.
[407] *The Pricing of Fetal Tissue: Hearing before the Select Investigative Panel of the H. Comm. on Energy and Commerce*, 114th Cong. (Apr. 20, 2016). In particular, the witnesses made the following statements when asked by Chairman Blackburn what information the Panel should pursue:

> Former Senior Litigation Counsel, U.S. Department of Justice - Brian Lennon: The only element where investigation is needed, and that would include I believe forensic accounting and analysis thereof, is whether the payments made by the research institutions that ultimately receive the human tissue to the procurement businesses were a valuable consideration or, alternatively, reasonable payments associated with the specific allowable services in the statute… Because the businesses do in fact incur costs associated with these delineated services, a forensic accounting would be essential to breaking down the company's financials. *Pricing of Fetal Tissue*, unedited transcript, at 53.
>
> Former United States Attorney- Kenneth Sukhia: I would also want to know what communications occurred between—other communications, email and so forth,

11. Novogenix Business Model

a) Marketing Activities

[Founder and Executive Director] stated that Novogenix had no formal marketing plan. Rather, researchers reached out to Novogenix for fetal tissue needs directly to [Founder and Executive Director], because of his reputation in the field of stem cell research.[408]

> back and forth between those people. We would seek those items as well, and of course the accounting records. *Pricing of Fetal Tissue*, unedited transcript, at 79.
>
> Former United States Attorney Mike Norton: First of all, I would start by looking at the videos, which I have seen. I would start by reading the forensic accounting report by Coalfire Investigations made up of former FBI agents, which found that the videos were credible and the redacted versions say what the longer versions say. I would obtain the accounting records, the financial records of the abortion clinic, of the procurement business, and, frankly, I would obtain the records of the end user as well, and subpoena both records and witnesses from all of those entities to flesh out the facts in this case, which I think are there. *Pricing of Fetal Tissue*, unedited transcript, at 125-26.
>
> Brian Lennon: As I said in my opening, you need a forensic—if I was a prosecutor, you have to have a forensic evaluation accounting of the procurement business, because that is not clear from the records here. So following the money, you have got to have the entire picture. *Pricing of Fetal Tissue*, unedited transcript, at 139.
>
> Mike Norton: I would get forensic accounting. I would get all of the financial records. I would get the profit and loss statements, the income and expense statements, and I would get people under oath before a grand jury. Letters are not particularly valuable. *Pricing of Fetal Tissue*, unedited transcript, at 139.
>
> Attorney Catherine Glenn Foster: There are two things that I would specifically seek among many different documents. First of all, financial records. That is something that must be brought to light. And, second, women of every generation are unique human beings who can speak for themselves, but the baby body parts profiteers have created a market in which their profits rise if they pressure and coerce women into signing donation consent forms. *Pricing of Fetal Tissue*, unedited transcript, at 140.
>
> Attorney Fay Clayton: The second thing I would do is ask them, in each particular case, what aspect of the actual costs does a particular clinic incur? For example, does the clinic provide space? Does the clinic, as we have seen in your charts, provide the blood draws which requires a technician, perhaps a nurse, materials? Does the clinic have to do paperwork? And, if so, how much? And, therefore, how much of the actual reasonable cost is incurred by the clinic itself as opposed to by the procurement business? *Pricing of Fetal Tissue*, unedited transcript, at 138.

[408] [Founder and Executive Director] Novogenix, briefing before Committee on Energy and Commerce (Sept. 3, 2015), Exhibit 5.42.

b) Novogenix's Relationship with Abortion Clinics

Novogenix had a contract to procure fetal tissue from Planned Parenthood Los Angeles (PPLA). The contract provided that Novogenix would "reimburse PPLA for reasonable administrative costs associated with the identification of potential donors, as well as the obtaining of informed consent. This amount will be $45 per donated specimen."[409] Novogenix's relationship with PPLA ended in 2015 as a direct result of the Center for Medical Progress' videos and resulting press reports.[410]

[Founder and Executive Director] stated that Novogenix obtained tissue from other unnamed clinics "on an ad hoc basis," but Novogenix had no contracts or written documents with those clinics, "just informal agreements."[411]

c) Revenue Growth

Novogenix counsel told the panel, "Novogenix has not sold fetal tissue. Rather, Novogenix contracted with a number of scientists to be reimbursed for the costs of services performed by Novogenix . . . ."[412] [Founder and Executive Director] acknowledged that his understanding of which costs are reimbursable was based on his legal understanding that Novogenix sold services, not fetal tissue.[413] When he was pressed on that point, [Founder and Executive Director] would not answer, citing attorney-client privilege.[414]

The company initially set its prices at $200 for each service performed, however those prices increased each year.[415] [Founder and Executive Director] calculated that figure by adding $50 related to reagents, and $150 based on his projection of fixed costs.[416] [Founder and Executive Director] said he did not calculate how many services Novogenix would perform, how many researchers would obtain his firm's products, or the service volume.[417] He explained that the costs increased each year.[418] [Founder and Executive Director]'s goal was for Novogenix to break even over time.[419]

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[409] Specimen Donation Agreement between Novogenix Laboratories, LLC, and Planned Parenthood Los Angeles (Mar. 1, 2010), Exhibit 5.41.
[410] [Founder and Executive Director] Novogenix, briefing before Committee on Energy and Commerce (Sept. 3, 2015), Exhibit 5.42; Planned Parenthood Federation of America, Response to Follow-Up Questions from the Committee on Energy and Commerce, Subcommittee on Oversight and Investigations (Aug. 20, 2016).
[411] [Founder and Executive Director] Novogenix, briefing before Committee on Energy and Commerce (Sept. 3, 2015), Exhibit 5.42.
[412] Letter from Joshua A. Levy, Cunningham Levy Muse LLP, to Panel staff 1 (Dec. 22, 2015), Exhibit 5.4.3; 5.4.4.
[413] [Founder and Executive Director] Novogenix, briefing before Committee on Energy and Commerce (Sept. 3, 2015), [Founder and Executive Director] Novogenix, briefing before Committee on Energy and Commerce (Sept. 3, 2015), Exhibit 5.42.
[414] *Id.*
[415] [Founder and Executive Director] Novogenix, briefing before Committee on Energy and Commerce, Sept. 3, 2015.
[416] *Id.*
[417] *Id.*
[418] *Id.*
[419] *Id.*

Invoices produced to the Panel by some of Novogenix' customers show that it received a total of $170,980.59 from 7 research institutions between June 2011 and December 2015.[420] The Panel cannot determine either the total number of Novogenix' customers or its revenue.

The firm's counsel represented that it lost a total of $160,540.03 on its fetal tissue operations.[421] Novogenix conceded that its "counsel created [the expenses and revenue document] . . ."[422] The Panel cannot rely on the expenses and revenue document because it was created by counsel, and Novogenix produced no primary source accounting records. Thus, the Panel cannot determine whether Novogenix actually lost money on its fetal tissue operations.

However, the list of expenses included an unknown amount for attorney fees.[423] Such fees are not included under the list of allowable reimbursements under § 289g-2. The list of expenses also included minimal amounts for delivery to researchers.[424] Invoices produced to the Panel by Novogenix customers show the firm charged delivery fees of up to $122.43 per shipment,[425] raising further questions about the reliability of the attorney-created cost document.

12. Consent

PPLA personnel obtained consent from patients to donate tissue from their aborted fetuses.[426] [PP Witness #1] explained that PPLA workers identified fetuses of between 9 and 16 weeks; obtained informed consent for the abortion, and informed women that PPLA had a program for tissue donation, and, if the patient was interested, PPLA workers obtained consent to donate fetal tissue.[427]

PPLA took the standard PPFA consent form,[428] which stated, "Research using . . . tissue that has been aborted has been used to treat and find a cure for such diseases as diabetes,

[420] Panel analysis of invoices produced by Children's Hospital of Philadelphia; City of Hope; Rockefeller University; Stanford University; the University of Connecticut Health Center; the University of California, Los Angeles; and the University of Southern California.
[421] Novogenix Laboratories, LLC, Expenses and Revenue FY 2011 – FY 2015, undated. [NOVOEC-0000006–NOVOEC-0000014], Exhibit 5.43. Novogenix' fiscal year ran from September through August of the following calendar year.
[422] Letter from Joshua A. Levy, Cunningham Levy LLP, to Charles Ingbertson, Chief Counsel, Committee on Energy and Commerce 2 (Sept. 2, 2015), Exhibit 5.4.1.
[423] Novogenix Laboratories, LLC, Expenses and Revenue FY 2011 – FY 2015, undated. [NOVOEC-0000006–NOVOEC-0000014], Exhibit 5.43.
[424] *Id.*
[425] Panel analysis of invoices produced by Children's Hospital of Philadelphia; City of Hope; Rockefeller University; Stanford University; the University of Connecticut Health Center; the University of California, Los Angeles; and the University of Southern California.
[426] [PP Doctor #1] briefing before the Committee on Energy and Commerce (Sept. 18, 2015), Exhibit 5.4.7
[427] *Id.*
[428] *Id.*

Parkinson's disease, Alzheimer's disease, cancer, and AIDS."[429] There is no cure for those diseases.

Numerous witnesses, including senior PPFA officials, testified that the consent form is misleading and unethical due to its contention that fetal tissue has been used to find a cure for diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS. [PP Witness #1] testified that the PPFA consent form contained inaccurate statements, and that she, the person who oversees the production of the PPFA manual that contains the consent form, was not happy that an inaccurate document was in the manual:

> Q: Have we found a cure for cancer?
> A: If we had found a cure, we wouldn't be asking for tissue donations to try to find a cure.
> Q: Have we found a cure for AIDS?
> A: Not that I'm aware of, not yet.[430]
> [A:] . . . To my knowledge there is no cure for AIDS. So that is probably an inaccurate statement . . . . a consent form should not have an incorrect statement [on it].[431]

When [PP Witness #1] was asked whether it bothered her that an inaccurate consent form was in the PPFA Manual of Medical Standards and Guidelines, she testified: "I guess it bothers me. I mean, I oversee the production of the standards . . . . it doesn't make me happy that there's something inaccurate in the manual."[432]

Regulations promulgated by the U.S. Department of Health and Human Services (HHS) on informed consent states that investigators "shall seek such consent only under circumstances that provide the prospective subject with . . . sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence."[433] The regulations further state: "When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as . . . pregnant women . . . additional safeguards" are included.[434]

[PP Witness #1] testified that the PPFA consent form used by Novogenix may coerce women to donate fetal tissue. When she was asked whether the "incorrect statement" that fetal tissue has found a cure for various diseases "could be viewed as coercive or . . . more likely to induce somebody to want to donate fetal tissue," [PP Witness #1] testified: "I can understand your concern that perhaps this may make someone think about donating fetal tissue because of

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[429] Planned Parenthood Federation of America, PPFA Manual of Medical Standards and Guidelines, Client Information and Informed Consent, Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research, Education, or Treatment," Revised June 2011, Exhibit 5.44.
[430] Unedited transcribed interview of [PP Witness #1] 130 (Oct. 6, 2016).
[431] *Id.* at 131.
[432] *Id.* at 134.
[433] 45 C.F.R. § 46.116.
[434] 45 C.F.R. § 46.111(7)(b).

this potential."[435] She also stated that the PPFA consent form's wording may make patients more likely to want to donate fetal tissue.[436]

Dr. Patrick Lee, a leading bioethicist testified at a Panel hearing that the PPFA form may be coercive and likely is unethical.

> Mr. Harris: . . . I am going to ask Dr. [Patrick] Lee, because you are a bioethicist, is [the PFFA consent] form ethical where you tell a patient that diabetes, Parkinson's disease, Alzheimer's disease, cancer and AIDS, that [fetal] tissue has been used to find a cure? Past tense. It is not that we going to use it to find a cure, it has been used to find a cure. . . . Is that unethical to ask this woman at a time when she is making a difficult decision to say that this tissue has been used to cure diseases when it hasn't?
>
> Mr. [sic] Lee: No, in order to make a fully informed consent, you have to be given accurate information.[437]

13. Procurement

PPLA procured the fetal tissue, as well as obtained consent. The Novogenix contract with PPLA stated that the firm would "provide PPLA with a sterile container, including storage media, for each Specimen."[438] The contract further states:

> On each PPLA operating surgery day during which the retrieval of Specimens is scheduled, PPLA will: (i) identify patients for potential donation; (ii) obtain informed consent from patients who agree to participate in tissue donation programs; (iii) following pathology analysis of donated specimens [conducted by PPLA], allow Novogenix's [sic] designated contact . . . to select material for collection.[439]

[PP Doctor #1] stated that PPLA surgeons would procure the tissue. She stated if women agreed to donate tissue, PPLA workers would flag their charts, so the surgeon would know that she had agreed to donate fetal tissue.[440] [PP Doctor #1] also stated that, if PPLA performed an abortion on a woman who had a 12-week-old fetus, Novogenix would take all or part of the fetus.[441]

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[435] Unedited transcribed interview of [PP Witness #1] 131-132 (Oct. 6, 2016).
[436] *Id.* at 132.
[437] *Bioethics and Fetal Tissue: Hearing before the Select Investigative Panel of the H. Comm. on Energy and Commerce*, Mar. 2, 2016, at 140-141.
[438] Specimen Donation Agreement between Novogenix Laboratories, LLC, and Planned Parenthood Los Angeles (Mar. 1, 2010), Exhibit 5.41.
[439] *Id.*
[440] [PP Doctor #1] briefing before the Committee on Energy and Commerce (Sept. 18, 2015), Exhibit 5.4.7.
[441] *Id.*

[PP Doctor #1] testified that she met with the Novogenix tissue technicians before abortions were performed to determine what type of fetal tissue the firm needed that day, and that such meetings are helpful:

> Q: Now, do you think that doctors in your position should huddle in the morning? You say, "I like to do that." It's sort of an ongoing tense. Do you think the doctors should huddle with a tissue tech to see what they're procuring, is on their list that day?
> A: I don't really have a feeling as to whether other doctors did. I like to be helpful.
> Q: And so you found it helpful that at least on this one day to huddle with the tissue tech and learn what [the Novogenix tissue technician] was searching for, what orders she had; is that right?
> A: I would ask her what tissue she was looking for, yes.
> Q: All right. Do you think that's a good idea for the whole fetal tissue donation program, that doctors and the tissue techs huddle each morning to discuss what they're going to try and procure that day?
> A: I think it could be helpful.[442]

14. Post-Procurement Practices

[PP Doctor #1] stated that, after the abortions were performed and PPLA surgeons procured the fetal tissue, a Novogenix technician would take the tissue to the firm's facility.[443] Novogenix processed the tissue. This generally involved methods to isolate specific cells, generate a single cell suspension from a parent tissue, machine the cell to allow for the simultaneous separation into 4-6 populations of cells based on the protein expression on the surface of the cells.[444]

[Founder and Executive Director] stated that there were two basic post-procurement procedures: In the first, fetal tissue would be collected at the clinics by Novogenix personnel, who would take the specimens back to the laboratory; the firm would freeze the tissue with various chemical fixatives, which preserves the cells; after that step was completed, workers would wash the chemicals out of the material; prepare it for shipping, which included the dissection of the tissues into thin slices; and ship the finished product to the researcher. The second method involved fetal tissue that already had been isolated under the first method. The isolated cells would be stored on-site at Novogenix, double-layered to preserve it, prepared for shipment, and shipped once a researcher requested those particular cells.[445]

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[442] Unedited transcribed interview of [PP Witness #1] 142 (Oct. 6, 2016).
[443] [PP Doctor #1] briefing before the Committee on Energy and Commerce (Sept. 18, 2015), Exhibit 5.4.7.
[444] [Founder and Executive Director] Novogenix, briefing before Committee on Energy and Commerce (Sept. 3, 2015), Exhibit 5.42.
[445] *Id.*

Because Novogenix did not produce any primary source accounting records, the Panel cannot determine many of the firm's costs. Invoices produced to the Panel by a number of leading research institutions show that Novogenix charged some of its customers for what the firm called services, as well as shipping. Those costs varied. Due to the dearth of any accounting records, the Panel cannot determine what caused those variations.

15. Clinics

Novogenix received tissue from two PPLA clinics and an unknown number of unnamed clinics.[446] The firm signed its contract with the Planned Parenthood affiliate in 2010, but tissue donations started sometime in 2011 and ended in July 2015.[447]

[PP Doctor #1] stated that PPLA's contract with Novogenix was approved by PPFA's medical division.[448] That statement directly contradicts the testimony of [PP Witness #1] who testified that her department did not oversee fetal tissue donation contracts between affiliates and outside entities.[449]

b) Payments received by clinic

Under its contract with PPLA, Novogenix paid the PPFA affiliate $45 per donated specimen. The revenue documents created by the firm's counsel indicate that the between 2011 and July 2015, the firm paid PPLA a total of $52,965. As previously noted, because Novogenix did not provide primary source materials, the Panel cannot verify whether that figure is accurate.

[PP Doctor #1] stated that she "did [a] rough calculation of what the costs [to PPLA for consent of patients and the procurement of fetal tissue]" before she agreed to Novogenix's proposed $45 per specimen proposal. [PP Doctor #1] said she did not employ anyone to do an audit or retain an independent outside auditor, rather she consulted other PPFA affiliates, looked at the staff time involved in the following: triage; discussions with patients on fetal tissue donation; consent; her negotiations with Novogenix; and "parking spaces."[450]

The Panel is troubled by [PP Doctor #1]'s statements. None of the costs she cited are reimbursable under federal law.[451] In addition, a memorandum from PPFA's in-house counsel to all affiliate medical directors required that affiliates who participate in fetal tissue donation programs either accept no reimbursement or hire an independent auditor to calculate the affiliate's costs.[452] [PP Doctor #1] stated that, at the time PPLA entered into its contract with

[446] [Founder and Executive Director] Novogenix, briefing before Committee on Energy and Commerce (Sept. 3, 2015).
[447] *Id.*
[448] [PP Doctor #1] briefing before the Committee on Energy and Commerce (Sept. 18, 2015), Exhibit 5.4.7.
[449] Unedited transcribed interview of [PP Witness #1] 145 (Oct. 6, 2016).
[450] [PP Doctor #1] briefing before the Committee on Energy and Commerce (Sept. 18, 2015), Exhibit 5.4.7.
[451] 42 U.S.C. § 289g-2(e)(3).
[452] Memorandum from [PPFA Lawyer], et al. to Affiliate Chief Executives, Affiliate Medical Directors, Patient Service Directors, Re: Federal Regulations for Aborted Pregnancy Tissue Donation Programs (Apr. 4, 2001) [PPFA-HOU_E&C_00148–PPF-HOU_E&C-000150], Exhibit 5.45.

Novogenix, she knew they had received the memorandum and "was aware of it floating around in [her] head."[453] PPLA's blatant disregard for the memo on reimbursement for the cost of fetal tissue donation is the rule rather than the exception at PPFA affiliates (see "Planned Parenthood" section for a more detailed discussion on this issue).

16. Customers that Received Fetal Tissue from Novogenix

Novogenix received $170,980.59 from 7 research institutions between June 2011 and December 2015.[454] The Panel cannot determine the full universe of Novogenix's customers, or Novogenix' total revenue. Below is a list of Novogenix's known customers, and the amounts the customers paid the firm.

CLIENT	**TOTAL PAID**
University of Southern California	$100,995.89
University of California, Los Angeles	$ 58,299.89
City of Hope	$ 6,625.60
University of Connecticut Health Center	$ 2,138.56
Stanford University	$ 1,000.00
Children's Hospital of Philadelphia	$ 1,000.00
Rockefeller University	$ 960.65

17. Potential Violations of Law

c) Applicable Laws & Regulations

Novogenix was under not only a legal but also a contractual obligation to obey all laws: A provision of its contract with PPLA stipulated that "Novogenix agrees to conduct cell and stem cell research in compliance with all applicable federal and state laws."[455]

[453] [PP Doctor #1] briefing before the Committee on Energy and Commerce (Sept. 18, 2015), Exhibit 5.4.7.
[454] Panel analysis of invoices produced by Children's Hospital of Philadelphia; City of Hope; Rockefeller University; Stanford University; the University of Connecticut Health Center; the University of California, Los Angeles; and the University of Southern California.
[455] Specimen Donation Agreement between Novogenix Laboratories, LLC, and Planned Parenthood Los Angeles (Mar. 1, 2010), Exhibit 5.41.

i) 42 U.S.C. § 289g -2

The applicable federal law on fetal tissue is 42 U.S.C. § 289g-2(a), which states, "It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce." Under that law, "The term 'valuable consideration' does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."[456] Human fetal tissue is defined broadly to include any "tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth."[457]

ii) California Health and Safety Code Section 125320

The California Health and Safety Code contains virtually identical language to 42 U.S.C. § 289g-2. That law states that:

> (g) A person may not knowingly, for valuable consideration, purchase or sell embryonic or cadaveric fetal tissue for research purposes pursuant to this chapter.
>
> (h) For purposes of this section, "valuable consideration" does not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of a part.
>
> (i) Embryonic or cadaveric fetal tissue may be donated for research purposes pursuant to this chapter.[458]

As with 42 U.S.C. § 289g-l(g), another provision of the California Health and Safety Code also broadly defines tissue to "mean a human cell, group of cells, including the cornea, sclera, or vitreous humor and other segments of, or the whole eye, bones, skin, arteries, sperm, blood, other fluids, and any other portion of a human body . . ."[459]

iii) HHS Regulations on Informed Consent

HHS requires investigators to obtain informed consent from each human being used as a research subject.[460] The "basic elements of informed consent" include the following information:

> (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's

[456] 42 U.S.C. § 289g-2(e)(3)
[457] 42 U.S.C. § 289g-l(g).
[458] Cal. Health & Safety Code § 125320.
[459] Cal. Health & Safety Code § 1635(c).
[460] 45 C.F.R. 46 § 116.

participation, a description of the procedures to be followed, and identification of any procedures which are experimental; . . . [and]

(2) A description of any benefits to the subject or to others which may reasonably be expected from the research . . .[461]

Federal regulations promulgated by HHS requires investigators to obtain informed consent from each human being used as a research subject.[462] There are eight basic elements of informed consent which, under the Common Rule, "shall be provided to each subject:"

1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

2) A description of any reasonably foreseeable risks or discomforts to the subject;

3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.[463]

[461] *Id.*
[462] 45 C.F.R. § 46.116.
[463] *Id.*

iv) HHS Regulations on Institutional Review Boards (IRBs)

HHS regulations require IRBs to "prepare and maintain adequate documentation" of its activities, including:

> (1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
> (2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
> (3) Records of continuing review activities. [and]
> (4) Copies of all correspondence between the IRB and the investigators.[464]

Those regulations only cover "clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products."[465] It is unclear whether any of the fetal tissue procured by Novogenix was used for any purpose covered by the regulations.

v) California Revenue and Tax Code

A provision of the California Revenue and Tax Code that states:

> [E]very retailer engaged in business in this state and making sales of tangible personal property for storage, use, or other consumption in this state, not exempted . . . shall, at the time of making the sales or, if the storage, use, or other consumption of the tangible personal property is not then taxable hereunder, at the time the storage, use, or other consumption becomes taxable, collect the tax from the purchaser and give to the purchaser a receipt therefore in the manner and form prescribed by the [California State Equalization Board].[466]

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[464] 45 C.F.R. § 46.115(a).
[465] 21 C.F.R. § 56.101(a).
[466] Cal. Rev. & Tax Code § 6203. A publication put out by the State Board of Equalization (SBE) states that provision applies to corporations, individuals, Limited Liability Companies, Limited Liability Partnerships, Limited Partnerships, partnerships, married co-owners, registered domestic partnerships, and organizations. Cal. State Bd. of

The law defines a "retailer engaged in business in" California as "Any retailer maintaining, occupying, or using, permanently or temporarily, directly or indirectly, or through a subsidiary, or agent, by whatever name called, an office, place of distribution, sales or sample room or place, warehouse or storage place, or other place of business."[467]

There is an exemption for the sale of human blood and human body parts.[468] However, Novogenix was not a tissue or blood bank. Rather it effectively sold fetal tissue cells, cell lines, and other products directly to customers. The California State Board of Equalization (SBE) recently collected nearly $82,000 for unpaid sales taxes for a non-profit organization that saves dogs, draws blood from those dogs, and sells the white blood cells, plasma, and red blood cells for transfusions into other canines.[469]

The statute defines tangible personal property as "personal property which may be seen, weighed, measured, felt, or touched, or which is in any other manner perceptible to the senses."[470] Thus, cells and cell lines are tangible personal property under the California Sales and Use Tax.

An SBE publication states that California companies can pass along the amount of sales tax to customers, provided the business lists a separate amount for sales tax reimbursement on its receipts or invoices, or if the sales agreement "specifically calls for the addition of sales tax reimbursement."[471] If the business includes sales tax reimbursement in its prices, companies "must inform the buyer that tax is included" by making one of the following statements on a price tag or in an advertisement: "All prices of taxable items include sales tax reimbursement computed to the nearest mill," or "The price of this item includes sales tax reimbursement to the nearest mill."[472] It is unclear whether Novogenix's contracts with its customers included those statements.

d) Findings

j) 42 U.S.C. § 289g-2 & California Health and Safety Code Section 125320

The Panel's investigation finds reason to believe that Novogenix may have violated 42 U.S.C. § 289g-2 and Cal. Health & Safety Code § 125320(a). The list of attorney-created

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Equalization, "Your California Seller's Permit: Your Rights and Responsibilities under the Sales and Use Tax Law," Pub. 72, May 2014, at 1.

[467] Cal. State Bd. of Equalization, "Laws, Regulations & Annotations, Sales and Use Tax Law, Chapter 3. The Tax," https://www.boe.ca.gov/lawguides/business/current/btlg/vol1/sutl/6203.html.

[468] Cal. Rev. & Tax Code § 33 ("Human whole blood, plasma, blood products, and blood derivatives, or any human body parts held in a bank for medical purposes, shall be exempt from taxation for any purpose.").

[469] Chris Haire, "Greyhound Dog Rescue Hemopet Fights to Stay Open after $82,000 Tax Bill," *Orange County Register*, Oct. 10, 2016, http://www.ocregister.com/articles/blood-731674-hemopet-greyhounds.html.

[470] Cal. Rev. & Tax Code § 6016.

[471] Cal. State Bd. of Equalization, "Your California Seller's Permit: Your Rights and Responsibilities under the Sales and Use Tax Law," Pub. 72, May 2014, at 5.

[472] *See* Cal. State Bd. of Equalization, "Your California Seller's Permit: Your Rights and Responsibilities under the Sales and Use Tax Law," Pub. 72, May 2014,

Novogenix expenses included an unknown amount for attorney fees.[473] Such fees are not included under the list of allowable reimbursements under § 289g-2. The list of expenses also included minimal amounts for delivery to researchers.[474] Invoices produced to the Panel by Novogenix customers show the firm charged delivery fees of up to $122.43 per shipment.[475] The Panel questions whether that apparent contradiction indicates that Novogenix charged its customers more for transportation than it cost the firm.

ii) HHS Regulations on Informed Consent

Statements by [PP Witness #1] and documents produced by PPFA to the Panel indicate that Novogenix did not follow the HHS regulations on informed consent. The PPFA form the firm used to obtain consent to donate fetal tissue states:

> Research using donated tissue and blood is currently underway to uncover the causes of and ultimately find cures for things like: Heart Disease, Diabetes, Parkinson's Disease, Sickle Cell Anemia, Leukemia, Lymphoma, Cancer, Spinal Cord Disease, and more.
>
> . . . The benefits of consenting to donation today include furthering medical research in finding cures for disease like diabetes, leukemia, lymphoma, Parkinson's disease and more.[476]

That consent form specifically does not conform to the requirements for informed consent mandated under 45 C.F.R. § 46.116. Witnesses at a Panel hearing agreed that the PPFA form may not comply with the HHS regulations on informed consent.[477]

The requirements for informed consent further state that investigators "shall seek such consent only under circumstances that provide the prospective subject with . . . sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence."[478]

[473] [Founder and Executive Director] Novogenix, briefing before Committee on Energy and Commerce (Sept. 3, 2015), Exhibit 5.42.
[474] *Id.*
[475] Panel analysis of invoices produced by Novogenix Laboratories, LLC.
[476] Planned Parenthood Federation of America, PPFA Manual of Medical Standards and Guidelines, Client Information and Informed Consent, Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research, Education, or Treatment," Revised June 2011, Exhibit 5.44.
[477] *See* H. Comm. on Energy and Commerce, Select Investigative Panel on Infant Lives, *Hearing on Bioethics and Human Tissue*, Mar. 2, 2016. http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-Transcript-20160302.pdf
[478] 45 C.F.R. § 46.116.

iii) HHS Regulations on IRBs

Novogenix's counsel represented that the [Founder and Executive Director] was fully aware of the HHS IRB regulations.[479] Before he started the firm, the [Founder and Executive Director] had submitted proposals to an IRB.

Through that application process before the institutional review board, [Founder and Executive Director] was required to review and comply with certain rules and regulations and this developed an understanding of them. Such subjects included, but were not limited to the following:

- Anonymity [sic]
- Informed Consent [sic]
- Donation of fetal tissue for scientific research [sic][480]

The Panel has no evidence that Novogenix followed the HHS regulations on IRBs, despite [Founder and Executive Director]'s knowledge and understanding of the regulations.

iv) California Revenue and Tax Code

The Panel has uncovered evidence that shows Novogenix also may have violated the California Revenue and Tax Code. Novogenix sold its services to customers in California; it should have collected tax on those transactions. The Panel reviewed every invoice and purchase order that were provided by Novogenix's known California customers. Based on that review, there were 17 purchases by the University of Southern California upon which Novogenix did not charge the legally required sales tax.[481] What makes the missing sales tax more striking is that Novogenix did charge the required sales tax to all other purchases by the University of Southern California, as well as Stanford University, and the University of California, Los Angeles. A chart of those purchases is below (the Bates Stamp number column refers to the documents, as provided by the university).

[479] *See* Letter from Joshua A. Levy, Cunningham Levy LLP, to Charles Ingeberston, Chief Counsel, Committee on Energy and Commerce, Sept. 2, 2015, at 3.
[480] *Id.* at 2.
[481] Purchase orders produced by the Keck School of Medicine at the University of Southern California to the Panel Exhibit 5.46.

DATE OF PURCHASE ORDER	AMOUNT	SALES TAX	BATES STAMP NUMBER
3/12/2013	$ 1,700.00	0	KSM0001002
4/11/2013	$ 1,700.00	0	KSM0000978
5/20/2013	$ 2,450.00	0	KSM0000973
5/20/2013	$ 2,100.00	0	KSM0000968
8/30/2013	$ 700.00	0	KSM0000944
2/18/2014	$ 200.00	0	KSM0000888
5/14/2014	$ 1,000.00	0	KSM0000834
7/24/2014	$ 431.20	0	KSM0000781
7/24/2014	$ 629.60	0	KSM0000777
7/29/2014	$ 1,000.00	0	KSM0000768
8/20/2014	$ 630.40	0	KSM0001090
8/21/2014	$ 350.00	0	KSM0001086
9/29/2014	$ 431.20	0	KSM0001058
9/29/2014	$ 231.20	0	KSM0001054
10/9/2014	$ 231.20	0	KSM0001050
10/9/2014	$ 431.20	0	KSM0001046
10/27/2014	$ 1,000.00	0	KSM0001032
11/6/2014	$ 2,100.00	0	KSM0001028
11/13/2014	$ 229.60	0	KSM0001023

18. Conclusions

The Panel referred Novogenix' potential violations of 42 U.S.C. § 289g-2 to the U.S. Department of Justice. It referred Novogenix's possible violations of the California Health and Safety Law and the California Tax Revenue and Tax Code to the Los Angeles County District Attorney. Finally, the Panel referred Novogenix' potential violations of federal regulations on consent to the U.S. Department of Health and Human Services.

D. Advanced Bioscience Resources, Inc.

1. Summary

The Panel conducted an investigation of Advanced Bioscience Resources, Inc. (ABR) and uncovered evidence that ABR may have violated 42 U.S.C. § 289g-2 and the California Health and Safety Law.

a) Background of ABR

ABR, a non-profit corporate foundation, was started in 1989 as a resource for "biomedical, scientific, and educational purposes."[482] It "specializes in the procurement, preservation and distribution of both human fetal tissues and full term umbilical cord blood for research."[483] ABR obtains fetal tissue from abortion clinics and offers it to researchers for a fee.[484] ABR generally pays abortion clinics a flat per-tissue fee regardless of the type or amount of tissue procured. The tissue is obtained by tissue technicians embedded by ABR in abortion clinics. The technicians harvest, package, and ship the tissue to the researchers. The abortion clinic staff obtains consent from the patients for fetal tissue donations. ABR's business model is that of StemExpress. Notably the CEO of StemExpress began her career in the fetal tissue industry as a tissue technician at ABR.

b) History of the Panel's Interactions with ABR

On September 3, 2015, ABR responded to a document request by the House Energy and Commerce Committee.[485] When H. Res. 461 created the Panel on October 7, 2015, Energy and Commerce gave the Panel the production from ABR. Seeing the need for additional information, the Panel sent ABR a document request on January 21, 2016.[486] When ABR did not fully produce, the Panel issued a subpoena to ABR on April 29, 2016.[487]

The Panel and ABR's counsel came to a verbal agreement that ABR could respond to the subpoena on a rolling production basis. To date, ABR has still not fully complied with the

[482] Advanced Bioscience Resources, Inc., Production to the Subcommittee on Oversight and Investigations of the US House of Representatives Energy and Commerce Committee, Sept. 3, 2015 (HCEC000004), Exhibit 5.47.
[483] *Id*.
[484] *Id*.
[485] *Id*., (HCEC000001), Exhibit 5.47.
[486] Document Request to Advanced Bioscience Resources, Inc. (Jan. 21, 2016), Exhibit 5.48.
[487] Subpoena to Advanced Bioscience Resources, Inc. (Apr. 29, 2016), Exhibit 5.49.

subpoena. It has not produced bank records or internal communications and has fully redacted names from the documents it has produced.

2. ABR's Business Model

ABR obtains fetal tissue from abortion clinics and offers it for resale to researchers. It pays the clinics "a flat fee for services on a product of conception (POC) basis, regardless of how many, or what type, of specimens are procured . . . ."[488] The fees range from $45 to $60, depending upon the year and the clinic.[489] The tissue is obtained by ABR tissue technicians who are embedded in the abortion clinics; the technicians harvest, package, and ship the tissue to the researchers.[490] The abortion clinic staff obtains consent from the patients for fetal tissue donations.[491]

ABR represented that it does not have a website through which researchers request tissue. It is unclear whether that is accurate. Researchers apply for tissue through email. Applications are reviewed by senior ABR officials, including the president. The review is focused on the scientific creditability and feasibility of their studies. Once approved, researchers send their specific tissue requests via facsimile, email, or phone call.

In order to harvest the tissue, ABR embedded tissue technicians within the abortion clinics. ABR has not yet produced sufficient documents for the Panel to determine how customers' tissue orders are communicated to the embedded technicians. The technicians' typical workday went as follows:

- The technicians contacted the clinics about the surgery schedule.

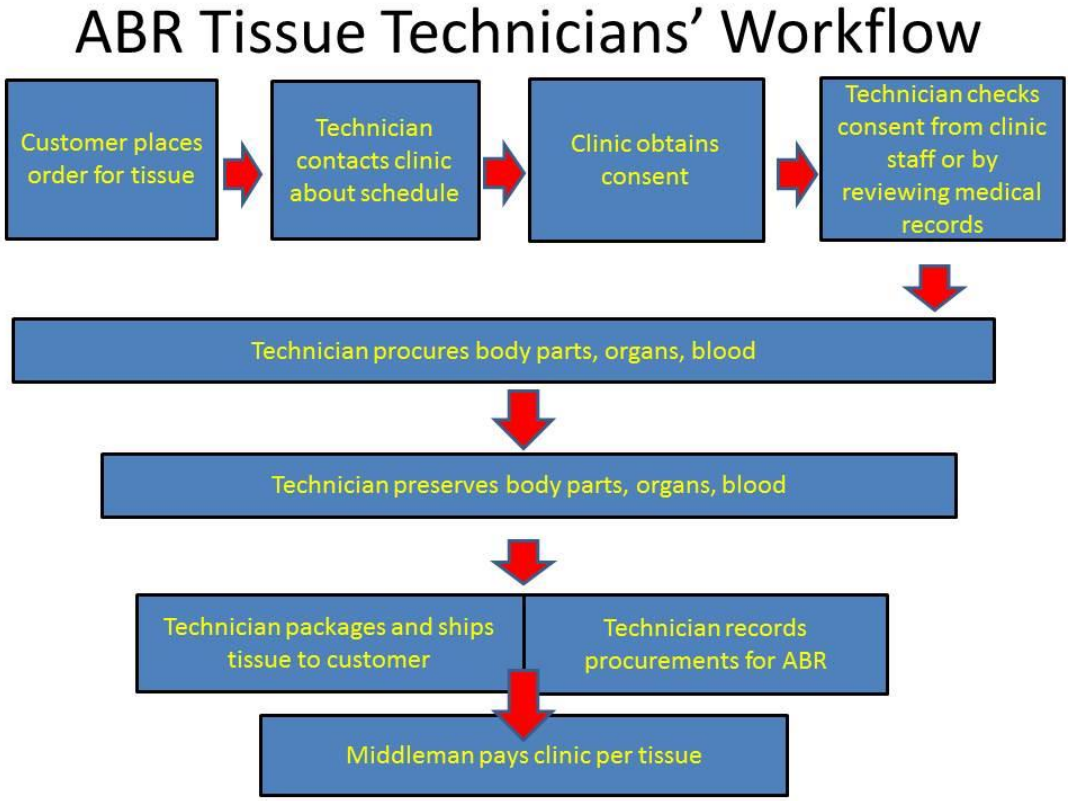
- They confirmed that the clinics had obtained consent from women undergoing abortions, either by speaking with clinic staff or by reviewing medical records. The clinics used an ABR consent form, similar to that used by StemExpress. The form states: "Recent advancements in medical research have been developed through the use of human tissues . . . Diseases such as diabetes, hemophilia, Parkinson's disease, cancer, AIDS, heart and lung diseases . . . are being investigated for the development of cures through the use of human fetal tissues."

- After the abortions were performed, the technicians identified and procured tissue per researchers' requests, placed the tissue in preservatives, packaged it, put it in shipping boxes, and delivered it to a courier or courier company.

- The technicians updated ABR on the tissue requests as they were fulfilled.

[488] Advanced Bioscience Resources, Inc., "ABR Overview: Key Points," at 5 (SP000752), Exhibit 5.50.
[489] Advanced Bioscience Resources, Inc., Production to the Subcommittee on Oversight and Investigations (HCEC000028 – 41), Exhibit 5.51.
[490] Advanced Bioscience Resources, at 7 (SP000754), Exhibit 5.50.
[491] *Id.* at 5.

- In contrast to the StemExpress case study, ABR employees are paid a salary or hourly wage and do not receive any bonus or other incentive payments based on the number or type of tissues they collect.[492]



3. ABR Payments to Abortion Clinics

According to productions made by 25 clinics from which ABR has received fetal tissue, ABR paid them a total of $1,002,147 from 2010 to 2015. ABR has only produced the payments it made in 2015, during which ABR made nearly $80,000 in payments to its top five abortion clinic sources from which it procured human fetal tissue. ABR paid the clinics' "costs for clinical staff obtaining consents, maintaining records, transferring fetal tissue, clinical space, and utilities."[493] The chart below shows ABR facility fee payments from 2010 through 2015 to the abortion clinics from which it obtained fetal tissue:

[492] Advanced Bioscience Resources, Inc., Production to the Subcommittee on Oversight and Investigations (HCEC000045), Exhibit 5.52.
[493] ABR Overview: Key Points at 5 (SP000752), Exhibit 5.50

CLINIC	TOTAL
Atlanta Women's Center	$ 1,972
Cherry Hill Women's Ccenter	$ 22,424
Choice Medical Group	$397,966
Downtown Women's Center, Inc	$ 4,550
Family Planning Specialist	$ 36,585
Feminist Women's Health Center	$ 300
Lovejoy Surgical Center	$ 135,565
M. Hanson	$ 28,970
Meadowbrook Women's Center	$ 13,585
Philadelphia Women's Center	$ 10,860
Planned Parenthood Riverside	$ 163,140
Planned Parenthood First Avenue	$ 145,315
Planned Parenthood Mar Monte (Sacramento)	$ 5,390
Planned Parenthood San Diego	$ 5,500
Pregnancy Consultation Center	$ 10,395
Whole Women's Health	$ 6,600

4. ABR Revenue from Customers

ABR's payments to the clinics should be contrasted with the amounts ABR has received from its customers. ABR produced payments from only a limited number of researchers to whom it transferred fetal tissue, covering invoices for a single year. Its production of invoices presents an incomplete picture of its income. ABR's income tax forms report $6.5 million in total revenue for the last five reporting years (2010-2014).

Pursuant to document request letters, researchers produced payments to ABR. According to these documents produced by the customers, ABR received $1,425,769.08 from the years 2010-2015. According to ABR's production, customers paid the non-profit $1,148,538.08 from

2010-2015. Therefore, according to the incomplete information the Panel has received, ABR received $423,622.08 more from customers than it paid to the clinics for the fetal tissue. Due to ABR's incomplete production, it is difficult to draw a complete conclusion based on these numbers. The chart below shows the amount of money ABR received from its customers:

Comparison of fetal tissue sales invoices obtained from ABR and directly from ABR's customers

Names of Customers	Produced by ABR			Produced by Customer			Variance
	2010-2015	2016	Total	2010-2015	2016	Total	Based on 2010-2015 Totals
All Cells LLC	27,405.08	-	**27,405.08**	27,405.08		**27,405.08**	-
Celula, Inc.	85,755.00	-	**85,755.00**	-		**-**	85,755.00
Childrens Hospital of Philadelphia	9,650.00	-	**9,650.00**	9,650.00		**9,650.00**	-
City of Hope	12,830.00	-	**12,830.00**	12,830.00		**12,830.00**	-
CO State University	20,100.00	-	**20,100.00**	-		**-**	20,100.00
Columbia University	27,940.00	-	**27,940.00**	185,430.00		**185,430.00**	(157,490.00)
Dartmouth	8,780.00	-	**8,780.00**	8,780.00		**8,780.00**	-
FDA/CDER	24,890.00	-	**24,890.00**	-		**-**	24,890.00
Johns Hopkins Medicine	-	-	**-**	1,020.00		**1,020.00**	(1,020.00)
Lonza Walkersville	23,835.00	-	**23,835.00**	-		**-**	23,835.00
Mass General Hospital	215,454.00	-	**215,454.00**	209,109.00		**209,109.00**	6,345.00
National Institute of Health	92,320.00	-	**92,320.00**	-		**-**	92,320.00
Rockefeller University	32,330.00	-	**32,330.00**	143,685.00		**143,685.00**	(111,355.00)
Samsung Biomed Res Inst	31,810.00	-	**31,810.00**	-		**-**	31,810.00
Sciencell Research Labs	21,840.00	-	**21,840.00**	-		**-**	21,840.00
Stanford University	-	-	**-**	7,860.00	1,220.00	**9,080.00**	(7,860.00)
SUNY Health Sciences Center	22,600.00	-	**22,600.00**	24,865.00		**24,865.00**	(2,265.00)
Temple University	-	-	**-**	26,140.00	1,835.00	**27,975.00**	(26,140.00)
University of CA SF	25,290.00	-	**25,290.00**	-		**-**	25,290.00
University of CA-LA School of Medicine	51,420.00	-	**51,420.00**	62,615.00		**62,615.00**	(11,195.00)
University of CT Health Center	1,280.00	-	**1,280.00**	1,280.00		**1,280.00**	-
University of MA Medical School	122,169.00	-	**122,169.00**	231,970.00	51,500.00	**283,470.00**	(109,801.00)
University of NC at Chapel Hill	155,120.00	-	**155,120.00**	286,280.00		**286,280.00**	(131,160.00)
University of PA Medical Center	50,460.00	-	**50,460.00**	132,295.00		**132,295.00**	(81,835.00)
Vertex Pharmaceuticals	40,870.00	-	**40,870.00**	-		**-**	40,870.00
Yale University Medical School	44,390.00	-	**44,390.00**	-		**-**	44,390.00
	1,148,538.08	**-**	**1,148,538.08**	**1,371,214.08**	**54,555.00**	**1,425,769.08**	

ABR transferred both human fetal tissue and body parts to researchers. Among those body parts were brains, hearts, eyes, skulls, eyes, spinal cords, spinal columns, and skin.

ABR 2015 Fetal Sales to Top 5 Customers Product and Totals

80 Fetal Brains totaling $26,160
51 past 20 weeks gestation

36 Pairs of Eyes totaling $25,160
15 past 20 weeks gestation

8 Hearts totaling $2,720
6 past 20 weeks gestation

16 Spinal Cords totaling $5,100
7 past 20 weeks gestation

2 Intact Calvarium totaling $1,100
1 past 20 weeks gestation

2 Spinal Columns totaling $680
1 past 20 weeks gestation

2 Skins totaling $680
Both past 20 weeks gestation

Summary Total for Top 5 Customers……..….$61,600

5. ABR May Have Violated Federal and State Laws and Regulations

The Panel compared materials provided by ABR to § 289g-2, which prohibits receipt of valuable consideration for fetal tissue. Valuable consideration excludes costs "associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."[494] Materials produced to the Panel by ABR created an unclear picture of their conduct and income. For example, ABR stated that it pays clinics "costs for clinical staff obtaining consents, maintaining records, transferring fetal tissue, clinical space, and utilities."[495] Only the costs of transfer of fetal tissue can offset valuable consideration. The same ABR document states that its tissue technicians procure the tissue, package it, and ship it.[496] When the Panel asked ABR whether it prepares tissue for research, or modifies it into cell lines, the firm's attorney stated "ABR does not provide any other services other than simple tissue procurement. . . ."[497]

[494] 42 U.S.C. § 289g-2(e)(3).
[495] Advanced Bioscience Resources, Inc., "ABR Overview: Key Points," at 5 (SP000752), Exhibit 5.50.
[496] *Id.* at 7.
[497] Letter from Jonathan F. Lopez, Orrick, Herrington & Sutcliffe, to Rep. Blackburn, Chairman, Select Investigative Panel 2 (Feb. 24, 2016), Exhibit 5.53.

Due to ABR's failure to produce a complete response to the Panel's subpoena and based on a thorough assessment of the information received, the Panel saw the need for a criminal investigation into ABR's fetal tissue practices. Therefore, the Panel sent criminal referrals to U.S. Attorney General Loretta Lynch and the District Attorney of Riverside County, California, urging them to conduct an investigation into whether ABR violated federal and state statutes and regulations, and to take appropriate action if the investigation reveals criminal behavior.

E. Human Fetal Tissue Repository

6. Summary

The Panel sought to determine whether the Human Fetal Tissue Repository (HFTR) fully complied with the applicable federal law and regulations. HFTR only produced a partial list of the entities from which it received and to which it distributed fetal tissue to the Panel. HFTR did not produce detailed accounting or cost documents to the Panel. As a result, the Panel had insufficient evidence to determine whether HFTR complied with the applicable federal law.

a) Background of the Human Fetal Tissue Repository

HFTR operated within the Albert Einstein College of Medicine ("Einstein") of Yeshiva University, located in The Bronx, New York.[498] HFTR began operations in March 1993.[499] Einstein's executive dean provided two different closure dates: He first told the Panel that HFTR closed on March 2, 2015.[500] The dean later told the Panel HFTR closed in September 2015.[501] The dean stated that in September 2015, Einstein's "operations were spun out from Yeshiva University to under [the] operational control of Montefiore Health Systems."[502]

The Panel sought to determine the disposition of the fetal tissue held by HFTR after its closure. The Panel had insufficient evidence to make that determination. However, there are indications that Einstein offered the tissue to the Planned Parenthood Federation of America (PPFA). [PP Witness #3] stated that after HFTR closed, "The people from Einstein came to visit us to see if [PPFA] would take over their repository."[503] The PPFA official added that Planned Parenthood abandoned the proposal because "It seemed like a lot of effort . . . ."[504]

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[498] Letter from [Einstein Executive Dean], Albert Einstein College of Medicine, to Rep. Marsha Blackburn, Chairman, Select Panel on Fetal Lives [sic] 1 (Feb. 10, 2016).
[499] Email from [Einstein Executive Dean], Albert Einstein College of Medicine, to Panel staff. (Nov. 27, 2016).
[500] Letter from [Einstein Executive Dean], Albert Einstein College of Medicine, to Rep. Marsha Blackburn, Chairman, Select Panel on Fetal Lives [sic] 1 (Feb. 10, 2016).
[501] *Id.* at 2.
[502] *Id.* at 1.
[503] Center for Medical Progress video FNND0569_ 20150226165708. The video was produced to the H. Comm. on Oversight and Government Reform pursuant to a subpoena. Panel staff viewed it under the terms of an agreement between the Chairman and Ranking Member of the H. Comm. on Oversight and Government Reform.
[504] *Id.*

HFTR received fetal tissue from three New York City hospitals, and it distributed the tissue to Einstein researchers and to fourteen other educational and research institutions.[505] HFTR received "reasonable payments associated with necessary activities such as transportation, processing, preservation, or quality control of the tissue" from the research institutions to which it provided fetal tissue.[506] The payments were $100 per sample for Einstein researchers and $250 per sample for outside researchers.[507] Documents produced by a research institution that received fetal tissue from HFTR show payments to HFTR of $250 per fetal tissue specimen.[508]

b) History of the Panel's Interactions with HFTR

On December 18, 2015, the Panel sent HFTR a document request letter asking for, among other items, a list of all entities from which it procured fetal tissue, a list of all entities to which it sold or donated fetal tissue, an organization chart, all communications that direct its employees to procure fetal tissue, all accounting records, and banking records related to the procurement, sale, donation, and distribution or shipment of fetal tissue.[509]

Einstein's response was delayed until after the production deadline of December 31, 2015, because after the closure of HFTR, the person to whom the letter was addressed was no longer employed by Einstein.[510] The Panel granted Einstein a production extension until January 31, 2016.[511] In the course of its review of HFTR records, Einstein discovered that it was missing all records for the period of January 2010 through July 2010.[512]

Einstein produced a list of entities from which it obtained and distributed fetal tissue to the Panel.[513] Einstein represented that it could not locate accounting records.[514] To date, the Panel has not received any communications that relate to fetal tissue or any accounting or banking records.

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[505] Letter from [Einstein Executive Dean], Albert Einstein College of Medicine, to Rep. Marsha Blackburn, Chairman, Select Panel on Fetal Lives [sic] 1-2 (Feb. 10, 2016).
[506] *See id.* at 1.
[507] *See id.* at 2.
[508] Invoices produced by the University of Connecticut Health Center to the Panel [000005-000007], Exhibit 5.54.
[509] *See* Letter from Rep. Marsha Blackburn, Chairman, House Select Investigative Panel, to [HFTR Official] (Dec. 18, 2015).
[510] Email from [Einstein Vice-President, Government and Community Relations], Albert Einstein College of Medicine of Yeshiva University, to Panel staff (Jan. 12, 2016).
[511] Telephone conference between [Einstein Vice-President, Government and Community Relations], Albert Einstein College of Medicine of Yeshiva University, and Panel staff (Jan. 12, 2016).
[512] Letter from [Einstein Executive Dean], Albert Einstein College of Medicine, to Rep. Marsha Blackburn, Chairman, Select Panel on Fetal Lives [sic] 2 (Feb. 10, 2016).
[513] Documents produced by Albert Einstein College of Medicine of Yeshiva University to the Panel (Jan. 27, 2016) [hereinafter Documents produced by Albert Einstein], Exhibit 5.55.
[514] Telephone conference between [Einstein Vice-President, External Affairs], Albert Einstein College of Medicine of Yeshiva University, and Panel staff (Jan. 27, 2016).

7. Hospitals from which HFTR Procured Fetal Tissue

HFTR did not procure fetal tissue directly from abortion clinics; rather, it "received" tissue from Jacobi Medical Center, North Central Bronx Hospital, and Weiler Hospital.[515]

8. Procurement Process

The Panel sought to determine HFTR's procurement procedures, including whether it had contracts with the hospitals from which it procured fetal tissue. Due to the lack of records provided by Einstein, the Panel had insufficient evidence to determine whether HFTR had contracts with those medical facilities; how much, if any anything, HFTR paid for the tissue; whether the hospitals or HFTR obtained consent; how the consent was obtained; and the content of the consent form.

The Panel sought to determine the number of women from which HFTR obtained fetal tissue and the number of fetal tissue samples HFTR obtained. Documents produced by Einstein to the Panel show that a total of 2,701 "subjects" were "enrolled" in HFTR studies.[516] The Panel had insufficient evidence to determine the number of fetal tissue samples HFTR obtained.

Documents produced by the University of Wisconsin School of Medicine and Public Health (UW SMPH) to the Panel show that HFTR required detailed information from each of its potential customers. HFTR sent each applicant a letter that listed the information it required. The letter stated:

> In order to expedite your request, please provide [HFTR] with [the] following information:
>
> - An abstract and brief summary of your IRB-approved human experimentation protocol. Clearly state which tissues you will use for your study and why you must use human tissues – and human *fetal* tissues in particular.
> - A copy of your local IRB approval letter. When filing out your IRB application, be sure to state that you will be receiving tissue from [HFTR].
> - Please read and sign the enclosed Risk Handling Statement.
> - Please read and sign the Non-Transplant Fetal Tissue Request Form. . . . These agreements emphasize several issues:
>
> 1. You are responsible for understanding and adhering to appropriate safety standards for the protection of yourself and laboratory personnel under your supervision who will be handling the human tissue.

[515] Letter from [Einstein Executive Dean], Albert Einstein College of Medicine, to Rep. Marsha Blackburn, Chairman, Select Panel on Fetal Lives [sic] (Feb. 10, 2016).
[516] Documents produced by Albert Einstein, Exhibit 5.55.

2. Unless you are licensed to do so by New York State, you may not distribute any portion of the tissue disbursement or products derived therefrom to colleagues or other investigators.[517]

The Non-Transplant Fetal Tissue Request Form stated that researchers who received fetal tissue from HFTR agreed to use the specimens "in compliance with all applicable standards and regulations, including, but not limited to those relating to research involving human and animal subjects . . ."[518] The form further stated that researchers "will pay a transmittal fee of $250 per sample to reimburse [HFTR] for its preparation and distribution costs."[519]

In addition to the non-transplant fetal tissue request form, HFTR required researchers to sign a Material Transfer Agreement, which stated in part that the fetal tissue "IS NOT FOR USE IN HUMAN SUBJECTS," and "will be used for teaching or for not-for-profit research purposes only."[520]

9. Researchers that Received Fetal Tissue from HFTR

The incomplete documents produced by Einstein to the Panel show that HFTR distributed fetal tissue to fourteen research institutions. The Panel had insufficient evidence to determine whether the list below, which was compiled from Einstein's incomplete production, encompasses the entire universe of research institutions that received fetal tissue from HFTR:

- Montreal Neurological Institute
- University of California, Irvine
- New York University School of Medicine
- Memorial Sloan-Kettering Cancer Center
- Yale University School of Medicine
- Wayne State University School of Medicine
- Rockefeller University

[517] Albert Einstein College of Medicine of Yeshiva University, Human Fetal Tissue Repository (Dec. 15, 2010), produced by the University of Wisconsin-Madison School of Medicine and Public Health to the Panel (emphasis in original) [0171], Exhibit 5.56.
[518] Documents produced by Albert Einstein, Exhibit 5.55.
[519] *Id.*
[520] Albert Einstein College of Medicine of Yeshiva University, Material Transfer Agreement for Transfer of Material to Academic, Non-Profit Organizations (Sept. 3, 2009), produced by the University of Wisconsin-Madison School of Medicine and Public Health to the Panel [0172] (emphasis in original), Exhibit 5.57.

- University of Connecticut Health Center
- University of Virginia
- Johns Hopkins
- State University of New York, Buffalo
- University of Wisconsin
- University of Medicine and Dentistry of New Jersey
- Children's National Medical Center[521]

The Panel sought to determine the number of fetal tissue samples each research institution received and the amount of money that HFTR received from those institutions. Due to Einstein's lack of production, the Panel lacked sufficient evidence to make such a determination.

10. Conclusions

HFTR produced a limited set of documents to the Panel. Among the types of documents that HFTR did not produce were accounting records. Thus, the Panel has insufficient evidence to determine the cost to HFTR for the transportation, processing, preservation, quality control, or storage of fetal tissue. The Panel has insufficient evidence to determine the total amount that HFTR received from the research institutions that obtained tissue from the repository.

Documents produced by HFTR to the Panel show that it required researchers to submit summaries of their IRB-approved protocols, and copies of their IRB approval letters. Those documents show HFTR also required researchers to state what tissues they will use for their study, why they must use human tissue generally, and fetal tissue in particular. The documents produced by HFTR to the Panel show the repository required researchers who applied to receive fetal tissue to use the samples in compliance with all applicable laws and regulations, including the HHS regulations on research that involves human subjects.

Based solely on HFTR's limited productions, The Panel determined it appears that HFTR complied with the applicable HHS regulations, or at least made an attempt to do so. The Panel has insufficient evidence to make a conclusive determination whether HFTR and the research institutions to which it supplied fetal tissue fully complied with the HHS regulations.

[521] Letter from [Einstein Executive Dean], Albert Einstein College of Medicine, to Rep. Marsha Blackburn, Chairman, Select Panel on Fetal Lives [sic] 1 (Feb. 10, 2016). *See generally* documents produced by Albert Einstein College of Medicine of Yeshiva University (Jan. 27, 2016).

VII. Case Studies of the Fetal Tissue Industry—The University/Clinic Model

Chapter VI Redaction Key:

1. [Clinic A Dr. #1] is an employee of Southwestern Women's Options and a faculty member of the University of New Mexico.

2. [Dr. Administrator] is a faculty member of the University of New Mexico.

3. [NM Doctor #2] is a faculty member of the University of New Mexico.

4. NM Doctor #3] is a director of Southwestern Women's Options and a faculty member of the University of New Mexico.

5. [NM Doctor #4] is a faculty member of the University of New Mexico.

6. [NM Doctor #5] is an employee of Southwestern Women's Options and a faculty member of the University of New Mexico.

7. [NM Doctor #6] is an employee of Southwestern Women's Options.

8. [Dr. Administrator #2] is a faculty member of the University of New Mexico.

9. [NM Research Doctor] is a faculty member of the University of New Mexico.

10. [NM Patient] was a patient at Southwestern Women's Options.

11. [WA Clinic Director] Executive Director and co-founder of the Cedar River Clinics.

12. [WA Doctor #1] is a faculty member at the University of Washington and also works at the Cedar River Clinics.

13. [WA Doctor #2] is a physician who works at the Cedar River Clinics.

14. [WA Doctor #3] is a faculty member at the University of Washington and also works at the Cedar River Clinics.

15. [WA Doctor #4] is a faculty member at the University of Washington and also works at the Cedar River Clinics.

16. [WA Doctor #5] previously worked at the Cedar River Clinics while a faculty member at the University of Washington.

17. [WA Doctor #6] is a former University of Washington resident who worked at the Cedar River Clinics and currently works at the Swedish Medical Center.

18. [WA Doctor #7] is a former University of Washington resident who worked at the Cedar River Clinics and currently works at Northwest Women's Healthcare.

19. [WA Doctor #8] is a faculty member at both the University of Washington and Northwestern University and owner and operator of All Women's Health-North.

20. [WA Doctor #9] is a physician who formerly worked at the Cedar River Clinics and now works at All Women's Health-North.

21. [WA Patient] was a patient at the Cedar River Clinics who filed a medical malpractice suit against [WA Doctor #2] for injuries alleged following an abortion performed at 25+ weeks.

22. [WA Doctor #10] is a former resident and current faculty member at the University of Washington who served as medical director of the Planned Parenthood of Greater Washington and North Idaho.

23. [WA Doctor #11] is a faculty member at the University of Washington and also works at the Planned Parenthood of Greater Washington and North Idaho.

24. [WA Research Doctor #1] is a faculty member at the University of Washington and the author of the university's Birth Defects Research Laboratory's NIH grant proposals.

25. [WA Research Doctor #2] is a research scientist at the University of Washington who has participated in fetal tissue research studies.

26. [WA Research Doctor #3] is a former resident at the University of Washington who has participated in fetal tissue research studies.

27. [WA Research Staff] is a technical operations manager at the University of Washington School of Medicine's WWAMI Institution for Simulation in Healthcare. He has participated in fetal tissue research studies.

28. [WA Administrator] is an administrator in the University of Washington's government relations office.

29. [PP Witness #1] is an abortion provider in Los Angeles, California, an executive with Planned Parenthood Federation of America (PPFA) who is in charge of the PPFA Manual of Medical Standard and Guidelines.

30. [PP Witness # 2] is a manager of research projects at Planned Parenthood Gulf Coast (PPGC).

31. [PPFA Lawyer] is a legal official at PPFA.

32. [PPFA Medical Officer #1] is a PPFA official who was responsible for medical issues.

33. [PPFA Medical Officer #2] is a PPFA official who was responsible for medical issues.

34. [PPGC Abortion Services Official] is a manager of abortion services at PPGC.

35. [PPGC Abortion Doctor] is a doctor who performed abortions at PPGC.

36. [PPGC Staff] is a PPGC staff worker who assisted in the abortion clinic.

37. [UTMB Researcher # 1] is a researcher at the University of Texas Medical Branch who worked with PPGC on fetal tissue procurement.

38. [PPGC Executive] is the director of abortion services and medical director at PPGC.

39. [UTMB Researcher #2] is a second researcher at the University of Texas Medical Branch who worked with PPGC on fetal tissue procurement.

40. [UTMB Staff] is a UTMB staff worker who administers contracts for researchers.

41. [BCM Researcher] is a researcher at the Baylor College of Medicine who worked with PPGC on fetal tissue procurement.

42. [BCM Staff] is a staff employee at the Baylor College of Medicine who worked with PPGC on fetal tissue procurement.

43. [BCM Contract Manager] is an employee of the Baylor College of Medicine who manages contracts.

44. [MO Doctor #1] is a faculty member of the Ob/Gyn department of the Washington University School of Medicine and also works at Planned Parenthood of the St. Louis Region and Southwest Missouri.

45. [MO Doctor #2] is Planned Parenthood of the St. Louis Region and Southwest Missouri's pathologist and the owner of Pathology Services, Inc.

46. [MO Doctor #3] is a faculty member of the Ob/Gyn department of the Washington University School of Medicine and also works at Planned Parenthood of the St. Louis Region and Southwest Missouri.

47. [MO Doctor #4] is a faculty member of the Ob/Gyn department of the Washington University School of Medicine and also works at Planned Parenthood of the St. Louis Region and Southwest Missouri.

48. [MO Doctor #5] is a faculty member of the Ob/Gyn department of the Washington University School of Medicine and also works at Planned Parenthood of the St. Louis Region and Southwest Missouri.

49. [MO Doctor #6] is or was a clinical fellow in the Ob/Gyn department of the Washington University School of Medicine and also works at Planned Parenthood of the St. Louis Region and Southwest Missouri.

50. [WI Doctor #1] was an assistant professor of Ob/Gyn at the University of Wisconsin, School of Medicine and Public Health, while serving as the associate medical director of Planned Parenthood of Wisconsin.

51. [WI Doctor #2] is the director of the Ryan Fellowship and a member of the Ob/Gyn faculty at the University of Wisconsin, School of Medicine and Public Health, and also works at Planned Parenthood of Wisconsin.

52. [MI Doctor] is both an associate professor in University of Michigan's Ob/Gyn department and medical director for Planned Parenthood in Ann Arbor.

A. Summary

The Panel identified several research institutions across the United States, most of them state universities and virtually all of them recipients of federal as well as state funding, that have formed a close relationship with one or more abortion clinics. They regularly acquire tissue from those clinics for research purposes and in some cases distribute fetal tissue to other research institutions. Typically, the research institution requests specific human fetal organs or tissue, of a specific gestational age, from an abortion clinic, and the clinic informs the research institution when they have abortions scheduled that may produce the desired human body parts. Over time, the clinic learns which human fetal organs and tissue are useful to the research institution and often alerts the research institution to their availability without prior solicitation. Once available, the research entities make arrangements to transfer the fetal organs and tissue from the clinic. In some cases, the research institutions also have relationships with tissue procurement companies. In still other cases, partnerships do not involve the transfer of fetal tissue between the clinics and universities, but they share medical school faculty and residents in common, raising additional issues about the role of government-funded institutions in providing abortions and driving the demand for fetal tissue. The Panel sought to understand these and other factors relevant to its analysis of fetal tissue transactions under 42 U.S.C. § 289g-2 and to determine what role, if any, government funding plays in the transactions between abortion clinics and universities.

B. The University of New Mexico, Southwestern Women's Options, and Planned Parenthood

8. Summary

The Panel's investigation examined the relationship between the University of New Mexico and a late-term abortion clinic near the university. A tissue technician employed by the University of New Mexico (UNM) traveled frequently to Southwestern Women's Options (SWWO), a clinic located one mile from UNM that performs abortions through the third trimester, to procure human fetal organs or tissue an average of 39 times a year since 2010. Additionally, several UNM medical faculty were scheduled on a weekly basis to perform abortions at a local Planned Parenthood affiliate.

The Panel submitted document requests to UNM and SWWO on January 6, 2016. Following both entities' refusal to make a complete production,[522] the Panel issued subpoenas dated February 12, 2016. The Panel conducted depositions of [Clinic A Dr. #1] of SWWO on May 6, 2016, and of [Dr. Administrator] of UNM on May 11, 2016. The Panel sought to understand whether the safeguards anticipated by § 289g-2 were in place, including whether too close a relationship might be formed between an abortion clinic and researchers. In the course of its inquiry, the Panel uncovered a lattice work of close connections between UNM and SWWO. SWWO is the sole provider of fetal tissue to UNM, and according to [Dr. Administrator], no fetal tissue resulting from abortions performed at UNM are donated for fetal tissue research.[523]

The transfer of fetal tissue from SWWO to UNM was only one part of a much larger regime of activities whereby UNM aggressively expanded abortion advocacy and services in New Mexico. In a concerted and organized effort, the offices, personnel, and resources of UNM and, in particular, leadership personnel at UNM medical school: (1) expanded UNM's role both in providing abortions and in training new abortion doctors; (2) expanded UNM's referral for abortion services to outside clinics, including the clinic from which it obtained fetal tissue; (3) supplied residents and fellows to perform abortions for SWWO during the period that UNM was obtaining fetal tissue from that clinic; (4) expanded the faculty of UNM by providing "volunteer faculty" status to local abortion practitioners; (5) provided staff physicians for the Planned Parenthood in Albuquerque from UNM faculty after that clinic transitioned from one owner to another; and (6) leveraged their status to organize UNM employees and students for partisan political activities.

UNM has stated that the fetal tissue transferred from SWWO is of great value to its research department. But this close relationship led to shoddy clinical practices. For example, while a UNM consent form for fetal tissue donation does exist, testimony obtained by deposition and affidavit revealed that the form is not regularly used and that SWWO improperly combines consent for tissue donation with consent for the underlying abortion procedure. In a second

[522] *See* Chapter XI *infra*.
[523] Transcript of Deposition of [Dr. Administrator], May 11, 2016 ([Dr. Administrator] Tr.), at 44, 187.

example, neither UNM nor SWWO appears to have any apparatus or procedure to aid those infants who survive the abortion procedure.[524]

Documentation obtained by the Panel in the course of its investigation shows that the transfer of fetal tissue from SWWO to UNM for research purposes is a systematic violation of New Mexico's Jonathan Spradling Revised Uniform Anatomical Gift Act (Spradling Act). These violations occurred as UNM personnel procured fetal tissue from patients at SWWO for research by UNM entities. The Panel accordingly made a criminal referral to the Attorney General of New Mexico recounting evidence of violations of law involved in the transfer and use of fetal tissue between UNM and SWWO.

Based on a procurement log attached to that referral, a former patient at SWWO discovered that her aborted infant's remains were likely transferred to UNM for research. Because UNM and SWWO had not given her the opportunity to give informed consent required under 42 U.S.C. § 289g-1, 45 C.F.R. 46, and New Mexico's Maternal, Fetal and Infant Experimentation Act, the Panel followed with a second criminal referral to the Attorney General of New Mexico.

9. The University of New Mexico Becomes an Abortion Provider

Before 2000, neither the UNM Hospital nor any of its clinics offered abortions except in limited circumstances. Abortions were not performed except in rare cases of fetal anomaly or certain threats to a pregnant woman's health—and then only in the hospital's labor and delivery or operating rooms. When abortions were performed, nursing personnel and anesthesiologists often were unwilling to participate.[525]

UNM's practice changed dramatically following the efforts of an abortion policy committee—largely spearheaded by [Dr. Administrator] and [NM Doctor #2], respectively, faculty members of the university's departments of Obstetrics and Gynecology (Ob/Gyn) and Family Medicine—to have UNM become a provider of abortions beyond the former limited circumstances. The doctors' objective met with opposition from upper-level UNM Hospital administrators, who told them that UNM policy prohibited abortions at university clinics, that the hospital would not subsidize abortion, and that nurses would not want to participate in any aspect of abortion. Over the course of about a year and a half, the doctors pressed ahead with their agenda, disregarding the admonitions of administrators and reservations of most of the hospital staff who did not wish to be implicated in abortion practice. In 2002, the doctors succeeded in introducing medical abortion—through the use of mifepristone, or RU-486—into UNM clinics.[526]

The doctors then pressed further, against additional resistance by administrators, until they successfully introduced surgical abortion into UNM clinics. To do this they overrode

[524] *See* Chapter VII.E *infra*.
[525] [redacted], [redacted], "*You Can't Do That 'Round Here": A Case Study of the Introduction of Medical Abortion Care at a University Medical Center*, 71 Contraception 84, 84-85 (2005) [hereinafter *You Can't Do That*].
[526] *Id.* at 84-88; [Dr. Administrator] Tr. at 140-41.

objections of clinic staff, despite acknowledging that such opposition "may be intense, particularly due to the more extensive patient interaction required for surgical procedures and the increased complexity of the procedure." By that point, however, the doctors, whose salaries are paid by the taxpayers of New Mexico, were disinclined to accommodate such moral qualms, dismissively writing in a published article that while they "anticipate hiring dedicated nurses and support staff . . . . abortion opponents have limited rationale to prevent MVA [manual vacuum aspiration] for pregnancy termination."[527] Today, UNM Hospital performs surgical abortions for any reason through 25 weeks gestation.[528] At or beyond 24-25 weeks gestation, "pregnancy termination will be considered on a case-by-case basis for maternal or fetal reasons."[529] [Dr. Administrator] testified that "[t]here are situations where third trimester terminations take place" at UNM Hospital, when there is "a maternal indication or a fetal indication."[530] Such an indication could include a diagnosis of Down Syndrome.[531] At the UNM Center for Reproductive Health, surgical abortions are offered from the time when a pregnancy is first identified through 23 weeks gestation, and medical abortions are offered up to 10 weeks gestation.[532] UNM also refers patients to SWWO and to clinics in Colorado and Maryland, the Boulder Abortion Clinic and Germantown Reproductive Health Services, for late-term abortions.[533]

The advocacy that introduced UNM's practice of medical and surgical abortion did not occur as an initiative of activist faculty only. Grants from the Susan Thompson Buffett Foundation provided funding to promote the expansion of abortion at UNM, including the training of both faculty and students at UNM to become abortion providers.[534] Such training occurred through programs like the Center for Reproductive Health Education in Family Medicine for Family Medicine residents and the Kenneth J. Ryan Residency Training Program for Ob/Gyn residents.[535]

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[527] *You Can't Do That* at 88.

[528] For examples of protocols regarding surgical and medical abortions offered at UNM during the first trimester, see UNM Health Sciences Center, Medical Abortion [UNM01681], Exhibit 6.1; UNM Health Sciences Center, Management of Very Early Pregnancy Medical and Surgical Abortion [UNM01689-UNM01691], Exhibit 6.2. Abortions performed during the second trimester are either dilation and evacuation (D&E) or induction of labor. UNMHSC, Second Trimester Pregnancy Termination, D&E and induction of labor, Exhibit 6.3.

[529] UNMHSC, Second Trimester Pregnancy Termination, D&E and induction of labor [UNM01685], Exhibit 6.3.

[530] [Dr. Administrator] Tr. at 46.

[531] [Dr. Administrator] Tr. at 57.

[532] UNM Center for Reproductive Health, Abortion Care, http://unmmg.org/clinics/crh/abortion-care/index.html, Exhibit 6.4.

[533] [Dr. Administrator] Tr. at 46-47.

[534] The Susan Thompson Buffett Foundation 990-PF reports, Exhibit 6.5; [Dr. Administrator] Tr. at 128-29, 132-33. While the Foundation was the source of funds for this fellowship, Berkshire Hathaway is by means of a sole proprietorship the owner of Danco Laboratories, the sole distributor of mifepristone and the entity from which UNM would obtain the medication when it undertook medical abortions. [Dr. Administrator] Tr. at 137-39.

[535] *You Can't Do That*, at 85-86. These two programs and a third—the Access Project, which according to [Dr. Administrator] is a part of the Center for Reproductive Health Education in Family Medicine—entail three grants for student programs that involve abortion. The Susan Thompson Buffett Foundation funds all three. [Dr. Administrator] Tr. at 134-36.

10. UNM Provides Doctors to Southwestern Women's Options and Planned Parenthood

The doctors of UNM's Ob/Gyn department, with financial support from the Susan Thompson Buffett Foundation, formed the UNM School of Medicine Fellowship in Family Planning (UNM Fellowship), which served as the vehicle by which UNM medical residents were deployed to the nearby Albuquerque abortion clinics—SWWO and Planned Parenthood—to provide abortions. While, like any university fellowship, the UNM Fellowship had an educational purpose, its "major goal" was to send UNM doctors to SWWO in order to "give additional volume of 2nd trimester abortions" under the supervision of [NM Doctor #3] of SWWO.[536] [Dr. Administrator] initiated the training rotation with SWWO.[537]

The Panel obtained two UNM contracts with SWWO that provide for UNM residents to supply staffing at the clinic. One contract is a single-page "program letter of agreement" covering July 1, 2011, to June 30, 2012. It was not signed until January 2012, and the sole UNM signatory was the program director of UNM's Family Medicine Residency Program.[538] The other contract totals two pages, covers the two-year period beginning July 1, 2014, and describes assignments by which UNM fellows would perform abortion procedures at SWWO in two "two-week rotations."[539] These rotations were entirely dedicated to training the fellows to competency in the performance of the abortion procedure.[540] The sole UNM signatory to this contract was the director of the UNM Fellowship, [Dr. Administrator].

Neither the 2012 nor the 2014 contract was signed by an official with signature authority under UNM policy, and neither contract indicates that it was reviewed by a contract review officer in the University Counsel's Office, another UNM policy requirement.[541] The "resident rotation" was a large-scale program at UNM, according to [Dr. Administrator]. "All of the interns rotate through, unless they opt out. So we do a very large scope of training." Additionally, the "physician assistant and nurse practitioner and nurse midwifery programs have asked us to take nursing students, which we accommodate when we can."[542]

Under the New Mexico Tort Claims Act, UNM faculty, students, and residents had their malpractice insurance provided by the state for their work at outside abortion clinics, including

[536] UNM-SWWO agreement (June 2, 2014) [UNM03417-UNM03418] [hereinafter 2014 UNM-SWWO agreement], Exhibit 6.6.
[537] [Dr. Administrator] Tr. at 173-74.
[538] UNM-SWWO agreement signed Jan. 5 and Jan. 7, 2012 [UNM03419], Exhibit 6.7.
[539] 2014 UNM-SWWO agreement. In her deposition, [Dr. Administrator] testified that fellows would train for between two and six weeks. [Dr. Administrator] Tr. at 189.
[540] [Dr. Administrator] Tr. at 189; Transcript of Deposition of [Clinic A Dr. #1], May 6, 2016 ([Clinic A Dr. #1] Tr.), at 86-88.
[541] *See* University of New Mexico Regents' Policy Manual, Section 7.8: Signature Authority for Contracts, Exhibit 6.8; Administrative Policies and Procedures Manual, Section 5.2, Exhibit 6.9; University Business Policy 2010 Exhibit B2, Exhibit 6.10. When questioned about this deficiency in the UNM-SWWO contracts, [Dr. Administrator] testified that what the university had with SWWO was in fact "a program letter" and "not a contract." [Dr. Administrator] Tr. at 147. She proceeded to admit that the "program letter . . . defines the educational expectations of the fellow . . . when they do this rotation and the expectations of the preceptor." *Id.* at 148. Such a document setting forth mutual expectations would plainly seem to meet the legal definition of a contract.
[542] [Dr. Administrator] Tr. at 87-88.

SWWO and Planned Parenthood.[543] Neither SWWO nor Planned Parenthood provided fellows any compensation.[544] They received their entire compensation from UNM.[545]

[Clinic A Dr. #1], who participated in the fellowship while employed by UNM, testified that she spent four weeks—broken into two two-week shifts—at SWWO and up to another 20 days at Planned Parenthood.[546] During her fellowship, she was trained in the performance of the abortion procedure by [Dr. Administrator] and by at least two SWWO doctors.[547] In a given week, which consisted of a full-time work schedule at the clinic, she estimated she might see 30 patients.[548] After her fellowship ended, she joined the staff of SWWO, where she has worked full time since 2014, alternating between SWWO's Albuquerque clinic and a second clinic it operates in Dallas, Texas, where abortions are allegedly not performed beyond 21 weeks and six days gestation.[549] During the four weeks of her fellowship at SWWO in Albuquerque, she testified she performed or assisted in approximately 10 to 15 third-trimester abortions.[550] Including that number and factoring in her subsequent employment by the clinic, she estimated she performed over the course of her work at SWWO in Albuquerque a total of possibly more than 50 third-trimester abortions.[551] Considering that [Clinic A Dr. #1]'s employment at SWWO has been based mostly in Dallas, which allegedly does not provide third-trimester abortions, and that she spent only about a quarter of one year (2015) working at the Albuquerque location,[552] her estimate suggests a particularly high volume of third-trimester abortions at SWWO in Albuquerque.

Since the time when opposition to participating in abortion procedures was the predominant view of UNM medical staff, the culture appears to have changed, along with the composition of UNM hospital and clinic personnel, to one aggressively in favor of the expansion of abortion. [Dr. Administrator], [NM Doctor #4], and other UNM medical faculty members engage in political fundraising and lobbying for an expansion of abortion services and public funding in support thereof. [Dr. Administrator] herself has held leadership positions the last five years in the American College of Obstetricians and Gynecologists (ACOG) and the Society of Family Planning.[553] She testified that "advocacy is . . . a core requirement in our training program," one that falls under the ACGME accreditation requirements for Ob/Gyn residents.[554] UNM students are encouraged to participate in such activities as ACOG Lobby Day, the New Mexico Lobby Day, and the Congressional Leadership Conference, which are organized by

[543] [Dr. Administrator] Tr. at 151-54; [Clinic A Dr. #1] Tr. at 152.
[544] [Clinic A Dr. #1] Tr. at 92, 94-95, 97-98, 103.
[545] [Clinic A Dr. #1] Tr. at 97-98, 102-103.
[546] [Clinic A Dr. #1] Tr. at 86-88, 92-93. [Clinic A Dr. #1] recalled her compensation from UNM was "in the low fifties" at the time of her fellowship. *Id.* at 102.
[547] [Clinic A Dr. #1] Tr. at 89-91. [Clinic A Dr. #1] was already fully board certified at the time of her fellowship. [Clinic A Dr. #1] Tr. at 102.
[548] [Clinic A Dr. #1] Tr. at 147, 158-59.
[549] [Clinic A Dr. #1] Tr. at 266.
[550] [Clinic A Dr. #1] Tr. at 150, 247.
[551] [Clinic A Dr. #1] Tr. at 247.
[552] [Clinic A Dr. #1] Tr. at 266 (testifying that her employment at SWWO was exclusively in Dallas except for alternating weeks between there and Albuquerque between January and approximately July of 2015).
[553] [Dr. Administrator] Tr. at 126.
[554] [Dr. Administrator] Tr. at 141.

ACOG.[555] Meanwhile, the once-majority view among UNM medical personnel appears to have been marginalized, if not punished outright. In January 2016, a medical student filed a lawsuit against the UNM Board of Regents alleging that he was referred to a disciplinary committee by [Dr. Administrator] and sanctioned by UNM for posting his personal views against abortion on his Facebook page, despite the fact that the posts did not mention UNM.[556]

During the summer of 2015, amid the national news coverage of practices of abortion clinics and tissue procurement companies with respect to the handling and possible sale of fetal tissue, UNM fell under increased scrutiny. Members of the New Mexico state legislature began to investigate UNM's relationship with SWWO and the handling of fetal tissue, as did a private organization, the New Mexico Alliance for Life, and the *Albuquerque Journal*.[557] In a terse letter from [Dr. Administrator] to [NM Doctor #3] dated December 14, 2015, the UNM Fellowship program at SWWO was terminated, despite the fact that more than six months remained under the 2014 contract.[558] [Dr. Administrator] testified the termination occurred after a review conducted by the UNM Fellowship determined the fellows "did not have the volume of second trimester pregnancy terminations that were required for competency,"[559] but it is difficult to dispute that the timing of UNM's decision was related to the various investigations.

UNM's contracts with Planned Parenthood are referred to as "house officer affiliation agreements" and contain eight pages that provide details of the "close working relationship between the University" and Planned Parenthood, largely in the form of providing resident UNM physicians to staff the clinic.[560] Over the course of its relationship with UNM, the Planned Parenthood of New Mexico located in Albuquerque was acquired by Planned Parenthood of the Rocky Mountains, after which UNM staffed the Albuquerque Planned Parenthood location not only with fellows, but also with doctors from its Ob/Gyn department to serve as staff physicians.[561] Attached as an illustration of this relationship is a schedule generated by the department for the month of May 2016 detailing rotations at the clinic for staff physicians from UNM.[562]

11. UNM Confers Faculty Status and Benefits upon SWWO Personnel

Most of the doctors employed on the staff of SWWO also have what are described as "volunteer faculty" positions at UNM. [NM Doctor #3] is a clinical assistant professor in the Ob/Gyn department. [Clinic A Dr. #1] transitioned from employment at UNM to employment at

[555] [Dr. Administrator] Tr. at 123. *See also* ACOG legislative activities update screenshot (May 2013), Exhibit 6.11 (noting an ACOG event attended by 60 "Fellows, Junior Fellows, and medical students").
[556] Complaint at 2, 6, 8-10, Hunt v. Board of Regents of the University of New Mexico, No. D-202-CV-2016-00143 (N.M. Dis. Ct., Bernalillo Co., Jan. 15, 2016).
[557] Colleen Heild, *UNMHSC Halts Training at Private Abortion Clinic*, Albuquerque Journal, Dec. 20, 2015, at A1.
[558] Letter from [Dr. Administrator] to [NM Doctor #3], (Dec. 14, 2015) [UNM03429], Exhibit 6.12.
[559] [Dr. Administrator] Tr. at 149.
[560] UNM-Planned Parenthood of New Mexico, Inc., House Officer Affiliation Agreement (June 13, 2012), at 1, Exhibit 6.13; UNM-Planned Parenthood of the Rocky Mountains House Officer Affiliation Agreement (June 10, 2013), at 1, Exhibit 6.14.
[561] *See id.*; [Clinic A Dr. #1] Tr. 93-94, 167-69.
[562] *See* UNM staff rotations at Planned Parenthood, May 2016, Exhibit 6.15.

SWWO in 2014 and is a visiting instructor in the UNM Ob/Gyn department. [NM Doctor #5] is a clinical assistant professor in the Family Community Medicine department while being employed by SWWO.

Although as volunteers these SWWO physicians are not paid a salary by UNM, they do receive substantial benefits for their faculty status. For example, they receive "New Mexico Tort Claims Act professional liability insurance coverage provided to university employees" that is "extended to provide coverage for the duties and activities performed by the individual Volunteer Faculty members," provided that such activities were assigned to them by the department chairperson and that no other insurance covers such activities.[563] They also appear to have admitting privileges at the UNM Hospital.[564]

As volunteer faculty, these SWWO doctors also are entitled to a list of benefits at UNM that include the following:

> **HEALTH SCIENCES CENTER LIBRARY**—Access the HSC Library's online databases and extensive collection of over 600 full-text online journals check-out privileges; and educational classes
>
> **NEW MEXICO EDUCATORS FEDERAL CREDIT UNION**—membership
>
> **JOHNSON CENTER**—Facilities include the main and auxiliary gyms, handball courts, weight room, tennis courts and Olympic-size pool
>
> **ATHLETIC EVENTS**—50% discount on two season tickets for football, and men's or women's basketball games
>
> **POPEJOY CULTURAL SERIES**—discounts on event tickets
>
> **MUSEUMS**—Free admission to the Fine Arts Museum, Maxwell Museum of Anthropology, Geology Museums, Student Art Gallery, and Museum of Southwestern Biology
>
> **LIBRARIES**—Access to the Law Library on North Campus. The libraries on main campus include: Zimmerman Library, Fine Arts Center, Parish Library in the Graduate School of Management, Tireman Learning Materials Library in the Educational Complex and Centennial Science/Engineering Library

[563] Volunteer Faculty Professional Liability Insurance Extension of New Mexico Tort Claims Act [UNM03399], Exhibit 6.16.
[564] See [Clinic A Dr. #1] Tr. at 99-100.

> **UNIVERSITY PRESS**—Publications may be purchased at a discount at UNM bookstores
>
> **GOLF**—Reduced rates on quarterly/annual memberships for the 9-hole course. Discounts of the 18-hole Championship course may be available.
>
> **RECREATIONAL EQUIPMENT**—Nominal fees to rent tents, camping gear, backpacks, snowshoes, cross-country skis, volleyball sets, etc.[565]

From documents obtained by the Panel, there is also a question whether benefits such as access to UNM library items are enjoyed by SWWO employees who are not known to be UNM faculty members, whether because they were directly provided such access by UNM or because a coworker at SWWO who is also a faculty member provided them such access from their accounts.[566]

Apart from involvement in the UNM fellowship at SWWO, UNM volunteer faculty members employed by SWWO are given *no teaching or other academic obligations* to UNM in exchange for the benefits provided by UNM. In fact, to the question "what duties did you have at UNM as a volunteer faculty member?" [Clinic A Dr. #1] answered, "No specific duties come to mind" and added she was "not . . . compelled to perform any teaching activities since becoming volunteer faculty."[567] Despite having admitting privileges, [Clinic A Dr. #1] has treated only one patient at UNM Hospital since her employment began at SWWO, and that instance occurred only because she happened to be speaking with candidates for the UNM Fellowship one day when, due to a staff shortage, her services were needed in order for an abortion to proceed.[568] UNM does, however, continue to receive on a regular basis one substantial benefit from SWWO: fetal tissue.

12. UNM Performs Research Using Tissue from Infants Aborted at SWWO and Shares the Tissue with Other Research Entities

Since 1995, SWWO has served as the only source of aborted infant tissue for research purposes at the University of New Mexico Health Sciences Center (UNMHSC). UNMHSC

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[565] UNM School of Medicine, Volunteer Faculty Benefits [SWWO001234-SWWO001235], Exhibit 6.17. *See also* [Clinic A Dr. #1] Tr. at 155, 259.

[566] *See, e.g.*, email correspondence of Feb. 16, 2016, in which [Clinic A Dr. #1], a UNM faculty member, provides an article to [NM Doctor #6], an SWWO employee not known to be on the UNM faculty, after the latter noted, "Once again, I'm having problems accessing the UNMHC [sic] library system." [SWWO001246], Exhibit 6.18.

[567] [Clinic A Dr. #1] Tr. at 155-56. *See also id.* at 258 ("I have no clinical or academic obligations necessarily attached to that faculty status"). When asked whether other SWWO doctors who doubled as UNM faculty members "ever taught courses at the University of New Mexico," [Clinic A Dr. #1] testified, "I can recall being told of maybe one." *Id*. at 158. When asked to identify any service she performed for UNM as a faculty member, she could think of only one example, when she "was asked once to participate in medical student oral examinations for their OB-GYN rotation." [Clinic A Dr. #1] Tr. 260-61.

[568] [Clinic A Dr. #1] Tr. at 101, 194-95.

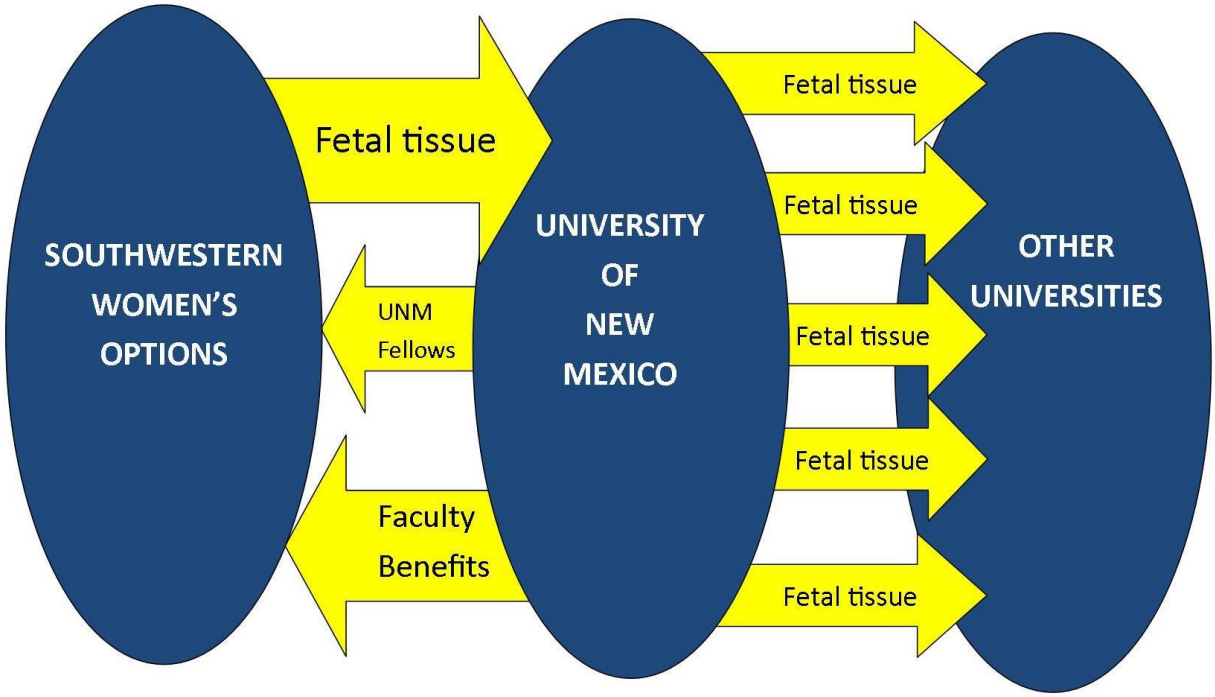
asserts that "[t]he tissue is donated at no cost to UNMHSC and it is picked up at the clinic by UNMHSC staff."[569] According to UNM's Human Research Review Committee, "[w]omen undergoing elective termination of pregnancy are consented by Southwest Women's Options clinic, and can elect to have tissue used for research . . . . No interaction between women undergoing the procedure and [UNM] laboratory personnel occurs."[570]

Laboratory notes produced to the Panel reveal that a UNMHSC employee has collected aborted infant tissue from SWWO an average of 39 times a year since 2010.[571] Organs harvested include brain/head, heart, lung, eyes/retina, kidney, spleen, adrenal gland, intestines, bone marrow, and stomach. At least some infants were administered digoxin. By July 2015, however, digoxin was administered only to infants "20wks+."[572]

The notes contain information on aborted infants whose gestations ranged from approximately 11.5 to 30.5 weeks, with many in the 14- to 18-week range. At least 20 aborted infants were past 20 weeks gestation. The infants described include twins with "clubbed feet" aborted at 16 weeks gestation, a 22.5-week aborted infant with Down Syndrome, 20-week aborted twins with intact brains, a 25.3-week aborted female infant with an orofacial cleft, and a 30.5-week aborted "intact" infant.[573] The remains of these and hundreds of other aborted infants were collected from SWWO by UNMHSC staff and then taken to UNMHSC for use in research.

As recently as May 5, 2015, [NM Doctor #3] of SWWO wrote a letter to UNM detailing his desire to continue to provide aborted infant tissue for research: "This letter reconfirms my ongoing assistance and support for your research involving human fetal tissue. I have reviewed and been kept updated on your research and feel that the use of fetal tissue continues to be appropriate for your studies. Therefore, I will continue to facilitate your collection of samples from my clinic, following the usual inspection of the tissue."[574] The Panel has no information to suggest that SWWO has ceased providing aborted infant tissue to UNMHSC. The following chart illustrates the operation of the university/clinic model through the UNM-SWWO relationship:

[569] UNM Second Submission to House Select Investigative Panel, at 1 (Feb. 16, 2016), Exhibit 6.19 [hereinafter UNM Second Submission]; UNM Document [UNM00560], Exhibit 6.20; UNM First Submission to House Select Investigative Panel, at 1 (Jan. 29, 2016), Exhibit 6.21; UNM Response to House Select Investigative Panel Subpoena, at 1 (Mar. 3, 2016), Exhibit 6.22; SWWO letter responding to document request, at 1 (Feb. 12, 2016), Appendix A, Exhibit 6.23.
[570] UNM Study Document [UNM00790], Exhibit 6.24.
[571] *See* Procurement notes [UNM00004-UNM00052] (Approximation: 2010–43 days; 2011–25 days; 2012–45 days; 2013–49 days; 2014–41 days; 2015–33 days), Exhibit 6.25.
[572] *Id.* at [UNM00049], Exhibit 6.25.
[573] *Id.* at [UNM00019, UNM00041, UNM00024, UNM00006], Exhibit 6.25.
[574] Letter from [NM Doctor #3] to UNM [UNM01086] (May 5, 2015), Exhibit 6.26.



The tissue transferred from SWWO to UNM is of substantial value. According to UNM, "[s]ome of UNMHSC's most significant discoveries have arisen from its research involving fetal tissue."[575] The university stated that their collaboration with SWWO was integral to their research: "improved neonatal care and infant outcomes . . . . would not have occurred without the translational research efforts of the DREAM [Developmental Research, Education, and Mentoring Laboratory within UNM's Division of Neonatology] Lab in collaboration with [redacted] and the providers at Southwest Women's Options."[576]

In a July 22, 2015, letter to New Mexico legislators, [Dr. Administrator #2] described five studies using aborted infant tissue conducted or being conducted by a neonatologist in the Department of Pediatrics.[577] Additionally, [NM Research Doctor] of the DREAM Lab has published at least eight studies which used tissue from aborted infants.[578] Documents provided to

[575] UNM Second Submission, at 2, Exhibit 6.19.
[576] UNM Documents [UNM00560], Exhibit 6.20; UNM Documents [UNM00812 & UNM01105], Exhibit 6.27.
[577] Letter from [Dr. Administrator #2] to New Mexico legislators 3-4 (July 22, 2015), Exhibit 6.28.
[578] [NM Research Doctor] is an author or co-author of the following studies: (1) J Neonatal Perinatal Med. 2016 Mar. 12;9(1):91-7. doi: 10.3233/NPM-16915052. *Epsilon globin gene expression in developing human fetal tissues*; (2) Pediatr Res. 2015 Apr.;77(4):500-5. doi: 10.1038/pr.2015.15. Epub 2015 Jan 14. *VEGF mRNA and protein concentrations in the developing human eye* [hereinafter *Human Eye Study*]; (3) Circulation. 2014 May 27;129(21):2144-57. doi: 10.1161/CIRCULATIONAHA.114.009124. Epub 2014 Apr. 7. *Existence, functional impairment, and lung repair potential of endothelial colony-forming cells in oxygen-induced arrested alveolar growth*; (4) Gastroenterology. 2011 Jan.;140(1):242-53. doi: 10.1053/j.gastro.2010.09.043. Epub 2010 Sep 24. *TGF-β2 suppresses macrophage cytokine production and mucosal inflammatory responses in the developing intestine*; (5) Am J Physiol Gastrointest Liver Physiol. 2009 Jul.;297(1):G1-G10. doi: 10.1152/ajpgi.90730.2008. Epub 2009 May 14. *Epithelial cells in fetal intestine produce chemerin to recruit macrophages*; (6) Pediatr Res. 2008 Apr.;63(4):394-7. doi: 10.1203/PDR.0b013e318165b8d1. *Elevated erythropoietin mRNA and protein concentrations in the developing human Eye*; (7) Acta Paediatr Suppl. 2002;91(438):27-30. *Erythropoietin and hypoxia inducible*

the Panel list 18 studies conducted in collaboration with SWWO since 1995.[579]

The procurement notes provided to the Panel by UNM further confirm their acquisition of aborted infant tissue from SWWO for research purposes. References to specific studies were written in the notes along with lists of infant parts harvested. A lab technician wrote in May 2012 that someone from UNMHSC "asked clinic for digoxin treated tissue 24-28 wks. for methylation study + because [redacted] wants whole, fixed brains to dissect w/ summer camp students. Clinic est. 27 and 28 wks."[580]

While [NM Research Doctor] appears to have conducted most of the research using aborted infant tissue, UNM claims to have "identified eleven (11) medical students or residents and eight (8) faculty members who participated in fetal tissue research but who may not be named in published articles."[581] Further, documents produced to the Panel indicate that the Pediatrics and Neonatology departments sometimes partner with researchers from other departments as well.[582]

UNMHSC also shares tissue that it acquires with other researchers, including "[o]ne researcher . . . at the University of South Florida (previously worked at University of Alabama, Birmingham and University of Illinois, Chicago)," "the University of Ottawa in Canada (previously worked at University of Edmonton)," and "at the University of California San Francisco." UNMHSC maintains that "no consideration is exchanged for the tissue as part of these collaborative research projects."[583] UNM provided the Panel with emails between UNMHSC staff and researchers at other institutions. For instance, one UNM researcher wrote to a researcher in Edmonton, "We will try to get later gestation lung for you, sometimes we can get up to 20-22 weeks, but it is unusual these days to get non-digoxin exposed samples beyond 18 weeks (i.e., no living tissues)."[584]

UNMHSC represented to the Panel that it bears the cost for shipping tissue domestically while for transactions in Canada, the Canadian researcher provides a Federal Express account number.[585] After the Panel's chief counsel subsequently sent a letter to UNM requesting more complete records that would reflect other entities' transactions with UNM, budgets, IRB approvals, and late-term abortion activity at UNM, the university responded with a 60-page production, of which 35 pages are Federal Express and other courier records with names redacted and 21 pages are entirely redacted with no content visible at all.[586] This leaves the Panel

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factor-1 expression in the mid-trimester human fetus; (8) Pediatr Res. 1995 Jun.;37(6):806-11. *Neutrophil pool sizes and granulocyte colony-stimulating factor production in human mid-trimester fetuses*.

[579] UNM Documents [UNM00768-UNM00785, UNM00815-UNM00817 & UNM01059], Exhibit 6.29.

[580] Procurement notes [UNM00024], Exhibit 6.25.

[581] UNM Response to House Select Investigative Panel Subpoena 2 (Mar. 3, 2016), Exhibit 6.22.

[582] *See* Emails with the UNM College of Pharmacy Dept. of Pharmaceutical Sciences [UNM01071-UNM01075, UNM01078-UNM01083], Exhibit 6.30.

[583] UNM Second Submission, at 1, Exhibit 6.19.

[584] Email from UNM to University of Edmonton [UNM00910], Exhibit 6.31.

[585] UNM Second Submission, at 1, Exhibit 6.19.

[586] Letter from T. March Bell, Chief Counsel and Staff Director, House Select Investigative Panel, to UNM (Nov. 18, 2016), Exhibit 6.32; UNM Documents [UNM03457-UNM03516], Exhibit 6.33.

with an incomplete picture of UNM's monetary arrangements with other institutions and its IRB approval process, assuming one even exists.

In its responses to the Panel, SWWO has asserted that it "does not participate 'in research, study, or other work involving fetal tissue.'"[587] Evidence collected by the Panel, however, calls into question whether that statement is a misrepresentation by SWWO. In one letter UNM produced to the Panel, for example, [NM Research Doctor] wrote to [NM Doctor #3] that "we realized how valuable it would be to be able to match the individual patient's blood to the fetal tissue obtained. . . . we would need your help in matching the blood to the fetal tissue."[588] Another UNM document refers to the "translational research efforts of the DREAM Lab in collaboration with [NM Doctor #3] and the providers at Southwest Women's Options."[589] SWWO medical staff was even acknowledged in a published 2015 study on the developing human eye based upon eyeballs taken from fetuses aborted at SWWO. There the authors "thank[ed] [NM Doctor #3] and staff at Southwestern Women's Options . . . for technical assistance."[590] Thus, both internal and published documents suggest that the clinic and its personnel, especially [NM Doctor #3], did in fact participate in fetal tissue research beyond supplying the tissue to UNM.

13. UNM and SWWO's Failure to Properly Obtain Consent

From the Panel's investigation, it is apparent that there were several deficiencies in the consent process used to procure fetal tissue. Although both SWWO and UNM provided the Panel a consent form that purported to give patients notice that tissue from their pregnancies would be donated to UNM,[591] there is evidence that this form was not used. While [Clinic A Dr. #1] testified that SWWO's practice was to provide women an opportunity to donate the tissue that resulted from their abortions and to obtain their consent to do so, she admitted she had never gotten a consent from a patient at SWWO to make a fetal tissue donation—and did not even recognize the consent form that SWWO and UNM produced to the Panel.[592] She also admitted she was unaware of whether consent was required prior to the donation of fetal tissue.[593]

Further evidence supports the inference that patients were not regularly given a fetal tissue donation consent form at SWWO. [NM Patient], a woman who obtained an abortion from SWWO, has brought suit against the clinic and attested in an affidavit that she was never given a

[587] Letter from SWWO to House Select Investigative Panel 1 (Nov. 30, 2016), Exhibit 6.34. SWWO purported to quote from the SWWO letter responding to document request (Feb. 12, 2016), at Appendix A, but this language does not appear in that document.
[588] UNM Document [UNM00562], Exhibit 6.35.
[589] UNM Document [UNM00812], Exhibit 6.27.
[590] *Human Eye Study* at 7.
[591] Client Information for Informed Consent, Donation of Fetal Tissue for Medical Research [SWWO000524], Exhibit 6.36. UNM produced the same form with Bates number UNM01103.
[592] [Clinic A Dr. #1] Tr. at 162-63, 165-67, 188-89, 212-13. The consent form itself was marked twice during [Clinic A Dr. #1]'s deposition, as Ex. 6 without a Bates number and as Ex. 12 with Bates number SWWO000524, the version the clinic produced to the Panel. *Id.* at 164-65, 212-13. [Clinic A Dr. #1] maintained it was the job of a counselor rather than a doctor to obtain a consent. *Id.* at 190.
[593] [Clinic A Dr. #1] Tr. at 273.

"consent to donate tissue that was separate from the consent for the [abortion] procedure."[594] Moreover, she alleges she was never informed by the doctors and staff at SWWO that her infant's remains were to be donated to UNM or another entity.[595] Neither, she alleged, was she informed of the nature and extent of any use of such remains, "which body parts were going to be used or donated," or what benefits could be expected from such use.[596] She added that she was not informed by SWWO doctors or staff that the doctor who treated her, [NM Doctor #5], and the director of SWWO, [NM Doctor #3], were volunteer faculty members at UNM, or that the clinic and the university had been collaborating on fetal tissue research since 1995.[597]

Even more problematically, the only semblance of consent SWWO allegedly sought from [NM Patient] for fetal tissue research was a phrase mentioning the use of "tissue and parts . . . in medical research" within a two-page consent form provided to her for the abortion procedure itself.[598] Thus, the only consent sought from her for fetal tissue donation came during what should have been a separate process of consent to the abortion procedure itself.

A letter from [NM Patient] to SWWO dated December 2, 2015, requested "all information regarding the disposal, donation or sale of any medical waste," but she allegedly never received any records regarding the disposition of her infant's remains.[599] Moreover, none of SWWO's or UNM's productions of documents to the Panel included the two-page consent form submitted to the Panel by [NM Patient] through her attorney. In September 2016, [NM Patient] read procurement notes dated October 17, 2012, that were attached to the Panel's referral of UNM and SWWO to the Attorney General of New Mexico that indicated brain tissue had been taken from one infant estimated at 11.5 weeks gestation and another at 12.7 weeks gestation.[600] Because [NM Patient]'s ultrasound taken on October 5, 2012, stated she was 12 weeks and two days pregnant, and because she obtained her abortion five days later on October 10—when staff informed her she was between 12 and 13 weeks pregnant—she believed her "baby was one of the two babies given to the University of New Mexico for their research."[601] This belief is consistent with SWWO's practice of storing fetal tissue in an on-site freezer until it is periodically picked up for transfer to UNM.[602] [NM Patient] attested, "If I had known my baby was going to be used for research I would have probably changed my mind about going through with the abortion," and added that the actions of SWWO and its doctors caused her "emotional

[594] Affidavit of [NM Patient], Nov. 18, 2016 ([NM Patient] Aff.), ¶ 30, Exhibit 6.37. *See also* Complaint ¶ 47, [NM Patient] v. [NM Doctor #3], No. [redacted]-CV-[redacted] (N.M. Dis. Ct. Bernalillo County Nov. 30, 2016) ([NM Patient] Compl.), Exhibit 6.38. In an email dated Nov. 28, 2016, [NM Patient] gave permission to the Panel to disclose her identity publicly. Nonetheless, her name is not disclosed in the instant report.
[595] [NM Patient] Aff. ¶ 10; [NM Patient] Compl. ¶ 32.
[596] [NM Patient] Aff. ¶¶ 21-22, 26; [NM Patient] Compl. ¶¶ 35-38.
[597] [NM Patient] Aff. ¶¶ 15, 18-20; [NM Patient] Compl. ¶ 32.
[598] [NM Patient] Aff. ¶ 8 & Ex. A, at 1; [NM Patient] Compl. ¶¶ 11-12 & Ex. A.
[599] [NM Patient] Aff. ¶¶ 32-33 & Ex. B; [NM Patient] Compl. ¶¶ 54-57.
[600] Compare [NM Patient] Aff. ¶¶ 35-36 and Procurement notes, UNM00029, Exhibit 6.25. *See also* [NM Patient] Compl. ¶ 52.
[601] [NM Patient] Aff. ¶¶ 7, 12-13, 37-38; [NM Patient] Compl. ¶¶ 49-53.
[602] SWWO letter responding to document request (Feb. 12, 2016), at 5; [Clinic A Dr. #1] Tr. at 182-85. According to SWWO's Feb. 12 letter, pickup occurred weekly, but as noted above, procurement notes record that pickup occurred an average of 39 times per year since 2010, 45 times in 2012.

distress and mental anguish."[603] [NM Patient] additionally alleged that she was advised by staff that she could apply for Medicaid funding for her abortion procedure and that the paperwork supporting such funding was prepared by a doctor she never saw, [NM Doctor #6], and not her treating physician, [NM Doctor #5].[604]

14. The Panel's Criminal Referrals of UNM and SWWO

c) The June 2016 Referral

On June 23, 2016, the Panel sent a criminal referral of UNM and SWWO to the Attorney General of New Mexico that cited both state and federal law. New Mexico's Jonathan Spradling Revised Uniform Anatomical Gift Act (Spradling Act)[605] is based on the Uniform Anatomical Gift Act (UAGA),[606] which is adopted in some form in every state. The Spradling Act was enacted in 2007 to replace the State's existing Uniform Anatomical Gift Act[607] with provisions mirroring the UAGA.[608]

The Spradling Act, like the UAGA, includes stillborn infants and fetuses in the definition of "decedent" for purposes of obtaining consent from a relative before the deceased infant's body is donated for experimentation or transplantation. In the official notes to the UAGA, the drafters explain that the inclusion of stillborn babies and fetuses ensures that they "receive the statutory protections conferred by this [Act]; namely that their bodies or parts cannot be used for transplantation, therapy, research, or education without the same appropriate consents afforded other prospective donors."[609]

However, the notes also mention that states may choose to treat aborted fetuses differently, given the "complicated legal, scientific, moral, and ethical issues which may arise."[610] That is exactly what the State of New Mexico chose to do in 2007. In the Spradling Act, "'decedent' means a deceased individual whose body or part is or may be the source of an anatomical gift." It "includes a stillborn infant and . . . a fetus *but [does] not includ[e] a fetus that is the subject of an induced abortion*."[611]

Further, the Spradling Act provides that the Act "applies to an anatomical gift or amendment to, revocation of or refusal to make an anatomical gift, whenever made."[612] In other

[603] [NM Patient] Aff. ¶¶ 39, 42; [NM Patient] Compl. ¶¶ 60, 142.
[604] [NM Patient] Aff. ¶¶ 14-17; [NM Patient] Compl. ¶¶ 61-64, 110.
[605] N.M. Stat. Ann. § 24-6B-1, *et seq*.
[606] Revised Uniform Anatomical Gift Act (2006) (last revised or amended in 2009), National Conference of Commissioners on Uniform State Laws, http://www.uniformlaws.org/shared/docs/anatomical_gift/uaga_final_aug09.pdf [hereinafter UAGA].
[607] N.M. Stat. Ann. § 24-6A-1 *et seq.*
[608] *See* Fiscal Impact Report, Revised Uniform Anatomical Gift Act (Mar. 14, 2007), at 3, https://www.nmlegis.gov/Sessions/07%20Regular/firs/HB1276.pdf.
[609] UAGA at 14.
[610] *Id*.
[611] N.M. Stat. Ann. § 24-6B-2 (emphasis added).
[612] N.M. Stat. Ann. § 24-6B-3.

words, all anatomical gifts in the State of New Mexico must comply with this act, and the bodies or body parts of aborted infants cannot be anatomical gifts.

SWWO's provision and UNM's acquisition of and research using aborted infant remains appears to violate the Spradling Act, which prohibits making an anatomical gift of the remains of any "fetus that is the subject of an induced abortion."[613] Even to the extent SWWO does use the fetal tissue donation consent form it produced to obtain consent from mothers of aborted infants, it still would not validate the donation of their infants' remains for research, because under the Spradling Act the bodies or parts of aborted infants may not be anatomical gifts.

UNM claims to have a "comprehensive Code of Ethical Conduct and compliance programs" in the area of "research involving tissue obtained from fetuses."[614] Further, the university maintains that "[o]versight for all research at UNMHSC is provided in the form of Institutional Review Boards, which ensure that all *federal* regulations and laws are followed regarding research studies" and that UNMHSC has "accreditation by the American Association of Human Research Participation."[615]

However, UNM's submissions to the Panel do not address compliance with the Spradling Act. Their efforts to conduct fetal tissue research in compliance with ethical standards and federal laws *do not* make UNM and SWWO less culpable for violating New Mexico state law. All anatomical gifts made in New Mexico must comply with the Spradling Act. Based on the information obtained and reviewed by the Panel, SWWO's provision of tissue from aborted infants, and the reception and use of the tissue by UNMHSC, arguably violates the Spradling Act.

Section 289g-2 is also implicated by the relationship between the two entities because of the value exchanged between them. As the clinic that provided abortions, SWWO incurred no extra expense in connection with the fetal tissue it transmitted to UNM, so there were no expenses to be reimbursed to SWWO. Indeed, the clinic might have been saved the expense it otherwise would have borne of disposing of the tissue that UNM received. While UNM may not have paid SWWO a sum of money it explicitly classified as consideration for the fetal tissue it received, UNM did provide SWWO a substantial value in the form of personnel offered to the clinic. The UNM Fellowship provided SWWO with medical personnel that expanded the volume of abortions it could provide without SWWO having to compensate them. UNM additionally conferred upon at least three staff physicians at SWWO faculty positions that gave them professional liability insurance coverage for UNM activities and access to numerous university facilities, in addition to numerous discounts. These faculty members in turn provided UNM no apparent benefit apart from the fetal tissue that came from SWWO, giving their relationship the components of an exchange of fetal tissue for valuable consideration. At a minimum, the intent and spirit of Section 289g-2 have been violated, and further investigation is necessary to determine whether criminal prosecution of SWWO or UNM should follow.

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[613] N.M. Stat. Ann. § 24-6B-2.
[614] UNM Second Submission, at 2, Exhibit 6.19.
[615] *Id.* (emphasis added).

d) The December 2016 Referrals

On December 21, 2016, after evidence of the failure of SWWO and UNM to provide informed consent were supplemented by the direct allegations of [NM Patient], the Panel sent another criminal referral to the Attorney General of New Mexico. If true, her allegation that the only informed consent to tissue donation sought from her was the cursory reference to the use of "tissue and parts . . . in medical research" in SWWO's abortion consent form amounts to violations of federal and state law by UNM and SWWO.

HHS regulations, which govern much of the human subject research conducted at UNM, requires in 45 C.F.R. § 46.116 a number of basic elements of informed consent:

> (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
>
> (2) A description of any reasonably foreseeable risks or discomforts to the subject;
>
> (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
>
> (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
>
> (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
>
> (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
>
> (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
>
> (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is

otherwise entitled.[616]

According to [NM Patient]'s allegations, both SWWO and UNM failed to provide any of these elements of informed consent, in violation of 45 C.F.R. § 46.116, accompanied by a violation of 45 C.F.R. § 46.117 for failing to present such consent in writing.

To the extent the research of the fetal tissue acquired by UNM related to transplantation for therapeutic purposes, any violations by SWWO and UNM would include violation of 42 U.S.C. § 289g-1(b)(1), which requires written consent from the woman acknowledging the nature of the research, the lack of "restriction regarding the identity of individuals who may be the recipients of transplantation of the tissue," and that the woman was not informed of any such recipients' identities. Moreover, the use of a consent form that simultaneously seeks consent for abortion and for fetal tissue donation under the alleged circumstances would appear to violate § 289g-1(b)(2)(A)(i), which requires the abortion consent to be "obtained prior to requesting or obtaining consent for a donation of the tissue . . . ."

UNM's own oversight policy provided as of 2015 that "appropriate informed consent by the mother" is required for "[t]he collection and storage of all fetal tissue for research."[617] The policy as revised April 11, 2016, further clarifies that UNMHSC

> will not acquire such fetal tissue from outside entities (a) without contractual and/or written assurance that the fetal tissue being acquired was collected in accordance with a process that separates the informed consent for the abortion procedure from the informed consent to donate such fetal tissue to the UNM HSC for Research, and (b) where there is contractual assurance that the terms of the acquisition complies fully with Section 112(a) of the NIH Act (42 U.S.C. § 289g-2(a)). In addition, the contractual assurance contemplated in Subsection 2 must indicate that there are no legal, ethical, or other restrictions against transferring the Research Tissues to the UNM HSC, nor against the UNM HSC's use of them.[618]

UNM did not produce this revised policy to the Panel.

Despite SWWO's inclusion of a fetal tissue donation consent form in its production, [NM Patient]'s allegation that it was never shown to her, combined with [Clinic A Dr. #1]'s admission that she did not even recognize the form and had never obtained consent to donate, raises a

[616] 45 C.F.R. § 46.116(a). These elements are the minimum required, subject to exceptions for public benefit or service programs under § 46.116(c) and potentially additional requirements under § 46.116(b).
[617] UNMHSC, Oversight of Human Tissue in Research, Policy # RC.05.002.PP (Sept. 16, 2015) [UNM03420-UNM03428, at UNM03423], Exhibit 6.39.
[618] UNMHSC, Oversight of Human Tissue in Research, Policy # RC.05.002.PP 3 (Apr. 11, 2016), Exhibit 6.40. This revised policy additionally reinforces the Panel's June 23, 2016, referral regarding violation of the Spradling Act by requiring that fetal tissue for research be acquired "in accordance with the provisions of the" Spradling Act "and/or with contractual assurance that it was obtained in accordance with" that statute. *Id.* at 3-4.

serious question as to whether SWWO and UNM systematically violated the law, not to mention UNM's own internal policy, by conducting fetal tissue donations without more than the perfunctory reference to tissue research in SWWO's abortion consent form.

The same alleged deficiencies in the consent process at SWWO would constitute a violation of New Mexico's state law. Regardless of whether government funding or transplantation research is involved, N.M. Stat. Ann. § 24-9A-5, which is part of the Maternal, Fetal and Infant Experimentation Act, prohibits any "clinical research activity involving fetuses, live-born infants or pregnant women" unless the woman

> has been fully informed of the following:
>
> > (1) a fair explanation of the procedures to be followed and their purposes, including identification of any procedures which are experimental;
> > (2) a description of any attendant discomforts and risks reasonably to be expected;
> > (3) a description of any benefits reasonably to be expected;
> > (4) a disclosure of any appropriate alternative procedures that might be advantageous for the subject;
> > (5) an offer to answer any inquiries concerning the procedure; and
> > (6) an instruction that the person who gave the consent is free to withdraw his consent and to discontinue participation in the project or activity at any time without prejudice to the subject.[619]

[619] N.M. Stat. Ann. § 24-9A-5(C). As discussed above, the Spradling Act prohibits use of fetal tissue resulting from induced abortion, but this informed consent provision provides a basis for liability separate from the underlying use of such tissue. It additionally should be noted that the Maternal, Fetal and Infant Experimentation Act defines the term "clinical research" as follows:

> "clinical research" means any biomedical or behavioral research involving human subjects, including the unborn, conducted according to a formal procedure. The term is to be construed liberally to embrace research concerning all physiological processes in human beings and includes research involving human in vitro fertilization, but shall not include diagnostic testing, treatment, therapy or related procedures conducted by formal protocols deemed necessary for the care of the particular patient upon whom such activity is performed and shall not include human in vitro fertilization performed to treat infertility; provided that this procedure shall include provisions to ensure that each living fertilized ovum, zygote or embryo is implanted in a human female recipient, and no physician may stipulate that a woman must abort in the event the pregnancy should produce a child with a disability. Provided that emergency medical procedures necessary to preserve the life or health of the mother or the fetus shall not be considered to be clinical research . . . .

N.M. Stat. Ann. § 24-9A-1(D).

This statute is notably cited in the standard operating procedures of UNM's Office of the Institutional Review Board, but UNM failed to produce that document to the Panel.[620] Other sections of the Maternal, Fetal and Infant Experimentation Act make clear that neither a pregnant woman nor a fetus shall be involved as subjects in clinical research activity unless "the mother is legally competent and has given her informed consent,"[621] subject to penalties of imprisonment for less than one year and/or payment of a fine up to $1,000.[622]

C. The University of Washington and the Nation's Largest Fetal Tissue Bank

6. Summary

The Panel's investigation into the nation's largest fetal tissue bank at the University of Washington (UW) and outside abortion clinics provides another example of the interdependence of clinics and public research institutions. Over the last five years, over a dozen clinics have provided UW fetal tissue, and 40 universities or other public research institutions have been recipients of fetal tissue. UW claims that recipients of tissue are charged a flat fee of $200 regardless of the nature of the tissue researched and that the only payments it makes to clinics are to cover costs. The university failed to make a complete production, however. The Panel's independent research found that UW deploys doctors to outside abortion clinics and that numerous physicians on the staffs of those clinics hold faculty positions at UW. The invoices produced by UW are heavily redacted, rendering it impossible without more information to conduct a full forensic analysis under § 289g-2 of payments made to and by UW in connection with transfers of fetal tissue.

7. The University of Washington, in Conjunction with Numerous Clinics, Establishes the Nation's Largest Fetal Tissue Bank

UW offers an illustration of a university's relationship with numerous abortion clinics as sources of fetal tissue, with a substantial research operation funded by the federal government. The UW School of Medicine manages and operates the Birth Defects Research Laboratory (UW BDRL), which contains the largest fetal tissue bank in the nation. UW BDRL received over $600,000 from the NIH for FY 2015.[623] The Panel issued UW BDRL a subpoena dated April 29, 2016, to which UW responded with a partial production. The university claimed in response to six subpoena items it could not yet produce more "[d]ue to the breadth of the Subpoena," but that responsive documents would "be provided as soon as possible."[624]

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[620] *See* UNM Office of the Institutional Review Board, Standard Operating Procedures, effective Mar. 1, 2016, at 1-2, http://irb.unm.edu/sites/default/files/511.0%20Compliance%20with%20Applicable%20Laws%20and%20Regulations.pdf, Exhibit 6.41.

[621] N.M. Stat. Ann. §§ 24-9A-2(B), 24-9A-3(B).

[622] N.M. Stat. Ann. § 24-9A-6.

[623] NIH research portfolio, https://projectreporter.nih.gov/project_info_description.cfm?aid=8882485&icde=0, Exhibit 6.42.

[624] UW responses to subpoena, Exhibit 6.43.

The documents UW BDRL produced did not include any contracts with donors or recipients of fetal tissue, but it did provide a list of such donors and recipients. Over the previous five years, UW BDRL has procured fetal tissue resulting from abortion from a number of clinics and hospitals, including at various times the following (with an asterisk * noting fetal tissue sources identified by UW's IRB as current in 2016):

3. All Women's Health-North*
4. Cedar River Clinic-Renton*
5. Cedar River Clinic-Tacoma*
6. Cedar River Clinic-Yakima*
7. Evergreen Medical Center*
8. Planned Parenthood of Greater Washington and North Idaho (PPGWNI)*
9. Seattle Children's*
10. Seattle Medical and Wellness Clinic*
11. University of Washington Medical Center*
12. Allentown Women's Center
13. Group Health Cooperative
14. Harborview Medical Center
15. Swedish Medical Center—Edmonds[625]

UW BDRL also produced a list of 40 universities or other research institutions to which it has provided fetal tissue between 2010 and 2015:

1. Allen Institute for Brain Science
2. Cedars Sinai Medical Center
3. Children's Hospital of Philadelphia
4. Children's Mercy Hospital
5. Children's National Medical Center
6. Cold Spring Harbor Laboratory
7. Duke University
8. Fred Hutchinson Cancer Research Center
9. Harvard University
10. Indiana University
11. Johns Hopkins University
12. Lady Davis Institute
13. McGill University
14. Medical College of Georgia
15. New York State—Department of Health
16. NIH
17. Oregon State University
18. Pacific Northwest National Lab

[625] UW first production [000002-000008], Exhibit 6.44. Aurora Medical Services, sometimes listed as a source, was acquired by the Cedar River Clinics. Note that Pacific Northwest Facility and Seattle Reproductive Medicine are also sources of fetal tissue, but they only provide tissue from pregnancy losses, not elective abortions. *Id.* at [000008].

19. The Rockefeller University
20. Scripps Whittier Institute
21. Stanford University
22. Temple University
23. UCLA
24. UC Merced
25. UCSD
26. University College London
27. University of British Columbia
28. University of Kent—Canterbury
29. University of Michigan
30. University of Miami
31. University of Nebraska
32. University of North Texas
33. University of Pittsburgh
34. University of Puerto Rico
35. University of South Carolina
36. University of Washington
37. University of Wisconsin
38. US Environmental Protection Agency—Virginia
39. Washington University
40. Yale University[626]

8. The Sharing of Personnel Between UW and Outside Clinics That Supply Tissue

Through information available outside UW BDRL's production, the Panel has learned that, as in the case of UNM in Albuquerque, the university maintains a close relationship with area abortion clinics that includes the deployment of medical students to the clinics and faculty status for the clinics' staff physicians. Besides providing abortions directly through its family planning program, UW participates in the Kenneth J. Ryan Residency Training Program in Abortion and Family Planning, which provides residents to outside abortion clinics.[627] Several faculty members perform abortions not only at UW's Medical Center, but also at outside clinics, several of which perform abortions at least well into the second trimester and raise questions about the standard of care for infants who survive the abortion procedure.

It is also noteworthy that a set of talking points produced to the Panel by the Allentown Women's Center designed to encourage women to give their consent to donate their infants' tissue misrepresents the necessity for fetal tissue research, including the following claims:

- Research that requires fetal tissue includes: Alzheimer's, Multiple sclerosis, Prostate and lung cancers, Diabetes, Spinal cord regeneration, Arthritis,

[626] UW first production [000010-000015], Exhibit 6.45.
[627] *See* The Kenneth J. Ryan Residency Training Program in Abortion and Family Planning, Map and locations, http://www.ryanprogram.org/map-and-locations; Fellowship in Family Planning, Where are the Fellowships located?, http://www.familyplanningfellowship.org/fellowship-programs, Exhibit 6.46.

Parkinson's, Brain tumors, Neuropathy of HIV, Macular degeneration, Osteoarthritis, Sickle-cell anemia, Hepatitis and liver regeneration, Respiratory distress syndrome, and Blindness.

- You have already made a heart-wrenching decision. We know this is one more decision to make. Only fetal tissue and stem cells can further birth defects research. . . .

- Some tissue is already being used to help regenerate spinal cells so paralyzed people can walk someday.[628]

This grossly misrepresents the state of scientific research and available treatment. This report's discussion below of biomedical research includes a survey of how much clinical research utilizes fetal tissue.[629] Not only is fetal tissue unnecessary to study the conditions listed above; there are *no* current clinical trials being conducted using such tissue to research most of those conditions, with three exceptions—spinal cord injury, macular degeneration, and diabetes—in which cases less than 1% of the trials use fetal tissue.[630] Moreover, the same survey lists ten conditions arising during fetal life that affect infants and children, and there are currently no clinical trials for any of those conditions that use fetal tissue.[631] Further inquiry is necessary as to which personnel have made such claims in order to induce women to provide their consent and whether such misrepresentations are limited to one clinic or extend to UW and its other partners.

UW never produced documents sufficient to identify the doctors shared between the university and outside clinics.[632] Based upon other sources, the Panel learned of the following examples of the close ties between UW and area clinics that provide the university fetal tissue:

- The Cedar River Clinics: These clinics were co-founded by their executive director, [WA Clinic Director], in 1979 as the Feminist Women's Health Center. Its staff physicians include [WA Doctor #1], who had been medical director of Aurora Medical Services, a supplier of fetal tissue to UW, between 2000 and 2014. They are a major supplier of fetal tissue, with recipients that include

[628] Counseling suggestions for discussing tissue donation, Allentown Women's Center production, ALWC-001, Exhibit 6.47.
[629] *See* Chapter IX *infra*.
[630] *See* Chapter IX.C, table 1.
[631] *Id.* (diseases arising in the fetus and/or affecting children).
[632] That information should have been evident if a full production were made pursuant to UW BDRL's subpoena, including item 4: "Documents sufficient to reflect UW's organization chart, including information detailing UW personnel that procure(d) fetal tissue at the clinic level and the supervisory personnel for those procurers of fetal tissue." UW produced only one chart listing six positions under the principal investigator at UW BDRL. UW first production, 000017, Exhibit 6.48. The Panel followed up on September 14 with various inquiries, including requests for a list of doctors "who have performed abortions at outside clinics while affiliated with UW" and a list of "doctors at outside abortion clinics who have faculty positions at UW." UW's second production, however, did not include information sufficient to inform the Panel on these points.

StemExpress and ABR.[633] The clinics perform late-term abortions—advertising their services up to 26 weeks:[634]



Among several lawsuits the clinics have faced was at least one medical malpractice suit arising from an abortion performed at 25+ weeks by [WA Doctor #2] that was alleged to have caused a woman excessive bleeding, threatening her life, and necessitated an emergency hysterectomy.[635] Several UW faculty members provide abortions at the Cedar River Clinics on at least a part-time basis, including [WA Doctor #3], associate professor of Ob/Gyn at UW and director of UW's Family Planning Division and the Family Planning Fellowship; [WA Doctor #4], acting assistant professor in UW's Ob/Gyn department; and [WA Doctor #1], clinical assistant professor at UW's Family Medicine Residency. Former Cedar River staff physician [WA Doctor #5] worked at the clinic while simultaneously working as an assistant clinical professor, "volunteer staff," between 1999 and 2010. Former Cedar River staff physicians [WA Doctor #6], who is now on the staff of the Swedish Medical Center, and [WA Doctor #7], currently with Northwest Women's Healthcare, were also UW residents.

- All Women's Health-North: [WA Doctor #8], owner and operator of All Women's Health-North, which is incorporated as ABBR Enterprises, and a clinic in Chicago also named All Women's Health, is a clinical instructor both at UW's Family Medicine Residency and Northwestern University's Feinberg School of Medicine. All Women's Health-North conducts abortion training for UW residents.[636] Although he is not known to be on UW faculty, [WA Doctor #9], the former medical director for the Cedar River Clinics, now performs abortions at All Women's Health-North. According to the former staff member at Germantown Reproductive Health Services interviewed confidentially by the Panel, [WA Doctor #9] told her he would push the gestational limit of abortions he performs as far as he could go.

- PPGWNI: [WA Doctor #10], who was medical director of PPGWNI for eight years, was trained as a UW resident and is a clinical associate professor at UW's

[633] *See* Chapter V *supra*.
[634] Abortion Clinics Online, Late Abortion Clinic, https://abortionclinics.com/clinic-category/late-abortion-clinic/.
[635] Investigative Report Prepared for the Medical Quality Assurance Commission, Exhibit 6.49; Complaint, [WA Patient] v. [WA Doctor #2] at 2-3, No. [redacted] (Wash. Super. Ct. King Co., June 25, 2010); telephone conference between Panel staff and plaintiff's attorney, Dec. 7, 2016. The case was ultimately referred to an arbitration panel and settled.
[636] Abortion in Washington blog, http://abortionstate.blogspot.com/2009/10/north-seattle-late-term-killing-field.html.

Central Washington Family Medicine Residency Program. PPGWNI doctor [WA Doctor #11] is also a clinical faculty member at UW.

9. Fetal Tissue Research at UW BDRL

UW BDRL conducts a substantial amount of fetal tissue research. [WA Research Doctor #1], a professor of pediatrics and author of numerous papers involving fetal tissue research, holds several titles at UW, including director of medical genetics at Seattle Children's and co-director of the Alaska Genetics & Birth Defects Clinic—programs that "provide virtually all of the pediatric genetic services for the states of Washington and Alaska," according to UW's website.[637] [WA Research Doctor #1] has been the author of UW BDRL's NIH grant proposals since at least 2005.[638] [WA Research Doctor #1]'s research includes a paper on optimal abortion techniques. Among other UW personnel who have authored or otherwise assisted fetal tissue studies[639] are [WA Doctor #3]; [WA Doctor #4]; [WA Research Doctor #2] of the pediatrics department's hindbrain malformation research program; [WA Research Doctor #3], a UW resident; and [WA Research Staff], technical operations manager at the medical school's WWAMI Institution for Simulation in Healthcare.

10. UW's Productions Were Insufficient for the Panel to Conduct a Full Analysis of UW's Fetal Tissue Transactions

UW BDRL claimed in its initial response to the subpoena that it "does not sell fetal tissue."[640] It added, however, that it "makes tissue available for research use by academic and non-profit research facilities. The recipient is invoiced a flat fee of $200. This fee is intended to cover UW's costs associated with the technical effort and related expenses in preparing the tissues that are not covered by the NIH grant."[641] Thus, UW BDRL did not represent that no money changes hands when tissue is received or donated, and it made no representation as to whether it purchased fetal tissue. The cover letter accompanying the partial production did admit that "the clinics or hospitals are reimbursed for costs associated with obtaining the fetal tissue for research."[642] Analysis under § 289g-2 requires clarification of the precise amounts that were expended as well as which costs were claimed for reimbursement since only certain costs may lawfully be reimbursed.

UW BDRL's initial production did not provide accounting records, invoices, other financial records, or communications that would have permitted the Panel to analyze and make

[637] Excerpt from UW Division of Genetic Medicine, https://depts.washington.edu/genediv/directory/[WA Research Doctor #1], Exhibit 6.50.
[638] Grantome entries under [WA Research Doctor #1], http://grantome.com/search?q=@author%20%20[/[WA Research Doctor #1]], Exhibit 6.51.
[639] *See, e.g.*, [redacted] et al., "Effects of Digoxin and Delayed Dilation and Evacuation on Fetal Tissue Quality: Maximizing Opportunities for Research Participation," 92 Contraception 367 (2015).
[640] UW responses to subpoena item 2, Exhibit 6.43.
[641] UW responses to subpoena item 19, Exhibit 6.43.
[642] Letter from UW School of Medicine to Panel (May 10, 2016), at 1, Exhibit 6.52.

an independent assessment of the money that changed hands when fetal tissue was transferred.[643] This would be necessary to conduct a forensic analysis of UW's practices under § 289g-2, as would an examination of other value exchanged among various entities. The Washington attorney general, who is also responsible for representing the university, found without apparently conducting such analysis that PPGWNI had not received direct payment for fetal tissue from UW.[644] That office's inquiry apparently ended without an examination of an agreement between UW and one of the nine clinics that comprise PPGWNI. In emails exchanged between the AG's office and UW, UW representative [WA Administrator] told ADA Paige Dietrich he could send a business associate agreement and IRB authorization agreement between the entities, but after he asked whether they would remain confidential, Dietrich replied, "I don't think we'll need copies of the agreements."[645]

Months passed without UW BDRL following up on the production it represented in May would be made as soon as possible. In an effort to obtain expeditiously the information most critical to its investigation, on September 14, 2016, following several communications with UW's attorneys in the state attorney general's office, Panel staff distilled its pending subpoena categories to 14 specific inquiries to UW. In response, UW claimed that due to a temporary restraining order (TRO) issued August 3, 2016, by the United States District Court for the Western District of Washington blocking UW's release of records pursuant to a lawsuit filed under the Public Records Act, it was "unable to provide" records or other information responsive to 13 of the Panel's 14 inquiries.[646] While the TRO was broad enough to bind state and private parties, well established case law makes clear that any construction of the TRO that would prohibit compliance with a validly conducted congressional investigation would violate the Constitution. Chairman Blackburn accordingly sent a letter to the court citing such authority and requesting that the court make clear its TRO may not be construed to preclude UW's compliance with the Panel's subpoena.[647] The court issued a preliminary injunction dated November 13, 2016, that did not address Congress specifically, but narrowed the language of the TRO to permit disclosure while requiring redaction of personal identifying information.[648] While applicable law would not bind a party to make redactions in response to a congressional committee, the Panel, as a matter of accommodation, permitted UW to make such redactions, provided that the production would be accompanied by a redaction log disclosing any missing names. The log would be kept in a locked safe within the Panel's offices and accessed only if necessary to the investigation.

UW made its second production to the Panel on December 1, 2016. The vast majority of documents produced were various invoices, and they included extensive redactions without an accompanying redaction log. In addition to names, UW redacted identities of departments at the

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[643] *See* UW responses to subpoena items 5 ("communications . . . that direct or relate to a direction to UW personnel to procure fetal tissue"), 6 ("accounting records"), and 8 & 10 ("invoices" relating to fetal tissue), Exhibit 6.43.
[644] Memorandum from Deputy Attorney General and Senior Assistant Attorney General to Attorney General of Washington (Nov. 12, 2015), at 2, Exhibit 6.53.
[645] Emails (Sept. 17, 2015), Exhibit 6.54.
[646] UW second set of responses, Exhibit 6.55.
[647] Letter from Chairman Blackburn to Hon. James L. Robart, U.S. District Court for the Western District of Washington, Nov. 8, 2016, Exhibit 6.56.
[648] *Jane Does 1-10 v. University of Washington*, Case No. C16-1212JLR, Order Granting Motion for a Preliminary Injunction and Denying Motion to File a Supplemental Hearing, (W.D. Wash. Nov. 13, 2016), at 25.

university involved in various transactions, shipment dates, and even (in many but not all cases) descriptions of the tissue involved. To the extent discernible, the invoices reflect that UW charged $200 "per unit," $100 where the number of units involved was 0.5, and $300 where the number was 1.5, but it is unclear by what methodology these fractional units would be defined if in fact UW sets a flat fee schedule.[649] UW failed to produce communications involving UW personnel regarding fetal tissue and did not answer the Panel's questions regarding doctors who simultaneously work for the university and outside abortion clinics.

UW additionally produced 25 invoices for "clinic services" listing individual charges ranging from to $521 to $2,500. The invoices either do not specify what clinic services are involved or, when they apparently elaborate on the nature of such services, those elaborations are redacted—rendering it impossible for the Panel to conduct a forensic analysis of UW's financial arrangements with clinics.[650] UW's incomplete production raises more questions than it answers and demonstrates the need for further investigation.

D. Planned Parenthood Gulf Coast: A University Case Study

7. Summary

The Panel conducted an investigation of Planned Parenthood Gulf Coast (PPGC), a Planned Parenthood Federation of America (PPFA) affiliate that had its own research department. The Panel uncovered evidence that PPGC's research department may have violated 42 U.S.C. § 289g-2, Texas Penal Code § 48.02, and Tex. Penal Code Title 8 § 37.08.

c) Background on Planned Parenthood Gulf Coast

PPGC has a research department[651] that conducted studies for pharmaceutical companies,[652] the medical device industry,[653] and academic institutions, mostly in Texas.[654] PPGC bought its headquarters in 2010 largely because it met the needs of the research department.[655]

PPGC conducts in-house fetal tissue extraction, processing, storage, and shipping.[656] PPGC also ships tissue, but it requires the study sponsors to set up a FedEx account. PPGC prints the air bill, puts the air bill on the container, places the shipment on dry ice, and either has FedEx

[649] *See*, *e.g.*, Invoices for tissue collection and distribution, UW second production [000388, 000397, 000399, 000400, 000402, 000418, 000420, 000424, 000425, 000431, 000432, 000442, 000449, 000450, 000455, 000485, 000503, 000508, 000519, 000526, 000567, 000569, 000571, 000582, 000583, 000591, 000623, 000627, 000641, 000646, 000653, 000666, 000667, 000669, 000677, 000680, 000699, 000700, 000860], Exhibit 6.57.
[650] *See* Invoices for clinic services, UW second production [000941-000965], Exhibit 6.58.
[651] Center for Medical Progress, Transcript, Meeting with [PP Witness #2], [PPGC Abortion Services Official], [PPGC Staff], & Medical Assistant 4 (Apr. 9, 2015) [hereinafter CMP Meeting with PPGC personnel Tr.].
[652] *Id.* at 5.
[653] *Id.* at 6.
[654] *Id.* at 35.
[655] *Id.* at 96.
[656] *Id.* at 9, 14, 19-20, 29; 31, 40.

pick up the shipments or a PPGC staffer will drop it off.[657] PPGC bills customers for any sterile supplies needed for tissue procurement.[658]

From 2010 through 2012, PPGC procured placenta, blood, and fetal membranes for the University of Texas Medical Branch, Galveston (UTMB).[659] PPGC also unsuccessfully negotiated a contract to procure fetal tissue for the Baylor College of Medicine (BCM). PPGC ended its negotiations with BCM after the CMP videotapes were released. [PP Witness #2] told [BCM Staff] that the PPFA affiliate would not commit to contractual relations for the procurement of fetal tissue with any Texas academic institutions, unless those institutions spoke out about their need for fetal tissue.

The Panel has uncovered evidence that, despite those costs, PPGC may have made a profit from its procurement of fetal tissue. On a CMP videotape, [PP Witness #2] stated "this research department generates more revenue than the entire OB GYN research program at Baylor [College of] Medicine. . . . multiple, multiple times more revenue."[660]

d) History of Panel's Interactions with PPGC and Related Entities

During the course of its investigation, the Panel learned that PPGC procured fetal tissue for UTMB and BCM. On January 21, 2016, the Panel sent a document request letter to UTMB that asked for the production of a list of all entities from which it received or to which it donated fetal tissue, all communications related to the procurement of fetal tissue, all accounting records, and other materials.[661] During telephone conferences with UTMB officials, Panel staff agreed to narrow the scope of the request to include only communications, invoices and purchase orders.[662] UTMB produced the agreed upon documents on February 17, 2016.[663]

The Panel sent a document request letter to BCM that asked for the production of a list of all entities from which it received or to which it donated fetal tissue, all communications related to the procurement of fetal tissue, all accounting records, and other materials.[664] On February 9, 2016, BCM produced documents related to fetal tissue procurement from PPGC, letters it exchanged with the Texas Attorney General related to fetal tissue procurement, and documents

[657] *Id.* at 19-20.
[658] *Id.* at 90.
[659] Documents produced by the University of Texas Medical Branch to the Panel [UTMB 239], Exhibit 6.59.
[660] CMP Meeting with PPGC personnel Tr. at 90.
[661] Letter from Rep. Marsha Blackburn, Chairman, Select Investigative Panel on Infant Lives to President, University of Texas Medical Branch (Jan. 21, 2016).
[662] Telephone conference between Senior Public Affairs Officer, Department of Legal Affairs, University of Texas Medical Branch, and Panel staff (Feb. 2, 2016); Telephone conference between Senior Public Affairs Officer, Department of Legal Affairs, University of Texas Medical Branch, and Panel staff (Feb. 10, 2016).
[663] *See* Email from University of Texas Medical Branch official to Panel staff (Feb. 17, 2016).
[664] Letter from Rep. Marsha Blackburn, Chairman, Select Investigative Panel on Infant Lives to Dean, Baylor College of Medicine (Jan. 21, 2016).

specifically requested by the Panel staff.[665] BCM produced to the Panel the remaining responsive documents on February 24, 2016.[666]

8. PPFA Policy on Reimbursement for Fetal Tissue Donation Programs

c) April 2001 PPFA memorandum

On April 4, 2001, several PPFA officials sent a memorandum to affiliate chief executives, affiliate medical directors, and patient service directors, on federal regulations for participation in fetal tissue donation programs.[667] The memorandum notes that applicable federal laws "forbid the payment or receipt of valuable consideration for fetal tissue. However, they permit 'reasonable payments associated with the transportation, implantation, processing, perseveration, quality control, or storage' of fetal tissue."[668]

The memorandum states that PPFA affiliates "can choose one of two methods to comply with these laws," as follows:

> One method would be to recover no costs associated with any aspect of participation in a fetal tissue donation program. This would mean that all staff time, clinic space, supplies, etc., would be donated by the affiliate, and the affiliate would receive no payments or in-kind services from the entity to whom the tissue is being donated.
>
> . . . The second method would be to employ an independent auditor to conduct a credible and good-faith analysis of the actual costs incurred by the affiliate in the transportation, implantation, processing, preservation, quality control, or storage of the fetal tissue and, if the research is supported by federal funds, for the removal of the fetal tissue. Under this method, affiliates must maintain careful records of actual tissue donations and of payments received from the researcher or the tissue-gathering entity. Affiliates must be able to demonstrate that the payments do not exceed the actual costs of the actual tissue donations.
>
> Sometimes tissue-gathering entities offer to pay rent for space occupied by one of their employees who would be on-site at a clinic on a regular basis. If an affiliate determines to enter into such an arrangement, then the independent auditor would also conduct a

[665] *See* Letter from Senior Vice-President and General Counsel, University of Texas Medical Branch, to Rep. Marsha Blackburn, Chairman, Select Investigative Panel on Infant Lives (Feb. 9, 2016).
[666] *See* Letter from Senior Vice President and General Counsel, University of Texas Medical Branch, to Rep. Marsha Blackburn, Chairman, Select Investigative Panel on Infant Lives (Feb. 21, 2016).
[667] Memorandum from [PPFA Lawyer], [PPFA Medical Officer #1], & [PPFA Medical Officer #2] to Affiliate Chief Executives, Affiliate Medical Directors, & Patient Service Directors (Apr. 4, 2001) [PPFA-HOU_E&C-000149-000150], Exhibit 6.60.
[668] *Id.*

> credible and good-faith computation of the actual cost of the space occupied by the tissue-gathering entity employee, in order to determine the amount of rent to be paid by that entity.[669]

The memorandum goes on to "remind affiliates that, in addition to the federal laws outlined above, there are laws in many states governing fetal tissue donation programs. Affiliates must take great care to assure compliance with those laws as well."[670]

[PP Witness #2] testified that she had seen the original. Despite that knowledge, the Panel has learned that the costs included in PPGC's contract and proposed contract with UTMB were based not on an independent auditor's credible and good-faith analysis of the actual costs it incurred to procure fetal tissue for UTMB. [PP Witness #2] testified that the costs "were basically back of the envelope type calculations" that she derived.[671] Rather it was based on back-of-the-envelope calculations by a single PPGC official. The fact that PPGC ignored the long-standing advice of PPFA's legal director when it drafted the UTMB contract and proposed amendment goes directly to PPGC's knowledge of the duty to comply with the applicable law and its willful decision to ignore the legal advice of its organization.

d) January 2011 redistribution of PPFA memo

The April 2001 memorandum was redistributed to PPFA affiliates in January 2011 under the signature of [PP Witness #1].[672] The memorandum sought

> . . . to remind affiliates about the federal law relating to payment for participation in such programs. The attached memo was sent almost exactly 10 years ago (yikes!). Given the time that has elapsed and that there has likely been staff turnover, we thought it would be helpful to resend it to assure continuing compliance with the statutes.[673]

Thus, PPFA affiliates, including PPGC, were twice put on notice about the steps they would have to undertake in order to participate in a fetal tissue donation program, and to ensure that any reimbursable costs they received did not constitute valuable consideration under the applicable federal and state laws.

9. PPGC Relationship with University of Texas Medical Branch

According to its production, from 2010 through 2012, PPGC procured "non-fetal tissues" from UTMB, which it admitted "included maternal tissues such as blood, placenta, and fetal

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669 *Id.*
670 *Id.*
671 Transcribed Interview of [PP Witness #2] at 26 (Oct. 19, 2016).
672 Memorandum from [PP Witness #1] to Affiliate CEOs, Medical Directors, & Patient Services Directors (Jan. 26. 2011) [PPFA-HOU_E&C-000148], Exhibit 6.61.
673 *Id.*

membranes (i.e., amniotic sac)." PPGC continued, "No fetal tissues were acquired by UTMB from [PPGC] as part of these transactions."[674] During her transcribed interview, however, [PP Witness #2] testified that the UTMB study involved fetal tissue:

> The last research study that required the collection of first trimester fetal tissue was with the University of Texas Medical Branch. PPGC supplied pregnancy tissue for that study, which focused on a molecule called dystroglycan on placentas in an effort to prevent miscarriages. That research study ended in 2011.[675]

[PP Witness #2] testified that placenta is fetal tissue:

> [Q]: The placenta is a fetal or maternal organ; which is it?
>
> . . . A: It's a fetal organ, if I remember my training in nursing school correctly.[676]

PPGC personnel generally obtained consent from patients to donate fetal tissue. Emails produced by UTMB indicate that its personnel also obtained consent from patients and procured the fetal tissue.

a) PPGC Procures Fetal Tissue for UTMB

In September 2010, [UTMB Researcher # 1] sent an email to [PPGC Executive] that stated:

> So sorry for interrupting your Saturday. I generally am not one to go outside the chain of command, but I'm getting nowhere with this study that has been IRB approved since April. . . . It is essentially the same as the protocol we have been using for collection of chorionic villi, except that it calls for collection of one tube of blood at the time of IV start and also decidua at the time of CV collection. We provide all supplies, and my technician can do all the record-keeping,
>
> My previous study has been going well, and I don't think it has disrupted the flow of [the] clinic significantly. I have not received any invoice for the consents of 20 subjects, but the fee is negotiable.

[674] Documents produced by the University of Texas Medical Branch to the Panel [UTMB 239], Exhibit 6.59.
[675] Transcribed interview of [PP Witness #2] at 11 (Oct. 19, 2016).
[676] *Id.* at 83.

> We are hoping to establish and maintain a long-term relationship for collection of first and second trimester tissue for our studies . . . .[677]

[PP Witness #2] replied to [PPGC Executive]:

> If it's all the same to you, I'd prefer that you bounce the topic back to me knowing the following issues:
>
> 1. The study is not essentially the same. It now involves acquiring maternal blood, and the original contract is only for fetal tissue.
> 2. The original budget for the original study compensates PPGC only for the staff time obtaining informed consent. However the prep for sample collection entails sterile POC [Products Of Conception], and is more involved than prior tissue studies. SS actually brought this issue up with me. [PPGC Abortion Services Official] and I have had sporadic discussions about this, but haven't had time to formally discuss an appropriate budget. We are planning to meet this afternoon so I can bring a more realistic budget to [UTMB Reseacher # 1].
> 3. This study will require a separate contract and budget from the original study.[678]

UTMB did not produce to the Panel the original study or any related documents.

On October 1, 2010, [UTMB Researcher #1] wrote to [PP Witness #2] that "I deserve to know where we stand and what our potential timelines are."[679] [PP Witness #2] replied:

> We'll need to draw up a new contract, as the prior one was only for fetal tissue. We will only be able to enroll clients who get IV sedation into the study with the blood draw, otherwise it is not standard of care and the current ICF doesn't address the risk of a study-related blood draw.
>
> We need to renegotiate the budget for both studies based on feedback from SS. I met with SS mgmt last week and here is their proposal:
>
> $50 enrollment/consent process (consent per PPGC SOP, physician statements)

[677] Email from [UTMB Researcher # 1] to [PPGC Executive], [UTMB 320-UTMB 325 at UTMB 324-UTMB 325], Exhibit 6.62.
[678] *Id.* at [UTMB 323].
[679] *Id.* at [UTMB 322].

> $100 room set up/collection (strip machines, sterile equipment, rinse hosing with sterile water, biologic sample collection)
>
> $50 enrollment/consenting fee if tech leaves without tissue (staff performed the work and tech didn't/couldn't stay to collect sample).
>
> $2000 annual admin fee (new or retraining staff, SS and Research Mgmt oversight, consent storage, supply storage).
>
> It would also be preferable if we amended the contracts to provision $Xamount/yr for a spend-down grant. PPGC is paid in advance for a set number of samples/yr, and then you collect at will . . . .
>
> Fee TBD – I was informed that you need help getting some of your supplies. I can check with our purchasing manager to see if we can do this, but I will need a list of supplies. The more detailed, the better such as manufacturer, product number, etc.
>
> Going forward I'll need to add these terms to the contract for the tissue-only study, and have both parties resign. I'll need to create a new contract for the blood&tissue study – we can copy and edit the original one to expedite the process. PPFA approval of the blood/tissue study will be expedited once we get this in order.[680]

[UTMB Researcher #1] replied, "That's fine . . . . [UTMB Researcher #2] will be the one to sign off and pay for his study that I'm collaborator on, and I will sign the new contract for my study. Can we split the $2000 admin fee between us? Or will it be faster just to list 'UTMB' and do the accounting on our end?"[681] On November 15, 2010, [PP Witness #2] sent an email to [UTMB Researcher #1] that stated, "I am waiting for CEO signature on the amended contract. I'll email you a copy once he's signed it."[682]

Invoices produced to the Panel by UTMB show that PPGC billed UTMB a total of $21,424.98 in annual administrative fees, consent payments, staff training, and supplies.[683] The Panel cannot determine whether those payments were made pursuant to first or the second contract.

On September 2, 2011, [PP Witness #2] sent an email to [UTMB Staff], the administrative assistant to [UTMB Researcher #2], who took over as the researcher on the

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[680] *Id.* at [UTMB 321-22].
[681] *Id.* at [UTMB 321].
[682] Email from [PP Witness #2] [UTMB Researcher # 1] (Nov. 17, 2010) [UTMB 326], Exhibit 6.63.
[683] Invoice from Planned Parenthood Gulf Coast to University of Texas Medical Branch (Nov. 11, 2010,) [UTMB 328]; Invoice from Planned Parenthood Gulf Coast to University of Texas Medical Branch (Nov. 11, 2010) [UTMB 329]; Invoice from Planned Parenthood Gulf Coast to University of Texas Medical Branch (June 11, 2011) [UTMB 344]; Invoice from Planned Parenthood Gulf Coast to University of Texas Medical Branch (Sept. 29, 2011) [UTMB 252], Exhibit 6.64.

UTMB-PPGC project.[684] In her email, [PP Witness #2] stated, "Attached is the draft revised contract. Please review and return edits to me with tracked changes."[685] A version of the proposed contract, which was signed by [UTMB Researcher #2] but not by PPGC,[686] stated that PPGC "will consent up to 500 patients."[687] UTMB would have paid $150 per consent ($50 for "[s]taff time expense involving informed consent and relevant study documentation," plus $100 for "[s]terile procedure room set-up, sample preparation (strip machines, sterile equipment, rinse hosing with sterile water), biological specimen collections (ie blood, urine; non-fetal tissue) performed by staff").[688]

The draft contract stipulated:

> Per calendar year . . . Planned Parenthood is expected to obtain at least 25 executed informed consents at One Hundred Fifty Dollars ($150.00) each for a total of Seven Thousand Five Hundred Dollars ($3,750.00) [sic]. If within the course of the year the need arises for additional subject enrollment beyond 25, this number can be increased with mutual agreement by both parties, and an amendment to this agreement.
>
> [UTMB Researcher #2] will reimburse Planned Parenthood for actual number of fully executed informed consents, regardless of if a sample is obtained, at the rates above with the following payment schedule.
>
> > I. Annually in October, [UTMB Researcher #2] will pay Planned Parenthood 100% of the expected 25 executed informed consents.
>
> ii. Should the number of consents exceed 25, Planned Parenthood will invoice [UTMB Researcher #2] for these additional costs on a monthly basis. [UTMB Researcher #2] will pay Invoices within 30 days of receipt.
>
> iii. Failure to pay invoices will result in immediate halt to study enrollment.[689]

In addition to the fee for each executed informed consent, UTMB would have paid PPGC an annual administrative fee of $2,000, and $1,500 "for expenses related to staff time utilized in CITI Training as required by the UTMB Institutional Review Board. This reimbursement will be

[684] Transcribed interview of [PP Witness #2] at 63 (Oct. 19, 2016).
[685] Email from [PP Witness #2] to [UTMB Staff # 1] (Sept. 7, 2011) [UTMB 314], Exhibit 6.65.
[686] Tissue Supply and Biological Specimen Agreement, Amendment No. 2, between Planned Parenthood Gulf Coast, Inc. and [UTMB Researcher #2] of UTMB (July 26, 2011) [UTMB 299–UTMB 301], Exhibit 6.66.
[687] *Id.* at [UTMB 299].
[688] *Id.* at [UTMB 300].
[689] *Id.*

paid by [UTMB Researcher #2] upon receipt of certificates of training by Planned Parenthood Staff."[690]

The contract would have required [UTMB Researcher #2] to "provide all supplies necessary to conduct this study at Planned Parenthood. Supplies may be purchased by Planned Parenthood with the approval of the Director of Research and reimbursed by [UTMB Researcher #2] on a pass-through basis by [UTMB Researcher #2]."[691] The Panel notes that, had the July 2011 contract been executed as drafted, PPGC would have received $75,000 solely for the consent of patients.

10. PPGC's Relationship with Baylor College of Medicine

From November 1, 2013, through November 4, 2015, PPGC entered into negotiations to procure fetal tissue for BCM. On November 1, 2013, [PPGC Abortion Doctor] of PPGC sent an email to [BCM Researcher], a copy of which was sent to [PPGC Executive] and [PP Witness #2]. [PPGC Abortion Doctor] "putting" [BCM Researcher] "in touch with [PP Executive] "who oversees all research, as well as" [PP Witness #2] "who will be your primary contact person during the IRB approval/coordination phase."[692]

BCM personnel coordinated closely with the clinic, looking to [PP Witness #2] for direction. On March 24, 2014, [BCM Researcher] sent an email to [PP Witness #2]:

> Thank you for speaking with me today, and for your help with the IRB. Attached, please find my original submission. the consent form draft, and the response from the IRB. . . . Please feel free to contact me any time with any questions you may have[.][693]

On repeated occasions, including email correspondence on May 20 and June 3, 2014, [BCM Researcher] asked [PP Witness #2] for additional assistance by commenting on questions raised by BCM's IRB.[694]

Other emails evidence the close communication [BCM Researcher]'s staff had with [PP Witness #2]. In an October 20, 2014, email, [BCM Staff] thanked [PP Witness #2] "for the productive phone call." She continued, "I spoke with [BCM Researcher] after our phone call ended and she was really excited to know we had made so much progress. I have outlined some of her comments/feedback below . . . ."[695]

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[690] *Id.*
[691] *Id.* at [UTMB 301].
[692] Email from [PPGC Abortion Doctor] to [BCM Researcher] (Nov. 1, 2013), Exhibit 6.67.
[693] Email from [BCM Researcher] to [PP Witness #2] (Mar. 24, 2014), Exhibit 6.68.
[694] Email from [BCM Researcher] to [PP Witness #2] (May 20, 2014), Exhibit 6.69; Email from [BCM Researcher] to [PP Witness #2] (May 20, 2014), Exhibit 6.70.
[695] Email from [BCM Staff] to [PP Witness #2] (Oct. 20, 2014), Exhibit 6.71.

BCM produced to the Panel copies of a draft contract with PPGC for the procurement of fetal tissue that were never executed to the Panel.[696] The contract terms were similar to those proposed to UTMB: Under the proposed contract, BCM would have been required to pay PPGC $150 per executed informed consent, which included $50 for "staff time expense involved in obtaining consent and relevant study documentation" and $100 per-informed consent for sterile procedure room set-up and sample collection.[697] Under the contract, PPGC "will consent up to 500 patients."[698] The contract also called for BCM to reimburse PPGC annual administrative fees of $2,000 for "Surgical Services and Research Management oversight, consent storage, and supply storage. This list is not all inclusive."[699]

On November 17, 2014, [BCM Staff] sent [PP Witness #2] an email, the subject of which was "Pediatrics Research Proposal – BCM Researcher/Baylor College of Medicine – IRB Approval Obtained," that stated: "I would like to thank you for your support through our IRB review process. . . . Our IRB proposal for your outlining the study procedures/objectives is also attached for your reference."[700] [PP Witness #2] replied, "Thank you!"[701] Multiple email exchanges between [PP Witness #2] and BCM employees show that PPGC knew the BCM IRB had approved the proposal. For example: On June 22, 2015, [BCM Contract Manager] sent an email to [PP Witness #2] "to follow up on the status of the review for the MTA [Material Transfer Agreement] for [BCM Researcher] of Baylor College of Medicine."[702] On July 7, [PP Witness #2] replied suggesting modifications to the MTA, adding that "a contract specialist from BCM should edit it."[703]

On July 14, 2015, CMP began its release of videotapes obtained during the course of its 30-month long investigation into the sale of fetal tissue by PPFA affiliates to tissue procurement companies.[704] The release of the videos prompted several congressional investigations, and led to the Panel's creation by the U.S. House of Representatives. The timing behind the start of CMP's release of its videotapes is relevant in light of how PPGC ended its negotiations with BCM.

On October 13, 2015, [BCM Researcher #2] sent [PP Witness #2] an email in which she stated:

> . . . I hope you are well and had a great weekend.
>
> In light of recent events, do we need to make a change to our contract?

[696] Tissue Supply and Biological Specimen Agreement between PPGC and BCM, Exhibit 6.72.
[697] *Id.* at ¶ 2(b)(i).
[698] *Id.* at ¶ 2(b)(i).
[699] *Id.* at ¶ 2(b)(iii).
[700] Email from [BCM Staff] to [PP Witness #2] (Nov. 17, 2014, 10:31 AM), Exhibit 6.73.
[701] Email from [PP Witness #2] to [BCM Staff] (Nov. 17, 2014, 12:01 PM), Exhibit 6.73.
[702] Email from [BCM Contract Manager] to [PP Witness #2] (June 22, 2015), Exhibit 6.74.
[703] Email from [PP Witness #2] to [BCM Contract Manager] (July 7, 2015), Exhibit 6.74.
[704] *See* Center for Medical Progress website, http://www.centerformedicalprogress.org/human-capital/.

> I still very much believe in the value of my NIH funded studies, and would very much like to proceed if that is possible.[705]

[PP Witness #2] responded in a November 4, 2015, email in which [PP Witness #2] stated that PPGC "will not commit to engage in any fetal tissue research endeavors at this time." [PP Witness #2] continued, "Academic institutions in Texas cannot remain publicly silent regarding their need for donated fetal tissue in research, yet have expectations that research collaboration with Planned Parenthood will remain intact."[706]

11. Potential Violations of Law

b) Applicable Laws

i) 42 U.S.C. § 289g-2

The applicable federal law on fetal tissue is § 289g-2, which is discussed above.[707]

ii) Texas Penal Code § 48.02

The Texas Penal Code makes it a misdemeanor if anyone "knowingly or intentionally offers to buy, offers to sell, acquires, receives, sells, or otherwise transfers any human organ for valuable consideration."[708] Under the statute, "valuable consideration" does not include "a fee paid to a physician or to other medical personnel for services rendered in the usual course of medical practice or a fee paid for hospital or other clinical services," "reimbursement of legal or medical expenses incurred for the benefit of the ultimate receiver of the organ;" or "reimbursement of expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ."[709]

The statute defines a human organ as "the human kidney, liver, heart, lung, pancreas, eye, bone, skin, fetal tissue, or any other human organ or tissue, but does not include hair or blood, blood components (including plasma), blood derivatives, or blood reagents."[710]

iii) Texas Penal Code § 37.08

Another provision of the Texas Penal Code makes it a misdemeanor for a person to lie to a law enforcement officer. The law states:

> A person commits an offense if, with intent to deceive, he knowingly makes a false statement that is material to a criminal investigation and makes the statement to: . . . a peace officer or

[705] Email from [BCM Researcher] to [PP Witness #2] (Oct. 13, 2015), Exhibit 6.75.
[706] Email from [PP Witness #2] to [BCM Staff] (Nov. 4, 2015), Exhibit 6.76.
[707] *See* Chapters I.C, II.B.3 *supra*.
[708] Tex. Penal Code § 48.02(b).
[709] Tex. Penal Code § 48.02(c).
[710] Tex. Penal Code § 48.02(a).

> federal special investigator conducting the investigation; or . . . any employee of a law enforcement agency that is authorized by the agency to conduct the investigation and that the actor knows is conducting the investigation.[711]

12. Findings

c) 42 U.S.C. § 289g-2 and Texas Penal Code § 48.02

The Panel's investigation raises questions of whether PPGC may have violated § 289g-2 and Texas Penal Code § 48.02. PPGC was paid for consent from patients. Consent is not a cost for which an entity can be reimbursed under § 289g-2. It is valuable consideration.

Documents produced to the Panel by UTMB show that PPGC also transferred fetal tissue to UTMB in exchange for valuable consideration as defined by the Texas Penal Code. Documents produced to the Panel by BCM show that PPGC knowingly offered to sell or transfer fetal tissue to BCM.

d) Texas Penal Code § 37.08

On October 22, 2015, nearly a year after PPGC learned that BCM's IRB had given its approval[712] and [PP Witness #2] sent her email to [BCM Researcher] in which she stated that PPGC would not commit to engage in any fetal tissue research endeavors at this time,[713] representatives of the Texas Department of Public Safety Texas Ranger Division, the House Police Department homicide division, and the Harris County district attorney's office visited PPGC headquarters to investigate allegations that PPGC may have violated Tex. Penal Code § 48.02.[714] (The report refers to PPGC as GCPP.)

During the course of this visit, PPGC's attorney introduced the law enforcement representatives to [PP Witness #2], who the attorney described as being a "Long time Baylor employee" who "had been instrumental in building the current research program."[715] The Texas Department of Public Safety Texas Ranger Division report stated that:

> [PPGC's attorney] advised that the last collected fetal tissue specimen collected by GCPP for a scientific study was on 07-26-2011, for the University of Texas Medical Branch. GCPP was recently approached by the Baylor College of Medicine and Rice

[711] Tex. Penal Code Title 8, § 37.08.
[712] Email correspondence between [BCM Staff] & [PP Witness #2] (Nov. 17, 2014), Exhibit 6.73; Email correspondence between [BCM Contract Manager] & [PP Witness #2] (June 22 & July 7, 2015), Exhibit 6.74; Email from [BCM Researcher] to [PP Witness #2] (Oct. 13, 2015), Exhibit 6.75; Email from [PP Witness #2] to [BCM Staff] (Nov. 4, 2015), Exhibit 6.76.
[713] Email from [PP Witness #2] to [BCM Staff] (Nov. 4, 2015), Exhibit 6.76.
[714] Tex. Dept. of Pub. Safety Tex. Ranger Div., Report of Investigation Exhibit 6.77.
[715] *Id.*

> University for fetal tissue studies. The Institutional Review Board had not yet given approval for the Baylor or Rice studies.[716]

[PP Witness #2] and potentially other PPGC officials knew that BCM's IRB had approved the research project, despite representations of PPGC's attorney to Texas law enforcement officials that no IRB approval had been obtained by BCM.

C. The University of Minnesota

The practices of the University of Minnesota (UM) with respect to fetal tissue research and disposal were the subject of media and legislative inquiry that came to evoke skepticism of its institutional candor. Amid the heightened attention to questions surrounding fetal tissue trafficking in 2015, UM spokespeople initially denied to journalists and state legislators that fetal tissue research occurred on campus, but after a news outlet uncovered receipts of fetal tissue purchases, the university reversed course and admitted that such research had taken place.[717] Following a request it made under Minnesota's Open Records Law, the news outlet apparently had triggered the correction after it discovered that UM made payments for fetal tissue since between 2008 and 2014 from both tissue procurement companies and abortion clinics.[718]

After it was formed, the Panel followed with a request to UM dated January 21, 2016, for relevant documents dating back to 2010. UM responded with a production on February 29 that confirmed they had in fact procured fetal tissue from two procurement companies—Advanced Bioscience Resources (ABR) and StemExpress—the National Disease Research Interchange, and an abortion clinic, the Meadowbrook Women's Clinic of Minneapolis, which operates today under the banner of the Texas-based Whole Woman's Health Clinic.[719] This list may well be incomplete: UM's produced correspondence includes references to tissue orders from the university to Coriell Cell Repositories and the biotech company Regenx.[720] UM did identify ABR as its primary supplier of fetal tissue. Additionally, in stark contrast to its earlier denials of any fetal tissue research activity, UM disclosed that "approximately 10 researchers at the University of Minnesota" have used such tissue "currently or in the recent past" and that UM was the recipient of well over $1 million in NIH grants for projects that used fetal tissue.[721]

To the Panel's request for all accounting records related to the cost and pricing of fetal tissue, UM produced only invoices from ABR, which showed charges ranging from $275 to $2,675 that reflected ABR's varying fee schedule for different types of fetal tissue.[722] Thus, its

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[716] *Id.*
[717] *See* Letter from Marion O'Neill, Vice-Chair, House Higher Education Policy and Finance Committee, to University of Minnesota Board of Regents, at 1 (Oct. 22, 2015), Exhibit 6.78; Jeremy Olson, *After Awkward Flip-Flop, U Toughens Its Policies and Defends Practices*, Star Tribune, Jan. 31, 2016, at 1A; Youssef Rddad, *U Revisits Fetal Tissue Practices*, Minnesota Daily, Feb. 3, 2016, at 1.
[718] *See id.*
[719] UM letter responding to document request, at 1 (Feb. 29, 2016), Exhibit 6.79.
[720] UM production, Attachment A excerpts (Coriell & Regenx references), Exhibit 6.80.
[721] UM production, Attachment C, Exhibit 6.81.
[722] UM production, Attachment A excerpts (copies of ABR fees for services schedule), Exhibit 6.82; Attachment B (invoices), Exhibit 6.83.

practices with respect to fetal tissue raise questions of liability under § 289g-2 that have been examined in the above analysis of ABR and StemExpress.[723] Moreover, the monetary range of its tissue orders is apparently not reflected in the produced ABR invoices: the above referenced correspondence notes $3,555 of charges incurred by a UM lab manager on September 9, 2014, for tissue from Regenx.[724] UM did not disclose its payment practices or other exchanged value with respect to the area abortion clinic, a matter that merits further inquiry.

Independent of the question of what payments or other value exchanged implicate federal law, UM's underlying fetal tissue practices potentially violate several provisions of state law. Minnesota's Anatomical Gift Act permits the donation of fetal tissue only if it is "a stillborn infant or an embryo or fetus that has died of natural causes in utero."[725] Minnesota law also establishes as a "gross misdemeanor" the "use of a living human conceptus for any type of scientific, laboratory research or other experimentation except to protect the life or health of the conceptus, or" except for research "verifiable scientific evidence has shown to be harmless to the conceptus."[726] The state also requires fetal remains, whether "resulting from an abortion or miscarriage," to be disposed of "by cremation, interment by burial, or in a manner directed by the commissioner of health."[727]

UM apparently violated these laws by conducting research on aborted fetuses and additionally by disposing of fetal remains as biohazard waste. Following public disclosure of its practices, the university continues to procure fetal tissue, but it changed its policy to require such tissue to come from sources outside Minnesota and to provide for its disposal in the same way as donated human cadavers.[728] The institution's decision to cross state lines to procure fetal tissue appears to be an effort to avoid criminal liability under Minnesota law. This should prompt Congress to pass legislation that would prohibit the crossing of state lines to evade such basic protections of human dignity at the most vulnerable stages of life.

D. Colorado State University

Colorado State University (CSU) entered a contract with Planned Parenthood of the Rocky Mountains (PPRM) in March 2010.[729] Under the "Agreement for Transfer of Human Fetal Tissue" between PPRM and CSU, university personnel were permitted to collect tissue at the Planned Parenthood clinic. Planned Parenthood personnel were tasked with obtaining informed consent from patients, and the agreement specified that the university would "reimburse Planned Parenthood for reasonable expenses incurred during the tissue retrieval process such [as] the time involved in obtaining consent and packaging donations."[730]

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[723] *See* Chapter V *supra*.
[724] UM production, Attachment A excerpts (Regenx reference), Exhibit 6.80.
[725] Minn. Stat. § 525A.02 subdiv. 5.
[726] Minn. Stat. § 145.422 subdiv. 1 & 2.
[727] Minn. Stat. § 145.1621 subdiv. 3 & 4.
[728] *See* Jeremy Olson, *After Awkward Flip-Flop, U Toughens Its Policies and Defends Practices*, Star Tribune, Jan. 31, 2016, at 1A; Youssef Rddad, *U Revisits Fetal Tissue Practices*, Minnesota Daily, Feb. 3, 2016, at 1.
[729] *See* CSU and Planned Parenthood of the Rocky Mountains MTA, Exhibit 6.84.
[730] *Id.*

One invoice dated April 27, 2010, included a $1,500 charge to the university for "Administrative Start Up." Another invoice charged $1,600 for consent and processing for 10 specimens. These charges merit investigation given that, under their agreement, CSU provided the "packaging materials," and it is not apparent that there were any associated shipping costs.[731]

After public exposure of CSU's relationship with Planned Parenthood, a subsequent lawsuit against CSU claiming that CSU's contractual relationship with Planned Parenthood violated the state constitution,[732] and Congress' inquiry into the fetal tissue research industry, CSU halted acquisition of fetal tissue from any vendors implicated in the investigation.[733]

Like UM, CSU receives a significant amount in federal grants and obtains much of its fetal tissue from ABR and StemExpress. Between 2010 and 2015, CSU received seven NIH grants to support their projects using fetal tissue, at a taxpayer expense of $3.5 million.[734] During that same period, according to documents it produced to the Panel and in litigation, CSU paid ABR nearly $100,000[735] and paid StemExpress over $2,000 for fetal tissue.[736] As with UM, CSU's practices with respect to fetal tissue raise the same questions of liability under § 289g-2 that arise in the cases of ABR and StemExpress.

E. University of California at San Francisco

The University of California San Francisco (UCSF) has been characterized as "the hub of the abortion-rights countermovement in medicine."[737] The Fellowship in Family Planning began at the Bixby Center for Global Reproductive Health at UCSF—a two-year program following residency that pays doctors to "sharpen their skills in abortion and contraception, to venture into research and to do international work.[738] The program spread to around 30 other universities and presently has 246 graduated fellows.[739]

The Ryan Residency Training Program in Abortion and Contraception also began at the Bixby Center for Global Reproductive Health at UCSF in 1999. The Ryan Program "provide[s] resources and technical expertise to departments of obstetrics and gynecology to establish a formal, opt-out rotation in family planning, either by establishing or expanding an outpatient family planning service within the academic medical center or by linking institutions with a

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[731] *See* CSU documents [CSU000002, CSU000019-CSU000022], Exhibit 6.85.
[732] *See* First Amended Complaint, McIntire v. Board of Governors of the Colorado State University System d/b/a Colorado State University, No. 2015CV30865 (Dis. Ct. Larimer County Oct. 7, 2015) (McIntyre Am. Compl.).
[733] Rob White, *CSU halts some fetal tissue acquisition*, Coloradoan, July 28, 2015, http://www.coloradoan.com/story/news/2015/07/28/colorado-state-university-stem-express/30809431/.
[734] *See* NIH Research Portfolio Online Reporting Tools, https://projectreporter.nih.gov/reporter_searchresults.cfm.
[735] *See* McIntyre Am. Compl. at ¶ 42 & Ex. 4 (summarizing ABR invoices). This is consistent with documents CSU produced to the Panel.
[736] StemExpress documents, Exhibit 6.86.
[737] Emily Bazelon, *The New Abortion Providers*, N. Y. Times Mag., July 18, 2010, at MM30, http://www.nytimes.com/2010/07/18/magazine/18abortion-t.html?pagewanted=all&_r=0.
[738] *Id*.
[739] *See* Fellowship in Family Planning, Where are the Fellowships located?, http://www.familyplanningfellowship.org/fellowship-programs, Exhibit 6.46; Fellowship in Family Planning, Application information, http://www.familyplanningfellowship.org/application-information.

freestanding clinic, such as Planned Parenthood."[740] There are over 80 Ryan Program sites in the U.S. and Canada.[741]

Both the Fellowship in Family Planning and the Ryan Residency Training Program are funded by the Susan Thompson Buffett Foundation, which is heavily financed by Warren Buffett.[742]

UCSF is also involved in fetal tissue research. Between 2010 and 2015, UCSF received nearly $17.5 million in taxpayer funding from the National Institutes of Health for research projects using human fetal tissue.[743]

F. Washington University and Planned Parenthood of St. Louis

Planned Parenthood of the St. Louis Region and Southwest Missouri (PPSLR), reportedly the only clinic in Missouri that provides abortions, became the subject of a state legislative investigation in the wake of the revelations regarding Planned Parenthood in 2015. In one of the undercover CMP videos, [PP Witness #1] made a statement suggesting that the clinic was extensively involved in fetal tissue research when asked about tissue procurement opportunities: "[MO Doctor #1] is the Medical Director of the St. Louis region [of PP]. They do 2nd tri's they have a few extensive collaboration with all kinds of research, pretty dynamic medical director, his name is [MO Doctor #1]. I think that's definitely worth your while. And just looking at the map, if there was one place that was untapped, I would say St. Louis."[744]

On July 5, 2016, the Majority Caucus of the Missouri State Senate announced the initial results of their investigation into PPSLR. According to its report, the Senate was hindered in its investigation by "months of stonewalling by Planned Parenthood executives and also by top officials in Gov. Nixon's Department of Health and Senior Services," as well as the refusal of [MO Doctor #2], PPSLR's pathologist and the owner of Pathology Services, Inc., to testify, invoking his Fifth Amendment privilege against self-incrimination. The Senate did obtain enough information to assert that the clinic displayed "a shocking callousness towards vulnerable young women who seek their services" and employed procedures that "may very well constitute outright medical malpractice." The report concluded, "It appears that Planned Parenthood may very well have violated both state statute and Department of Health regulations in their [fetal] disposal practices."[745]

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[740] The Kenneth J. Ryan Residency Training Program in Abortion and Family Planning, About the Ryan Program, http://www.ryanprogram.org/node/1.
[741] The Kenneth J. Ryan Residency Training Program in Abortion and Family Planning, Map and locations, http://www.ryanprogram.org/map-and-locations, Exhibit 6.46.
[742] *See* Emily Bazelon, *The New Abortion Providers*, N. Y. Times Mag., July 18, 2010, at MM30, http://www.nytimes.com/2010/07/18/magazine/18abortion-t.html?pagewanted=all&_r=0.
[743] *See* NIH Research Portfolio Online Reporting Tools, https://projectreporter.nih.gov/reporter_searchresults.cfm.
[744] Center for Medical Progress, Transcript of Videotape of Center for Medical Progress journalists and [PP Witness #1] (July 25, 2014), at 19.
[745] Missouri Senate Planned Parenthood Review Statement, at 1 (July 5, 2016), http://www.senate.mo.gov/16web/wp-content/uploads/2016/07/Missouri-Senate-Planned-Parenthood-Review-Statement.pdf.

The state senate investigation did not focus on the relationship between the clinic and Washington University of St. Louis, but the Majority Caucus' findings are relevant to analysis of that relationship. PPSLR's medical director, [MO Doctor #1], and four other physicians known to work at PPSLR have positions at the Ob/Gyn department of the Washington University School of Medicine:

- [MO Doctor #1] is an assistant professor.
- [MO Doctor #3] is an instructor.
- [MO Doctor #4] is a professor.
- [MO Doctor #5] is an associate professor in the division of family planning.
- [MO Doctor #6] is or was a clinical fellow.

Moreover, Washington University's medical school offers the Ryan Fellowship, by which university fellows are deployed to perform abortions at PPSLR.[746] The university has been acknowledged as a recipient of fetal tissue from UW, but the details of those acquisitions are unclear from UW's extensive redactions. That question merits further investigation, as do the questions of whether PPSLR supplies Washington University fetal tissue and, if so, whether monetary payments or other value is exchanged among the entities' shared personnel.

G. University of Wisconsin

The University of Wisconsin, School of Medicine and Public Health (UW SMPH) provides another example of a close relationship between a public research institution and Planned Parenthood—in this case, Planned Parenthood of Wisconsin (PPWI). The two entities have maintained a relationship in which UW SMPH would deploy faculty members of its Ob/Gyn department to work at a clinic designated by PPWI while still being paid by UW SMPH. The relationship was outlined in a memorandum of understanding obtained by the Panel and signed in 2008. It provided among other things that [WI Doctor #1], an assistant professor of Ob/Gyn at UW SMPH, would serve as the clinic's associate medical director.[747] The move was apparently part of a broader plan that included the procurement and transfer of fetal tissue for research, and UW SMPH admitted in response to a January 21, 2016, document request from the Panel that at the time, it obtained fetal tissue from PPWI.[748] [WI Doctor #1] was central to plans to provide late-term, second-trimester abortions in Madison, Wisconsin. When she departed Wisconsin for Harvard in 2010, a UW SMPH spokesperson made clear that this was "a change in who provides the service, but otherwise there is no change in our plans."[749] Both [WI Doctor #1] and another UW SMPH faculty member who also worked at PPWI, [WI Doctor #2], were

[746] Kenneth J. Ryan Residency Training Program in Abortion and Family Planning, Map and locations, http://www.ryanprogram.org/map-and-locations, Exhibit 6.46. The deployment of fellows to PPSLR was confirmed by a confidential witness and the following article: Abigail Golden, *The Medical Community's Hidden Abortion-Training War*, Daily Beast, Feb. 27, 2014, http://www.thedailybeast.com/articles/2014/02/27/the-medical-community-s-hidden-abortion-training-war.html.
[747] Memorandum of Understanding between the University of Wisconsin Madison and Planned Parenthood of Wisconsin, Inc. (Dec. 2008), Exhibit 6.87.
[748] Letter from UW SMPH to House Select Investigative Panel 3 (Feb. 15, 2016), Exhibit 6.88.
[749] Ryan J. Foley, *Doctor Key to UW Abortion Plan Leaving for Harvard*, Associated Press (June 14, 2010).

acknowledged "for their support with tissue collection and processing" in a 2014 article that had relied on the collection of 10 fetal brains at gestational ages of 10 to 18 weeks.[750]

[WI Doctor #2] remains active on both UW SMPH's Ob/Gyn faculty and PPWI, and she serves as director of the Ryan Fellowship at UW SMPH. The University of Wisconsin deploys residents to PPWI and memorializes this program in a separate contract between the University of Wisconsin Hospitals and Clinics Authority (UWHC) and PPWI.[751] As under the faculty contract, residents who participate in this program would be paid not by the clinic, but by the university via UWHC. Additionally, the contract provided that while at PPWI, residents would be supervised "by physicians who have UWSMPH faculty appointments and are members of the medical staff at PPWI, or, at the specific direction of the Director of Medical Education at PPWI," a position the contract also provided would be held by a UW SMPH doctor, "by other[]licensed PPWI physicians."[752]

While UW SMPH's relationship with PPWI continues, the school maintains that it has not obtained fetal tissue from that clinic network since November 2010. UW SMPH identifies the Albert Einstein College of Medicine, the University of Washington, and ABR as its sources of fetal tissue since 2010.[753] The vast majority of invoices it produced to the Panel come from ABR, dated between 2010 to 2015, and those range in amount from $310 to $2,200.[754] This is pursuant to ABR's high, tissue-specific fees for services schedule.[755] This range differs considerably from UW SMPH's charges from the University of Washington, which average under $300.[756] The transactions illustrate the problematical nature of ABR's practices under § 289g-2, which were examined above.[757] This is clearly material to any analysis of compliance by universities like UW SMPH.

H. University of Michigan

The University of Michigan (UMich) is a public research institution that conducts research using fetal tissue obtained from tissue procurement businesses and universities, though mostly from the former. In response to a January 21, 2016, document request from the Panel to the UMich Medical School, the university acknowledged eight research studies that utilized fetal tissue since 2010. Five researchers from different departments of UMich—psychiatry, urology, human genetics, environmental health sciences, and internal medicine—each procured fetal tissue for a separate research study.[758] Three more studies came from researchers in the

[750] Prenatal Diagnosis 2014, 34, 431-437. Doi: 10.1002/pd.4322. *Differential Changes in Gene Expression in Human Brain During Late First Trimester and Early Second Trimester of Pregnancy*.
[751] Agreement for the Affiliation of Planned Parenthood of Wisconsin, Inc., with University of Wisconsin Hospitals and Clinics Authority for the Training of Residents (Apr. 14, 2009), Exhibit 6.89.
[752] *Id.* at 2.
[753] Letter from UW SMPH to House Select Investigative Panel 3 (Feb. 15, 2016), Exhibit 6.88.
[754] UW SMPH production [00052, 00069 (invoices for $310)] & [00012 (invoice for $2,200)], Exhibit 6.88.
[755] UW SMPH production [00002-00003], Exhibit 6.88.
[756] *See* UW SMPH production [00017-00018, 00027-00028, 00029-00030 (three charges of $200)] & [00023-00024, 00025-00026 (two charges of $400)], Exhibit 6.88.
[757] See Chapter V.D *supra*.
[758] Letter from UMich to House Select Investigative Panel 2-3 (Feb. 29, 2016), Exhibit 6.90.

department of ophthalmology.[759] ABR supplied the fetal tissue used in all three ophalmology studies and the internal medicine studies. Novogenix supplied tissue to internal medicine and human genetics. UW supplied tissue to the departments of urology and environmental health sciences, and the psychiatry department researcher obtained tissue from the UMich Health System.[760]

Physicians from UMich's Health System staff a Planned Parenthood clinic in Ann Arbor, Michigan, and medical students are eligible to provide abortions there through the Ryan Fellowship, in which UMich is a participant.[761] The Planned Parenthood clinic is even listed in the "our locations" section of the UMich Health System website.[762] Among the shared staff between UMich and Planned Parenthood, statements captured on undercover video by [MI Doctor] are of particular concern. [MI Doctor], who is both an associate professor in UMich's Ob/Gyn department and medical director for Planned Parenthood, told the following to a Center for Medical Progress journalist regarding her prospective involvement in the acquisition of fetal tissue for research:

> If I'm involved, it would have to go through my University of Michigan IRB, and they tend to be pretty easy about stuff and actually not require informed consent because that would be the biggest breach of confidentiality and of tissue discarded anyway, their feeling is you don't even need to consent people. Which is interesting. Planned Parenthood, on the other hand, does feel like you need to sign [unintelligible].[763]

This admission obviously raises serious questions about UMich's compliance with IRB and informed consent requirements.

In another part of their conversation, when [MI Doctor] was asked whether her past work in this area was "with a dedicated procurement organization," she replied, "No, it was with individual researchers who needed either decidual tissue or fetal, they were tr—fetal orbits, or, you know, specific, short-term research projects." While she had never encountered "a per-specimen fee" in such arrangements, she added that "all research projects . . . pay for the effort. . . . they've had sort of like grants to the agency to cover my time."[764] This statement is problematical because, if in fact she were paid for her time procuring fetal tissue, there arises the

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[759] *Id.*
[760] *Id.*
[761] *See* Michigan Outreach, Family Medicine Medical Consulting (Planned Parenthood), http://outreach.umich.edu/programs/family-medicine-medical-consulting-planned-parenthood/, Exhibit 6.91; The Kenneth J. Ryan Residency Training Program in Abortion and Family Planning, Map and locations, http://www.ryanprogram.org/map-and-locations, Exhibit 6.46.
[762] Ann Arbor Planned Parenthood, http://www.uofmhealth.org/our-locations/ann-arbor-planned-parenthood, Exhibit 6.92.
[763] Center for Medical Progress videotape produced to the Committee on Oversight and Government Reform, FNNF0991_20140408112137 (065000).
[764] Center for Medical Progress videotape produced to the Committee on Oversight and Government Reform, FNNF0991_20140408115753 (009300-011300).

question of whether the grants she refers to cover more than statutorily permissible reimbursements for costs under § 289g-2. As for UMich institutionally, its use of ABR and Novogenix, both of which companies the Panel has discovered did charge per specimen, suggests the need for further inquiry into its fetal tissue acquisition practices.

VII. Case Studies of Late-Term Abortion Clinics

Chapter VII Redaction Key:

1. Abortion Doctor #1 is an abortion provider in Nebraska and Maryland.

2. Abortion Doctor #2 is an abortion provider in Colorado.

3. Abortion Doctor #3 is an abortion provider in Texas.

4. Dr. Administrator is a faculty member at the University of New Mexico.

5. Clinic A Dr. #1 is an employee of Southwestern Women's Options and a faculty member of the University of New Mexico.

6. Clinic B Staff #1 is an employee of a late-term abortion clinic in Maryland for [Abortion Doctor #1].

7. Clinic B Staff #2 is an employee of a late-term abortion clinic in Maryland for [Abortion Doctor #1].

8. Clinic B Staff #3 is an employee of a late-term abortion clinic in Maryland for [Abortion Doctor #1].

9. Clinic B Staff #4 is an employee of a late-term abortion clinic in Maryland for [Abortion Doctor #1].

10. Employee #1 is an employee of a late-term abortion clinic in Texas for [Abortion Doctor #3].

11. Employee #2 is an employee of a late-term abortion clinic in Texas for [Abortion Doctor #3].

12. Employee #3 is an employee of a late-term abortion clinic in Texas for [Abortion Doctor #3].

13. Employee #4 is an employee of a late-term abortion clinic in Texas for [Abortion Doctor #3].

14. Patient #1 is a former patient of [Abortion Doctor #3].

A. Summary

Abortion clinics and hospitals typically use one of two methods when performing abortions in the second and third trimesters of pregnancy—dilatation and evacuation (D&E) or induction. Both of these procedures require a patient's cervix to be dilated over a period of hours to days prior to the actual procedure. During that dilation process, an infant can be delivered spontaneously.[765] If the infant has not been administered feticide—typically intracardiac potassium chloride injection (KCl) or intrafetal/intra-amniotic digoxin injection[766]— or if the feticide fails, infants are sometimes born alive.[767] While infants are not likely to be born alive during the D&E procedure, which entails dismembering and removing the infant and the placenta with forceps, infants have been born alive following the induction process in an induction abortion.[768]

The business practices and procedures of late-term clinics implicate numerous legal and ethical concerns. When human infants are born alive in late-term abortion clinics or hospitals, abortion providers are obligated to ensure that these infants are afforded all of the protections guaranteed by federal and state law. However, pressure from research institutions or procurement companies to provide human fetal organs and tissue at late gestations could negatively impact the treatment born-alive infants receive. Infants with congenital health problems are particularly vulnerable to neglect or abuse.

According to the Centers for Disease Control, between 2003 and 2014, 588 reported infant deaths included a code indicating that a cause of death was "termination of pregnancy, affecting fetus and newborn." At least 143 of these deaths could definitively be classified as involving an induced abortion; however, the CDC acknowledges that this could be an underestimate.[769]

A careful investigation of late-term abortion providers is necessary to ensure that entities are complying with the federal Born-Alive Infants Protection Act,[770] 42 U.S.C. § 289g, *et seq.*, federal regulations pertaining to human fetal tissue research, and state laws, including anatomical gift laws.

The significance of this inquiry includes the issue of the taxpayers' indirect support of late-term abortion. In fact, most of the doctors west of the Mississippi who openly perform third-trimester abortions have faculty positions at either the University of New Mexico or the

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[765] *See* SFP Clinical Guidelines: *Cervical preparation for second-trimester surgical abortion prior to 20 weeks' gestation*, Contraception 89 (2014) 75-84, http://www.contraceptionjournal.org/article/S0010-7824(13)00686-0/pdf.
[766] *See* SFP Clinical Guidelines: *Induction of fetal demise before abortion*, Contraception 81 (2010) 462-473, http://www.contraceptionjournal.org/article/S0010-7824(10)00019-3/pdf.
[767] *See* SFP Clinical Guidelines: *Labor induction abortion in the second trimester*, Contraception 84 (2011) 4-18, http://www.contraceptionjournal.org/article/S0010-7824(11)00057-6/pdf.
[768] *Id.*
[769] Centers for Disease Control and Prevention, Mortality Records with Mention of International Classification of Diseases-10 code P96.4 (Termination of Pregnancy): United States, 2003-2014, http://www.cdc.gov/nchs/health_policy/mortality-records-mentioning-termination-of-pregnancy.htm.
[770] 1 U.S.C. § 8.

University of Colorado. The broad public disapproval of such practices raises the question of why institutions that receive public funds should carry the tacit imprimatur imparted by institutional affiliation.

The Panel investigated several abortion providers and clinics around the country: [Abortion Doctor #1], [Abortion Doctor #2], [Abortion Doctor #3], University of New Mexico, and Southwestern Women's Options.

B. [Abortion Doctor #1]

1. Background on [Abortion Doctor #1]

[Abortion Doctor #1], M.D., performs abortions at two clinics—one in Nebraska, which he owns, and one in Maryland. [Abortion Doctor #1] began doing abortions full-time in 1988 in Nebraska.[771] [Abortion Doctor #1] has been very open about being an abortionist. He challenged the Partial-Birth Abortion Ban Act and lost before the United States Supreme Court in 2005. On his website, he shares that the *Washington Post*, Huffington Post, the *New York Times*, *Ms.* Magazine, and *Newsweek* have all featured him in their publications. Also, he was one of the late-term abortion doctors featured in the film *After Tiller*.[772]

In his Nebraska clinic, he offered late-term abortions, having worked with George Tiller for over 10 years, until Nebraska outlawed abortions after 20 weeks.[773] Because he could no longer provide abortions after 20 weeks in Nebraska, he began performing late-term abortions in a clinic in Maryland, thus splitting his week between the two clinics.

2. The Panel Issues a Subpoena to [Abortion Doctor #1]

On May 15, 2016, the Panel sent [Abortion Doctor #1] a subpoena, inquiring into whether his abortion clinics, specifically the clinic in Maryland, have participated in fetal tissue donation, what abortion procedures are conducted in the clinics, and the clinics' protocols in the event an infant is born alive following an abortion procedure.

[Abortion Doctor #1] partially complied with the subpoena by producing information from his clinic in Nebraska. He stated that he has not donated any fetal tissue at the clinic in Nebraska.[774] However, he did not produce any information for the Maryland clinic, claiming he did not have the authority to do so since he is not an agent of the facility.[775]

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[771] *About [Abortion Doctor #1]*, http://www.abortionclinics.org.
[772] *Id.*
[773] *Id.*
[774] Letter from Pillsbury Winthrop Shaw Pittman LLP, to Rep. Marsha Blackburn, Chairman, House Select Investigative Panel 3 (May 23, 2016), Exhibit 7.1.
[775] *Id.* at 4.

3. The Panel's Investigation into the Clinic in Maryland

Therefore, the Panel decided to interview several of the employees of the clinic in Maryland in order to investigate the above-mentioned items. In the interviews, when questioned on when [Abortion Doctor #1] thinks viability occurs, the employees stated 27 weeks.[776] [Clinic Worker #1] stated that up to 27 weeks, the woman does not need to provide a justification for the abortion, as shown in the following excerpt from the transcript:

> Q Can I just, the 20- to 27-week range, which is about 50 percent of your practice, so do the women have to provide any justification for the abortion during that period of time from 20 to 27 weeks?
>
> A No, ma'am.
>
> Q So it's only after 27 weeks?
>
> A Correct.[777]

In a video filmed undercover by the Center for Medical Progress (CMP) at the National Abortion Federation (NAF) conference, [Clinic Worker #1] said that they do not do many abortions before 18 weeks. She said, "We're one of the big three. We do up to 35 weeks."[778] According to an affidavit written by a confidential informant who has been a sidewalk counselor (*i.e.*, an individual who prays outside the clinic and tries to dissuade women from having abortions) outside the clinic for 5 years, "many of the 3rd-trimester abortions are elective."[779] She goes on to say that since [Abortion Doctor #1] has been working in Maryland, "we have recorded over 40 such post-viability abortions being done for trivial reasons having nothing to do with the health or life of either mother or baby."[780]

In addition to the concerns that purely elective, post-viability abortions are taking place, there have been several medical complications that have occurred at the clinic, under the watch of [Abortion Doctor #1]. Since December 2010, 9 women have been transferred to a nearby hospital due to complications from an abortion at this clinic, with 7 of them being emergency transports.[781] The most alarming factor is that 5 of the 9 transfers have occurred since December 2015. In April 2016, the Panel met with a confidential informant, a former employee of the clinic, who claimed that [Abortion Doctor #1] is not fit to practice due to arthritis in his hands.

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[776] Transcribed interview of [Clinic Workers #1, #2, #3, and #4] (July 21, 2106) at 37, 139.
[777] *Id.* at 38.
[778] Center for Medical Progress videotape produced to the Committee on Oversight and Government Reform, FNPB0298_20150419143440.
[779] Affidavit of [Confidential Informant], Dec. 3, 2016 ([Confidential Informant] Aff.), ¶ 3, Exhibit 7.2.
[780] [Confidential Informant] Aff., ¶ 4, Exhibit 7.2.
[781] Transcribed interview of [Clinic Workers #1, #2, #3, and #4] (July 21, 2106) at 32.

Recently, [Abortion Doctor #1] did not practice at the Maryland clinic for 8 weeks. Rumor spread that he had stopped his practice in Maryland. However, he returned to the clinic on December 11, 2016, and resumed providing abortions.[782]

C. [Abortion Doctor #2]

1. Background on [Abortion Doctor #2]

[Abortion Doctor #2], M.D., M.P.H., Ph.D., owner of the Boulder Abortion Clinic, has been an abortionist since 1973.[783] He wrote *Abortion Practice*, a medical textbook on abortion.[784] He also was featured in the movie *After Tiller*, in which he spoke openly about his practice.

In 2003, [Abortion Doctor #2] wrote a paper titled "Has the Human Species Become a Cancer on the Planet?: A Theoretical View of Population Growth as a Sign of Pathology." In the paper, he discusses how population growth is one of the greatest problems we face today.[785] Throughout the paper, he analogizes human population growth on the planet with cancer in the body—rapidly growing and damaging.[786] He concludes with stating that the world must decide to lower the number of births or it will occur "because of ecological limitations and resource degradation with the result of an increased number of deaths or declining fertility through social disorganization (warfare)."[787] He states that the debates over abortion make the problem worse because it limits options to couples who wish to decrease their fertility, and he praises the United States' decision to help countries around the world with their family planning programs.[788]

In 2003, after the passage of the Partial-Birth Abortion Ban Act, [Abortion Doctor #2] wrote an article for *Slate* in which he states that the Partial-Birth Abortion Ban is ambiguous and that his patients are afraid the law will prevent them from getting abortions in the future. He finishes the article by describing an abortion he had recently done on a woman who was 17 weeks pregnant:

> I ruptured the membranes and released the fluid to reduce the risk of amniotic fluid embolism. Then I inserted my forceps into the uterus and applied them to the head of the fetus, which was still alive, since fetal injection is not done at that stage of pregnancy. I closed the forceps, crushing the skull of the fetus, and withdrew the forceps. The fetus, now dead, slid out more or less intact.[789]

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[782] *The Return of [Abortion Doctor #1] to Germantown*, Pray for Germantown (Dec. 11, 2016), http://www.prayforgermantown.com.
[783] *About [Abortion Doctor #2]*, Boulder Abortion Clinic, P.C. (2010) http://www.drhern.com.
[784] *Id.*
[785] [Abortion Doctor #2], *Has the Human Species Become a Cancer on the Planet?: A Theoretical View of Population Growth as a Sign of Pathology*, 36 Current World Leaders, 1089, at 1.
[786] *Id.* at 17.
[787] *Id.* at 18.
[788] *Id.* at 18.
[789] [Abortion Doctor #2], "Did I Violate the Partial-Birth Abortion Ban?," Slate (Oct. 22, 2003) http://www.slate.com/articles/health_and_science/medical_examiner/2003/10/did_i_violate_the_partialbirth_abortion_ban.html.

He finished the article by stating, "Did I do a 'partial-birth' abortion? Will John Ashcroft prosecute me? Stay tuned."[790]

2. The Panel's Investigation into [Abortion Doctor #2]

On November 2, 2016, the Panel sent [Abortion Doctor #2] a document request letter, inquiring into whether his abortion clinic has participated in fetal tissue donation, what abortion procedures are conducted in the clinic, and the clinic protocols for if an infant is born alive following an abortion procedure. Shortly after the Panel sent the letter to [Abortion Doctor #2], he bought a full-page ad in the *Denver Post* in which he published the letter from Chairman Blackburn and his response to the letter. The Panel had not disclosed to the public that it had sent a letter to [Abortion Doctor #2]. In his letter, he writes, "[Y]our letter to me and letters to other physicians constitute a program of target identification for anti-abortion assassins. . . .Your 'investigation' is legislative harassment that endangers our lives. The blood of any of us who are assassinated is on your hands."[791]

[Abortion Doctor #2]'s accusation carries no weight due to the fact that he himself made it public that the Panel sent him a document request. The Panel kept this information confidential. It did not issue a press release. The public would not have known about this letter if [Abortion Doctor #2] had not told them through the publication of his letter in the *Denver Post*. He then, after exposing his own name, asked the public for money to cover security costs for his clinic through a fundraising website, an unnecessary measure if he had kept his involvement with the investigation confidential, as the Panel had done for him.[792] Furthermore, [Abortion Doctor #2] has always been open and public about his abortion practice, through his clinic's website, his advertisements, his outspoken articles, and his participation as a star of the film *After Tiller*.

In [Abortion Doctor #2]'s response to the Panel, he concludes by citing the Fifth Amendment as his reason for not complying with the document request.

D. [Abortion Doctor #3]

1. Summary

Over the course of its investigation, the Panel collected statements and video from former employees and a patient of [Abortion Doctor #3] who have alleged numerous violations of law at one or more of his clinics, describing the practitioner as conducting himself with depraved indifference to infant life and committing acts of murder. [Abortion Doctor #3] was previously referred to the District Attorney of Harris County, but the investigation into the matter was

[790] *Id.*
[791] Letter from [Abortion Doctor #2] M.D., M.P.H., Ph.D. to Rep. Marsha Blackburn, Chairman, House Select Investigative Panel 4 (Nov. 16, 2016), Exhibit 7.3.
[792] [Abortion Doctor #2], *Boulder Abortion Clinic Renovation and Security Upgrades*, crowdrise, https://www.crowdrise.com/boulder-abortion-clinic-renovations-and-security-upgrades. As of December 13, 2016, [Abortion Doctor #2] had earned $53,325 on the fundraising website.

deficient. After [Abortion Doctor #3]'s attorney agreed to forward a document request from the Panel to his client, the Panel made such a request for documents due November 16, 2016, but received no response to the request. Due to the gravity of the allegations against him, the Panel made a criminal referral forthwith to both the United States Attorney General and the Texas Attorney General on December 7, 2016. The allegations of violations of both federal and state law are recounted below.

2. Allegations Against [Abortion Doctor #3]

[Abortion Doctor #3] is an abortion provider who has operated at three locations in Houston, Texas and one in Dallas. Several former employees who worked with him at one or more of the Houston locations have come forward alleging numerous violations of law.

According to several of his employees, including [Employee #1] and [Employee #2], who were medical assistants, and [Employee #3], who assisted with administrative tasks, numerous patients of [Abortion Doctor #3] delivered infants alive prior to their demise, which the doctor himself brought about. Specifically, [Employee #1], who assisted the doctor in the operating room at the Aaron Women's Clinic (Aaron), estimated that "[d]uring a typical week with a full patient load, . . . [Abortion Doctor #3] would perform abortions at 20 or more weeks gestation, *i.e.*, later in the second trimester or in the third trimester, on approximately 40 patients."[793] Of that number, [Employee #1] asserted:

> approximately three or four infants would show signs of life. This typically happened when infants were extracted from the cervix in a breech position. At times, the infant would slide completely out because of the extent of the dilation caused by the laminaria administered to patients. In all such cases, [Abortion Doctor #3] would terminate their lives. The signs of life they exhibited would include movement of the stomach as the infant breathed or movement of the toes or fingers.[794]

[Abortion Doctor #3] would terminate the lives of these infants, [Employee #1] further alleged based on those incidents she witnessed, by any of several methods, including the following:

> snipping the infant's spinal cord with scissors; cutting the neck with Sopher forceps or similar instruments; twisting the infant's head; using forceps, other instruments, or his finger to crush the "soft spot" of the infant's head, or crushing it by the same means through its stomach; or inserting his finger down its throat. If the infant's cranium was coming out first, he would usually use his index finger

[793] Affidavit of [Employee #1], Dec. 5, 2016 ([Employee #1] Aff.), ¶¶ 1-2, Exhibit 7.4. [Warning: Graphic Content]
[794] *Id.* ¶ 3.

> to puncture its head, but if it was coming out feet first, he would instead insert an instrument in the back of the infant's head.[795]

Several of the same allegations were also made by [Employee #2].[796]

[Employee #3] was not in the treatment rooms when abortions took place, but she alleges she learned from her coworkers of numerous infants whose lives were terminated by [Abortion Doctor #3] after showing signs of life following partial or full extraction from the uterus.[797] On one occasion, she stated that she learned from a coworker of an infant killed by the doctor after surviving an abortion; as he was preparing to put it into a bag for disposal, she maintained, the infant had "opened up his eyes and grabbed his hand."[798]

[Employee #1] stated that "[o]f the three to four infants terminated in a typical week by [Abortion Doctor #3] while showing signs of life, on average, approximately one or two would be put to death after they had left the birth canal entirely. The balance were terminated while they were partially out of the birth canal."[799] [Employee #1] added that she never observed [Abortion Doctor #3] "make an attempt to keep alive or resuscitate any infant who showed any signs of life or to direct anyone else to do so," an observation consistent with [Employee #3]'s understanding.[800]

[Employee #1] also alleged that "[Abortion Doctor #3] performed numerous abortions during the third trimester in cases that did not involve any serious threats to the mother's or the infant's health."[801] [Employee #2] asserted, "As long as the patients had the cash, he was going to do it past the 25 weeks."[802] Four photographs identified by [Employee #1] and [Employee #3] as taken in the sterilization room of one of [Abortion Doctor #3]'s clinics, the Women's Pavilion, in 2012 depict the remains of infants clearly in their third trimester when they were allegedly terminated by [Abortion Doctor #3].[803] According to [Employee #1], the tears in the neck line visible in the photos are "inconsistent with" terminations done "while the infant[s were] entirely inside the uterus."[804] Thus, besides being late-term abortions, they were likely either partial-birth abortions or homicides committed after full delivery.

[Employee #1] and two other employees at the clinic, [Employee #3] and [Employee #4], additionally alleged that the doctor regularly falsified sonogram results to misrepresent the

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[795] *Id.* ¶ 4.
[796] *See* Redacted video—see key. [hereinafter Redacted video] ("Sometimes he would go through the stomach as well. . . . He would like force it [the instrument] through the stomach . . . and he twists it.") ("he would put, like, his finger . . . through the throat") (statements of [Employee #2]).
[797] Affidavit of [Employee #3], Dec. 6, 2016 ([Employee #3] Aff.), ¶ 2, Exhibit 7.5. [Warning: Graphic Content]
[798] Redacted video.
[799] [Employee #1] Aff. ¶ 5.
[800] *Id.* ¶ 5; [Employee #3] Aff. ¶ 2.
[801] [Employee #1] Aff. ¶ 6.
[802] Redacted video.
[803] [Employee #1] Aff. ¶ 6; [Employee #3] Aff. ¶ 3. According to [Employee #3], the photos were taken July 26, 2012. *Id.*
[804] [Employee #1] Aff. ¶ 6.

gestational age of the fetus. Some sonograms, they maintained, would be falsified to "overstate the gestational age of the fetus in order to overbill customers."[805]

In other cases, according to [Employee #1] and [Employee #3], "sonograms would be falsified to conceal the advanced gestational age of the fetus beyond the legal limit in Texas."[806] [Employee #1] claimed:

> I have witnessed this happen in cases involving fetuses as old as 28 weeks. [Abortion Doctor #3] would typically tell his ultrasound technician in cases involving fetuses beyond a certain gestational age to allow him to perform the ultrasound himself; he would then bring the patient an ultrasound picture showing another fetus at the gestational age he was misrepresenting to the patient.[807]

An affidavit from a patient attached hereto alleges another specific case of manipulation: [Patient #1], a woman who obtained an abortion in 2002 at "24 to 25 weeks" gestation, "worried that I was too far along. The girl doing my ultrasound told me that 'ultrasounds can be manipulated.' The clinic determined me to be 23 weeks."[808] "On two occasions that I witnessed," [Employee #1] also alleged that "[Abortion Doctor #3] failed to inform a patient she was pregnant with twins."[809]

According to [Employee #1] and [Employee #3], the doctor "would regularly make use of pre-drawn medicine," including Demerol and Nubain, "without properly logging or storing it." They added:

> This included improperly storing medicine in a food refrigerator. On one occasion, [Abortion Doctor #3] concealed these practices during an inspection from the Harris County Public Health office by having a nurse put pre-drawn medicine in basins, which she hid in the trunk of her car while the inspector was present."[810]

[Employee #1] and [Employee #3] also allege the doctor failed to keep a registered nurse on site in the recovery room at Aaron, which "left unqualified workers to draw and administer drugs."[811] [Employee #1] added that [Abortion Doctor #3] concealed this deficiency from authorities by "hir[ing] a nurse from a temp agency for a few days at a time when a government inspection was

[805] *Id.* ¶ 7; [Employee #3] Aff. ¶ 4; Statement of [Employee #4], Nov. 23, 2012, at 1, Exhibit 7.6.
[806] [Employee #1] Aff. ¶ 7; [Employee #3] Aff. ¶ 4.
[807] [Employee #1] Aff. ¶ 7.
[808] Affidavit of [Patient #1], June 17, 2013, Exhibit 7.7.
[809] [Employee #1] Aff. ¶ 8.
[810] *Id.* ¶ 9; [Employee #3] Aff. ¶ 5. *See also* Redacted video.
[811] [Employee #1] Aff. ¶ 10; [Employee #3] Aff. ¶ 6.

scheduled."[812] [Employee #1] recorded examples of storage, recordkeeping, and personnel violations in an undercover video she took in 2011.[813]

Additionally, according to [Employee #1]:

> [Abortion Doctor #3] would regularly fail to observe proper sterilization procedures. This included the doctor's habitual reuse of a bottle of Betadine, which is used for cleaning prior to the procedure, that was not cleaned or stored, and which he handled with his gloved hand for patient after patient when going inside the cervix. Additionally, after removing instruments such as Hawkins-Ambler's dilators and Bierer and Sopher forceps from sterile packages, he would place unused instruments back in the sterile package to use on other patients. He often would do so wearing gloves that he did not change between seeing one patient and another, or between trips to the restroom. . . . Instruments in [Abortion Doctor #3]'s clinic were not regularly soaked in sterilizing solutions as they needed to be for specified periods of time in order to be sterile. The exception to this occurred prior to government inspections. The vast majority of the doctor's assistants in the sterilization room were uninformed on proper methods of sterilization. In order to reduce his costs, [Abortion Doctor #3] also habitually disposed of biohazardous waste in standard garbage bags instead of sterile bags required for such waste.[814]

The same failure with respect to sterilization was also alleged by [Employee #2], [Employee #3], and [Employee #4].[815]

3. Violations of Applicable Laws

Federal law makes clear that infants that are born, regardless of whether naturally or by extraction during an abortion, are entitled to the same protections given to every other person. Under the Born-Alive Infants Protection Act of 2002, "every infant member of the species homo sapiens who is born alive at any stage of development" is considered a person.[816] This is so whenever an infant undergoes "complete expulsion or extraction from his or her mother" and "has a beating heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, regardless of whether the umbilical cord has been cut, and regardless of whether the expulsion or

[812] [Employee #1] Aff. ¶ 10. For additional information regarding the deficiencies in [Abortion Doctor #3]'s nursing staff and other allegations regarding possible violations at his clinics, see Statement of [Employee #1] in support of Complaint against [Abortion Doctor #3], D.O., Apr. 26, 2010, Exhibit 7.8.
[813] Clinic in Texas video by [Employee #1].
[814] [Employee #1] Aff. ¶¶ 11-12. See also Statement of [Employee #1] in support of Complaint against [Abortion Doctor #3], D.O., Apr. 26, 2010, at 3.
[815] Redacted video; Statement of [Employee #4], Nov. 23, 2012, at 1.
[816] 1 U.S.C. § 8(a).

extraction occurs as a result of natural or induced labor, cesarean section, or induced abortion."[817]

The Partial-Birth Abortion Ban Act of 2003 makes clear that such protections apply even if the infant is only partially extracted from the mother's body at the time its life is ended. Specifically, a prohibited "partial-birth abortion" occurs when a person knowingly commits "an overt act . . . that kills the partially delivered living fetus" after the fetus is partially delivered with its entire head "outside the body of the mother, or, in the case of breech presentation, any part of the fetal trunk past the navel."[818] The only exceptions occur when such a procedure "is necessary to save the life of a mother whose life is endangered" by certain categories of physical conditions.[819] Violations of the 2003 act are punishable by fines, imprisonment for up to two years, or both.[820]

The foregoing allegations advance numerous federal violations against [Abortion Doctor #3]—of the Partial-Birth Abortion Ban Act in those cases involving his terminations of partially delivered infants and of the Born-Alive Infants Protection Act in those cases where the infants have completely exited a mother's body. In at least the latter cases, they also amount to allegations that [Abortion Doctor #3] violated Texas' criminal homicide statutes. First, the allegations constitute murder, defined by the Texas Penal Code as "intentionally or knowingly caus[ing] the death of an individual."[821] Second, the allegations against [Abortion Doctor #3] constitute capital murder under Texas law in both of the following circumstances, either one of which is sufficient to establish that offense:

- "the person murders more than one person . . . during different criminal transactions but the murders are committed pursuant to the same scheme or course of conduct;"[822] and

- "the person murders an individual under 10 years of age . . . ."[823]

The murders alleged against [Abortion Doctor #3] occurred on a repeated basis, and all occurred pursuant to his course of conduct as a provider of abortion who was alleged to have systematically killed any infant aborted while showing signs of life. The second circumstance is independently established by the obvious fact that every alleged victim was under 10 years of age.

[Abortion Doctor #3]'s alleged conduct would also violate the gestational age limit established under Texas law. Former employees of the doctor allege he performed abortions as late as the third trimester.[824] Third trimester abortions are prohibited with narrow exceptions, inapplicable according to the allegations in the instant case, where "the abortion is necessary to

[817] 1 U.S.C. § 8(b).
[818] 18 U.S.C. § 1531(b)(1).
[819] 18 U.S.C. § 1531(a).
[820] *Id.*
[821] Tex. Penal Code § 19.02(b)(1).
[822] Tex. Penal Code § 19.03(a)(7).
[823] Tex. Penal Code § 19.03(a)(8).
[824] [Employee #1] Aff. ¶ 6; [Employee #3] Aff. ¶ 2.

prevent the death of the woman," the "unborn child has a severe, irreversible brain impairment; or . . . the woman is diagnosed with a significant likelihood of suffering imminent severe, irreversible brain damage or . . . paralysis."[825] Since H.B. 2 became effective October 29, 2013, abortions additionally have been prohibited when "the probable post-fertilization age of the unborn child is 20 or more weeks."[826] [Abortion Doctor #3]'s abortion practice is believed to continue to the present day, so it merits investigation whether he has violated both gestational limits.

The allegations that [Abortion Doctor #3] regularly falsified sonogram results to misrepresent the gestational age of the fetus in order to overbill also potentially implicate both state and federal law. Regardless of whether the patient or another entity is responsible for payment, Texas law clearly prohibits fraudulent billing. Such conduct would constitute a form of theft[827] in addition to violating Texas' prohibition on insurance fraud.[828] In those cases in which patients were eligible for Medicaid coverage, such allegations would implicate numerous federal criminal prohibitions on false statements to federal agencies[829] and on false statements involving health care benefit programs,[830] as well as the prohibitions on health care fraud.[831] Such conduct would also violate the federal False Claims Act[832] and Texas' prohibition of Medicaid fraud.[833]

Other provisions of Texas law prohibit additional conduct alleged above on the part of [Abortion Doctor #3], including the following:

- Misrepresentation of sonogram readings: In addition to violating the above-cited statutes prohibiting fraud, tampering and altering records containing patient data is prohibited under 25 Tex. Admin. Code § 135.9(d).

- Failure to properly store and log medication: The obligation to maintain and provide drugs safely and to properly log their use is set forth in detail under 22 Tex. Admin. Code

[825] Tex. Occ. Code § 164.052(a)(18). The Texas Health and Safety Code contains an additional prohibition of third-trimester abortions, under which such abortions are permitted only when they are "necessary to prevent the death or a substantial risk of serious impairment to the physical or mental health of the woman" or "the fetus has a severe and irreversible abnormality," in which case the physician is required to submit a written certification of the applicable conditions to the Department of State Health Services. Tex. Health & Safety Code §§ 170.002(b)-(c).
[826] Tex. Health & Safety Code §§ 171.044, 171.045. Exceptions apply when abortion is deemed necessary "to avert the woman's death or a serious risk of substantial and irreversible physical impairment of a major bodily function, other than a psychological condition." Tex. Health & Safety Code § 171.046. Note that these provisions of H.B. 2 were not challenged in *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016).
[827] Tex. Penal Code § 31.03.
[828] Tex. Penal Code § 35.02.
[829] 18 U.S.C. § 1001; 18 U.S.C. § 287. An accompanying prohibition on conspiracy in connection with such claims is established by 18 U.S.C. § 286.
[830] 18 U.S.C. § 1035.
[831] 18 U.S.C. § 1347; 42 U.S.C. § 1320a-7b(a). If fraud is proven to have been carried out by utilizing either the mails or other applicable interstate carriers or communications, the federal mail and wire fraud statutes would also be implicated. *See* 18 U.S.C. §§ 1341, 1343.
[832] 31 U.S.C. § 3729(a)(1).
[833] Tex. Penal Code § 35A.02.

§ 291.76 and made applicable to ambulatory surgical centers under 25 Tex. Admin. Code § 135.12.

- Lack of adequate medical staff: 25 Tex. Admin. Code § 135.7 requires health care practitioners to meet numerous requirements that include necessary and appropriate training and to adhere to state law and "the standards and ethics of their professions." 25 Tex. Admin. Code § 135.15 specifies requirements for an organized nursing service under the direction of a qualified registered nurse and other personnel that must be present at the medical facility. [Abortion Doctor #3]'s former employees allege a violation of these sections. Additional investigation is warranted into whether clinic practices were in compliance with other requirements for adequate medical staff, including 25 Tex. Admin. Code § 135.10, which addresses additional facility requirements, and 25 Tex. Admin. Code § 135.11, which addresses anesthesia and surgical services.

- Failure to observe proper sterilization procedures and disposal practices: 25 Tex. Admin. Code § 135.11(b)(12) requires the development, implementation, and enforcement of such procedures, and 25 Tex. Admin. Code § 135.52(d)(14) requires sterilizing facilities to be included and properly maintained and utilized.

- Fraudulent concealment from government authorities of the foregoing alleged violations: The fabrication, alteration, and in applicable cases concealment involved in these allegations entail conduct proscribed by Tex. Penal Code § 37.09. It also subverts the state's right to inspect facilities containing controlled substances pursuant to Tex. Health & Safety Code § 481.181.

E. University of New Mexico and Southwestern Women's Options

As noted above, Albuquerque, New Mexico, is one of the known providers of late-term abortions. SWWO openly performs a large quantity of abortions into the third trimester, and UNM Hospital will provide abortions beyond 25 weeks where there is "a maternal indication or a fetal indication."[834] Yet neither UNM nor SWWO appears to have any apparatus or procedure to ensure the survival of infants who show signs of life following extraction from the uterus. This is evident from [Dr. Administrator]'s deposition testimony when she was questioned on this subject:

> Q . . . I'm trying to understand if any of the doctors that were on the fellows program that . . . went to Southwestern Women's Options, or any of the doctors from the University of New Mexico that were on a fill-in rotation at Planned Parenthood, or any of the doctors at the University of New Mexico reproductive health center, or any of the doctors at the University Hospital ever told you,

[834] [Dr. Administrator] Tr. at 46.

reported to you, or discussed with you, that an abortion failed and a live birth resulted?

A . . . The answer is no at the Planned Parenthood and Southwest Women's Options and the Center for Reproductive Health. There are situations in the hospital where a planned abortion, an induction of labor for a fetus, for example, with severe anomalies is born alive.

Q If one of the fellows from UNM had been at Southwest, would they have been trained in what to do if a child was born alive?

A I don't know.

Q So does your curriculum call for training of doctors of what to do if a child is born alive because of an induced abortion?

A No.

Q No training at all?

A No.

Q There's no resuscitation training?

A OB/GYN doctors do not resuscitate neonates.

Q So who at the Southwest Clinic would do that resuscitation if it was necessary?

. . . [A]I don't know.[835]

[Dr. Administrator] was subsequently asked about a provision in UNM's own protocol for infants that survive abortion: "When an induced abortion results in a live-born infant showing any signs of life, such as a heartbeat or voluntary movement, a birth certificate should be completed. . . . A death certificate will be completed if the infant dies."[836] When asked why such language would be included in the UNM protocol, [Dr. Administrator] expressed her ignorance of, and perhaps obliviousness to, the subject matter:

A So I was responsible for editing and helping to draft and review this document, except for the administrative procedures. The administrative procedures are -- these are procedures that are -- that

[835] [Dr. Administrator] Tr. 24-25.
[836] [Dr. Administrator] Tr. 28-29 (quoting UNMHSC, Second Trimester Pregnancy Termination, D&E and induction of labor 2, UNM01686).

are carried out by nursing. So this -- this was added after the medical content of the document. And this -- this was added by -- by nursing.

Q Do you agree with that statement?

A So I think that—that we actually need to update this document to reflect what we—

Q Welcome to have you update it. My question is: do you agree with the statement? . . .

A So there are requirements through the hospital and through the state, and we comply with—with those requirements. I am not sure right now that these are what conform to the current requirements of the state and of the institution.

Q Do you agree with the statement?

A I don't understand your question.

Q It's a very easy question to answer. If an induced abortion results in a live-born infant showing any signs of life, such as a heartbeat, like A[P]GAR 1, or voluntary movement, a birth certificate should be completed.

A So a birth certificate is an administrative matter that I don't have an opinion about. I follow the appropriate administrative procedures as outlined by the institution and the state, but it's not something I have an opinion about.

Q So you have no opinion on whether this policy is a good policy, correct policy, what we should do, what we shouldn't do; no opinion at all?

A The medical component of this policy I stand behind. The administrative procedures, again, are not under my purview. I am very much in agreement with following the institution and the state regulations around birth certificates.

Q So is the diagnosis part of the doctor's responsibility?

A Diagnosis of what?

> Q Of a patient's situation? Is that what the doctor does, they diagnose patients? I just want to read you the rest of this paragraph, in light of diagnosis. "The diagnosis on the woman's chart should be induced abortion, secondary diagnosis giving the indication for the procedure. In addition, a diagnosis of 'live-born infant' should be made as a secondary diagnosis. This reflects the unusual outcome of the live birth from an induced abortion. Do not make an entry in the delivery room log." Where would that entry be made?
>
> A I don't know.[837]

[Dr. Administrator] would not directly answer the question whether "the decision to resuscitate a child that comes out of the birth canal" alive should be left to the woman and doctor alone, suggesting that "there is no answer" or that the answer would "depend on the individual circumstances of the patient."[838] When she was read the language of the Born-Alive Infants Protection Act and asked if she agreed with it, she responded, "I'm not familiar with the law."[839] She admitted she never discussed the law with counsel and did not "understand the relevance of this to my practice."[840]

Coming from the official who is arguably most responsible for making UNM an abortion provider and providing the same function to outside clinics—an official responsible for training in multiple competencies in abortion and family planning—this testimony is a startling reflection of the absence of attention given to any standard of care for infants that survive the abortion procedure.

When [Clinic A Dr. #1] was questioned about infants showing signs of life following abortions, she denied ever seeing such signs of life and testified that "if you want to talk about signs of life, . . . I don't know what criteria would necessarily be applied to that, but I would have to extend my knowledge of obstetrical practice."[841] She surmised that such signs would be "assessed by . . . an Apgar score, meaning respiration, color, the color of the neonate, grimace, reflexes to certain stimulus, crying," only to be challenged by Rep. Harris, whose experience as a physician includes being the chief of obstetric anesthesiology at the Johns Hopkins Hospital: "I've been in the delivery room a lot of times and witnessed Apgar scores of zero and one" on babies that were resuscitated.[842] Did she in fact conclude that "if a baby didn't grimace or didn't have reflex response to . . . painful stimulus or wasn't breathing," there was "no sign of life?" She responded, "Yes."[843] When Rep. Harris pressed further for clarification, [Clinic A Dr. #1] admitted that she was not even performing an Apgar score.[844] On "assess[ing] signs of life," she

[837] [Dr. Administrator] Tr. at 30-32.
[838] [Dr. Administrator] Tr. at 51-53.
[839] [Dr. Administrator] Tr. at 56.
[840] [Dr. Administrator] Tr. at 56-57.
[841] [Clinic A Dr. #1]Tr. at 230.
[842] [Clinic A Dr. #1] Tr. at 230-31.
[843] [Clinic A Dr. #1] Tr. at 232.
[844] [Clinic A Dr. #1] Tr. at 233.

continued, “I haven’t thought about this. I have not given this deep consideration.”[845] Despite the fact that SWWO performed abortions in the third trimester, the infant was not even routinely checked for a heartbeat.[846] This was the case even though [Clinic A Dr. #1] admitted there were cases in which an infant exited the womb spontaneously, before it was expected to do so.[847]

The testimony of both abortion providers suggests a lack of medical training and of any sense of obligation to be trained to preserve the life of an infant that survives the abortion procedure. It reflects a philosophy that a right to abortion somehow carries a guarantee of the death of the infant expelled during the procedure.

[845] [Clinic A Dr. #1] Tr. at 234.
[846] [Clinic A Dr. #1] Tr. at 234-35.
[847] [Clinic A Dr. #1] Tr. at 250.

VIII. Case Studies of the Fetal Tissue Industry – Planned Parenthood

Chapter VIII Redaction Key:

1. [PP Witness #1] is an abortion provider in Los Angeles, California, an executive with Planned Parenthood Federation of America (PPFA) who is in charge of the PPFA Manual of Medical Standard and Guidelines.
2. [PP Witness #2] is a manager of research projects at Planned Parenthood Gulf Coast.
3. [PP Witness #3] is a university professor, an abortion provider and serves on the PPFA National Medical Committee.
4. [PP Witness #4] works for the Consortium of Abortion Provider Services at PPFA which provides technical assistance to PPFA affiliate clinics.
5. [PP Doctor #1] is an abortion provider in Los Angeles, California, who also works for the Medical Directors' Council.
6. [PPGC Abortion Services Official] is a manager of abortion services at PPGC.
7. [PPFA Executive] works for the Medical Standards Department at PPFA
8. [PPFA Medical Officer #1] is a PPFA official who was responsible for medical issues
9. [PPFA Medical Officer #2] is a PPFA official who was responsible for medical issues
10. [PPFA Lawyer] is a legal official at PPFA.
11. [CRR lawyer] works for the Center for Reproductive Rights.
12. [ANSIRH lawyer] works for Advancing New Standards in Reproductive Health.
13. [NARAL executive] works for the Policy department at the National Abortion and Reproductive Rights Action League.
14. [StemExpress Founder and CEO] refers to the founder and CEO of StemExpress
15. [Abortion Doctor] is any doctor who provides abortions.
16. [Researcher FT] refers to any person who is involved in fetal tissue transactions.

17. [Procurement Technician] refers to any person who procures fetal tissue.

A. Summary

Planned Parenthood executives who spoke with the Panel noted that 2016 is the 100th anniversary of the founding of Planned Parenthood. A closer look at the history of the organization, however, leaves little to celebrate. The organization was founded by eugenicists who believed in limiting the rights of people to form families and have children if they had mental or physical disabilities or were of the wrong race.

Harvard studies about Planned Parenthood's business model have pointed out financial struggles the organization has faced in recent years, including smaller margins and lower revenues. Substantial evidence exists that Planned Parenthood clinics—at least 51 times—have overbilled Medicaid and improperly billed items to cover the costs of abortion services, in violation of the Hyde Amendment

During some of Planned Parenthood's difficult financial years, tissue procurement companies like StemExpress saw an opportunity to market their services to Planned Parenthood affiliate clinics and even the entire Federation. This move was welcomed by top Planned Parenthood executives, some of whom were remarkably candid about the revenue possibilities for clinics.

However, the relationship that has formed between tissue procurement companies and abortion clinics and universities is fraught with questionable practices, including the possible use of illegal, late-term abortion practices to procure the best tissues and organs, violating federal guidelines on patient consent, and systematic violations of patient HIPAA rights. The Panel has been investigating these practices for the past year.

This chapter reveals the findings of that investigation.

B. Planned Parenthood: A Corrupt Founding

According to the 2014 audited financial statement of Planned Parenthood Federation (PPFA) and related entities:

> The Federation is . . . affiliated with 68 independent medical and related entities, and 101 ancillary entities (including 34 Political Action Committees and 55-501(c)(4) organizations), all of which are separately incorporated in their respective states and which collectively constitute PPFA's membership.[848]

Planned Parenthood operates 57 affiliates directly as of 2016, a number that has been declining since 2009 based on annual reports released by the organization. In 2015, for example,

[848] Planned Parenthood Federation of America, Inc. and Related Entities: Consolidated Financial Statements and Supplementary Information 9 (June 30, 2014 and 2013), https://www.plannedparenthood.org/files/5014/1936/7155/PPFA_Audited_FS_FY2014.PDF [hereinafter PPFA 2014 Financial Statements].

PPFA oversaw 59 affiliates which operated 667 health centers (outpatient clinics) in the United States. When asked by House Energy and Commerce Committee staff why the number of affiliates has declined in recent years, PPFA attorneys responded that it is "due primarily to mergers, and in some cases disaffiliation. . . . In cases of disaffiliation, contributing factors range from compliance issues, the adoption of core services, protection of the Trademark and strategic restructuring."[849]

Until recently, PPFA also included the Planned Parenthood Foundation, which raised funds for various projects and affiliates and which was collapsed into PPFA in 2013.[850] The Planned Parenthood Action Fund (incorporated in 1989)[851] engages in public and political advocacy. Another entity, Voxent (incorporated as of 2010)[852] exists to acquire medical technology for PPFA. Additionally, PPFA maintains many programs and initiatives such as the Consortium of Abortion Providers (CAPS) which raises funds to subsidize abortion services for affiliates and provides technical assistance, including for fetal tissue programs. The PPFA also maintains three global offices.[853]

This year, 2016, marks the 100-year anniversary of Planned Parenthood. The organization has its origin in a single "birth control clinic" in Brooklyn in 1916.[854] Today it has become the highest volume abortion provider in the United States, and in 2015 alone performed 323,999 abortions.[855]

Before it was renamed Planned Parenthood in 1942, the reproductive health services provider was known as the American Birth Control League (ABCL).[856] Among the founders of the ABCL were a group of eugenicists, including Planned Parenthood founder Margaret Sanger, who sought to reduce and control population growth, including among the African American community. Sanger saw the eugenics movement as a chance to rid civilization of "racial, political and social problems."[857] In a 1921 article titled "The Eugenic Value of Birth Control Propaganda," she wrote:

> Seemingly every new approach to the great problem of the human race must manifest its vitality by running the gauntlet of prejudice, ridicule and misinterpretation. Eugenicists may remember that not many years ago this program for race regeneration was subjected to

[849] U.S. House of Representatives Committee on Energy & Commerce Subcommittee on Oversight & Investigations Follow-Up Questions 8 (Aug. 20, 2015) [PPFA-HOU_E&C-000169], Exhibit 8.1.
[850] PPFA 2014 Financial Statements, at 9.
[851] *Id.* at 8.
[852] *Id.*
[853] Planned Parenthood website, https://www.plannedparenthood.org/about-us/planned-parenthood-global/contact-the-international-program.
[854] Planned Parenthood Minnesota, North Dakota, and South Dakota website, https://www.plannedparenthood.org/planned-parenthood-minnesota-north-dakota-south-dakota/who-we-are/history/1916-1952.
[855] Planned Parenthood Annual Report 30 (2014-2015), https://www.plannedparenthood.org/files/2114/5089/0863/2014-2015_PPFA_Annual_Report_.pdf.
[856] The Margaret Sanger Papers Project website, https://www.nyu.edu/projects/sanger/aboutms/organization_abcl.php.
[857] Margaret Sanger, *The Eugenic Value of Birth Control Propaganda* (Oct. 1921), https://www.nyu.edu/projects/sanger/webedition/app/documents/show.php?sangerDoc=238946.xml.

> the cruel ridicule of stupidity and ignorance. Today Eugenics is suggested by the most diverse minds as the most adequate and thorough avenue to the solution of racial, political and social problems. The most intransigent and daring teachers and scientists have lent their support to this great biological interpretation of the human race. . . . The doctrine of Birth Control is now passing through the stage of ridicule, prejudice and misunderstanding. . . . Gradually the criticisms are lessening-–understanding is taking the place of misunderstanding. *The eugenic and civilizational value of Birth Control is becoming apparent to the enlightened and the intelligent.*[858]

Sanger believed eugenics would make the human race healthier by ridding society of people whom she saw as a burden: those who were perpetuating a cycle of poverty and illness. In her 1922 book *Pivot of Civilization*, she wrote:

> Those vast, complex, interrelated organizations aiming to control and to diminish the spread of misery and destitution and all the menacing evils that spring out of this sinisterly fertile soil, *are the surest sign that our civilization has bred, is breeding and is perpetuating constantly increasing numbers of defectives, delinquents and dependents.* My criticism, therefore, is not directed at the "failure" of philanthropy, but rather at its success.[859]

She calls those with mental disabilities a "dead weight of human waste" and a "burden of unthinking and indiscriminate fecundity." Sanger again bemoans the "perpetuation of defectives, delinquents and dependents."[860]

Further, in a 1939 report co-authored by her organization's secretary, Mary Woodward Reinhardt, and her personal secretary Florence Rose, Sanger wrote that "negroes present the great problem of the South."[861] In a letter that same year to her friend Clarence Gamble, she stressed the importance of training an African-American physician so the community will "more or less lay their cards on the table which means their ignorance, superstitions, and doubts."[862] She was concerned that African-Americans would be more open to the idea of birth control if they were speaking to a doctor who shared their race. She then wrote, "We do not want the word to go out that we want to exterminate the Negro population and the minister is the man who can straighten out that idea if it ever occurs to any of their more rebellious members,"[863] indicating—at best—that she was concerned with the growth of African-American families.

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[858] *Id.* (emphasis added).
[859] Margaret Sanger, *The Pivot of Civilization,* Chapter V: The Cruelty of Charity, http://www.gutenberg.org/files/1689/1689-h/1689-h.htm (emphasis added).
[860] *Id.*
[861] *Birth Control or Race Control? Sanger and the Negro Project,* The Margaret Sangers Papers Project, https://www.nyu.edu/projects/sanger/articles/bc_or_race_control.php.
[862] Letter from Margaret Sanger to Dr. C. J. Gamble (Dec. 10, 1939), https://libex.smith.edu/omeka/files/original/d6358bc3053c93183295bf2df1c0c931.pdf.
[863] *Id.*

For all her shocking and discriminatory statements, the organization she founded, Planned Parenthood Federation of America, has not shied away from the legacy of their founder. Since 1966, PPFA has given "individuals of distinction in recognition of excellence and leadership in further reproductive health and reproductive rights" the Margaret Sanger Award.[864] They have further appointed her grandson, Alexander Sanger, as Chair of the International Planned Parenthood Council.[865]

C. Planned Parenthood: Problems with the Business Model

In 1994, PPFA created a "reinvention team" in partnership with the Harvard Business School to address problems that PPFA saw in its affiliates. There was "a general concern that the financial condition of the national organization had deteriorated."[866] In short, net margins were declining, smaller affiliates were faring poorly, and private fundraising (20% of affiliate revenue) was declining. The nationwide rise of managed care clinics also posed several threats to PPFA, most importantly in the area of client composition.

First, most managed care plans increasingly covered the reproductive services that Planned Parenthood affiliates offered. Planned Parenthood affiliates, therefore, needed to expand their services. Private physicians also began to serve more Medicaid patients, taking a portion of Planned Parenthood's customer base with them. At the same time, the number of uninsured patients grew, increasing the demand at Planned Parenthood affiliates for reduced-cost services. The reinvention team drafted a proposal recommending a shift from a "specialty provider" model to a broad range of women-centered healthcare; creating a for-profit entity by which PPFA could distribute revenue; and restructuring governance of PPFA to add weight to the vote participation by the affiliate clinics with more clients.[867] When the draft was reviewed, some complained that "abortion was mentioned only eight times in the entire, 123-page document."[868] The second draft, therefore, "explicitly embraced protecting abortion rights as a key function."[869]

Throughout their reinvention process, the abortion giant was careful to protect its most lucrative procedure. Former Planned Parenthood facility director Abby Johnson blew the whistle on the importance Planned Parenthood placed on abortion quotas. She shared a photo in 2014 of an award given to Planned Parenthood of Aurora, Colorado, by Planned Parenthood of the Rocky Mountains "for exceeding abortion visits in the first half of FY13 compared to first half of FY12."[870] Johnson wrote on her blog that when she expressed concerns to her supervisor about the pressure to increase the number of abortions at their clinic, the supervisor "laughed and said,

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[864] Planned Parenthood website, https://www.plannedparenthood.org/about-us/newsroom/ppfa-margaret-sanger-award-winners.
[865] International Planned Parenthood Federation Western Hemisphere Region website, https://www.ippfwhr.org/en/who-we-are/alexander-sanger.
[866] Elaine V. Backman & V. Kasturi Rangan, *Planned Parenthood Federation of America (C)*, Harvard Business School, Feb. 13, 1998, at 1, Exhibit 8.2.
[867] Elaine V. Backman & V. Kasturi Rangan, *Planned Parenthood Federation of America (B)*, Harvard Business School, Oct. 21, 1997, at 2, Exhibit 8.3.
[868] *Id.* at 3.
[869] *Id.* at 4.
[870] Image of Planned Parenthood of the Rocky Mountains Certificate on LifeNews website, http://lifenews.wpengine.netdna-cdn.com/wp-content/uploads/2014/06/plannedparenthood108.png.

'But Abby, abortion is how we make our money.'"[871] Moreover, in 2010, affiliates were asked to make sure that at least one of their clinics perform abortions.[872] Based on PPFA's own numbers from annual reports, abortion accounts for about 30% of its annual income.

Almost 15 years after the initial reinvention process, in 2008, PPFA was faced with more financial troubles. According to a 2009 Harvard report:

> [The Great Recession had] further exacerbated fundraising challenges at both the local and national levels . . . . Everything from reduction in state family-planning budgets to worsening credit crunches to reduced donations influenced the wave of consolidations that had already been occurring throughout the organization. Reducing costs became a key focus due to continued revenue declines. Affiliates were asking themselves if there were more efficient ways of running their operations.[873]

Some Planned Parenthood executives have been remarkably candid about the financial problems faced by the organization and the abortion industry as a whole. The Panel found the following panel discussion at a national meeting:

> [PP Witness #4]: **So it's true that we have kept the price low**, but it is those of us who are in this room who have kept that price low. That, we have in some part done that to ourselves. And I understand all the reasons behind that, but that other case in point, that **we're not doing ourselves any favors by doing that.**
>
> [ANSIRH lawyer]: Yeah, I mean, and I think the tough thing is, if you have competitors in a market, I mean if you have more than one provider in a market, I think lots of providers feel like if they raise their prices at all to reflect new costs that have been imposed on them, that the other providers in the market will not do so, and then they will lose all their business and they'll go out of business. So, I think, it's, this is a really tough thing—
>
> [NARAL executive]: Or you get a Kermit Gosnell. You get a predator.
>
> [ANSIRH lawyer]: Yeah, so, yeah. I think there's a lot of areas of the country where I think people just feel that they cannot adjust their prices to reflect the actual costs because of competition, and as a result, I mean, as a result, providers are really struggling, it's also

[871] Abby Johnson, *And Then There Were None* blog, July 22, 2014, http://archive.aweber.com/exposingthelie/A1RpD/h/Abortion_Quotas_EXPOSED_.htm.
[872] *Local Planned Parenthood Chapter Drops Affiliation*, Corpus Christi Caller Times, Dec. 20, 2010, http://archive.caller.com/news/local-planned-parenthood-chapter-drops-affiliation-ep-359672010-316353321.html.
[873] Allen Grossman, Thomas Steenburgh, Lauren Mehler, & Matt Oppenheimer, *Planned Parenthood Federation of America in 2008*, Harvard Business School, Oct. 29, 2010, at 9, Exhibit 8.4.

probably one of the most efficiently provided forms of health care in the entire country [audience laughter]. Because, you know, people have managed to just take on all these new costs without raises prices. I mean it's really quite shocking.

[PP Witness #4]: Oh I agree, I mean, and I think it's the tenacity of, again, many in this room that have hung on for so long to those early business models that have allowed it to work. **But as a long-term strategy, I don't think it's the smartest strategy we have come up with.**

[ANSIRH lawyer]: Yeah, I agree.

[CRR lawyer]: **Are you saying that maybe we should be raising prices?**

[PP Witness #4]: I think we should charge for an abortion what it costs to provide an abortion. And right now we're not. And it's at the expense of, um, at the expense of owners, and staff, and in some cases quality. And that's not good for anybody. And if regulations are going to continue to come down, whether they be TRAP regulations or just changes in health care—which I agree there's both—I think that's just something that we need to consider.

[ANSIRH lawyer]: I think that's a good point.

[PP Witness #4]: And it's a complicated case**, I mean there's going to be casualties, and there's going to be women that don't get abortions, and there's going to be women who self-induce, and there's going to be, you know, really adverse outcomes as a result, so I understand it's not a popular strategy, but I just think at some point, we can't continue to—and I don't want to have a "price-fixing conversation" [nervous laughter]—but I don't think we can continue to provide high-quality abortions for $500 a piece, and incur expenses like that we need to do for ambulatory surgical centers.** We have, are all, we all have our eggs—or all of our eggs are in a couple baskets. And if those baskets ever are no longer available, I think that, again, I think that it's not a great long-term strategy for women.[874]

Thus, for over a decade, the economic trajectory of PPFA faced challenges of market changes, management issues, and cash flow problems, even with one of the nation's top business schools trying to assist. It was at the end of this decade that organizations seeking to procure and resell fetal tissue saw an opportunity. In particular, StemExpress sought to market its services to

[874] Center for Medical Progress videotape produced to the Committee on Oversight and Government Reform FNNI0773_20150421125757 (emphasis added).

Planned Parenthood clinics and even to the whole of PPFA as a revenue enhancement. Fetal tissue donation was welcomed and even encouraged by top PPFA executives:

[PP Witness #1] said that clinics on "razor thin budget[s]" are eager to participate in fetal tissue programs:

> **But there is not a provider out there, who doesn't want this.** Everybody just sees this as a way to add another layer of good on top of what they're already doing. They already feel that what they're doing is good. Again, the majority of the providers are non-profit organizations like Planned Parenthood or operating on a razor-thin budget. So as low impact that you can be on them, the better.[875]

[PP Witness #4] admitted to undercover journalists, "We have independent colleagues who generate a fair amount of income doing this."[876] She also admitted that the national federation cannot prevent affiliates from entering into contracts with tissue procurement companies in order to increase revenue, thereby implying the need that some affiliates feel to find additional sources of revenue.[877]

In one video,[878] two journalists posing as tissue procurers are speaking to [PP Witness #4]. She seems to agree with the journalists that fetal tissue programs are indeed profitable to clinics. She even admits in a publicly released video that Planned Parenthood's independent colleagues "generate a fair amount of income doing this."[879]

> Buyer I: I was thanking [PP Witness #1] for her tip of the day; Don't bring up [unintelligible]
>
> [PP Witness #4]: It's not don't bring it up, it's . . . your headline
>
> Buyer II: What's "it?"
>
> [PP Witness #4]: The money. Making a profit off of it. What did you say?
>
> Buyer I: Just that it's financially . . .

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[875] Center for Medical Progress, Transcript of Meeting with [PP Witness #1] at 18 (July 25, 2014) (emphasis added), Exhibit 8.5.
[876] Center for Medical Progress videotape produced to the Committee on Oversight and Government Reform 0569_20150227151723.
[877] Planned Parenthood Rep Admits Affiliates Can't Stop Harvesting, https://www.youtube.com/watch?v=_4P3oHI7KFQ&index=1&list=PLJCNTv4YXhz2JbXxCADboQK_kvOAbxxHK.
[878] Center for Medical Progress videotape produced to the Committee on Oversight and Government Reform FNNI0773_20150421063222.
[879] "Top Planned Parenthood Exec: Baby Parts Sales 'A Valid Exchange,' Can Make 'A Fair Amount of Income,'" https://www.youtube.com/watch?v=c9EU_02c5bM.

> [PP Witness #4]: Profit [trails off]
>
> Buyer I: . . . beneficial to the clinic . . .
>
> [PP Witness #4]: But the truth is, is that some [Planned Parenthood affiliates] might want to do it [fetal tissue donation] for, to increase their revenues. **And we can't stop them**. We only have carrots and sticks.[880]

[PP Doctor #1] said in a conversation with the journalists posing as a tissue procurement company about remuneration for fetal tissue, "Well, you know in negotiations the person who throws out the figure first is at a loss, right? . . . I don't want to play games, I just don't want to lowball, because I'm used to low things from . . . [trails off]."[881]

In a another video,[882] a journalist is speaking to [Abortion Doctor] of Planned Parenthood New York City about fetal tissue remuneration. The following transcript recounts their conversation:

> [Abortion Doctor]: Okay, yeah, that's great, and I think that the fact there's like a, like for me, just like somebody would take it is great, but I think a financial incentive from you guys is going to be like to, I think we have to get this approved, but [we?] will be very happy about it, so—
>
> Buyer: Right, the financial incentive would make people happy.
>
> [Abortion Doctor]: Yeah, exactly.
>
> Buyer: Is that what I'm hearing you saying?
>
> [Abortion Doctor]: Yeah, absolutely!

In fact, Planned Parenthood's own job descriptions discuss the need to increase "revenue." The job description for Reproductive Health/Abortion and/or Prenatal Program Coordinator[883] at Planned Parenthood Mar Monte lists under Essential Duties, "contribute to achieving health center productivity goals."[884]

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[880] Center for Medical Progress videotape produced to the Committee on Oversight and Government Reform FNNI0773_20150421063222.

[881]Center for Medical Progress, Transcript of Meeting with [PP Doctor #1] at 9-10 (Feb. 6, 2015) (emphasis added), Exhibit 8.6.

[882] Center for Medical Progress videotape produced to the Committee on Oversight and Government Reform, FNPB0298_20150421080120.

[883] While this position includes delivery of and referring for prenatal care, PPFA performed 18.6 abortions for every 1 prenatal service in 2014. *See* PPFA Annual Report (2014-2015), https://www.plannedparenthood.org/files/2114/5089/0863/2014-2015_PPFA_Annual_Report_.pdf.

[884] Job description [PPMM-SIP_E&C-000023-000025], Exhibit 8.7.

Similarly, at the same affiliate, an Essential Duty of the Health Center Manager is to manage "the health center to meet or exceed goals in productivity, financial performance and client visits."[885]

The same duty was seen on many other job descriptions at other affiliates for a variety of positions. For example, the position of Mid-Level Clinician at Planned Parenthood Los Angeles included under General Duties, "Participate in health center/affiliate efforts to achieve established revenue cycle goals."[886]

The position of Medical Assistant III-Specialty Services at Planned Parenthood Pacific Southwest also said under Essential Functions, "Participate in health center/affiliate efforts to achieve established revenue cycle goals."[887]

D. PPFA – Affiliate Relationship

PPFA invites abortion clinics to become affiliates and thereby join the Federation. The Panel has learned through interviews with Planned Parenthood executives that affiliates undergo accreditation by the national office.[888] Periodically, a team inspects each affiliate clinic and reports on any violations they see.[889] PPFA requires a wide range of accreditation compliance, use of internal manuals, and obedience to policy directives designed to ensure compatibility with PPFA policy. This compliance includes rules and guidelines that address donation of fetal tissue for research or transplantation. The Panel examined one particular manual titled the *PPFA Manual of Medical Standards and Guidelines* (MS&G), which is updated every two years. The MS&G sets guidelines for affiliate conduct that impacts the transfer of fetal tissue. The Panel conducted interviews with PPFA executives to better evaluate the implementation of the guidelines as they apply to the accreditation process at the affiliate clinic level. Affiliated clinics are subject to "accreditation reviews," which are conducted every three or four years.

To qualify for affiliation, clinics must offer the core services as determined by PPFA. The list of PPFA Core Services includes:

- Well Woman Exams, including cervical screening and breast exams
- Pregnancy Testing and Options Education
- Contraception, Education, Prescribing/Dispensing for all FDA approved methods
- STI screening, testing, treatment for women and men
- HIV Point of Service Rapid Testing for Women and Men
- HPV Vaccine[890]

[885] Job description [PPMM-SIP_E&C-000034-000036], Exhibit 8.8.
[886] Job description [PPLA-SIP_E&C-000093-000095], Exhibit 8.9.
[887] Job description [PPPSW-SIP_E&C-000004-000006], Exhibit 8.10.
[888] Transcribed Interview of [PP Witness #1] at 25-26 (Oct. 6, 2016), Exhibit 8.11.
[889] *Id.* at 58.
[890] U.S. House of Representatives, Committee on Energy & Commerce, Subcommittee on Oversight & Investigations Follow-Up Questions at 2 (Aug. 20, 2015) [PPFA-HOU_E&C-000163-000164], Exhibit 8.1.

"Additionally, abortion services must be offered in at least one health center per affiliate, as follows: First Trimester medical abortion; AND/OR First Trimester surgical abortion."[891] Each of these "core services" involves a financing source, often federal or state taxpayer funding.[892]

Another aspect of affiliate oversight is performed by the Consortium of Abortion Providers (CAPS), a unit within the PPFA. [PP Witness #3] told the Panel that "CAPS advises affiliates and supports affiliates that provide abortion services in doing their job better."[893] …. [PP Witness #4] told Panel staff, "if an affiliate at Planned Parenthood requests technical assistance, whether that be for clinical services or other, we will provide those technical services for them. We will consult with them. We will provide onsite assistant."[894]

PPFA relies upon the 1000-page guidance document, *The Medical Standards and Guidelines* (MS&Gs) to regulate affiliate practices and policies. They "are the clinical guidelines that all affiliates follow in terms of core services to provide their care."[895] According to [PP Witness #1] whose duties include oversight of the MS&G, "The accreditation team develops a list of accreditation indicators. They draw those indicators from a variety of documents, one of which is the Standards and Guidelines, and then they use that when they do their accreditation visits."[896]

The Panel sought to understand whether a significant "management gap" exists between the PPFA written guidance, specifically the MS&G and the clinical practices of affiliates. Inadequate compliance with internal management requirements, when they include federal law and regulation are questions that Congress seeks to have answered in light of the large amount of federal funding the PPFA receives. The PPFA national office reviews and approves research projects at the affiliates. [PP Witness #3] told Panel staff, "If an affiliate is proposing to initiate or become involved in a research project, the affiliate presents information about that project to the National Research Office."[897] The relationship between management and affiliates was further explained as follows:

- [PP Witness #1]: "An affiliate undergoes accreditation by the national office . . .[898]

- [PP Witness #1]: "If an accreditation team was at an affiliate doing an accreditation visit and notes there was a violation of one of the policies, they would make a notation of it, whatever the policy was."[899]

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[891] *Id.* at 3.
[892] See Chapter II.D.2 *supra*.
[893] Transcribed Interview of [PP Witness #3] at 12 (Nov. 1 2016), Exhibit 8.13.
[894] Transcribed Interview of [PP Witness #4] at 11 (Nov. 17 2016), Exhibit 8.14.
[895] Transcribed Interview of [PP Witness #3] (Nov. 1, 2016). See above for list of core services, Exhibit 8.13.
[896] Transcribed Interview of [PP Witness #1] at 26 (Oct. 6 2016), Exhibit 8.11.
[897] Transcribed Interview of [PP Witness #3] at 34 (Nov. 1, 2016), Exhibit 8.15.
[898] Transcribed Interview of [PP Witness #1] at 25-26 (Oct. 6, 2016), Exhibit 8.11.
[899] Transcribed Interview of [PP Witness #1] at 58 (Oct. 6, 2016), Exhibit 8.12.

- [PP Doctor #1]: IF you are an affiliate you apply to [the] medical division for permission [to conduct fetal tissue donation].[900]

- [PP Witness #3]: "CAPS advises affiliates and supports affiliates that provide abortion services in doing their job better . . . . MS&Gs are the clinical guidelines that all affiliates follow in terms of core services to provide their care"[901]

- [PP Witness #3]: "If an affiliate is proposing to initiate or become involved in a research project, the affiliate presents information about that project to the National Research Office."[902]

- [PP Witness #3]: "My main job as Senior Medical Advisor was the creation of and guidance of a national quality improvement department. All the affiliates already have their own quality improvement departments or sorts of departments like that, but we did not have a unified national effort, and we now like everybody else use electronic medical records. . . . We provide quarterly reports to all of our affiliates on their outcomes. . . ."[903]

- [PP Witness #3]: "Planned Parenthood has actually always done research. At the time it was founded there was a branch of the federal 100 years ago called the Planned Parenthood Research Bureau that worked on developing new contraceptives, and so there's a long history of research at Planned Parenthood, but most recently we've made a concerted effort to think about as an organization where we can contribute."[904]

- [PP Witness #3]: "In looking back to when I was chair of the National Medical Committee is when Planned Parenthood instituted the concept of poor medical services for the first time, and surveys showed that most affiliates back then did provide most services, but this was really a way to codify that women's preventive screening, care for sexually

[900] [PP Doctor #1] Briefing with the House Energy and Commerce Committee at 3.b.iii.4.b (Sept. 18, 2015), Exhibit 8.16.
[901] Transcribed Interview of [PP Witness #3] at 12 (Nov. 1, 2016), See Exhibit 8.13.
[902] Transcribed Interview of [PP Witness #3] at 34 (Nov. 1, 2016), Exhibit 8.15.
[903] Transcribed Interview of [PP Witness #3] at 93 (Nov. 1, 2016), Exhibit 8.17.
[904] Transcribed Interview of [PP Witness #3] at 95 (Nov. 1, 2016), Exhibit 8.18.

> transmitted infections. All contraceptive services and abortion services were tied together in the core mission and needed to be available to all of our patients."[905]

The Panel noted that despite these affirmations of a closely managed organization by several of its key leaders, the Panel found instead a management gap of significant proportions.

E. Planned Parenthood Federation Failure to Ensure Compliance by: Affiliates with Legal Billing Practices; Federal Law Governing Fetal Tissue Donation Projects; Federally Required Affirmation about Changing Abortion Procedures; Patient Consent; and HIPAA Regulations.

1. Summary

The Panel sought to understand even more broadly whether the trajectory of the economic business culture and compliance control exercised by PPFA influenced clinical practice of its affiliate clinics. Significant deficiencies described below were revealed by the investigation.

First, the clinics have a checkered history of overbilling Medicaid and of improperly billing items to cover the costs of abortion services, in violation of the Hyde Amendment.

Second, the clinics did not follow PPFA guidance about compliance with federal criminal statutes that govern the terms of fetal tissue donation. Accounting documents from middleman tissue organizations showed that several PPFA affiliates made a profit from the transfer of fetal tissue.

Third, PPFA failed to secure compliance with the requirement that doctors who perform abortions certify in writing that the method of abortion has not been changed to facilitate fetal tissue donation. The PPFA executive in charge of this requirement admitted that she regularly changed the method of abortion to facilitate intact fetal specimens and further admitted that she had never certified that the method of abortion was not altered.

Fourth, PPFA guidance on patient consent and the affiliate practice violates federal consent regulations.

Fifth, the affiliate clinics routinely violated HIPAA privacy regulations to facilitate the harvesting of fetal tissue for which the clinics were paid on a per specimen basis.

2. Planned Parenthood: Failure to Properly Steward Federal Funds

The Panel sought to understand participation in fetal tissue transfer within the context of the affiliate clinics' general business practices and financial stability. Participation in fetal tissue donation requires competent accounting and record-keeping practices as well as fiscal precision in recordkeeping to prevent any possibility of violating the prohibition against profiting from the

[905] Transcribed Interview of [PP Witness #3] at 98 (Nov. 1, 2016), Exhibit 8.19.

sale of fetal tissue. Thus, the Panel reviewed the history of Planned Parenthood's stewardship of federal and state funds designated for family planning and other women's health concerns.

This review sought to identify whether the individual clinics maintained accounting practices that guaranteed the separation of federal funds designated for family planning from funds that paid for abortion procedures. The Panel found a significant history of flawed and unlawful management of federal funds by Planned Parenthood.[906] Planned Parenthood's improper practices were revealed primarily through audits performed by the Office of Inspector General at the U.S. Department of Health and Human Services and by state-level family planning agencies. Of particular concern is the clinics' false designation of abortion services as family planning services. This practice misallocates federal funds designated for family planning to underwriting abortion procedures, a violation of the provisions of the Hyde Amendment.

It is difficult to discern exactly how much funding Planned Parenthood receives from the government. Planned Parenthood's own annual reports over recent years report the following:

FY 2002: $240.9 million[907]	FY 2007: $336.7 million[908]	FY 2012: $542.4 million[909]
FY 2003: $254.4 million[910]	FY 2008: $349.6 million[911]	FY 2013: $540.6 million[912]
FY 2004: $265.2 million[913]	FY 2009: $363.2 million[914]	FY 2014: $528.4 million[915]
FY 2005: $272.7 million[916]	FY 2010: $487.4 million[917]	FY 2015: $553.7 million[918]

[906] During the Panel's investigation, it discovered numerous "reports" about Planned Parenthood. Panel staff met with personnel from the Office of Inspector General from HHS and reviewed numerous publicly available audits of Planned Parenthood. During its investigation, research by the Charlotte Lozier Institute and the Alliance Defending Freedom was provided to the Panel. This section substantially relies upon reporting by the Charlotte Lozier Institute and the Alliance Defending Freedom.

[907] Planned Parenthood Annual Report (2001-2002), http://prolifeaction.org/wp-content/uploads/docs/pp/PPAnnualReport2001-2002.pdf.

[908] Planned Parenthood Annual Report (2006-2007), http://liveaction.org/research/wp-content/uploads/2011/06/2006-2007-Planned-Parenthood-Annual-Report.pdf.

[909] Planned Parenthood Annual Report (2011-2012), https://www.plannedparenthood.org/files/4913/9620/1413/PPFA_AR_2012_121812_vF.pdf.

[910] Planned Parenthood Annual Report (2002-2003), http://prolifeaction.org/wp-content/uploads/docs/pp/PPAnnualReport2002-2003.pdf.

[911] Planned Parenthood Annual Report (2007-2008), http://www.mdrtl.org/files/PP_AnnualRpt08_vFinal.pdf.

[912] Planned Parenthood Annual Report (2012-2013), https://www.plannedparenthood.org/files/7413/9620/1089/AR-FY13_111213_vF_rev3_ISSUU.pdf.

[913] Planned Parenthood Annual Report (2003-2004), http://www.plannedparenthoodrx.com/annualreport/report-04.pdf.

[914] Planned Parenthood Annual Report (2008-2009), http://www.toomanyaborted.com/wp-content/uploads/2010/PDFs/PP_AR_011011_vF-1.pdf.

[915] Planned Parenthood Annual Report (2013-2014), https://www.plannedparenthood.org/files/6714/1996/2641/2013-2014_Annual_Report_FINAL_WEB_VERSION.pdf.

[916] Planned Parenthood Annual Report (2004-2005) http://www.stopp.org/PPFAReports/PPFA200405002.pdf.

[917] Planned Parenthood Annual Report (2009-2010) http://liveaction.org/research/wp-content/uploads/2011/06/2009-2010-Planned-Parenthood-Annual-Report.pdf.

[918] Planned Parenthood Annual Report (2014-2015) https://www.plannedparenthood.org/files/2114/5089/0863/2014-2015_PPFA_Annual_Report_.pdf.

FY 2006: $305.3 million[919] FY 2011: $538.5 million[920]

However, the General Accounting Office reports receipt of only $657.1 million, with International Planned Parenthood Federation receiving $3.9 million.[921] The discrepancy is the indirect funding the Planned Parenthood receives from Title XIX Medicaid reimbursements. Any accountability of the individual clinics relies upon the auditing resources of the state and federal inspector generals.

3. Recent History of Planned Parenthood Audits

There have been 51 external audits of Planned Parenthood affiliates. These audits are summarized below. Additionally, there have been 61 federal audits of state family planning agencies. The consistent pattern is the practice of billing of abortion procedures as family planning or other services such as STD testing. One practice called "unbundling" or "fragmentation" consists of schemes that bill for several types of allowed services to "cover" the non-allowed costs of an abortion.

Limited resources and the volume of Medicaid reimbursement billing make it impossible to audit all federal Medicaid reimbursements. In fact, by design the audits summarized below reflect a very small sample of the total Medicaid reimbursements received by Planned Parenthood. For example, during a review of a New York Planned Parenthood affiliate, $11,818,856.30 was paid for services rendered to 21,413 patients during the audit period. The review itself consisted of a random sample of 100 patients with Medicaid payments of $53,977.99. The narrow sample also pales when compared to a GAO estimate that in Fiscal Year 2013 there were $14.4 billion in improper Medicaid payments.[922]

Audits of Planned Parenthood Affiliates: Audited Years and Averages[923]

State	Audited Years	Total Overbilling	Overbilling by Audited Year
California	1	$5,213,645.92	$5,213,645.92

[919] Planned Parenthood Annual Report (2005-2006) http://liveaction.org/research/wp-content/uploads/2011/06/2005-2006-Planned-Parenthood-Annual-Report.pdf.
[920] Planned Parenthood Annual Report (2010-2011) https://issuu.com/actionfund/docs/ppfa_ar_2011_110112_vf.
[921] *See* U.S. GOVERNMENT ACCOUNTABILITY OFFICE, FEDERAL FUNDS: FISCAL YEARS 2002-2009 OBLIGATIONS, DISBURSEMENTS, AND EXPENDITURES FOR SELECTED ORGANIZATIONS INVOLVED IN HEALTH-RELATED ACTIVITIES (GAO-10-533R) (2010), at Table 7, http://www.gao.gov/new.items/d10533r.pdf; *see also id.* at Tables 10, 16, 18.
[922] U.S. GOVERNMENT ACCOUNTABILITY OFFICE, MEDICAID PROGRAM INTEGRITY: INCREASED OVERSIGHT NEEDED TO ENSURE INTEGRITY OF GROWING MANAGED CARE EXPENDITURES (GAO-14-341) (2014), at 2 (citing a figure calculated by the Centers for Medicare & Medicaid Services (CMS), the federal agency within the Department of Health and Human Services (HHS) that oversees Medicaid).
[923] Charlotte Lozier & Alliance Defending Freedom, *Profit. No Matter What.* (Nov. 1. 2016).

Connecticut	unknown	$18,791.00	unknown
Illinois	2	$387,000.00	$193,500.00
Louisiana	1	$6,147.18	$6,147.18
Louisiana	1	$0	$0
Maine	5.02	$33,294.83	$6,632.44
Nebraska	0.166	$3537.00	$21,307.23
New York – I	unknown	$207,809.00	unknown
New York – II	1	$15,723.91	$15,723.91
New York – III	2	$1,254,603.00	$627,301.50
New York – IV	1	$886.26	$886.26
[New York – V	3	$112,490.31	$37,496.77
[New York – VI	3	$12,031.29	$4,010.43
[New York – VII	3	$11,539.48	$3,846.49
Ohio	unknown	$0	$0
Oklahoma	unknown	unknown	unknown
Oklahoma	unknown	unknown	unknown
Oklahoma	unknown	unknown	unknown
Texas – I	unknown	$409,675.10	unknown
Texas – II	1.58	$129,028	$81,663
Washington – I	unknown	unknown	unknown
Washington – II	2.96	$629,142.88	$212,548.27
Washington – III	unknown	$11,453	unknown
[Wisconsin – I	0.75	$450.39	$600.52
[Wisconsin – II	0.75	$1,276.31	$1,701.75
[Wisconsin – III	0.75	$135.18	$180.24

[Wisconsin – IV	0.75	$128.28	$171.04
Wisconsin – V	1	$74.28	$74.28
[Wisconsin – VI	2	$368.51	$184.26
[Wisconsin – VII	2	$467.02	$233.51
[Wisconsin – VIII	2	$381.99	$191.00
[Wisconsin – IX	2	$404.59	$202.30
[Wisconsin – X	2	$2,533.46	$1,266.73
[Wisconsin – XI	2	$277.31	$138.66
[Wisconsin – XII	2	$613.19	$306.60
[Wisconsin – XIII	2	$773.84	$386.92
Wisconsin – XIV	1	$1,864.42	$1,864.42
[Wisconsin – XV	3	$800.00	$266.67
[Wisconsin – XVI	3	$5,139.71	$1,713.24
[Wisconsin – XVII	3	$1,968.71	$656.24
[Wisconsin – XVIII	3	$2,096.00	$698.67
[Wisconsin – XIX	3	$13,270.11	$4,423.37
[Wisconsin – XX	3	$468.71	$156.24
[Wisconsin – XXI	3	$2,198.13	$732.71
[Wisconsin – XXII	3	$700.00	$233.33
[Wisconsin – XXIII	3	$3,200.00	$1066.67
[Wisconsin – XXIV	3	$1,100.00	$366.67
[Wisconsin – XXV	3	$378.40	$126.13
Wisconsin – XXVI	1	$2,204.26	$2,204.26
Wisconsin – XXVII	1	$52,193.24	$52,193.24
TOTAL	**83.726**	**$8,552,264.20**	**$6,497,049.07**

4. Summary Details of the Known Audits of Planned Parenthood Affiliates

Approximately one-third of Planned Parenthood's 57 U.S. affiliates[924] have been audited. Each audit typically considers only a small sampling of the total accounting records for a selected period of time. Thus, a reasonable extrapolation is possible about the audited organizations financial practices.

l) California Audits

i) California Audit I – San Diego and Riverside Counties, 2004

The California Health and Human Services Agency, Department of Health Services conducted the audit of paid claims to Planned Parenthood San Diego and Riverside Counties (PPSDRC) from July 1, 2002, to June 30, 2003, for Codes X1500 (contraceptive barrier products) and X7706 (oral contraceptives), and February 2, 2003, to May 30, 2004 for Code X7722 (Plan B products).

The audit revealed that (PPSDRC) had received a deep discount from the manufacturer on certain products and should still be allowed to bill the State of California as though they had paid a normal wholesale price.

Due to this noncompliance, (PPSDRC) was compelled to repay $5,213,645.92.

ii) California Audit II – Golden Gate, 2010

An Internal Revenue Service criminal investigative audit of PPFA affiliate Planned Parenthood Golden Gate (PPGG) discovered substantial losses for the 2009 tax year and inaccurate information in the PPGG tax returns.[925] PPFA had already conducted an accreditation review of PPGG in 2004, during which the affiliate failed five of PPFA's nine indicators of financial health. In a 2010 warning letter, the California Attorney General's Charitable Trusts Division cited PPGG Action Fund, PPGG's political advocacy and public policy arm, for failure to file its tax documents with that office for at least 10 years.[926]

m) Connecticut Audit

The U.S. HHS-OIG conducted an audit of Planned Parenthood of Connecticut Inc. & Subsidiar., finding $18,791 in overbilling.[927]

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[924] Planned Parenthood website, *see* Local & State Offices, http://www.plannedparenthood.org/about-us/local-state-offices.

[925] *See also* Katharine Mieszkowski, *IRS Looking into Planned Parenthood Golden Gate After Complaint*, THE BAY CITIZEN, Sept. 2, 2010, https://www.baycitizen.org/news/health/irs-looking-planned-parenthood-after/.

[926] *See, e.g.*, Katharine Mieszkowski, *Internal Concerns About Fiscal Health and Tax Documents Suggest Long-Term Disarray*, THE BAY CITIZEN, Aug. 12, 2010, https://www.baycitizen.org/news/health/financial-docs-raise-questions-about/.

[927] A-01-99-59104, released Aug. 1999. *See* U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL, SEMIANNUAL REPORT OCTOBER 1, 1999 – MARCH 31, 2000 (2000), at D-8,

n) Illinois Audit

This audit by the Illinois Department of Healthcare and Family Services' Inspector General of Planned Parenthood of Illinois (PPIL) found 641 missing records, 31 instances of billing for non-covered services, and 10 instances of billing for services actually performed by someone else, as well as improper procedure codes. As a result of the audit,[928] PPIL and its medical director, Caroline Hoke, agreed to repay the state $367,000 to settle findings of Medicaid overbilling and failure to document services allegedly provided, primarily contraceptives.[929]

o) Louisiana Audits

i) Louisiana Audit I

As the result of an audit conducted by the Louisiana Department of Health and Hospitals (DHH), one Planned Parenthood clinic repaid $6,147.18 to DHH to settle findings of improper billings.[930]

ii) Louisiana Audit II – 2014

In response to Louisiana Senate Concurrent Resolution No. 57 and House Resolution No. 105, 2013 Regular Session, Louisiana's Legislative Auditor reviewed Planned Parenthood Gulf Coast's billings during calendar year 2012. In a report issued February 19, 2014, the legislative auditor found that overall, they could find no evidence that PPGC's billings were not allowable, and that they had no evidence of PPGC pressuring clients into abortion.[931]

p) Maine Audit

The Maine Department of Health and Human Services audited Planned Parenthood of Northern New England (PPNNE), finding that PPNNE billed nearly double its acquisition costs for Levonorgestrel IUDs. PPNNE agreed to repay the state $33,294.83.[932]

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https://oig.hhs.gov/publications/docs/semiannual/2000/00ssemi.pdf. Charlotte Lozier Institute is working to obtain full audit records.

[928] This audit, case number 1074160, covered the period January 1, 2006, to December 31, 2007.

[929] *See* Andrew L. Wang, *Planned Parenthood Settles with Illinois on Medicaid Payments*, MODERN HEALTHCARE, Sept.6,2012,http://www.modernhealthcare.com/article/20120906/
INFO/309069993; Andrew L. Wang, *Medicaid Probes Planned Parenthood Fees*, CRAIN'S CHICAGO BUSINESS, July 9,2012http://www.chicagobusiness.com/article/20120707/
ISSUE01/307079977/medicaid-probes-planned-parenthood-fees.

[930] Specifically, the clinic had billed clinic services under the laboratory Medicaid provider code and vice versa.

[931] However, Louisiana sources report that Planned Parenthood is not currently performing abortions in Louisiana, making allegations of abortion referrals more difficult to track.

[932] *See* Letter from Herbert F. Downs, Director of Audit, Maine Department of Health and Human Services, to [redacted] (June 21, 2012) (on file with Charlotte Lozier Institute). The original audit finding was $90,169.27 in overbillings. Letter from Michael Bishop, Auditor II, Program Integrity,

q) Nebraska Audit

The Nebraska Auditor of Public Accounts audited Planned Parenthood of the Heartland (PPH) and other organizations that receive $500,000 or more in federal funds. PPH was found to have billed and been paid $3,537 for abortion expenses.

r) New York Audits

i) New York Audit I – New York City, January 2009

A January 2009 audit of Planned Parenthood of New York City, Inc. (PPNYC)/Margaret Sanger Center resulted in PPNYC electing to repay the amount of $207,809.00. [933]

ii) New York Audit II – Hudson Peconic, June 2009

A June 2009 audit of Medicaid payments for family planning and reproductive health services paid to Planned Parenthood Hudson Peconic, Inc. (PPHP) on behalf of Medicaid beneficiaries while they were enrolled in Community Choice Health Plan and Health Insurance Plan of New York found significant overpayments for family planning and reproductive health services claims, resulting in an overpayment of $15,723.91, inclusive of interest. [934]

iii) New York Audit III – New York City, June 2009

A June 2009 audit of payments to PPNYC/Margaret Sanger Center for diagnostic and treatment center services paid by Medicaid found improper practices, with sample overpayments of $7,960.01 and total overpayments of at least $1,254,603.00. During the audit period, $11,818,856.30 was paid for services rendered to 21,413 patients. The review consisted of a random sample of 100 patients with Medicaid payments of $53,977.99. [935]

iv) New York Audit IV – New York City, December 2009

A December 2009 audit of Medicaid payments for family planning and reproductive health services paid to PPNYC/Margaret Sanger Center on behalf of Medicaid beneficiaries while they were enrolled in VidaCare Inc. found overpayments, inclusive of interest, of $886.26.

The audit found that PPNYC had improperly billed Medicaid $719.55 for family planning and reproductive health services that were rendered to VidaCare enrollees; as a result,

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Financial Services – Audit, Maine Department of Health and Human Services, [redacted] (Dec. 14, 2010).

[933] Audit # 08-3045.

[934] The audit (Family Planning Chargeback to Managed Care Network Providers, 09-1415, June 10, 2009) covered the period Jan. 1, 2004, through Dec. 31, 2004.

[935] The audit (06-6696) covered the period Jan. 1, 2004, through Dec. 31, 2005.

18 NYCRR § 515.2 and § 540.6 requirements were violated. OMIG then calculated $166.71 in interest, resulting in $886.26 in required restitution. PPNYC was invited to respond to the draft report but did not do so within 30 days as directed. [936]

v) New York Audits V-VII – February/May 2010

Three audits conducted of New York Planned Parenthood affiliates found six categories of overbilling, resulting in a total overpayment of $136,061.08, inclusive of interest. The audits found total overpayments of $136,061.08.[937]

s) Oklahoma Audits

In three apparently separate audits covering the Planned Parenthood affiliates in Oklahoma, Planned Parenthood of Central Oklahoma, Inc., and Planned Parenthood of the Heartland, auditors found overbilling rates of 14.1%, 18%, and 20.3%.[938]

t) Texas Audits

i) Texas Audit I

On June 30, 2009 Planned Parenthood Center of El Paso closed its seven centers for financial reasons and filed for bankruptcy. The closure led to an audit by Texas Department of State Health Services (DSHS). The audit revealed numerous example of fiscal mismanagement, including unpaid subcontractors in the amount of $529,707.97. The OIG determined that PPCEP was not in compliance with the applicable DSHS contracts since it had requested DSHS reimbursement for subcontractor billings it had never paid. Subcontractors identified the outstanding billings as totaling $529,707.97.[939]

ii) Texas Audit II

The U.S. Department of Health and Human Services, Office of the Inspector General, released an audit[940] of the Texas Health and Human Services Commission that revealed missing

[936] The audit (Family Planning Chargeback to Managed Care Network Providers, 09-4845, Dec. 16, 2009) covered the period Jan. 1, 2005, through Dec. 31, 2005.

[937] The audits of PPHP (Prenatal Care Assistance Program, 2009Z33-136W, May 27, 2010), Planned Parenthood of Nassau County, Inc. (PPNC) (Prenatal Care Assistance Program, 2009Z33-083W, May 27, 2010), and Planned Parenthood of South Central New York, Inc. (PPSCNY) (Prenatal Care Assistance Program, 2009Z33-048O, Feb. 24, 2010) covered the period Jan. 1, 2006, through Dec. 31, 2008.

[938] *See* Letter from Mary Fallin, Governor, State of Oklahoma, to Nico Gomez, Director, Oklahoma Health Care Authority Board (Nov. 18, 2015) (on file with Charlotte Lozier Institute); *see also, e.g.*, Kate Richey, *What Really Happened with WIC?*, OKLAHOMA POLICY INSTITUTE, Oct. 24, 2012, http://okpolicy.org/what-really-happened-with-wic/. Charlotte Lozier Institute is working to obtain full audit records.

[939] *See Financially Troubled Planned Parenthood of El Paso Closes Doors*, LIFESITENEWS.COM, July 1, 2009, http://www.lifesitenews.com/news/financially-troubled-planned-parenthood-of-el-paso-closes-doors.

[940] The audit (Texas Claimed Unallowable Federal Reimbursement for Some Family Planning Services, A-06-11-00016) covered the period Mar. 1, 2007, through Sept. 30, 2008.

documentation and overbilling of $129,028 ($67,019 from Medicaid and $62,009 from the waiver program).

u) Washington State Audits

There are three known Washington State audits of Planned Parenthood affiliates. In sum, they uncovered overpayments of at least $640,595.88, inclusive of interest.

i) Washington Audit I

In 2000 and 2001, an audit of a Planned Parenthood clinic uncovered "inflated billings;" a lengthy analysis and negotiation process resulted in an untenable and apparently illicit agreement.[941]

ii) Washington Audit II – Inland Northwest, 2007-2009

A 2007-2009 audit of the Planned Parenthood of the Inland Northwest (PPINW) affiliate[942] found numerous instances of overbilling or other irregularities, resulting in an overpayment of $629,142.88, inclusive of interest. [943]

iii) Washington Audit III – Great Northwest

In May 2012, Planned Parenthood of the Great Northwest (PPGNW) reimbursed the Medicaid program $11,453 as a result of a sample audit conducted by the Washington Medicaid Fraud Control Unit (MCFU) as the result of complaints from concerned citizens alleging "questionable billing practices." Additionally, one portion of the audit that related to a particular type of contraceptive billing was provided to the U.S. Attorney's office for independent investigation. [944]

v) Wisconsin Audits

The State of Wisconsin has released 26 audits it conducted of Planned Parenthood of Wisconsin from 2006-2012. These 26 audits uncovered total potential overpayments of at least $43,272.80. Another audit conducted of Planned Parenthood of Wisconsin revealed an additional $52,193.24 for family planning in 2014. These audits are summarized below:

- # 2006 37543 (Milwaukee - West Wisconsin Avenue): $450.39
- # 2006 50088 (Kenosha): $1,276.31

[941] Email from Myra S. Davis, Medical Assistance Administration Rules and Publications, to Heidi Robbins Brown, Deputy Assistant Secretary, Medical Assistance Administration, Washington Department of Social and Health Services (Sept. 17, 2004, 11:56 PDT) (on file with the Alliance Defending Freedom).
[942] Doing business as Planned Parenthood of Spokane.
[943] The audit (MA 07-13, July 20, 2009) was conducted May 8-10, 2007.
[944] Audit # 09-04-08, of Yakima County.

- # 2006 96759 (Milwaukee - North Jackson Street): $135.18
- # 2006 98176 (Milwaukee - North Jackson Street): $128.28
- # 2007 03883 (Appleton): $368.51
- # 2007 27407 (Madison): $467.02
- # 2007 29154 (Sheboygan): $381.99
- # 2007 49325 (Waukesha): $404.59
- # 2007 66774 (Milwaukee): $2,533.46
- # 2007 70591 (Chippewa Falls): $277.31
- # 2007 86622 (Fond du Lac): $613.19
- # 2007 88039 (Kenosha): $773.84
- # 2010 15792 (Madison): $800.00
- # 2010 38805 (Milwaukee - West Wisconsin Avenue): $5,139.71
- # 2010 55068 (Kenosha): $1,968.71
- # 2010 75330 (Beaver Dam): $2,096.00
- # 2010 22240 (Racine): $13,270.11
- # 2010 34897 (Green Bay): $468.71
- # 2010 39809 (Waukesha): $2,198.13
- # 2010 40664 (Shewano): $700.00
- # 2010 46459 (Chippewa Falls): $3,200.00
- # 2010 58443 (Fond du Lac): $1,100.00
- # 2010 84963 (Milwaukee - South 7th Street): $378.40

5. Conclusion

There are three important conclusions the Panel reached regarding Planned Parenthood's stewardship of federal funds. First, local affiliates regularly and with little accountability substitute billing codes for approved reimbursements for prohibited activities that violate the prohibition against use of federal funds for abortion services. Second, the affiliates operate with disregard of accepted accounting procedures. Third, the local affiliates that seek to increase Medicaid payment through false billing practices also require close scrutiny about compliance with federal law on receiving valuable consideration for the transfer of fetal tissue.

6. Compliance with Federal Law Governing Fetal Tissue Donation Programs

As early as April 4, 2001, chief executives of affiliate clinics were directed via written memorandum by PPFA executives to follow federal regulations for aborted pregnancy donation programs. The memorandum reminded affiliates that fetal tissue donation is governed by federal laws:

> Fetal tissue donation programs are governed by two federal laws, the National Organ Transplant Act (42 U.S.C. 274e) (NOTA) and the NIH Revitalization Act of 1993 (42 U.S.C. 289g-1 and 2) (NIHRA). These laws, particularly NIHRA, govern many aspects of fetal tissue donation programs, and the attached Standard addresses

> all of these issues that affect medical practice and clinical functions.[945]

The memorandum warned that:

> These laws also forbid the payment or receipt of valuable consideration for fetal tissue. However, they permit "reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage" of fetal tissue. In addition, NOTA permits reasonable payments for the "removal" of fetal tissue when the research is supported by federal funds. (These laws do not affect a provider's ability to charge its normal and customary fee for the abortion.)[946]

Affiliates were advised that compliance with the requirements of these laws could be achieved in one of two ways:

> 1. One method would be to recover *no costs* associated with any aspect of participation in a fetal tissue donation program. This would mean that all staff time, clinic space, supplies, etc., would be donated by the affiliate, and the affiliate would receive no payments or in-kind services from the entity to whom the tissue is being donated.[947]
>
> 2. The second method would be to employ an independent auditor to conduct a credible and good-faith analysis of the actual costs incurred *by the affiliate* in the transportation, implantation, processing, preservation, quality control, or storage of the fetal tissue and, if the research is supported by federal funds, for the removal of the fetal tissue. Under this method, affiliates must maintain careful records of actual tissue donations and of payments received from the researcher or the tissue-gathering entity. Affiliates must be able to demonstrate that the payments do not exceed the actual costs of the actual tissue donations.[948]
>
> Sometimes tissue-gathering entities offer to pay rent for space occupied by one of their employees who would be on-site at a clinic on a regular basis. If an affiliate determines to enter into such an arrangement, then the independent auditor would also conduct a credible and good-faith computation of the actual cost of the space

[945] Email from [PP Witness #1] and [PPFA Executive], (Jan. 26, 2011) containing Memorandum (Apr. 3, 2001). from [PP Lawyer], [PP executive] and [PP executive], [PPFA-HOU_E&C-000148-000150], Exhibit 8.20.
[946] *Id.*
[947] *Id.*
[948] *Id.*

> occupied by the tissue-gathering entity employee, in order to determine the amount of rent to be paid by that entity.[949]

Affiliates were reminded that the accreditation reviews conducted by PPFA would hold the affiliates accountable for compliance with the memorandum:

> PPFA accreditation reviews will confirm, in the same way as for any other Medical Standard, that one of these two methods has been employed by any affiliate that chooses to participate in an aborted pregnancy tissue donation program.[950]

Affiliate clinic chief executives were also reminded that they must comply with all state and local laws regarding fetal tissue programs:

> C. Compliance With (sic) State Laws
>
> We remind affiliates that, in addition to the federal laws outlined above, there are laws in many states governing fetal tissue donation programs. Affiliates must take great care to assure compliance with those laws as well.
>
> If you have questions about the federal statutes, feel free to call [PP Lawyer] at: . . .[951]

Ten years later, on January 26, 2011, [PP Witness #1] and [PPFA Executive] reissued the memorandum to "Affiliates CEOs, Medical Directors, and Patient Services Directors" under their names as a reminder of the importance of compliance with the MS&G and federal law.

The memorandum formed the basis for two lines of investigation undertaken by the Panel: (1) the Panel sought to obtain the background accounting documents prepared or relied upon by affiliates in forming their basis for compliance with the memorandum and federal law;[952] and (2) the Panel sought to conduct interviews with PPFA executives about compliance with the memorandum.

[PP Witness #1] participated in a transcribed interview with the Panel on October 6, 2016. Early in the interview, [PP Witness #1] explained that although her name appears on the memorandum "send line," it was sent not by her, but by a staff member of hers, [PPFA Executive]. [PP Witness #1] was asked if she supported the memorandum's guidance:

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[949] *Id*.
[950] *Id*.
[951] *Id*.
[952] *See* Letter from March T. Bell, Staff Director, House Select Investigative Panel, to K. Lee Blalack II, Esq, O'Melveny & Myers, LLP (Sept. 8, 2016) [hereinafter Blalack letter], Exhibit 8.21.

> [PP Witness #1]: As to what my opinion is, my opinion is that the affiliates need to follow the guidance that they are provided with.
>
> BY MR. BELL:
>
> Q And that would include, would it not, either getting no recovery of costs or hiring an auditor, one of those two?
>
> A That is what the guidance says.
>
> Q And you support that guidance?
>
> A That's the PPFA guidance. That's—I don't know what my other option is.[953]

The Panel found no compliance with the requirement that affiliates rely upon an auditor before entering into a fetal tissue donation program.

7. Planned Parenthood Clinics Profited from the Sale of Fetal Tissue

The Panel initially designed its investigation into the whole of the nation's fetal tissue industry as described in the "Investigative Design section" above. Later in the year, the Panel relied upon the confluence of six important factors that caused it to look into the records of individual Planned Parenthood abortion clinics that chose to participate in fetal tissue donation:

- First, many of the clinics contracted with StemExpress whose marketing materials offered a profit to clinics who allowed it "plug-in" tissue procurement program in their clinics.[954]

- Second, The CMP undercover videos revealed a "wink and a nod" attitude by PPFA executives who seemed to communicate that fetal tissue programs help with revenue but don't get caught because the headlines would be a disaster.

- Third, the economic environment of the clinics seemed conducive to measures that would improve revenue.

- Fourth, the Panel's hearing on *The Pricing of Fetal Tissue*, sought the judgment of seasoned federal prosecutors to compare the federal statute prohibiting profit from fetal tissue sales with the first tranche of materials from the investigation. Two former U.S. attorneys and a senior federal litigator agreed that, based on the materials presented to them, they would open a case against a middleman company. The former prosecutors also suggested that accounting and bank records would be critical to understanding

[953] Transcribed Interview of [PP Witness #1] at 32 (Oct. 6, 2016).
[954] StemExpress Brochure [NAF 000001-000002-Brochure.pdf], Exhibit 8.22

whether there was a violation of federal law. Minority witnesses agreed with this approach and urged the panel to obtain such records.

- Fifth, the production from StemExpress and their bank revealed substantial payments to Planned Parenthood affiliate clinics.

- Sixth, interviews with [StemExpress founder and CEO] revealed that the staff of StemExpress was performing all the tasks in the Planned Parenthood affiliates clinics required for procuring fetal tissue.

8. The Panel Investigates Planned Parenthood Affiliate Clinics

PPFA and their affiliate abortion clinics agreed to cooperate voluntarily with the Panel's investigation. PPFA had produced several costs estimates to the House Energy and Commerce's Oversight and Investigations Subcommittee that reported that PP affiliates lost money participating in fetal tissue donation:

> PP Los Angeles—$1,065.65 loss on $15,750.00 in fetal tissue revenues;
> PP Mar Monte—$2,209.32 loss on $18,955.00 in fetal tissue revenue;
> PP of Northern California—$830.64 loss on $1373.00 fetal tissue revenue;
> PP Pacific Southwest—$18,670.84 loss on $18,960.00 in fetal tissue revenue[955]

Thus, the Panel delivered a document request to PPFA's counsel that listed detailed requests for accounting support documents that formed the basis for the materials produced by each clinic.[956] The Panel sought to rely upon a forensic accounting analysis to verify whether these cost estimates were reasonable,[957] accurate, and whether they were allowable under 42 U.S.C. §§ 289g-2(a) and (e)(3). A complete review of the PPFA production produced an incomplete picture. First, the cost analysis and revenue materials produced by PPFA were for 2015, a year in which PPFA decided to stop taking payments for fetal tissue. Second, PPFA produced no background accounting documents to support its cost claims. Third, the Planned Parenthood affiliate cost claims were on their face ambiguous because they assigned costs to the Planned Parenthood affiliate that were clearly paid by the contracted middleman tissue company. Thus, on November 14, 2016, the Panel wrote a further document request to obtain genuine accounting documents.[958]

The Planned Parenthood affiliate clinic cost estimates were analyzed under the rubric of longstanding federal law. On March 10, 1993, the House debated two competing amendments to H.R. 4, the National Institutes of Health Revitalization Act of 1993. The amendments, one offered by Rep. Bliley and one by Rep. Waxman, focused on safeguards governing the donation

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[955] Planned Parenthood Fetal Tissue Expenses Chart, [PPLA-HOU_E&C-0000019, PPMM-HOU_E&C-000002, PPNC-HOU_E&C-000002, PPPSW-HOU_E&C-000002], Exhibit 8.23.
[956] Blalack letter, Exhibit 8.21.
[957] Planned Parenthood Fetal Tissue Expenses Chart, Exhibit 8.23.
[958] Letter from March T. Bell, Staff Director, House Select Investigative Panel, to K. Lee Blalack II, O'Melveny & Myers, LLP (Nov. 14, 2016), Exhibit 8.24.

of fetal tissue for transplantation and for research. The House passed the Waxman Amendment to H.R. 4, the National Institutes of Health Revitalization Act of 1993. That Amendment includes the provisions codified as 42 U.S.C. §§ 289g-2(a) and (e)(3):

- 42 U.S.C. § 289g-2(a) states, "It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce."

- 42 U.S.C. § 289g-2(e)(3) adds, "The term "valuable consideration" does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."

During floor debate, supporters of the Waxman Amendment repeated over and over that "fetal tissue may not be sold."[959] Rep. Morella expressed her support for the legislation because "fetal tissue could not be sold."[960] Rep. Waxman himself said:

> This amendment that I am offering as a substitute would enact the most important safeguards, and those are the safeguards to prevent any sale of fetal tissue for any purpose, just not for the purpose of research. It would be abhorrent to allow for a sale of fetal tissue and a market to be created for that sale.[961]

The floor debate corroborates the Committee Report language. The Report from the Committee on Energy and Commerce stated, "Section 498B prohibits the purchase of human fetal tissue as well as the solicitation or acceptance of directed fetal tissue donations."[962] The Committee prohibition on the sale of fetal tissue is described as making the transfer of fetal tissue parallel with donation of other organs under the Organ Procurement and Transplantation Act.[963] The Committee Report adds, however, "Indeed the Committee has dealt with fetal tissue more restrictively . . . ."[964] The Committee intent is to disallow payment for procurement of any organs.

The intent of the statute is best understood through a simple contrast between two modes of transferring fetal tissue from one entity to another. With the first, an abortion clinic or middleman procurement business transfers tissue to a researcher, and the researcher may reimburse the abortion clinic or procurement business for its reasonable costs incurred by the transportation, processing, preservation, and quality control of the tissue. With the second, the payment from the researcher exceeds those reasonable costs, enabling the abortion clinic or procurement business to make a profit and thus violate the statute.

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[959] 139 Cong. Rec. H1099 (1993) (statement of Rep. John Edward Porter in support of the Waxman Amendment).
[960] 139 Cong. Rec. H1099 (1993) (statement of Rep. Connie Morella in support of H.R. 4 and the Waxman Amendment).
[961] 139 Cong. Rec. H1099 (1993) (statement of Rep. Henry Waxman).
[962] H.R. Rep. No. 103-28 at 76 (1993).
[963] Pub. L. No. 98-507, 98 Stat. 2339 (1984).
[964] H.R. Rep. No. 103-28 at 76 (1993).

Not a violation of § 289g-2

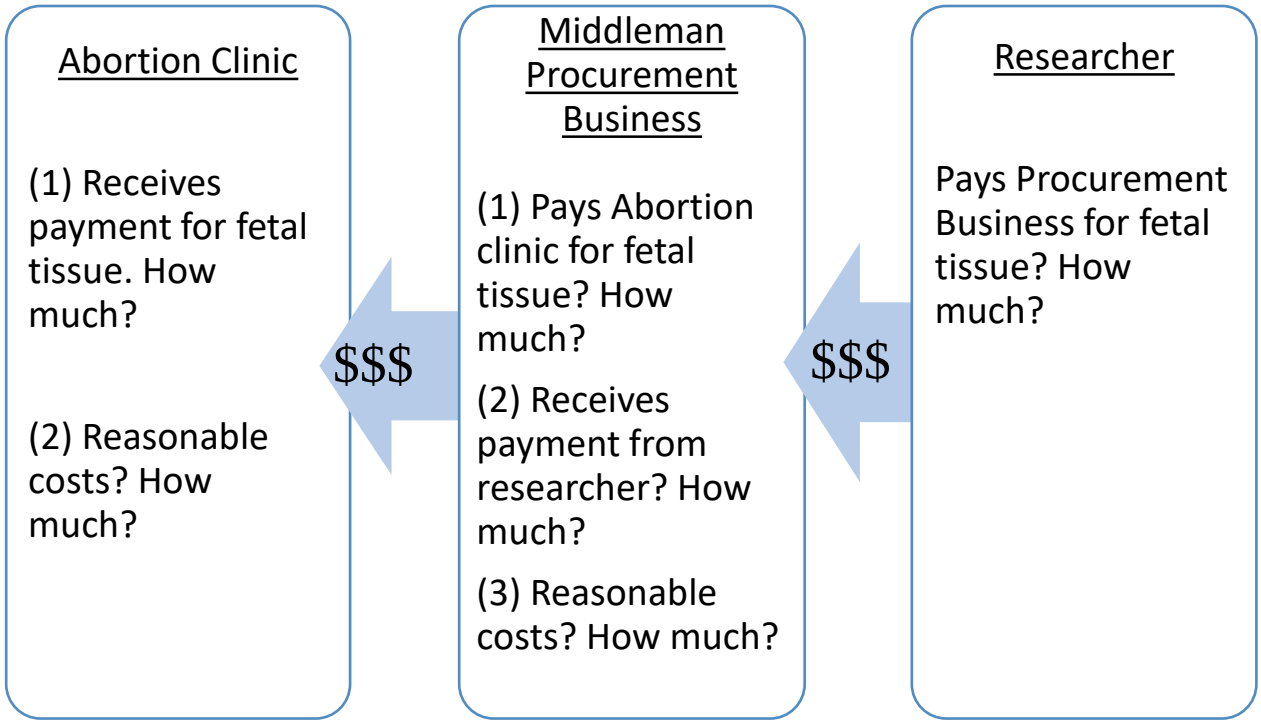


Violation of § 289g-2



The congressional intent of the Waxman Amendment served as a guide for the Panel's investigative plan of the Planned Parenthood affiliate clinics. The core question became the following: If fetal tissue is transferred from one entity to another, does the transfer violate the intent of § 289g-2? To answer this question, the panel identified four business models currently operating in the market sector and one operating in the public sector. The *Middleman Model* comprises a middleman tissue procurer who obtains tissue directly from a source such as a PPFA affiliate clinic and then transfers the tissue to a customer, usually a university researcher.

The Panel started its inquiry into the middleman or tissue broker model, the primary business model for the transfer of human fetal tissue. The statute raises several fundamental questions about this model as displayed by the graphic below.


Abortion Clinic
(1) Receives payment for fetal tissue. How much?
(2) Reasonable costs? How much?
$$$
Middleman Procurement Business
(1) Pays Abortion clinic for fetal tissue? How much?
(2) Receives payment from researcher? How much?
(3) Reasonable costs? How much?
$$$
Researcher
Pays Procurement Business for fetal tissue? How much?

The middleman investigation, and in particular the investigation of StemExpress, produced information about several PPFA affiliate clinics.[965] In particular, it became clear that StemExpress was doing all the work to obtain consent for donation from individual patients, that StemExpress was doing the work of harvesting the fetal tissue after an abortion was complete, and that StemExpress was doing the work and passing on its costs of shipping to customers. This raised a profound issue for the Panel: Both the middleman and the PPFA affiliate clinic were claiming the same expenses against their revenue to show a loss on fetal tissue sales.

9. PPFA Affiliates and StemExpress Claim the Same Expenses

Attorneys for StemExpress created several cost estimates that purport to show that StemExpress loses money each time it procures a fetal tissue sample and ships it to a customer. These are graphically summarized in the column with orange numbers in the chart below.

COMPARISON OF STEMEXPRESS COST ANALYSIS WITH GENERALLY ACCEPTED INDUSTRY STANDARDS FOR ONE UNIT OF FETAL TISSUE IN 2013

COST ITEMS AND ESTIMATE PRODUCED BY STEMEXPRESS

ADJUSTED BASED ON REASONABLE INDUSTRY STANDARDS

COSTS ALLOCATED TO MATERNAL BLOOD ESTIMATED AT 50%

Cost Item	Description	Estimated Time	Estimated Cost/Expense	Recalculated Time	Recalculated Cost/ Expenses	½ Costs for Maternal Blood
Procurement Management Labor	Receive and evaluate purchase order, enter into Computer system and task board, assign to clinics.	1 hour x $35	**$25.00**	.5 hour x $35	$12.50	**$ 6.25**
Packaging Supplies Labor	Packaging all supplies needed for procurement.	1 hour x $10	**$10.00**	.5 hour x $10	$5.00	**$2.50**
Shipping	Supplies to Clinic	N/A	**$15.00**		$15.00	**$7.00**
Mileage	Mileage paid to technician (.56/mile)	N/A	**$75.00**		$75.00	**$35.00**
Supply cost	Box, conical tube, media, petri dish, labels, biohazard bag, gel packs, etc.	N/A	**$30.00**		$30.00	**$15.00**

[965] *See* Chapter V.A *supra*.

Technician Base Labor	Patient consent, procurement, paperwork packaging.	8 hour x $10	**$80.00**	1 hour x $10	$10.00	**$5.00**
Technician Supplemental Compensation	Technician Supplemental Compensation	N/A	**$30.00**		$0.00	**$0.00**
Clinic Reimbursement	Technician space, storage of supplies, blood draw chair usage, consent space	N/A	**$55.00**		$55.00	**$27.50**
Infectious Disease Draw	Supplies: tubes, labels, needle, biohazard bag, etc.	N/A	**$15.00**		$15.00	**$7.50**
Infectious Disease Screening	Screening for HIV, HepB, HepC, LCMV	N/A	**$70.00**		$70.00	**$35.00**
Shipping	Average Shipment cost to the Lab (blood and/or tissue)	N/A	**$20.00**		$20.00	**$10.00**
Procurement Management Labor	Review paperwork, communications with courier, communications with researcher	1 hour x $35	**$35.00**		$35.00	**$5.00**
Product Receipt	Receipt of product at front desk, check into Sage, check into log	1 hour x $15	**$15.00**	.25 hour x $15	$4.00	**$2.00**
Inventory & Supply Management	Prorated stores management	1 hour x $20	**$20.00**	.25 hour x $20	$5.00	**$2.50**
			$495.00		**$351.50**	**175.75**

Shown in orange, the cost estimates produced by the attorneys are inconsistent with accounting records produced by StemExpress itself. For example, StemExpress lists clinic reimbursement defined as "Technician space, storage of supplies, blood draw chair usage, consent space" which the Panel found was **not** an actual payment made by StemExpress to the clinics. Also, the costs associated with shipping and infectious disease are passed on to the customer and thus are **not** a cost to StemExpress. Finally, management labor costs at one hour per item ordered, which are counted twice, are dramatically inconsistent with the number of orders actually handled by StemExpress. Similarly, StemExpress estimates do **not** allocate any costs (such as mileage) to maternal blood which is harvested at the abortion clinic at the same time the human fetal tissue is harvested.

StemExpress has consistently refused to produce subpoenaed accounting documents that the Panel requires to complete its analysis. In the summary below, StemExpress claimed as expenses various items that were reimbursed by customers. Our forensic accounting analysis revealed that if these reimbursements were accounted for, they would yield a profit to StemExpress.

Sample review of a sale of maternal blood to customer Baylor per invoice #1940 of 1/12/2013

Sale price for Tissue	$250.00
Disease screening charged to client	$125.00
Shipping charged to client	$85.00
Total Revenue obtained from this sale	$460.00
Estimated cost of Tissue (per above)	$175.75

Sample review of a sale of fetal tissue to customer Baylor per invoice #1940 of 1/12/2013

Sale price for Tissue	$250.00
Disease screening charged to client	$125.00
Shipping charged to client	$85.00
Total Revenue obtained from this sale	$460.00
Estimated cost of Tissue (per above)	$351.00
Excess of revenue over cost	$108.50

StemExpress and other productions reveal that the payments to Planned Parenthood affiliates are for each item of fetal tissue.[966] The graphic below summarizes the known payments to various Planned Parenthood clinics for fetal tissue.

Procurement Business	Planned Parenthood Clinic	2010	2011	2012	2013	2014	2015	Total
ABR	First Avenue	52,075	36,000	20,400	18,600	18,240	-	**145,315**
	Mar Monte	5,390	-	-	-	-	-	**5,390**
	Riverside	16,020	21,660	36,720	33,540	31,740	23,460	**163,140**
	Pacific Southwest	-	-	-	-	-	18,960	**18,960**
	San Diego	-	-	-	-	-	13,080	**13,080**
	San Jose	5,500	-	-	-	-	-	**5,500**
Stem Express	Mar Monte	2,910	48,388	74,625	40,220	40,630	18,955	**225,728**
	Shasta Pacific	-	-	2,520	8,340	8,690	1,375	**20,925**
Novogenix	Los Angeles	-	-	-	-	-	15,750	**15,750**
		81,895	**106,048**	**134,265**	**100,700**	**99,300**	**91,580**	**613,788**

10. Planned Parenthood Production Schedule of their Costs Associated with Fetal Tissue Donation

Deductions from the revenue summarized above were described in Planned Parenthood affiliates' cost estimates produced to the House Committee on Energy and Commerce to each show a net loss resulting from their participation in fetal tissue donation for research. Section 289g-2 makes certain costs associated with fetal tissue allowable as a deduction from and

[966] See StemExpress contracts with PP Mar Monte, PP Shasta Pacific and PP Santa Barbara, [Stem.House.OGR-_000001-6 and 000015-17/Stem.House.Select_0167-172 and 0181-0183], Exhibit 8.25.

valuable consideration received for the tissue. The Panel sought to investigate and analyze these costs from several perspectives:

1) Did the affiliate rely upon an auditor to create a framework for allowing costs?

2) Did PPFA executives take seriously the statute's requirement that profiting from the sale of fetal tissue is a Section 289g-2 violation?

3) Did any middleman organization provide services to the affiliate or claim expenses that would disqualify costs claimed by the affiliate?

4) Are the affiliate-listed costs allowable under the limitations of Section 289g-2?

5) Did the affiliate include job descriptions of its employees for which it listed costs?

Costs Listed by Planned Parenthood Affiliates

Four affiliates provided schedules listing cost and revenue for a one-year time period (FY 2015). These schedules are listed below.[967]

Planned Parenthood Los Angeles

Listed costs:	$16,815.65
Reimbursements:	$15,750.00
Net Loss:	($1,065.65)

Planned Parenthood Mar Monte

Listed costs:	$21,245.32
Reimbursements:	$18,955.00
Net Loss:	($2,209.32)

Planned Parenthood Northern California

Listed costs:	$16,815.65
Reimbursements:	$15,750.00
Net Loss:	($830.64)

[967] Planned Parenthood Fetal Tissue Expenses Chart, Exhibit 8.23.

Planned Parenthood Pacific Southwest

Listed costs:	$16,815.65
Reimbursements:	$15,750.00
Net Loss:	($18,670.84)

11. The Planned Parenthood Cost Documents Are Unsupported

In the transmittal letter to the Committee on Energy and Commerce dated November 10, 2015, that included the PPFA affiliate fetal tissue cost estimates, the Counsel for PPFA explains that these are estimates only:

> The affiliates have each performed a good-faith accounting of their costs associated with facilitating fetal tissue donation, and have demonstrated conclusively that those costs exceeded the payments they received. Your September 30 Letters separately request that the affiliates provide to the Committee all audits conducted of the fetal tissue donation programs, along with documents, such as calculation sheets and budgets, relating to the reimbursements they received. We have determined that these four affiliates either did not conduct or cannot locate contemporaneous cost analyses, or secure independent audit opinions as articulated by PPFA's then-existing guidance.[968]

This representation is consistent with the non-production of such documents requested a year later by the Panel. In fact, the Planned Parenthood affiliate costs requests are riddled with flaws. And they are inconsistent with the statements of PPFA's own employees. In an interview with [PP Doctor #1],[969] Committee on Energy and Commerce staff asked her about the history of contracting with Novogenix, a tissue procurement middleman. The memorandum described above in Section 5 was in effect at the time, so the staff wanted to know whether an auditor was consulted when evaluating the per specimen payment from Novogenix:

> In 2010—understanding was she received in and was aware of it [the MS&G] floating around in head, with updates; recall consulted protocol in 2010-**did not use independent auditor, did informal rough calculation of cost.**[970]

The Panel interviewed [PP Witness #2] on October 19, 2016. The interview focused on a contractual arrangement between Planned Parenthood Gulf Coast and the University of Texas Medical Branch which called for the Planned Parenthood affiliate to provide fetal tissue to the

[968] Letter from K. Lee Blalack II, O'Melveny & Myers LLP, to the Hon. Fred Upton, the Hon. Timothy Murphy, and the Hon. Joseph Pitts (November 10, 2015) at 3, Exhibit 8.26.
[969] [PP Doctor #1] Briefing (Sept. 18, 2015), Exhibit 8.16.
[970] *Id.* at 4 (emphasis added).

medical school. [PP Witness #2] was asked how she arrived at the costs related to how much to charge the medical school:

> Q Have you seen this agreement ever before?
>
> A I have.
>
> Q And is this the type of thing that you would participate in the development of?
>
> A I have.
>
> Q Okay. So the question—one of the questions that we have is, when you decided staff time for consent [$]50, sterile [$]100, did you do—how did you come up with those numbers?
>
> A They were basically **back-of-the-envelope-type calculations** involving the time it takes staff to conduct those procedures relative to the study.[971]

[PP Witness #1] also was asked a series of questions about StemExpress making a profit in its contractual collaboration with PP affiliates. The questions were focused on the markup of an intact fetal brain from $55 paid to the Planned Parenthood affiliate versus the $3,340 charged to the customer:

> Q Three thousand three hundred and forty. Now, that—that particular brain is shipped—is shipped out of the clinic.
>
> Now, here's the scenario, and we'll be done. Tissue tech learns who's available for contributing. She goes and gets the consent. She gets paid a bonus. The Planned Parenthood clinic, I believe, gets $55, but it's in the range of [$]30 to [$]100, and StemExpress resells that brain for over $3,000.
>
> And you'll notice—you may notice on there [the invoice] that the shipping and maybe some other things are paid for by the customer.
>
> Now, does that bother you?
>
> A No.
>
> Q Okay. So if StemExpress made a profit by marking up what they paid for the tissue 2,800 percent, would that bother you?
>
> A I don't know that they're ma[r]king [sic] it up. I have no idea what their costs are.

[971] Transcribed Interview of [PP Witness #2] at 26-27 (Oct. 19, 2016) (emphasis added), Exhibit 8.27.

Q Well, if they—if it was a profit would it bother you?

A It's really none of my business, no.

Q It's not your business what StemExpress does, but how is not your business when StemExpress does this work inside of Planned Parenthood Federation clinic?

They offer a profitable situation of the clinic. They get the consent. They get the tissue, and they resell it, and you're in a contractual relationship with them. They're a vendor of Planned Parenthood. If it was a profit of 2,800 percent, would that raise a red flag for you as an organization? . . .

Mr. Bell. What I'm trying to understand, counsel, is the management mindset of a senior manager at Planned Parenthood who may or may not have seen this error before today and may or may not have known how the consent works or how the tissue tech is paid or what StemExpress marks up the tissue for.

I'm saying as the senior manager of Planned Parenthood that oversees her scope of work, is it a concern—so when they're in a contractual relationship—is making what looks like a huge profit on selling fetal tissue.

[PP Witness #1]. So the first thing that I want to just correct is you said that they were offering a profitable service or something to our affiliates, which they're not. Our affiliates don't make a profit on tissue donation.

Mr. Bell. But I just –

[PP Witness #1] I just wanted to correct that statement.

Mr. Bell. I think you're right to correct that. My concern, my question to you, Doctor, is not to reach a factual conclusion. You're one of the top people in this organization. What I want to learn is are you concerned when an organization comes to your organization and offers a profit to them, which seems to violate the guidance in the legal memo that we read earlier.

BY MR. BELL:

Q Is that a concern to you?

They come in and say, "I know you're not supposed to make a profit, but partner with us because it'll be profitable.". . .

> Mr. Bell. And here's a more granular example. It looks like StemExpress, who for several years only did abortion clinics, now they do lots of stuff, lots of other stuff. But for several years of their life they only got tissue from Mar Monte, Shasta Pacific, and resold it at prices like this.
>
> And I just want to know what's sort of the global management perspective of a Planned Parenthood senior leader like you if that's a 2,800 percent profit.
>
> BY MR. BELL:
>
> Q Would that bother you?
>
> A So just so that I'm clear on the question you're asking me if it bothers me that StemExpress makes money reselling the tissue?
>
> Q Yeah.
>
> A It's none of my concern. It doesn't bother me.[972]

In an undercover video, [PP Witness #4] told journalists that [PP Lawyer], of PPFA's legal department, had warned them about the federal laws surrounding fetal tissue donation:

> Buyer: Yeah. And as far as the specifics of remuneration, is there any guidance from [PP Lawyer] other than how to—because one thing we've talked about with [PP Witness #1] before is just to make sure that's kind of back-ended in the right way so that it's a reasonable covering—
>
> [PP Witness #4]: Yes he gave very clear instructions, that the federal law says you cannot be remunerated for tissue, what you can be remunerated for is costs of collection. So if there's admin costs, extra staff time, transport fees, materials or supplies, you just need to really document what those are, and say, you know, "This is $100 worth of whatever, or $50 worth of, admin time, materials that it's costing us." So that if somebody comes in and says, "You're collecting money for tissue," we'll say, "No we're not, we're collecting money for administrative costs." So he gave them 4 or 5 things that they should consider. So he was very clear about that.[973]

[972] Transcribed Interview of [PP Witness #1] at 156-59 (Oct. 6, 2016), Exhibit 8.28.
[973] Center for Medical Progress, Transcript of Meeting with [PP Witness #4] at 16 (March 18, 2015), Exhibit 8.29.

12. Comparison of Costs Claimed by Planned Parenthood Affiliates and Expenses Claimed by Fetal Tissue Middleman StemExpress

The Panel took note of both StemExpress and the Planned Parenthood clinics listing the same expenses as costs against their revenue for fetal tissue transfers. In StemExpress' case, they list costs paid by the customer, but both StemExpress and Planned Parenthood list the same costs in their production to the Panel. This comparison is described in the graphic chart below.

StemExpress vs. Planned Parenthood

Cost Deduction Chart[974]

	Claimed By		
Cost Type	**Planned Parenthood**	**StemExpress**	**Comments: PP vs. SE**
Supplies	(Mar Monte) Y	Y	"Supplies/Equipment" for tissue collection and consent vs. "Supplies to clinics" and "supply costs"
Consent	(Mar Monte) Y	Y	"Staff time interpreting… verifying and signing…scanning" consent forms" vs. "patient consent," and "consent space"
Handling supplies	(Mar Monte) Y	Y	"Staff Time cleaning Stem Express Equipment" vs. "Storage of supplies"
Shipping supplies	(Mar Monte) Y	Y	"Shipping labels" vs. "packaging all supplies needed for procurement" and "Shipment to lab"
Work space	(Mar Monte) Y	Y	"Use of Space by StemExpress Representatives" vs. "technician space" and "consent space"

[974] Planned Parenthood Mar Monte and Shasta Pacific Fetal Tissue Costs [PPMM-HOU_E&C-000001-02, PPNC-HOU_E&C-000001-2], Exhibit 8.23.

Consent	(Shasta-Diablo) Y	Y	"Costs associated with obtaining patient consent…Staff time verifying and signing…scanning" consent forms" vs. "patient consent," and "consent space."
Tech Transportation	(Shasta-Diablo) Y	Y	"Costs associated with transportation...tubing for Sterile Instrument Transportation" vs. "packaging all supplies needed for procurement" and "Shipment to lab"
Tissue screening	(Shasta-Diablo) Y	Y	"Staff Time screening donated tissue" vs. "Screening for HIV, HepB, HepC, LCMV"
Work Space	(Shasta-Diablo) Y	Y	"Use of Space by StemExpress Representatives: Dedicated work areas and Storage areas" vs. "technician space" and "consent space"

The chart above illustrates how two Planned Parenthood clinics and a middleman company, StemExpress, both claimed expenses for the same costs. This "double counting" found by the Panel's forensic accounting analysis raised serious doubts about whether the affiliates' estimates were anything more the "back of the envelope" guesses. The timing of the creation also raises the question whether the cost estimates were created for public advocacy purposes.

13. Planned Parenthood Affiliates' Cost Schedules Compared to the Defined Allowable Costs in 42 U.S.C. § 289g-2

The Panel noted that the language describing "allowable costs" under Section 289g-2 are costs associated with activities that are downstream from the tissue procurement process that takes place inside an abortion clinic with the exception of "transportation." In virtually every example examined by the Panel, "transportation" was a cost passed on to the end user or customer, usually a university researcher.

- Since Section 289g was passed by Congress at a time when the state of biomedical research anticipated that fetal tissue would be transplanted into human subjects, the statute allows costs associated with *"implantation."* Since implantation does not occur at the abortion clinic level, it is unreasonable that any costs counted against payments for fetal tissue could be claimed by either a clinic or by a middleman tissue procurer.

- *Processing* of fetal tissue occurs in two places: (1) some middleman companies "process" fetal tissue into concentrated cell lines for specific research applications or the end user processes the tissue into a cell line or other research tool such as a humanized mouse. Thus, processing by definition cannot take place at the Planned Parenthood affiliate clinic.

- *Preservation* refers to one of several methods whereby recently harvested fetal tissue is stabilized so the cell properties will not deteriorate. This could be immediate refrigeration (possible cost to an affiliate clinic), placing the tissue in a serum such as a bovine calf serum for stabilization and shipment, or simply placing the tissue in packaging with an ice pack for shipping. Other preservation would be undertaken by the end user at the time of receipt.

- *Quality control* is similarly not the province of the abortion clinic. The remains of an unborn child are caught in a nominally sterile pan. A tissue technician sorts through the remains and harvests the tissue for which she has customer orders. In virtually all cases, the tissue is packaged immediately for shipping. This work is usually performed in a clinic pathology lab which exists to make sure all body parts are removed from the mother's uterus and then the remains are stored for disposal. There is no quality control performed by the abortion clinic at this point in the fetal tissue procurement process. Quality control refers instead to the downstream effort by the researcher to assure the purity and integrity of their specimen, anticipated at the time of passage of § 289g to be transplant into a human subject.

- *Storage* is a possible cost to an affiliate clinic if it allowed harvested tissue or partial baby cadavers to be stored by refrigeration. No Planned Parenthood clinic reported that it acquired additional refrigeration capacity as a result of participation in a fetal tissue donation project.

The locus of most storage costs would be again by the downstream end user, a researcher who may store a cell concentration or even frozen fetal tissue for months or years.

The chart below reveals that the claimed cost schedules produced by Planned Parenthood actually attempt to allocate costs to the clinics that are more properly assigned to the middleman procurer or the end user researcher.

Planned Parenthood Costs Compared to Allowable Reimbursements Under 42 U.S.C. § 289g-2

Planned Parenthood Affiliates Claimed Costs	Transportation	Implantation	Processing	Preservation	Quality Control	Storage
Planned Parenthood Mar Monte/SE						
Staff Time Coordinating and Managing Patient Flow	NO	NO	NO	NO	NO	NO
Staff Time Supervising / Coordinating with Stem Express Representative	NO	NO	NO	NO	NO	NO
Supplies / Equipment	NO	NO	NO	NO	NO	NO
Operations Costs	NO	NO	NO	NO	NO	NO
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Staff Time Interpreting Consent Forms	NO	NO	NO	NO	NO	NO
Staff Time Verifying and	NO	NO	NO	NO	NO	NO

Signing Consent Forms						
Staff Time Scanning Consent Forms	NO	NO	NO	NO	NO	NO
Supplies / Equipment	NO	NO	NO	NO	NO	NO
Operations Costs	NO	NO	NO	NO	NO	NO
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Staff Time Cleaning Stem Express Equipment	NO	NO	NO	NO	NO	NO
Staff Time Invoicing Stem Express	NO	NO	NO	NO	NO	NO
Supplies / Equipment	NO	NO	NO	NO	NO	NO
Operations Costs	NO	NO	NO	NO	NO	NO
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Use of Space by Stem Express Representatives	NO	NO	NO	POSSIBLY	NO	NO

Staff Time Supervising / Coordinating with Stem Express Representative	NO	NO	NO	NO	NO	NO
Operations Costs	NO	NO	NO	NO	NO	NO
Planned Parenthood Shasta Pacific						
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Staff Time Verifying and Signing Consent Forms	NO	NO	NO	NO	NO	NO
Staff Time Scanning Consent Forms	NO	NO	NO	NO	NO	NO
Operations Costs	NO	NO	NO	NO	NO	NO
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Staff Time Coordinating Courier Service for Stem	POSSIBLY	NO	NO	NO	NO	NO

Express Representative						
Staff Time Screening Donated Tissue	POSSIBLY	NO	NO	NO	NO	NO
Staff Time Invoicing Stem Express and Coordinating Program	NO	NO	NO	NO	NO	NO
Supplies / Equipment	NO	NO	NO	NO	NO	NO
Operations Costs	NO	NO	NO	NO	NO	NO
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Use of Space by Stem Express Representatives	NO	NO	NO	POSSIBLY	NO	NO
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Planned Parenthood Mar Monte/ABR						
Staff Time Communicating with ABR	NO	NO	NO	NO	NO	NO

Representative Prior to Collection						
Staff Time Supervising / Coordinating with ABR Representative	NO	NO	NO	NO	NO	NO
Supplies / Equipment	NO	NO	NO	NO	NO	NO
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Staff Time Discussing Program with Patients, Obtaining Consent or Declination	NO	NO	NO	NO	NO	NO
Staff Time Preparing Consent Forms, Whiteboard, and Anonymized Consent List	NO	NO	NO	NO	NO	NO
Staff Time Sending Consent Forms to Administrative Office	NO	NO	NO	NO	NO	NO

Supplies / Equipment	NO	NO	NO	NO	NO	NO
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Extra Tissue Examination Time	POSSIBLY	NO	NO	NO	NO	NO
Staff Time Transferring Tissue to ABR Representative	NO	NO	NO	NO	NO	NO
Staff Time Managing Deliveries, Moving Boxes, & Discarding Documents for ABR Representative	POSSIBLY	NO	NO	NO	NO	NO
Staff Time Coordinating Courier Service for ABR Representative	POSSIBLY	NO	NO	NO	NO	NO
Staff Time Invoicing ABR Reimbursement	NO	NO	NO	NO	NO	NO
Staff Time Installing Shelf for ABR Representative	NO	NO	NO	NO	NO	NO

Supplies / Equipment	NO	NO	NO	NO	NO	NO
General Administrative Overhead	NO	NO	NO	NO	NO	NO
Use of Space by ABR Representatives	NO	NO	NO	NO	NO	NO
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Planned Parenthood Los Angeles						
Staff Time Preparing Surgical List and Internal Coordination	NO	NO	NO	NO	NO	NO
Staff Time Coordinating with Novogenix Representative	NO	NO	NO	NO	NO	NO
Staff Time Attending Morning Meetings' Discussion of Donation Program	NO	NO	NO	NO	NO	NO
Staff Time Managing and	NO	NO	NO	NO	NO	NO

Overseeing Tissue Donation Program						
Supplies / Equipment	NO	NO	NO	NO	NO	NO
Management & General Overhead	NO	NO	NO	NO	NO	NO
Staff Time Discussing Program with Patients, Obtaining Consent or Declination	NO	NO	NO	NO	NO	NO
Staff Time Preparing, Processing, and Photocopying Consent Forms	NO	NO	NO	NO	NO	NO
Supplies / Equipment	NO	NO	NO	NO	NO	NO
Management & General Overhead	NO	NO	NO	NO	NO	NO
Staff Time Transferring Tissue to Novogenix Representative	POSSIBLY	NO	NO	NO	NO	NO

Staff Time Disposing of Unused Tissue	NO	NO	NO	NO	NO	NO
Staff Time Coordinating with Novogenix Representative	NO	NO	NO	NO	NO	NO
Staff Time Invoicing Novogenix Reimbursement	NO	NO	NO	NO	NO	NO
Staff Time Revising Electronic Health Records	NO	NO	NO	NO	NO	NO
Management & General Overhead	NO	NO	NO	NO	NO	NO
Use of Space by Novogenix Representatives	NO	NO	NO	POSSIBLY	NO	NO
Management & General Overhead	NO	NO	NO	NO	NO	NO

14. Job Descriptions of Planned Parenthood Staff ***do not*** Include any Reference to Tasks or Responsibilities Associated with Fetal Tissue

After reviewing the cost schedules of Planned Parenthood affiliates, the Panel requested and obtained job descriptions from the counsel representing the entities. The Panel sought to determine whether job descriptions or job announcements included any reference to tasks related to fetal tissue donation. The Panel similarly sought any information that the affiliates' participation in fetal tissue donation required the hiring of new staff. The Planned Parenthood affiliates produced no evidence to support either job description adjustments or hiring of new employees due to the tasks involved in any aspect of fetal tissue donation. The chart below summarizes the job descriptions of the employees at the affiliates.

Review of Staff Time Claimed by Planned Parenthood as Part of Costs Associated with Collecting and Processing Fetal Tissue as Compared to Job Descriptions of Staff

Staff Title	Includes Fetal Tissue	Does Not Include Fetal Tissue
Planned Parenthood Mar Monte:		
Health Services Specialist: Provides direct service in all health centers, provides clients with accurate info regarding PP services, screens patient history, etc.		☐
Abortion Coordinator: Scheduling, notify patients of follow-ups, provide medical record transfers, serve as liaison between PPMM and outside lab to follow-upon concerns with results interpretation and transmission.		☐
Center Manager: Responsible for the day-to day management of all health center activities.		☐
Chief Medical Officer: Oversee maintenance of medical records, credentialing of staff, hire and supervise senior staff, represent PPMM on managed care plan committees, and local, state, and national task forces, committees and Boards.		☐
Clinician: Review and interpret medical/social history of patients, perform screening procedures/exams, interpret lab		☐

data, provide contraceptive methods, provide non-surgical abortion, act as medical consultant to clinic staff.		
Check-Out Specialist: Posts charges to and ensures accuracy of Electronic Practice Management system, sends CDS to billing department, handles patient check-out, calculates and collects fees, solicits contributions, schedules future appointments.		☐
Assistant Lab Manager: Match specimens to requisitions, prepare specimens for testing, notify clinics of positive results, perform/supervise laboratory testing in compliance with appropriate policies/guidelines.		☐
Accountant: Conduct analysis as needed for the purpose of verifying appropriate allocation of Accounts Payable duties, responsible for completeness and accuracy of Accounts Payable vouchers, review and reconcile vendor statements to include analyzing charges and payments. Verify and maintain all rental, lease, and contract accounts.		☐
Registered Nurse: Provide care for patients under established Medical Protocols, perform various medical procedures, administer medication, assess status of patients.		☐
Center Manager: Ensuring efficient coordination, management of workflow, efficient implementation of new services, and management of health center staff resources for services provided. Assure medical center's compliance with agency's state and federal regulations. Oversight of supervisory responsibilities in accordance with policies and applicable laws.		☐
Medical Assistant: Responsible for all supporting functions in the delivery of reproductive health care services. Assist patients by providing testing, screening,		☐

and education required for the provision of medical productive health care.		
Clinician: Provide quality patient care including exam, diagnosis, treatment, education and counseling for clients in accordance with agency protocols.		☐
Surgical Technician: Member of an operating room team during surgical and endoscopic procedures. Serves as a scrub technician in an operating room and provides direct and indirect care to patients before, during, and after surgery.		☐
Medical Director: Responsible for ensuring provision, coordination and oversight of medical services. Assumes responsibility for training, supervisor and evaluation of all clinicians in concert with medical Management Leadership.		☐
Vice President of Patient Services: Ensures the continuing provision of high quality services to all patients. Oversees laboratory services, research and training program teams and clinical compliance and risk management.		☐
Administrative Assistant for Patient Services: Provides secretarial and administrative support to the Vice President, Patient Services, Medical director, and others in the Patient Services department.		☐
Vice President of Medical Services: Responsible for the overall development, management, and supervision of clinic staff and services. Collaborates with other departments to provide community services. Responsible for center planning and fiscal management.		☐

Center Director: Direct oversight for the overall development, management, and supervision of center staff and services. Monitor client volume, capacity and productivity. Provide direct patient care approx. 10-20% of the time. Plan and implement new programs and services as needed.		☐
Abortion Services Coordinator: Assist with management of abortion services, assist Center Director with compliance to protocols and licensing standards, program management including audits, statistical reports, medical follow-up and maintenance of manuals.		☐
Medical Director: proposes recommendations on medical policies, reviews all medical protocols, serves as the Director of Abortion, Ultrasound, Sedation, and Colposcopy Services.		☐
Medical Services Manager: Works with VP of Medical Services and other staff in development of systems, processes, and forms to enhance efficiency at the centers, manages the proficiency testing program, manages the surgical and medication abortion reporting systems, responsible for the abortion complication reports and colposcopy correlation data systems.		☐
Planned Parenthood Pacific Southwest:		
Front Desk: Responsible for greeting and checking-in clients, preparing, scanning and coordinating paperwork, determining payer source, collecting fees/receipts and donations, collecting IDs, answering phones, scheduling.		☐
Center Manager: Manage and oversee the provision and delivery of efficient center operations and client services in a specialty services (abortion, permanent birth control, colpo/LEEP) setting, as prescribed by the Agency's protocols, policies, and procedures.		☐

Flow Coordinator: Develop and maintain a system for optimal center flow. Monitor/minimize wait times and patient/staff schedules, ensure clinicians maximize productivity by arranging patient charts to keep all rooms filled.		☐
Medical Assistant: Obtain medical history, interview and educate clients ensuring informed consent, perform options and abortion education, make appointments/referrals for follow-up services, perform PC and recovery room responsibilities, perform basic lab work.		☐

The Panel concluded that costs associated with fetal tissue transfer, an important activity that requires permission from PPFA, is governed by PPFA guidance, and is not included in any job description, sullies the credibility of a claim that actual costs are associated with the duties of relevant employees.

F. Changing the Method of Abortion Procedure to Obtain More Fetal Tissue

The Panel investigated the possible impact on clinical medical care when a fetal tissue procurement company enters into a contract to procure fetal tissue with a Planned Parenthood affiliate clinic. The middleman company often embeds a tissue technician in a clinic on the days that abortions are performed. The procurement company pays the clinic on a per tissue basis. The number of saleable body parts in many ways depends upon the methodology of the doctor performing the abortion.

Current federal law forbids changing of the method of abortion for the purpose of obtaining tissue, but this prohibition applies only to fetal tissue that is to be used for transplant purposes. The Panel noted the scope of the statute but also learned that in virtually every instance, the doctor performing the abortion had no knowledge of whether the tissue was destined for research or transplantation.

One Panel witness, Dr. Goldstein, was in fact procuring brain tissue from a Planned Parenthood affiliate clinic and using it for transplant purposes.[975] Thus, the Panel sought to determine: (1) whether there was evidence that doctors changed the abortion procedure to serve the goal of fetal tissue donation; and (2) whether particular doctors met with or learned from the contracted embedded tissue technicians about what body parts they were procuring that day in a way that promoted altered abortion procedures.

[975] "We use fetal astrocytes, which are vital to these investigations. . . . Now, as a result of the work in animals, we have FDA approval to test these fetal stem cells in human patients . . . and have implanted them in four patients within the past year." *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong., at 149 (unedited transcript) (Mar. 2, 2016) (Testimony of Lawrence Goldstein, at 109-111), http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-Transcript-20160302.pdf.

Of additional concern to the Panel was the large number of intact calveriums (skulls) that were being purchased by researchers. Since most second trimester abortions are D&E procedures, the life of the baby is terminated inside the womb through dismemberment of the various body parts. The challenge for procurement of the calverium is its size relative to the amount of cervical dilatation. This inquiry took place during interviews with practicing abortion doctors and relied upon the initial evidence from the CMP undercover videotapes.

1. Changing the Presentation of the Baby to Harvest a Calverium

In one section of a CMP video transcript, the undercover journalist (Buyer) is talking with [PP Witness #1]:

> Buyer: Yeah. Or especially brain is where it's actually a big issue, hemispheres need to be intact, it's a big deal with neural tissue and the progenitors, because those are particularly fragile. If you've got that in the back of your mind, if you're aware of that, technically, how much of a difference can that actually make if you know kind of what's expected or what we need, versus—
>
> [PP Witness #1]**: It makes a huge difference. I'd say a lot of people want liver. And for that reason, most providers will do this case under ultrasound guidance, so they'll know where they're putting their forceps. The kind of rate-limiting step of the procedure is the calvarium, the head is basically the biggest part. Most of the other stuff can come out intact. It's very rare to have a patient that doesn't have enough dilation to evacuate all the other parts intact.**
>
> Buyer: **To bring the body cavity out intact and all that?**
>
> [PP Witness #1]: **Exactly. So then you're just kind of cognizant of where you put your graspers, you try to intentionally go above and below the thorax, so that, you know, we've been very good at getting heart, lung, liver, because we know that, so I'm not gonna crush that part, I'm going to basically crush below, I'm gonna crush above, and I'm gonna see if I can get it all intact. And with the calvarium, in general, some people will actually try to change the presentation so that it's not vertex, because when it's vertex presentation, you never have enough dilation at the beginning of the case, unless you have real, huge amount of dilation to deliver an intact calvarium. So if you do it starting from the breech presentation, there's dilation that happens as the case goes on, and often, the last, you can evacuate an intact**

calvarium at the end. So I mean there are certainly steps that can be taken to try to ensure—

Buyer: **So they can convert to breach, for example, at the start of the—"**

[PP Witness #1]: **Exactly, exactly. Under ultrasound guidance, they can just change the presentation.**

Buyer: Okay.

[PP Witness #1]: So the preparation would be exactly the same, it's just the order of the removal of the products is different. And most people see that as not very—

Buyer: Yea, we're not talking about it needs to be a hysterotomy or anything, or something crazy like that, in order to—there's probably an easier solution to this problem.

[PP Witness #1]: And, we've been pretty successful with that. I'd say.[976]

Thus, the Panel sought to investigate instances of "medically unnecessary" changes to the abortion procedure to obtain fetal tissue for transfer to a customer. In particular, the Panel noted that if the tissue technician was seeking an intact calvarium, the doctor would use an ultrasound to turn the baby to a breech position and then dismember the limbs and torso first so that greater dilation could occur and increase the likelihood that when the time came to remove the calvarium there might be greater dilatation.

This was not the only recounting by [PP Witness #1] of changing the method of abortion to obtain an intact calvarium:

[PP Witness #1]: I let the tech tell me what it is that they need, I usually don't let the trainee do those cases**, I try to do everything as intact as possible, because I know it's a research case**. She seems to be getting what she needs. **Sometimes she'll tell me she needs brain, and we'll leave the calvarium until last, and then try to basically take it, or, actually, you know, catch everything and even keep it separate from the rest of the tissue, so it doesn't get lost.** There will probably be providers who just want to keep

[976] Center for Medical Progress, Transcript of Meeting with Senior Director, Medical Services, Planned Parenthood of America at 11-12 (July 25, 2014), Exhibit 8.30.

> doing things the way that they do them, and others who kind of want to help facilitate the process.[977]

2. Abortion Doctor and Contract Tissue Technician Communicate Prior to the Abortion Procedure

The Panel sought to learn whether contact between the embedded tissue technician and the abortion doctor would lead to modification of the abortion procedure. This issue was raised in the following undercover CMP video:

> Buyer: **So yesterday was a clinic day. So for example, what did you procure?**
>
> [PP Witness #1]: **You know I asked her at the beginning of the day what she wanted, yesterday she wanted, she's been asking, a lot of people want intact hearts these days, they're looking for specific nodes. AV nodes, yesterday I was like wow, I didn't even know, good for them. Yesterday was the first time she said people wanted lungs. And then, like I said, always as many intact livers as possible. People just want—**
>
> Buyer: **Yeah, liver is huge right now.**
>
> [PP Witness #1]: **Some people want lower extremities too, which, that's simple. That's easy. I don't know what they're doing with it, I guess if they want muscle. . . .**
>
> Buyer: And so, if it's something as simple as converting to breech that doesn't require a separate consent? Does that make the procedure take longer? Is that another step for the provider?
>
> [PP Witness #1]: No, it's just what you grab versus what comes out. It doesn't make anything any different.[978]

3. Training of Clinic Personnel and Doctors is Required to Improve the Likelihood of Intact Tissue from an Abortion

The Panel also sought to investigate the impact on the conduct of all clinic employees under a contractual environment with an outside fetal tissue procurement company. For example, would such a contract lead to a change in training personnel about the importance of conducting the abortion procedure in such a way that promotes the harvesting of intact fetal organs?

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[977] Center for Medical Progress videotape produced to the Committee on Oversight and Government Reform FNNF0991_20140408125926 (emphasis added).

[978] Center for Medical Progress, Transcript of Meeting with [PP Witness #1] at 12-13 (July 25, 2014) (emphasis added), Exhibit 8.30.

> PP: The other consideration I think you guys need to make, is who does the training. Because when they do the training, you're basically guaranteed to not get anything.
>
> Buyer: Oh, you mean when it's a provider who's been training.
>
> PP: One who's training, who's basically doing the procedure, it comes out in a thousand—you're not going to get anything intact, so. What we did for a while, and I think it worked pretty well **if there's a trainee, I'd say, any research case, I'll do.** And as you get better, I'll let you do more, but we really need to do this, intact.[979]

This section of transcript provides a further inference that some doctors "work at" their abortion technique in a way that promotes intact fetal organs, while others who are just starting or who are less experienced will produce an abortion that "comes out in a thousand parts."

Some Planned Parenthood doctors took a cavalier approach to providing fetal tissue to a middleman company. In another video,[980] one of the journalists is talking to two Planned Parenthood Gulf Coast workers, [PPGC Abortion Services Official] and [PPGC Abortion Doctor]. They are both excitedly talking about partnering with Biomax (the fake TPC company) and the thrill of pulling out intact body parts. [PPGC Abortion Services Official] leans over to the journalist and says, **"We're a little different than other providers . . . Yeah I'm like, 'Yeah I have like a leg for you!' I'm like, oh shit, if other people were to hear me they'd be like, 'You are f[redacted]ing evil.'"**

4. Panel Interviews Consistent with the CMP Undercover Videos

The Panel did not set out to prove or disprove the veracity of the CMP videos. Instead they were viewed as citizen "leads" that might reveal matters that impact the effectiveness of federal law. The Panel conducted transcribed interviews with Planned Parenthood executives, policy makers, and abortion doctors to further investigate the influence of a contracted tissue technician in Planned Parenthood affiliate clinics. The transcript below recounts a series of questions between Panel staff and a Planned Parenthood executive about the relationship between the doctor and the tissue technician:

> BY MR. BELL:
>
> Q Now, do you think that doctors in your position should huddle in the morning?
> You say, "I like to do that." It's sort of an ongoing tense.

[979] Center for Medical Progress, Transcript of Meeting with [PP Witness #1] at 13 (July 25, 2014) (emphasis added), Exhibit 8.30.
[980] Center for Medical Progress videotape produced to the Committee on Oversight and Government Reform, FNND0569_20150419155634.

Do you think the doctors should huddle with a tissue tech to see what they're procuring, is on their list that day?

A I don't really have a feeling as to whether other doctors did. I like to be helpful.

Q And so you found it helpful that at least on this one day to huddle with the tissue tech and learn what [Procurement Technician] was searching for, what orders she had; is that right?

A I would ask her what tissue she was looking for, yes.

Q All right. Do you think that's a good idea for the whole fetal tissue donation program, that doctors and the tissue techs huddle each morning to discuss what they're going to try and procure that day?

A I think it could be helpful.[981]

After establishing that [PP Witness #1] believed that it would be helpful to meet with the contract tissue technician, she was asked whether she believed the method of the abortion could be changed to increase the likelihood of success:

BY MR. BELL:

Q Let's skip down just a couple lines. You say, "You know, everyone ha[s] [sic] a different technique. So that's the thing. There's definitely local variance like, you know, no two people do a C section the same way; no two people do a hysterectomy the same way; no two people do a D&E the same way."

And this is the part I'm interested in getting your opinion on. "With that said, if you maintain enough of a dialogue with the person who's actually doing the procedure so they understand what the end game is, there are little things, changes they can make in their technique to increase your success."

What did you mean by that sentence?

A I mean exactly what it said, which is their—**providers can change their technique to increase success**.

Q What would that—what would be that change in technique?

A I can't speak for every provider. If—every procedure is different. Providers make changes in technique as they're doing a procedure

[981] Transcribed Interview of [PP Witness #1] at 142 (Oct. 6, 2016), Exhibit 8.31.

the whole time for a variety of reasons. There are probably a myriad of changes that can be made.

Q Okay. Which ones could be made to increase the success of a fetal tissue donation?

A That's a very broad question and I think unless we were talking about a specific procedure I couldn't answer it for you.

Q "There are little things they can make in their technique to increase your success." What are those little things?

A Again, as I mentioned, **a change in instruments, a change in where they're grasping the tissue. These are changes in technique that a provider can make for a variety of reasons.** I—

Q **But it could be made to increase the success of fetal tissue donation.**

A Yes, that's what I'm saying.

Q Okay. Now, so those little techniques that you just described, if there was no fetal tissue donation to increase the likelihood of success, they wouldn't—they wouldn't make those little changes, would they?

A Well, providers make changes in technique for a variety of reasons.

Q Right. They would making them for other reasons, other than likelihood of success; isn't that right?

A [Pause.]

Mr. Bopp. Why don't you ask her the question directly, if she ever changes technique in order to—

Mr. Bell. Well, you suggest that providers may include—there are little things they can make in their technique to increase their success. You said what those were.

BY MR. BELL:

Q Now, the question is: if there was no fetal tissue donation, those little things, changes that would be made to increase their likelihood of success, those wouldn't be made, would they?

A Well, I can't say across the board they wouldn't be made because there's probably other reasons that a provider during a procedure—

Q **They wouldn't be made for the purpose of getting fetal tissue, would they?**

A No, they wouldn't.

Q So they would be made for other reasons.

A Yes.

Q **So one set of little changes is chosen for other medical reasons, and one set of little changes could be chosen to increase the likelihood of success.**

A Yes.

Q Thank you.[982]

It is clear that the PPFA executive in charge of directing the MS&G guidelines, [PP Witness #1], altered the method of the abortion procedure in her own practice. It is also clear that she has not complied with the directive of the MS&G manual regarding the requirement to affirm that the method of the abortion has *NOT* been changed to promote fetal tissue donation. The guidelines specifically require, "Notation signed by the clinician performing the abortion that . . . . no substantive alteration in the timing of terminating the pregnancy or of the method used was made for the purpose of obtaining the blood and/or tissue.[983]

During an interview with Panel staff, [PP Witness #1] was asked:

Q Do you sign those documents after every abortion you've participated in where there was a donation of blood or tissue?

A Are you asking me if I have personally signed a—a statement to this effect?

Q Yes.

A I have never signed a statement to this effect.

Q Have you ever been a clinician performing an abortion?

[982] Transcribed Interview of [PP Witness #1] at 181-82 (Oct. 6, 2016) (emphasis added), Exhibit 8.32.
[983] Programs for Donation of Blood And/Or Aborted Pregnancy Tissue For Medical Research, Education, or Treatment (Revised, June 2011) [PPFA-HOU_E&C-000029-30], Exhibit 8.33.

A I think we know I have.

Q But this is in the manual, and it says that someone is supposed to sign this document noting these three square bullets. Am I misunderstanding something?

A No, I don't think you are. . . .

Q. Well, you never signed on at any PP where you worked.

A That's correct.[984]

G. Planned Parenthood Affiliates Violated the Federal Guidelines on Patient Consent

1. Summary

Planned Parenthood affiliates were provided a form as part of the MS&G guidelines to obtain consent from patients for fetal tissue donations.[985] Some affiliates contracted with tissue procurement businesses (TPB's) who embedded technicians inside the affiliate clinics and who also provided their own version of a patient consent form.[986] The Panel learned that the form sanctioned for use by PPFA and used by Planned Parenthood abortion clinics and the forms often provided by outside TPB's do not meet federal consent requirements. Under the principles outlined in the Belmont Report, human research subjects must provide informed consent before they participate in a study. During the Panel's hearing on *Bioethics and Fetal Tissue*, witnesses agreed that Planned Parenthood's consent form was insufficient for obtaining informed consent.[987] Further, a comparison of Planned Parenthood's form and the form used by another fetal tissue supplier highlights the stark differences between a consent process that fails to meet federal requirements and a sufficient consent process. Finally, Planned Parenthood executives admitted that the form was legally insufficient.

2. Legal background[988]

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created on July 12, 1974, with the enactment of the National Research

[984] Transcribed Interview of [PP Witness #1] at 178-82 (Oct. 6, 2016), Exhibit 8.32
[985] Planned Parenthood consent form, [STEM.HOUSE.OGR_000007-8 / STEM.HOUSE.SELECT_0173-4] Exhibit 8.34
[986] Stem Express consent form, [STEM.HOUSE.OGR_00009-12 / STEM.HOUSE.SELECT_0175-0178] See Exhibit 8.35
[987] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong., (unedited transcript) (Mar. 2, 2016) (testimony of Paige Cunningham, at 77, testimony of Lawrence Goldstein at 149). http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-Transcript-20160302.pdf
[988] For a more detailed examination of these laws, see Chapter 2 *supra*.

Act.[989] The need for this Commission and for standardized protections for human research subjects became painfully evident after the Tuskegee Syphilis study received public scrutiny in 1972. One of the striking problems with the Tuskegee Syphilis study was the complete absence of informed consent from study participants. There was no evidence that the researchers had informed the participants, who thought they were receiving medical treatment, of the study or its real purpose—in fact, they were *misled* and "had not been given all the facts required to provide informed consent."[990]

Given that background, it is not surprising that "respect for persons" is one of the three principles of biomedical research included in the Commission's Belmont Report. Obtaining informed consent from patients or study participants is a critical component of respecting persons. Today, laws and regulations require informed consent from study participants. Under the "Common Rule,"[991] human subjects must give informed consent before research may take place. Further, an Institutional Review Board (IRB) must review the proposed research project, and IRB approval requires researchers to obtain informed consent.[992] Also, under federal law, research using fetal tissue requires a mother's written consent.[993] State anatomical gift acts also require informed consent.

3. The Panel asks experts to evaluate Planned Parenthood's consent form

During the Panel's hearing on *Bioethics and Fetal Tissue*, Rep. Vicky Hartzler (MO-4) addressed an important statement in the Belmont Report regarding informed consent—that "inducements [to consent] that would ordinarily be acceptable may become undue influences if the [research] subject is especially vulnerable."[994] She asked an ethics expert if a form known to be widely used by Planned Parenthood abortion clinics to obtain a mother's consent to donate fetal tissue complied with "HHS's mandate against inducement."[995] The form stated:

> Research using the blood from pregnant women and tissue that has been aborted has been used to treat *and find a cure* for such diseases as diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS."[996]

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[989] P.L. 93-348.
[990] *See* The Tuskegee Timeline, CDC, http://www.cdc.gov/tuskegee/timeline.htm.
[991] 45 C.F.R. § 46.
[992] 45 C.F.R. § 116.
[993] 42 U.S.C. § 289g-1.
[994] The Belmont Report, Office of the Sec., Ethical Principles and Guidelines for the Protection of Human Subjects of Research, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979), http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/.
[995] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong. At 77 (unedited transcript) (Mar. 2, 2016), http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-Transcript-20160302.pdf.
[996] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong., Majority exhibit A-3 (Mar. 2, 2016), http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-20160302-SD030.pdf (emphasis added).

The witness agreed that this was an important question, because the "idea of the promise of cures" found in the form was a "very powerful motivator."[997] The witness also indicated that the "consent" form was deficient in other ways: "The concern I have is that the standards that we have typically for fetal tissue donation are just absent here. And so in addition to the voluntariness, there is just the thoroughness of the consent [that] seems to be missing in this form."[998]

A researcher invited by the minority to testify agreed, stating that the form would not have "made it past" his IRB.[999] The testimony provided by all witnesses invited by both the majority and minority raised concerns that the principles embodied in the Belmont Report, and later incorporated into federal regulations, are not being followed by abortion providers seeking consent for the donation of human fetal tissue.

4. Planned Parenthood's consent form is inadequate compared to other entities' consent forms

The stark contrasts between Planned Parenthood's consent form and forms used by other entities providing fetal tissue further demonstrate the inadequacies of Planned Parenthood's "consent" process. In addition to containing wildly inaccurate claims about past results from fetal tissue research, Planned Parenthood's one-page form fails to provide basic information about the purpose for which the donation is being sought and the precise nature of the "pregnancy tissue" being donated.

The University of Washington Birth Defects Research Laboratory's lengthy consent form, in contrast, states the purpose of the study (*i.e.*, to study birth defects and other diseases), and graphically describes aspects of the fetal tissue procurement process. Further, the form acknowledges that "[e]xamples of tissue collected and sent to scientists for study are: brain, liver, kidney, ovary or testis, eyes, and skin."[1000] In other words, the mother is being asked to donate her deceased infant's body parts, not mere "pregnancy tissue" (as it is described in the Planned Parenthood form).

The Panel also uncovered a series of tissue procurement contracts between StemExpress and three abortion clinics: Planned Parenthood Mar Monte (PPMM), Planned Parenthood Shasta Pacific (PPSP), and Family Planning Specialists Medical Group (FPS). PPMM and PPSP may have used both StemExpress' consent form and the Planned Parenthood consent form described

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[997] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong., at 77 (unedited transcript) (Mar. 2, 2016), http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-Transcript-20160302.pdf.
[998] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong., at 77 (unedited transcript) (Mar. 2, 2016) (testimony of Paige Cunningham), http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-Transcript-20160302.pdf.
[999] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong., at 149 (unedited transcript) (Mar. 2, 2016) (testimony of Lawrence Goldstein), http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-Transcript-20160302.pdf.
[1000] University of Washington Birth Defects Research Laboratory, Consent form for the Donation of Embryonic or Fetal Tissue, Exhibit 8.36.

above. StemExpress' form also fails to meet federal requirements and leads with extravagant promises:

> Research using donated tissue and blood is *currently underway* to uncover the causes of and *ultimately find cures* for things like: Heart Disease, Diabetes, Parkinson's Disease, Sickle Cell Anemia, Leukemia, Lymphoma, Cancer, Spinal Cord Disease, and many more. [1001]

Further, the StemExpress form fails to provide any details regarding the purposes for which donated tissue may be used. Like Planned Parenthood's form, the StemExpress form refers to "pregnancy tissue" without acknowledging the nature of that tissue (*e.g.*, fetal heart, lungs, eyes).

5. The Planned Parenthood consent form does not indicate whether the tissue will be used for education, research, or treatment, including transplantation

As discussed above, the Planned Parenthood consent form does not provide any detailed information about how donated fetal tissue will be used—the form simply states that "blood and/or the tissue from the abortion [will be] used for education, research, or treatment." Further, the form states that the patient "understand[s] that there will be no changes to how or when [her] abortion is done in order to get [her] blood or the tissue."[1002]

Given that neither the abortion provider nor the patient knows the intended use for the tissue, and that the consent form explicitly states that there will be "no changes" to the patient's abortion procedure, Planned Parenthood is obligated to comply with the federal law stating, "No alternation of the timing, method, or procedures used to terminate the pregnancy [may be] made solely for the purpose of obtaining the tissue."[1003]

<u>Planned Parenthood Executives agreed that the consent form was legally insufficient</u>

During an interview with Panel staff, [PP Witness #1] agreed that Planned Parenthood's consent form was problematic:

> If I'm evaluating the form now, you are correct. To my knowledge there is no cure for AIDS. So that is probably an inaccurate statement. . . . a consent form should not have an incorrect statement.[1004]

[PP Witness #2] stated, "I would agree that that is insufficient for obtaining informed consent, correct."[1005]

[1001] *See* Exhibit 8.34
[1002] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong., Majority exhibit A-3, at 3 (Mar. 2, 2016), http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-20160302-SD030.pdf.
[1003] 42 U.S.C. § 289g-1(b)(2)(A)(ii).
[1004] Transcribed Interview of [PP Witness #1] at 131-32 (Oct. 6, 2016), Exhibit 8.37.
[1005] Transcribed Interview of [PP Witness #2] at 45 (Oct. 19, 2016), Exhibit 8.38.

6. PPFA Executive suggests that the middleman obtain the consent to donate tissue

Even with the admission that PPFA consent form is adequate, the following excerpt from an undercover video by investigative journalists reveals how [PP Witness #1] explained to a potential TPB how to provide a comprehensive service that would be attractive to surgical abortion centers. In particular, the advice focused on the embedded tissue technician doing the consent.

> [PP Witness #1]**:** I would say, barring [sic] some bizarre space issue, because some places have very limited space. Some people would be happy to do as little for you as possible. The more you can do for them, the easier it is. **That includes consenting the patients—**
>
> Buyer: Right, because I was imagining [we] would be doing consent a well.
>
> [PP Witness #1]: That's probably the biggest inconvenience, ugh that's one more thing my staff has to talk about. **They only have so many minutes to talk to the patient.** If you said you're going to do all the consenting, you're going to collect the tissue, I don't know who would really say no. I really don't.
>
> Buyer: That's really what they want to hear.
>
> [PP Witness #1]: That's what they want to hear, they want to hear you basically say, other than taking up a little bit of space, this is going to be as low impact as possible, on you and your flow. You're going to need a room, somewhere to consent the patients, once the patient is ready to be consented. So, you're going to need space in the lab, you're going to need a place to consent. That's it, otherwise, as long as you don't leave anything behind, they're going to be happy. There are affiliates who have been doing this for so long, they have staff that are so good at it, they may just say, that it's something that staff can do. Especially because you know, they know how to identify some stuff. They probably wouldn't know how to identify the stuff you need. They're looking for basically, all of the limbs a thorax a head, to present them, "We've got it all." That's the only concern.[1006]

The "buyer" then asks about the time that an abortion clinic staff spends with the patient. This time frame is particularly limiting to the integrity of the consent process.

[1006] Center for Medical Progress, Transcript of Meeting with [PP Witness #1] at 13-14 (July 25, 2014), Exhibit 8.39.

> [PP Witness #1]: How long, right now, is the average amount of time they spend with a patient?
>
> PP: I would say about ten minutes.
>
> [PP Witness #1]: Per patient.
>
> PP: Per patient. yes. And also contraceptive counseling and all that.
>
> Buyer: That's all pre procedure, pre op.
>
> [PP Witness #1]: The layout of the actual Planned Parenthood is counseling rooms and procedure rooms. So, yea those are just counseling rooms with a desk and a chair.
>
> Buyer: Certainly, I'm not an expert in your clinic flow, I don't presume to know where would best fit in. But, I know that what we've done for other practices, for example the cosmetic facilities. We have a clinic float, our tech kind of acts as a float, they have their clipboard, and kind of mark down all the interested patients, you know ahead of time to try to facilitate that. I don't know if that will help or hinder your process.
>
> [PP Witness #1]: That's how it works with a lot of the researchers, as well. They kind of just identify who is interested.[1007]

H. StemExpress and Planned Parenthood abortion clinics appear to have committed systematic violations of HIPAA

1. Summary

As discussed above, the Panel's investigation uncovered a series of business contracts between StemExpress[1008] and several Planned Parenthood abortion clinics. These contracts included provisions for the payment of fees by StemExpress to the Planned Parenthood abortion clinics for fetal tissue and maternal blood. StemExpress then resold the fetal tissue and blood to researchers.

StemExpress and at least two of these Planned Parenthood abortion clinics—Planned Parenthood Mar Monte (PPMM) and Planned Parenthood Shasta Pacific (PPSP)—appear to have committed systematic violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule from about 2010 to 2015. These violations occurred when the Planned Parenthood clinics intentionally disclosed patients' individually identifiable health

[1007] *See id.*
[1008] StemExpress and Stem-Ex are the same company.

information to StemExpress to facilitate the TPB's efforts to procure human fetal tissue for resale.

The Panel filed a complaint against each of these entities requesting a swift and full investigation by the Office of Civil Rights in the Department of Health and Human Services on June 1, 2016.

2. Legal Background

As discussed above,[1009] the HIPAA privacy rule (Privacy Rule) protects all "protected health information" (PHI) held or transmitted by a covered entity or its business associate.[1010] PHI identifies an individual, or can reasonably be believed to be useful in identifying an individual, and includes demographic data relating to an individual's health condition, health care, or payments for the provision of health care.[1011] A covered entity may not use or disclose an individual's PHI except as the Privacy Rule permits or requires,[1012] or as the individual or their representative authorizes in writing. Civil monetary penalties may be imposed, and criminal fines or imprisonment can follow violations of the Privacy Rule.[1013]

3. Factual Background

The Planned Parenthood abortion clinics are "covered entities" under HIPAA while StemExpress is not.[1014] StemExpress "procure[s] tissues and isolate[s] cells for researchers' individual needs in its own labs."[1015] From about 2010 to 2015, the Planned Parenthood abortion clinics collaborated with StemExpress by permitting StemExpress employees to: enter their clinics and procure human fetal tissue from aborted infants; obtain individually identifiable health information, or protected health information (PHI) about their patients; interact with patients; and seek and obtain patient consent for tissue donation.[1016] StemExpress embedded tissue procurement technicians inside the Planned Parenthood abortion clinics whose work sequence followed a daily routine:

1) A researcher/customer placed an order for human fetal tissue using an online business portal provided by StemExpress, requesting a particular gestational range for the fetal tissue.[1017]

[1009] *See* Chapter II.A.4 *supra*.
[1010] 45 C.F.R. § 160.103.
[1011] *Id.*
[1012] 45 C.F.R. § 164.502(a).
[1013] Pub. L. 104-191; 42 U.S.C. §§ 1320d-5–1320d-6.
[1014] *See* 45 C.F.R. Part 160.103 (Covered Entity means: (1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.) *See also* OCR Privacy Brief, Summary of the HIPAA Privacy Rule, http://www.hhs.gov/sites/default/files/privacysummary.pdf (used as reference throughout this section).
[1015] StemExpress, About Us, http://stemexpress.com/about/.
[1016] *See* Clinic Procedures & Policies, Exhibit 8.40.
[1017] *See* Researcher Procurement Record, Exhibit 8.41.

2) The Planned Parenthood abortion clinic faxed the next day's schedule of potential patients directly to the StemExpress tissue procurement technician assigned to the clinic.[1018]

3) The day the abortion procedures were scheduled, StemExpress posted the order on a website "task board" (order page) to be accessed by their procurement technician planted in the Planned Parenthood abortion clinic, or communicated the order to the tissue technician via email.[1019]

4) The StemExpress procurement technician informed the Planned Parenthood clinic what they wished to procure (*i.e.*, the type of tissue and gestational range) based on the order page, and the abortion clinic staff member provided the medical files, including PHI, for the patients with abortions scheduled for that day.[1020]

5) The StemExpress procurement technician then sought out particular patients *by name* and obtained their consent to donate fetal tissue while they were awaiting their procedures. The Planned Parenthood abortion clinic also permitted the procurement technician to interview patients and *obtain their PHI*.[1021]

6) StemExpress procurement technicians were paid an hourly wage and a per tissue "bonus" for each item they procured from the order page.[1022]

7) StemExpress paid the Planned Parenthood abortion clinic for each fetal tissue and each blood sample and then marked up the tissue four to six hundred percent for resale to the researcher.[1023]

The work sequence, when combined with supporting documentation, reveals that StemExpress did not have a medically valid reason to see, and the Planned Parenthood abortion clinics did not have a reason to provide, patients' PHI. Instead, the Planned Parenthood abortion clinics shared patients' PHI with StemExpress in furtherance of contractual agreements that financially benefited StemExpress and the Planned Parenthood abortion clinics.[1024]

[1018] *See* Fax from The Alameda, San Jose [Planned Parenthood clinics] to StemExpress (Jan. 10, 2013), Exhibit 8.42.
[1019] *See* Updated Task Assignment: Procurement Schedule Wednesday, 3/20/13 and Navigating the Task Board, Exhibit 8.43.
[1020] *See* StemExpress Emails, Exhibit 8.44.
[1021] *See* Clinic Procedures and Policies, *See* Exhibit 8.40; Consenting Patients, Exhibit 8.45.
[1022] *See* Procurement Technician Compensation Policy for Tissue and Blood Procurement, Exhibit 8.46.
[1023] See StemExpress Services Agreement with Planned Parenthood Shasta Pacific; StemExpress Services Agreement with Planned Parenthood of Santa Barbara, Ventura & San Luis Obispo Counties; Purchase Order No. 60856806; Purchase Order No. 3000014694; Purchase Order No. 60836838; Purchase Order No. 60858758; and StemExpress Invoice # 1439, Exhibit 8.47.
[1024] *See* Standard Operating Procedure, Exhibit 8.48.

4. The Contracts between StemExpress and the Planned Parenthood abortion clinics

Particular language, contained within the four corners of the written contracts between StemExpress and the Planned Parenthood abortion clinics, raises serious concerns that the parties violated the Privacy Rule:

> [a]ny information obtained from [the Planned Parenthood abortion clinics] patients' charts shall be privileged, and [Stem-Ex/StemExpress] will treat the information in order to preserve the confidentiality of the patients. [Stem-Ex/StemExpress] will not receive any information concerning identity of donors *except as necessary* to obtain patients' consent for use of POCs and maternal bloods (emphasis added).[1025]

This admission, on the face of the contracts, that the Planned Parenthood abortion clinics granted StemExpress access to patients' PHI raises the question whether any HIPAA provision permits or requires such disclosure without patients' express authorization. This question is compounded by the contracts' admission that StemExpress reviewed PHI *prior to* obtaining patients' consent to donate fetal tissue *or* patients' authorization to view their PHI.

5. Violations of the HIPAA Privacy Rule by StemExpress and the Planned Parenthood Abortion Clinics

The agreements between StemExpress and the Planned Parenthood abortion clinics, on their face and in practice, appear to be fundamentally flawed. A contractual agreement requiring StemExpress to "treat the information obtained from patients' charts in order to preserve the confidentiality of the patients" cannot trump a law *prohibiting* the Planned Parenthood abortion clinics from permitting these disclosures in the first place. As discussed below, the Planned Parenthood abortion clinics—covered entities under HIPAA—were not permitted to disclose or make available to StemExpress any patient's PHI without the patient's express authorization.

The Planned Parenthood abortion clinics and StemExpress violated the HIPAA privacy rule because: (1) The disclosures of patients' PHI made by the Planned Parenthood abortion clinics, and received by StemExpress, were neither required nor permitted under HIPAA, and in particular did not meet the exceptions for cadaveric organ, eye, or tissue transplantation, or for research; (2) The consents for fetal tissue donation ostensibly obtained by StemExpress from the Planned Parenthood abortion clinics' patients did not constitute sufficient authorizations for the disclosure of PHI; (3) The disclosures of patients' PHI made by the Planned Parenthood abortion clinics to StemExpress were not the minimum necessary disclosures to facilitate the procurement of human fetal tissue from aborted infants; and (4) StemExpress is not a *Business Associate* of the Planned Parenthood abortion clinics under HIPAA.

[1025] *See* Contracts, Exhibit 8.49 (emphasis added).

6. The disclosures of patients' PHI made by the Planned Parenthood abortion clinics, and received by StemExpress, were neither required nor permitted under HIPAA, and in particular did not meet the exceptions for cadaveric organ, eye, or tissue transplantation, or for research

The disclosures of PHI that the Planned Parenthood abortion clinics made to StemExpress are neither required[1026] nor permitted[1027] by law. StemExpress was not involved in the treatment of patients, in the payment for treatment, or in clinic operations.[1028] Rather, StemExpress wanted patients' PHI to facilitate the procurement of human tissue from aborted infants for resale to researchers, and the Planned Parenthood abortion clinics benefited from this arrangement because StemExpress paid them for the tissue.

a) Cadaveric organ, eye, or tissue transplantation

Importantly, Planned Parenthood's disclosures to StemExpress do not fall under the provision in law permitting disclosure of PHI to aid organ transplantation. While the contracts reference the "National Organ Transplant Act,"[1029] the Planned Parenthood abortion clinics were not facilitating the donation and *transplantation* of cadaveric organs, eyes, and tissue. Instead, the clinics were facilitating the donation of human fetal tissue from aborted infants for *research,* which is not covered by the cadaveric organ, eye, or tissue exception.[1030]

b) Research

Further, Planned Parenthood's disclosures to StemExpress do not meet the rigorous requirements applicable to PHI disclosures for research purposes. A covered entity is not permitted to disclose an individual's PHI for research purposes without the individual's authorization unless the covered entity (1) obtains verification of approval from an Institutional Review Board (IRB) for disclosure without authorization; (2) the researcher represents that the use or disclosure of the PHI is solely to prepare research protocol and the PHI will not be removed from the covered entity, and that the PHI is necessary for the research; or (3) the research is on PHI of deceased individuals.[1031]

c) Violations Preceding "Consent"

Because StemExpress employees actually sought consent for tissue donation from patients, the Planned Parenthood abortion clinics permitted the employees to view patients' charts. Medical charts are filled with HIPAA-protected PHI, including names, addresses, past

[1026] 45 C.F.R. § 164.502(a)(2) (The only "required" disclosures are to (1) an individual or their personal representative when they request access to, or an accounting of disclosures of, their protected health information; and (2) to HHS when it is undertaking compliance investigation or review or enforcement action).
[1027] *See* 45 C.F.R. § 164.502(a)(1).
[1028] *See* 45 C.F.R. § 164.506(c).
[1029] 42 U.S.C. § 274e(c)(1).
[1030] *See* 45 C.F.R. § 164.512(h).
[1031] 45 C.F.R. § 164.512(i).

and present medical treatment, and more. Each time a Planned Parenthood employee shared a medical chart with a StemExpress employee, both violated the HIPAA privacy rule.

No evidence suggests the Planned Parenthood abortion clinics' patients provided authorization for StemExpress staff to view their PHI *prior* to seeking their consent to donate tissue. Therefore, regardless of whether a patient *ultimately* consented to tissue donation and authorized disclosure of her PHI to StemExpress, her privacy was violated.

The Planned Parenthood abortion clinics could have directly consented their patients for tissue donation, and entered an agreement with StemExpress to provide a limited data set[1032] regarding the patients they were seeing on a particular day. Instead, they violated the Privacy Rule by permitting StemExpress to view the most intimate information about their patients.

These disclosures made by the Planned Parenthood abortion clinics to StemExpress were inarguably direct and intentional—not incidental.[1033] StemExpress employees did not merely overhear a patient's name while in the clinic—they were handed her medical chart by her Planned Parenthood healthcare provider in blatant violation of the HIPAA privacy rule.

7. The consent for fetal tissue donation obtained by StemExpress from the Planned Parenthood abortion clinics' patients did not constitute sufficient authorizations for the disclosure of PHI

While StemExpress purportedly obtained consents from patients prior to procuring human fetal tissue from their aborted infants, the forms that they used were insufficient to authorize the disclosure of PHI under the HIPAA privacy rule. The Privacy Rule requires a covered entity to obtain an individual's written authorization for any use or disclosure of PHI that is not permitted or required by law.[1034] Such authorization must be in plain language and contain specific information regarding the information to be disclosed or used, the person(s) disclosing and receiving the information, expiration, right to revoke in writing, and other data.[1035]

Neither the consent form provided by StemExpress nor the consent form provided by Planned Parenthood to obtain patient consent for the donation of human fetal tissue of aborted infants met these stringent requirements.[1036] The statement in the StemExpress form that a patient's "health information will be protected at all times" is ironic given that StemExpress' possession of the patient's PHI already placed the Planned Parenthood abortion clinics and StemExpress in violation of the HIPAA privacy rule.

[1032] *See* 45 C.F.R. § 164.514(e).
[1033] *See* 45 C.F.R. § 164.502(a)(1)(iii).
[1034] 45 C.F.R. § 164.508.
[1035] 45 C.F.R. § 164.508(c).
[1036] *See* StemExpress consent form, Exhibit 8.35, and Planned Parenthood consent form, Exhibit 8.34.

The StemExpress form also stated that "[i]n accordance with federal laws (HIPAA), your personal identifying information will be protected . . . health information . . . may be used or disclosed . . . [but] will NOT be connected to your name or any other personal identifier."[1037]

Like the privacy provision in the contracts between StemExpress and the Planned Parenthood abortion clinics, this nod towards HIPAA requirements failed to meet the requirements of the HIPAA privacy rule. The StemExpress form did not describe the specific patient information that will be disclosed or used, but rather provided a generic, nonexclusive list of information that *may* be disclosed. The StemExpress form did not state who will disclose or use the patient's PHI. It also did not state when the patient's authorization will expire, or that the patient can withdraw her authorization for the use of her PHI (it mentioned that the patient cannot withdraw her consent to the tissue donation after she leaves the clinic).

The Planned Parenthood form, purportedly used to obtain patient consent for human fetal tissue donation at Planned Parenthood Mar Monte and Planned Parenthood Shasta Pacific,[1038] was grossly insufficient. The form did not address privacy at all, with no information regarding: PHI that may be disclosed or used; the person(s) disclosing and receiving the PHI; any expiration on the availability of the patient's PHI to researchers or others; or the patient's right to revoke her authorization in writing.

One former StemExpress procurement technician, [Procurement Technician], was embedded at several California Planned Parenthood clinics and told investigative journalists of repeated consent violations she witnessed during her time with Planned Parenthood. In one instance, [Procurement Technician] told a StemExpress coworker that a woman had refused to consent to a blood draw for donation, but the coworker—with full knowledge of the patient's refusal—drew her blood anyway the following day without telling her it was for StemExpress.[1039]

8. The disclosures of patients' PHI made by the Planned Parenthood abortion clinics to StemExpress were not the minimum necessary disclosures to facilitate the procurement of human fetal tissue from aborted infants

The Planned Parenthood abortion clinics and StemExpress violated a central aspect of the Privacy Rule by disclosing/obtaining more than the "minimum necessary" PHI to facilitate the procurement of human fetal tissue from aborted infants.[1040] StemExpress employees did not need to know the names of patients, and they certainly did not need to directly obtain the patients' consent in order to procure fetal tissue. Instead, these deeply private activities could have been performed by Planned Parenthood employees.

[1037] StemExpress Consent Form, Exhibit 8.35.
[1038] Planned Parenthood consent form, Exhibit 8.34.
[1039] Human Capitol-Episode 2: Inside the Planned Parenthood Supply Site (YouTube) https://www.youtube.com/watch?v=ABzFZM73o8M (5 minutes, 30 seconds).
[1040] 45 C.F.R. §§ 164.502(b) and 164.514(d).

As addressed above, the Planned Parenthood abortion clinics could have established a relationship with StemExpress that did not require or result in the disclosure of any PHI. Instead, the Planned Parenthood affiliates permitted StemExpress to use PHI to directly encourage patients to donate human fetal tissue—tissue for which Planned Parenthood would be paid, and that would later be sold by StemExpress to researchers at a huge mark-up.

9. StemExpress is not a *Business Associate* of the Planned Parenthood abortion clinics under HIPAA

A *Business Associate* under HIPAA is a person or organization, other than a member of a covered entity's workforce, that performs certain functions or activities on behalf of, or provides certain services to, a covered entity that involve the use or disclosure of individually identifiable health information. *Business Associates* are generally involved in claim processing, data analysis, utilization review, and billing. Their services are limited to legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services, where the provision of the services involves the disclosure of PHI.[1041]

Clearly, StemExpress did not perform any of these services for the Planned Parenthood abortion clinics, and is therefore not a *Business Associate* permitted to obtain the PHI of the Planned Parenthood abortion clinics' patients.

[1041] 45 C.F.R. § 160.103.

IX. Biomedical Research and Human Fetal Tissue

Chapter IX Redaction Key:

Chapter IX cites numerous academic articles. None of the individuals in this chapter were part of the Panel's investigation into transactions involving fetal tissue. Thus, the names are left unredacted due to their academic contribution to biomedical research.

A. Success of the United States Biomedical Research Enterprise

The United States of America is a global leader in scientific research. A comprehensive report of world-wide research investment indicates that the 2014 gross expenditure on Research and Development (R&D) in the United States exceeded $485 billion, or nearly 27% of the global R&D budget.[1042] The same pattern holds for U.S. investment in biomedical research. A recent report in the New England Journal of Medicine indicates that the 2012 biomedical research expenditures in the United States exceeded $119 billion, with the next largest national investment being made by Japan, at just over $37 billion.[1043] Corresponding to this strong financial commitment, the United States is also global leader in biomedical research publication and innovation. For example, between 2000-2013, the Unites States published approximately 40% of all papers in the area of stem cell research, with the next closest contributor (the United Kingdom) producing less than 10% of all published research in this rapidly advancing field.[1044]

The National Institutes of Health (NIH) invests approximately $32 billion annually in medical research, funding over 300,000 researchers both in the United States and around the world.[1045] The NIH research portfolio includes over 83 thousand active projects.[1046] In addition, there are currently over 228 thousand U.S.-funded clinical trials both within the U.S. and abroad.[1047] This represents a massive research effort directed both at understanding the basic mechanisms of human disease and at discovering novel treatments to relieve human suffering.

American citizens have every right to be proud of the research enterprise in our country, and are wise to support it with tax dollars. The House Select Investigative Panel shares this support. We are strongly committed to promoting both basic and clinical research. However, as the history of biomedical research in the 20th century clearly demonstrates, when scientific research is uncoupled from either ethics or the law, grave injustice can result.[1048] Protections for

[1042] 2016 Global R&D Funding Forecast, https://www.iriweb.org/sites/default/files/2016GlobalR%26DFundingForecast_2.pdf.
[1043] Asia's ascent—global trends in biomedical R&D expenditures. Chakma J, Sun GH, Steinberg JD, Sammut SM, Jagsi R. N Engl J Med. 2014 Jan 2;370(1):3-6.
[1044] Human embryonic and induced pluripotent stem cell research trends: complementation and diversification of the field. Kobold S, Guhr A, Kurtz A, Löser P. Stem Cell Reports. 2015 May 12;4(5):914-25.
[1045] https://www.nih.gov/about-nih/what-we-do/budget.
[1046] 83,592 Active Research Projects. https://projectreporter.nih.gov.
[1047] 228,702 Clinical trials; https://www.clinicaltrials.gov.
[1048] For example, see: Some conditions of obedience and disobedience to authority. Milgram S. Int J Psychiatry. 1968 Oct;6(4):259-76; The Tuskegee study of untreated syphilis. Kampmeier RH. South Med J. 1972

the rights of patients and provisions for the ethical oversight of research procedures are not designed to "hinder" the advance of science, but rather to ensure that the scientific enterprise more perfectly fulfills its promise to society by advancing efficiently, while also being both just and ethical.

The goal of the House Select Investigative Panel is not to oppose science, but rather to determine how best to support science, so that this important work can advance as rapidly as possible without ethical compromise. To accomplish this goal, it is important that biomedical research be accurately understood and that obstacles to research are realistically addressed. Unfortunately, a number of false and misleading assertions have been made regarding the role of human fetal tissue in modern scientific research—inaccuracies that must be corrected before progress towards the goal of promoting sound and ethical research can be realized. Moreover, the results of this Panel's investigation suggest that in some cases, aggressive tissue procurement businesses have created an artificial market for human fetal tissue, even when it is not the most scientifically powerful or appropriate research model (*e.g.*, for the study of adult-onset diseases, such as macular degeneration). Facilitating cost-effective and convenient access to the most appropriate research models requires an accurate view of when human fetal tissue is necessary and/or advantageous for modern biomedical research.

Below we address common claims regarding the contribution of fetal tissue to modern biomedical research (Section B) and respond directly to the false and misleading statements made in "*Setting the Record Straight: The Unjustifiable Attack on Women's Health Care and Life-Saving Research*;" *i.e.*, the Minority report of the House Select Investigative Panel, dated December 5, 2016 (Section C). We then present an objective analysis of current, long-standing research programs that utilize human fetal tissue (Section D), concluding with recommendations for improving access to appropriate scientific models, including (when necessary) human fetal tissue (Section E).

B. Response to the misleading and false arguments made by scientific societies, medical societies, and universities

In February, the ranking member of the House Select Investigative Panel, the Honorable Jan Schakowsky, asked universities, scientific societies and medical societies for "assistance in providing the Panel with information that will further our understanding" of the following three topics (see letter in Exhibit 9.1):

1) Past benefits of fetal tissue research.

2) Potential future benefits that might be gained through continued fetal tissue research.

3) Unique aspects of fetal tissue in research, in comparison with adult cells, stem cells, or other cellular organisms that might be used for research purposes.

Oct;65(10):1247-51; Experiments at the Willowbrook State School. Krugman S. Lancet. 1971 May 8;1(7706):966-7.

To date, we have received responses from the following institutions (Exhibit 9.2):

American Academy of Pediatrics (AAP)
American Association for the Advancement of Science (AAAS)
American College of Obstetricians and Gynecologists (ACOG)
Association of American Medical Colleges (AAMC)
Baylor College of Medicine
Children's Hospital of Pennsylvania (CHOP)
Columbia University
Dartmouth University
Harvard University
John Hopkins University
Oregon Health Sciences University (OHSU)
Rockefeller University
University of California Los Angeles (UCLA)
University of California San Diego (UCSD)
University of Colorado (UCO)
University of Illinois at Chicago (UIC)
University of Minnesota (UMN)
University of Pennsylvania
University of Wisconsin-Madison (UWM)
Yale University

There are a number of reasons why the specific questions posed by the ranking member have limited value. First, while the past benefits of human fetal tissue research may be of historical interest, experiments conducted a half-century or more ago are no more relevant to the practice of modern science than vacuum tube-technology is relevant to modern television manufacturing. Second, speculation on the "potential" future benefits of human fetal tissue research is simply that: speculation. Scientific societies and research universities are no more capable of predicting the future than anyone else. Finally, while the question of whether human fetal tissue provides unique benefits to research is important, not a single one of the responding institutions provided substantive evidence relevant to this question. The issues and arguments raised in the letters to the Panel fell into eight major areas that are addressed in detail below.

1. Concerns regarding the privacy and safety of researchers involved in human fetal tissue research

A number of letters (AAAS, Hopkins, UCLA, UCO, UMN) expressed concern that the investigation of the House Select Investigative Panel would reveal the identities of researchers, compromising their privacy and potentially putting them at risk for reprisal. Yet this concern appears to reflect a false belief that publicly funded scientific research is somehow exempt from the Freedom of Information Act.[1049] Moreover, in compliance with the National Institutes of

[1049] Freedom of Information Act, 5 U.S.C. § 552 *et seq*. *See generally* https://www.foia.gov/.

Health (NIH) Reform Act of 2006,[1050] detailed information on all grants that employ human fetal tissue is posted on a publicly available website,[1051] including the names of the researchers and links to their publications. Therefore, the scientists involved in human fetal tissue research, as well as the names and affiliations of their colleagues and collaborators, have already been identified by the NIH.

2. The false claim that human fetal tissue was used in the last century to produce vaccines for polio and other diseases

Several letters (AAAS, AAP, ACOG, Columbia, Harvard, OHSU, UCLA, UIC, UWM) claim that research on fetal tissue was required for production of the polio vaccine. A similar claim is made by a *Guttmacher Policy Review* article that states, "Fetal Tissue Research dates back to the 1930s, and has led to major advances in human health, including the virtual elimination of such childhood scourges as polio, measles and rubella in the United States."[1052] However, the facts simply do not support these claims.

a) Early vaccine research did not rely in any way on human fetal tissue

Vaccine research was begun by Edward Jenner in the late 1700s, *more than 100 years before the first published use of human fetal tissue for biomedical research in the 1920s*.[1053] Jenner developed a vaccine against smallpox in 1798 which ultimately led to the eradication of this devastating disease. In fact, vaccines against 8 diseases (Rabies, Diphtheria, Typhoid, Cholera, Plague, Tetanus, Pertussis and Bacille-Calmette-Guerin disease) were <u>all</u> developed in the 1800s and early 1900s, well before the first use of fetal tissue in research.[1054]

b) The polio vaccine was not produced using human fetal tissue

Work on the polio virus began in the 1930s, when our knowledge of how to culture human cells in the laboratory was quite primitive. Polio virus was first successfully propagated in the laboratory by Albert Sabin in 1936 using human fetal tissue cultures.[1055] This early result was important for advancing our understanding of polio, but did not directly result in a vaccine. Moreover, human fetal tissue has <u>never</u> been used to make the polio vaccine. Jonas Salk and

[1050] National Institutes of Health (NIH) Reform Act of 2006, Pub. L. No. 109-482, 120 Stat. 3675 (2007).
[1051] https://projectreporter.nih.gov.
[1052] Fetal Tissue Research: A Weapon and a Casualty in the War Against Abortion. Boonstra, HD. Guttmacher Policy Review 2016 | Vol. 19, http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-20160302-SD011.pdf.
[1053] Addison's Disease, with Severe Anaemia, treated by Suprarenal Grafting. Hurst AF, Tanner WE, Osman AA. Proc R Soc Med. 1922;15(Clin Sect):19-20.
[1054] History of vaccine development. Stanley A. Plotkin, New York : Springer, c2010. *See also* Immunization Action Coalition Vaccine Timeline, http://www.immunize.org/timeline/.
[1055] Sabin A B, Olitsky P K. Cultivation of poliomyelitis virus in vitro in human embryonic nervous tissue. Proc Soc Exp Biol Med. 1936;34:357–359.

Albert Sabin used monkey cells to produce the Polio vaccine,[1056] and we are still using monkey cells to produce this vaccine today.

c) The Nobel Prize was not awarded for curing polio using fetal tissue

The Nobel Prize was awarded to John Enders, Thomas Weller, and Frederick Robbins in 1954 for work on the polio virus that involved human fetal tissue. However, the work of Enders, Weller and Robbins was not for "curing polio," but rather for basic research on the polio virus. Importantly, this work did not critically depend on the use of human fetal tissue; *i.e.*, we could have learned everything they discovered about polio using animal cells. Prior to the work of Enders, Weller and Robbins, people believed polio virus infected human brain tissue, because 1) this is the tissue most strongly affected in the disease and 2) the only successful propagation of polio virus in the laboratory used human fetal brain tissue. In their Nobel Prize awarded work, Enders, Weller and Robbins showed that in fact, polio virus could be harvested from cultures of multiple human tissues, both fetal[1057] and non-fetal.[1058]

Importantly, the central discovery for which the Nobel Prize was awarded had *nothing to do with the properties of human fetal cells*. Rather, the critical finding was that *polio virus could be propagated in a wide range of tissues*. This finding paved the way for Salk and Sabin to culture polio in monkey kidney cells to produce the polio vaccine. However, if Enders, Weller and Robbins had tried monkey cells or human foreskin fibroblasts before they tried human fetal tissue, they would have made the same discovery (that polio could be propagated in multiple cell types), and they still would have won the Nobel Prize for this discovery, *without* the use of human fetal cells.

d) The vaccine for Measles was not produced using human fetal tissue

Guttmacher asserts that fetal tissue research resulted in the eradication of measles, yet in reality, *fetal tissue and fetal cell lines were not used for development of the measles vaccine*. This vaccine was developed in 1963 by Peebles and Enders, using chicken eggs, human amnion cells (obtained from term placentas), and human kidney cultures obtained from adult surgical samples.[1059] The vaccine was tested on monkeys.[1060]

[1056] For a review of the treatment of polio, see Vaccine-derived polioviruses and the endgame strategy for global polio eradication. Kew OM, Sutter RW, de Gourville EM, Dowdle WR, Pallansch MA. Annu Rev Microbiol. 2005;59:587-635.

[1057] Cultivation of the Lansing Strain of Poliomyelitis Virus in Cultures of Various Human Embryonic Tissues. Enders JF, Weller TH, Robbins FC. Science. 1949 Jan 28;109(2822):85-7.

[1058] Cultivation of poliomyelitis virus in cultures of human foreskin and embryonic tissues. Weller TH, Robbins, FC, Enders JF. Proc Soc Exp Biol Med. 1949 Oct;72(1):153-5.

[1059] Milovanovic MB, Enders JF, Mitus A. Cultivation of measles virus in human amnion cells and in developing chick embryo. Proc Soc Exp Biol Med. 1957;95(1):120–127.

[1060] Enders JF, Katz SL, Milovanovic MV, Holloway A. Studies on an attenuated measles-virus vaccine. I. Development and preparation of the vaccine: technics for assay of effects of vaccination. N Engl J Med. 1960;263:153–159.

e) The vaccine for Mumps was not produced using human fetal tissue

The Mumps virus vaccine (MumpsVax) was licensed by Merck in 1967, at roughly the same time as the vaccine for Measles—a period when it is claimed that human fetal tissue was "necessary" for vaccine research and development. However, like polio and measles, production of the Mumps vaccine did not rely on human fetal tissue. The Mumps vaccine was developed by Maurice Hilleman, who isolated a wild type virus from his daughter, Jeryl Lynn, who was recovering from mumps. Hilleman propagated the Mumps "Jeryl Lynn strain" of virus in three different animal culture systems: monkey cells, chick embryo fibroblast cells, and embryonated chicken eggs. The Mumps vaccine is still produced using embryonated chicken eggs today (Exhibit 9.3).

f) The vaccine for Rubella; an isolated case

Of the diseases commonly used to illustrate the purported use of fetal tissue for the development of vaccines, Rubella is the single case for which this claim is at least partially correct. However, fetal tissue was not used to produce the first vaccine for Rubella, and the subsequent use of fetal tissue to manufacture Rubella vaccine was largely due to historical, not scientific factors.

Attenuated Rubella virus was first isolated in 1966.[1061] The earliest Rubella strains used for research were obtained by rinsing the throats of infected individuals and propagating the virus in animal cell culture. Work with these strains led to the development of the first Rubella vaccines in 1969.[1062]

Given that human fetal tissue was not used to produce the first Rubella vaccine, what is the basis for the claim that fetal tissue was "necessary" for combatting this disease? Beginning in the 1930s and continuing as late as the 1970s, fetal tissue was often used for propagation of virus, simply because (at the time) there was limited understanding of how to work with human cells and fetal tissue is easier to grow in the laboratory. Beginning in the 1960s, several laboratories were able to chemically alter cells derived from aborted fetuses such that the cells would continue to divide indefinitely in culture. Two of these "transformed cell lines," WI-38[1063] and MRC-5[1064] (each derived from a single aborted fetus), proved to be very robust and were rapidly adopted by many investigators. In addition, one strain of the Rubella virus (RA 27/3) was

[1061] Attenuated rubella virus. I. Development and laboratory characterization. Parkman PD, Meyer HM Jr, Kirschstein RL, Hopps HE. N Engl J Med. 1966 Sep 15;275(11):569-74.
[1062] Three rubella virus strains were licensed in the U.S. in 1969.: HPV-77 strain grown in dog-kidney culture (Rubelogen by Parke-Davis); HPV-77 grown in duck-embryo culture (Meruvax by Merck); and Cendehill strain grown in rabbit-kidney culture (Cendevax by RIT-SKF, and Lirubel and Lirutrin by Dow). See: http://www.immunize.org/timeline/
[1063] The serial cultivation of human diploid cell strains. Hayflick, L, Moorhead, PS. Exp Cell Res. 1961 Dec;25:585-621.
[1064] Characteristics of a human diploid cell designated MRC-5. Jacobs JP, Jones CM, Baille JP. Nature. 1970 Jul 11;227(5254):168-70.

isolated from an aborted human fetus in 1969,[1065] several years after the first isolation of attenuated Rubella from non-fetal sources and production of the first Rubella vaccine. The RA 27/3 Rubella strain was propagated in fetal-derived cell lines to produce an alternative Rubella vaccine.

For reasons that are unrelated to the fetal origin of the virus, the RA 27/3 strain proved to be very effective in eliciting a strong immune response, and earlier forms of the Rubella vaccine were abandoned. Consequently, the RA 27/3 strain (propagated in fetal-derived cell lines) is still used for production of Rubella vaccine today.[1066] But importantly, the Rubella vaccine developed using fetal tissue was not the *first* or the *only* Rubella vaccine produced. In contrast to the claims noted above, *human fetal tissue was not "required" for isolation and propagation of Rubella or for development of vaccines against this disease, even in the 1960s*.

3. False claims that the production of modern vaccines depends on human fetal tissue

Several letters (AAMC, AAP, ACOG, CHOP, Columbia, Dartmouth, Harvard, OHSU, Rockefeller, UCLA, UIC, UMN, UWM, Yale) suggest that human fetal tissue is used for modern vaccine production. In reality, none of the nearly 75 vaccine formulations currently licensed in the United States is produced using human fetal tissue (see Exhibit 9.3).

a) Historic use of fetal cell lines in vaccine production by pharmaceutical companies

The fetal-derived cell lines WI-38 and MRC-5 were adopted by the pharmaceutical industry as tools for the production of vaccines shortly after they were developed in the 1960s. And for a small minority of vaccines, these tools are still used today. However, these historic fetal-derived cell lines are still in use today for primarily economic, not scientific reasons.

Obtaining FDA approval for a new vaccine is very labor intensive and costly. Consequently, once FDA approval has been secured for a particular method of producing a vaccine, Pharmaceutical companies tend to rely on this method, to avoid incurring new costs associated with "validating" the safety and efficacy of new procedures. Three major Pharmaceutical players (Merck, GlaxoSmithKline and Sanofi) adopted the fetal cell lines MRC-5 and WI-38 in the 1970s, shortly after they were developed. These companies were successful in gaining FDA approval for vaccines produced in these cell lines, and have continued using them ever since. However, viable alternatives exist and are used by other pharmaceutical companies for production of very similar vaccines (see Exhibit 9.3).

[1065] Attenuation of RA 27-3 rubella virus in WI-38 human diploid cells. Plotkin SA, Farquhar JD, Katz M, Buser F. Am J Dis Child. 1969 Aug;118(2):178-85.
[1066] See: Plotkin SA. The History of Rubella and Rubella Vaccination Leading to Elimination. Clin Infect Dis. 2006 43 (Supplement 3): S164-S168.

b) Modern vaccine production and research

Of the nearly 75 vaccine formulations currently approved by the Food and Drug Administration for use in the United States,[1067] only 11 (directed against Zoster, Varicella, Rabies, Rubella, Hepatitis A, Polio and Adenovirus) are produced using historic, fetal-derived cell lines, and none are produced using freshly isolated fetal tissue. *Importantly, alternative vaccine formulations that do not rely on fetal-derived cell lines are available or all but five of these diseases* (Adenovirus, Hepatitis A, Rubella, Varicella and Zoster), and there is no scientific reason these vaccines could not be produced using animal cell lines. For example, although vaccines against Hepatitis A are produced using the historic fetal-derived cell line MRC-5, modern vaccines against the related Hepatitis B virus are produced using genetically engineered yeast cells. In fact, the vast majority of modern vaccines are manufactured using bacteria, yeast or animal cells—and all of them could be manufactured in this manner. Human fetal tissue is outdated technology that is not necessary for modern vaccine production or research. For example, current vaccine research for HIV/AIDS, Cancer, Malaria and Ebola does not rely on human fetal tissue (see Exhibit 9.3.).

4. Assertions that fetal tissue is necessary for the study of diseases that affect human brain development, including Zika and Down syndrome

Several institutions (AAAS, ACOG, CHOP, Columbia, Harvard, Hopkins, Rockefeller, UCLA, UIC, UMN, Penn and Yale) claim that human fetal tissue is required for study of human development, particularly brain development and human brain diseases, such as Zika and Down syndrome. Yet given the strong similarities between neural development in humans and in other mammalian species, this assertion is largely unwarranted. For example, less than 1% of the more than twenty thousand research articles returned by querying the NIH-maintained PubMed database[1068] for the term "neurogenesis" involve human fetal tissue. Moreover, the history of vaccine development for Cytomegalovirus (CMV), one of the most compelling parallels to the Zika virus, provides a clear illustration of why human fetal tissue is not required for the study of viruses that affect brain development.

The Zika virus has received a lot of attention, with many characterizing it as a "health crisis" and calling for immediate action—including expanded fetal tissue research to develop a vaccine and reduced restrictions on abortion to eliminate infected infants prior to birth.

And Zika is indeed an alarming virus. The Centers for Disease Control (CDC) estimates that if a woman is infected with Zika in the first trimester of pregnancy, there is a 1-13% risk that her child will be born with a serious brain defect, including microcephaly.[1069] Moreover, a recent

[1067] FDA approved vaccine formulations: http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm.
[1068] https://www.ncbi.nlm.nih.gov/pubmed.
[1069] http://www.nejm.org/doi/pdf/10.1056/NEJMp1605367.

study from Brazil,[1070] and a report by the CDC[1071] both suggest that Zika increases the risk of miscarriage, even for healthy infants who are not affected by the virus.

Understandably, Zika has become the focus of an intense research effort, with nearly 120 clinical and research articles published on the virus, most within the last few years.[1072] Importantly, only two of these have involved the use of fetal tissue.[1073] The major advances in our understanding of the Zika virus, published in world-renowned scientific journals such as *Lancet, The New England Journal of Medicine, Science,* and *Nature*, have not relied on the use of human fetal tissue at all.

Zika has only recently become the subject of intense scientific investigation, and therefore the potential role of human fetal tissue in this research is hard to predict. Yet Zika isn't the only virus that causes brain defects and miscarriage. Comparing Zika to similar viruses that have been investigated for a longer time provides a better measure of whether human fetal tissue is likely to be important in combatting this type of disease. And the best studied virus that affects brain development in a manner quite similar to Zika is Cytomegalovirus, or CMV.

Similar to Zika, if a mother becomes infected with CMV during the first trimester of her pregnancy, there is a 9% risk that her child will be born with a serious brain defect, including microcephaly (Fig. 1).[1074] Also similar to Zika, the effects of CMV on adults are mild, making it difficult for a pregnant woman to know for sure that she has been infected. Yet unlike Zika, CMV is a very prevalent virus, with an estimated 30-50% of women of childbearing age world-wide being infected.[1075] Consequently, the toll of CMV on women and their children is far greater than for Zika. The CDC estimates that 1 in every 750 children born in the United States,

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[1070] http://www.nejm.org/doi/pdf/10.1056/NEJMoa1602412.
[1071] http://www.cdc.gov/mmwr/volumes/65/wr/mm6508e1.htm.
[1072] Based on a search of the NIH PubMed database (http://www.ncbi.nlm.nih.gov/pubmed) using the following terms: ("zika virus" AND (("case reports"[Publication Type] OR "clinical study"[Publication Type] OR "clinical trial"[Publication Type] OR "clinical trial, phase i"[Publication Type] OR "clinical trial, phase ii"[Publication Type] OR "clinical trial, phase iii"[Publication Type] OR "clinical trial, phase iv"[Publication Type] OR "comparative study"[Publication Type] OR "controlled clinical trial"[Publication Type] OR "meta analysis"[Publication Type] OR "research support, american recovery and reinvestment act"[Publication Type] OR "research support, n i h, extramural"[Publication Type] OR "research support, n i h, intramural"[Publication Type] OR "research support, non u s gov't"[Publication Type] OR "research support, u s gov't, non p h s"[Publication Type] OR "research support, u s gov't, p h s"[Publication Type] OR "research support, u s government"[Publication Type])) NOT review[Publication Type].
[1073] Zika Virus Infection with Prolonged Maternal Viremia and Fetal Brain Abnormalities. Driggers RW, Ho CY, Korhonen EM, Kuivanen S, Jääskeläinen AJ, Smura T, Rosenberg A, Hill DA, DeBiasi RL, Vezina G, Timofeev J, Rodriguez FJ, Levanov L, Razak J, Iyengar P, Hennenfent A, Kennedy R, Lanciotti R, du Plessis A, Vapalahti O. N Engl J Med. 2016 Jun 2;374(22):2142-51. doi: 10.1056/NEJMoa1601824; The Brazilian Zika virus strain causes birth defects in experimental models. Cugola FR, Fernandes IR, Russo FB, Freitas BC, Dias JL, Guimarães KP, Benazzato C, Almeida N, Pignatari GC, Romero S, Polonio CM, Cunha I, Freitas CL, Brandão WN, Rossato C, Andrade DG, Faria Dde P, Garcez AT, Buchpigel CA, Braconi CT, Mendes E, Sall AA, Zanotto PM, Peron JP, Muotri AR, Beltrão-Braga PC. Nature. 2016 May 11;534(7606):267-71. doi: 10.1038/nature18296.
[1074] http://www.ncbi.nlm.nih.gov/pubmed/23297260; http://www.ncbi.nlm.nih.gov/pubmed/19800841.
[1075] CDC, Cytomegalovirus (CMV) and Congenital CMV Infection, http://www.cdc.gov/cmv/trends-stats.html#affected.

or over 5000 children each year, suffer permanent problems caused by CMV infection.[1076] CMV is clearly a health crisis for women and for children that is just as serious, if not more serious, than Zika.

So what are we doing about the CMV "crisis?" Shockingly, very little. We have known about CMV for over 100 years; the virus was originally isolated in the 1950s,[1077] but researchers have been aware of its effects on unborn children from as early as 1881.[1078] Since the 1950s, we have developed vaccines against measles, mumps, and a host of other viral diseases. Yet, despite many attempts, an effective vaccine against CMV has not been produced. And in the 60 years since the CMV virus was isolated, hundreds of thousands of American children with severe brain defects have been born, lived, and died, largely ignored by the media and by politicians.

Figure 1: Microcephaly caused by CMV (top) and by Zika (bottom).

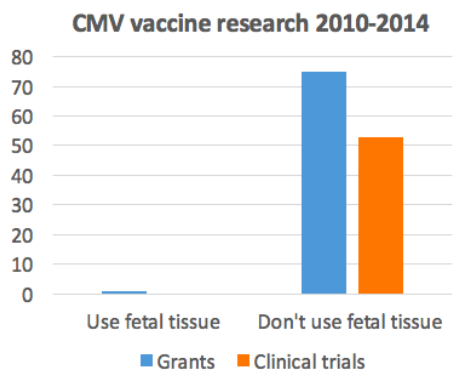


CMV is truly one of the darkest stories in modern medicine. But thankfully, the story has recently been brightened by a glimmer of hope. Several candidate vaccines have been developed and are currently being tested in clinical trials, with promising results.[1079] After decades of disappointment, we may be close to preventing this devastating disease.

After so many years of fruitless effort, what has turned the tide on CMV? Perhaps surprisingly in the face of repeated claims that human fetal tissue is "necessary" to develop a cure for viruses that disrupt brain development, *fetal tissue has made almost NO contribution to modern CMV vaccine research* (Figure 2). Between 2010 and 2014 the NIH awarded over 75 grants focused on finding a vaccine to prevent CMV, and only one involved human fetal tissue.[1080] Similarly, there are 53 ongoing clinical trials of CMV-vaccines, and *not a single one* involves the use of human fetal tissue.[1081] The break-through on this devastating disease did not depend on human fetal tissue research at all.

[1076] *Id.*
[1077] http://www.ncbi.nlm.nih.gov/pubmed/9042169.
[1078] *Id.*
[1079] http://www.ncbi.nlm.nih.gov/pubmed/25791890.
[1080] Based on a search of the NIH grant database (https://projectreporter.nih.gov) over the years 2010-2014 for the terms "congenital cytomegalovirus", "vaccine related" and "human fetal tissue."
[1081] Based on a search of the NIH clinical trials database (https://www.clinicaltrials.gov) for the terms "CMV vaccine" and "fetal tissue."

Figure 2: Modern CMV research.



The breakthrough on a CMV vaccine came from basic scientific research using animal models, human cell lines, and adult human tissue. Scientists working with adult blood cells in the 1990s discovered a protein complex that was important for CMV infection.[1082] It was later discovered that in women with natural immunity to CMV, this same complex was the target of antibodies that effectively neutralized the virus.[1083] These findings led to successful vaccination experiments in animals[1084] that have rapidly lead to similar human clinical trials.[1085]

So what can we learn from CMV, a virus that is parallel in many ways to Zika? First, as frightening as Zika is, it is not a health care crisis, unless we are willing to admit we have been living with a largely ignored CMV "crisis" for the last 60 years. It is certainly true that both Zika and CMV take a heavy toll on children and families. They should both be fought aggressively with the best possible science and medicine. But hysterical calls for enhanced fetal tissue research and expanded abortion license are a matter of ***POLITICS***, not medicine or science.

Second, developing an effective vaccine is sometimes a very difficult task. We know more about virology now than we did in the 1950s, but until very recently, CMV has resisted even our best modern efforts. We need to take a sober view of science and medicine, and accept that an effective, preventative vaccine for both CMV and Zika may be difficult to achieve—not because of any restrictions that may be placed on fetal tissue research, but because not every disease is easy to prevent.

Finally, we need to develop a more sophisticated view of how science and medicine actually work. The promising candidates for a CMV vaccine did not depend on fetal tissue research. They depended on observations of the natural human immune response and analysis of the CMV virus in cell lines and animals. We don't need human fetal tissue to develop a vaccine for Zika, and based on our modern experience with CMV, human fetal tissue is unlikely to provide a significant advantage in this fight (See Figure 2). The ethical research tools we have in hand are the best weapons against Zika, even if it proves to be as tenacious and confounding as CMV.

5. Assertions that human fetal tissue is vital for a wide range of life-saving research

Several letters (AAAS, CHOP, Dartmouth, Hopkins, OHSU, Rockefeller, UCLA, UCSD, UIC, UMN, Penn, UWM, Yale) voiced the opinion that human fetal tissue is "essential" (or "critical" or "vital") for a wide range of scientific investigations, often expressing alarm that

[1082] http://www.ncbi.nlm.nih.gov/pubmed/8397282.
[1083] http://www.ncbi.nlm.nih.gov/pubmed/19889756.
[1084] http://www.ncbi.nlm.nih.gov/pubmed/24297878; www.ncbi.nlm.nih.gov/pubmed/23107592.
[1085] *E.g.*, NCT00722839; NCT00439803.

cures would be delayed or prevented if human fetal tissue were not available for research. The same concerns were raised by Dr. Lawrence Goldstein in his March 2, 2016, testimony before the House Select Investigative Panel.[1086] Goldstein indicated that human fetal astrocytes are "vital" for his research on Alzheimer's disease and cannot be replaced by astrocytes derived from non-fetal or animal sources.

Yet all of these interlocutors fail to note that human fetal tissue research represents only a tiny fraction of the overall scientific enterprise. For example, of the 76,081 research grants funded by the NIH in 2014, only 160 (or approximately 0.2%) involved human fetal tissue.[1087] In the case of Alzheimer's disease specifically (the area of research singled out by Dr. Goldstein), a total of 1304 grants investigating Alzheimer's disease were awarded in 2014, *and not a single one involved fetal tissue*.[1088] Clearly, *the overwhelming majority of active, funded, research scientists—and the much larger number of their scientific peers who reviewed and endorsed these proposals for funding—have concluded that human fetal tissue is not "vital" for modern research on either Alzheimer's disease or other scientific questions.*

This fact raises a serious conundrum for those who claim human fetal tissue research is "essential" for advancing modern research. Given that the purpose of scientific peer review is to identify research proposals that use the most appropriate and powerful methods to address the most important scientific questions, why have the great majority of scientists elected not to employ human fetal tissue in their own research, and why have their scientific peers overwhelmingly endorsed this decision? Dr. Goldstein simply ignores this inconvenient reality, and presents his own minority opinion as if it reflected the view of the scientific community as a whole.

Dr. Goldstein also raises a second example of how human fetal tissue is "vital" for research, indicating that he uses such tissue in his attempt "to build new kidneys from stem cells," categorically asserting "it is only by examining this fetal tissue that it will be possible to determine the earliest biochemical signals that cells use . . . to make kidneys" (emphasis added). Yet Goldstein fails to note that substantial progress towards the goal of generating replacement kidneys *has already been accomplished* in other laboratories using stem cells from non-fetal sources.[1089] While Dr. Goldstein has clearly placed his faith in human fetal tissue research, his competitors have moved much more swiftly towards the goal of generating replacement organs

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[1086] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong., at 149 (unedited transcript) (Mar. 2, 2016) (Testimony of Lawrence Goldstein), http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-Wstate-GoldsteinL-20160302.pdf.

[1087] https://projectreporter.nih.gov.

[1088] A search of the NIH database of funded research (https://projectreporter.nih.gov) for 2014 using the NIH spending categories "Alzheimer's Disease" and "Human Fetal Tissue" returned two projects: one "core facility" (P50 award) that does not specifically generate research on Alzheimer's and one award that mentions Alzheimer's Disease, but is in fact focused on Down syndrome.

[1089] Generation of kidney organoids from human pluripotent stem cells. Takasato M, Er PX, Chiu HS, Little MH. Nat Protoc. 2016 Sep;11(9):1681-92.; Kidney organoids from human iPS cells contain multiple lineages and model human nephrogenesis. Takasato M, Er PX, Chiu HS, Maier B, Baillie GJ, Ferguson C, Parton RG, Wolvetang EJ, Roost MS, Lopes SM, Little MH. Nature. 2016 Apr 27;536(7615):238.

using an ethically uncontroversial approach. And for patients, actual results are undoubtedly far more compelling than Dr. Goldstein's personal ideology.

Finally, consistent with the view that fetal tissue is "essential" for research, tissue procurement companies such as StemExpress market cells derived from fetal tissue as valuable scientific reagents, often charging thousands of dollars for a single preparation.[1090] Yet ***all*** of the cell types obtained from human fetal liver by StemExpress can be obtained from alternative sources (placenta, umbilical cord and umbilical cord blood); including CD34+ cells,[1091] CD36+ cells,[1092] CD133+ cells,[1093] and stromal (mesenchymal) stem cells.[1094] While some individual scientists (such as Dr. Goldstein) may believe that fetal cells are somehow "superior" to cells with the same characteristics that have been isolated from other sources, fetal cells clearly do not have "unique" properties. The role of tissue procurement companies in creating a market for cells derived from human fetal tissue is difficult to determine, but it is obvious that a wide range of stem and progenitor cells can be obtained from ethically uncontroversial tissue sources—and from sources that are often more relevant to the study of adult or neonatal disease than cells derived from fetal tissue.

6. Claims that human fetal tissue is required for clinical trials and cures

Several institutions (AAAS, Hopkins, Rockefeller, UCLA, UCSD, UIC, Yale) make this claim. In support of this view, Dr. Goldstein correctly notes in his March 2 testimony before the House Select Investigative Panel[1095] that neural stem cells derived from fetuses are currently being tested in clinical trials. He further suggests that medical treatments will be halted or delayed if fetal tissue is not available for research. A similar claim was made by the *Guttmacher Policy Review*, which states, "Clinical trials transplanting fetal cells are currently underway for people with spinal cord injury, stroke and ALS (Lou Gehrig's disease), and may soon begin for those with Alzheimer's disease, Parkinson's disease and multiple sclerosis."[1096]

[1090] StemExpress website on fetal liver, http://stemexpress.com/product-category/fetal-liver/.

[1091] A novel method of CD34+ cell separation from umbilical cord blood. Mehrishi JN, Bakács T. Transfusion. 2013 Nov;53(11):2675-80.

[1092] Extensive ex vivo expansion of functional human erythroid precursors established from umbilical cord blood cells by defined factors. Huang X, Shah S, Wang J, Ye Z, Dowey SN, Tsang KM, Mendelsohn LG, Kato GJ, Kickler TS, Cheng L. Mol Ther. 2014 Feb;22(2):451-63.

[1093] Isolation and characterization of CD133+CD34+VEGFR-2+CD45- fetal endothelial cells from human term placenta. Sölder E, Böckle BC, Nguyen VA, Fürhapter C, Obexer P, Erdel M, Stössel H, Romani N, Sepp NT. Microvasc Res. 2012 Jul;84(1):65-73.

[1094] Novel isolation strategy to deliver pure fetal-origin and maternal-origin mesenchymal stem cell (MSC) populations from human term placenta. Patel J, Shafiee A, Wang W, Fisk NM, Khosrotehrani K. Placenta. 2014 Nov;35(11):969-71.

[1095] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong., at 149 (unedited transcript) (Mar. 2, 2016) (Testimony of Lawrence Goldstein, at 110), http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-Wstate-GoldsteinL-20160302.pdf

[1096] Fetal Tissue Research: A Weapon and a Casualty in the War Against Abortion. Boonstra, HD. Guttmacher Policy Review 2016 | Vol. 19, http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-20160302-SD011.pdf.

a) Fetal tissue is used in only a tiny fraction of clinical trials

Goldstein, Guttmacher, and the institutions noted above all fail to mention that human fetal tissue contributes to only a tiny fraction of the over 230 *thousand* clinical trials currently underway in the United States and around the world.[1097] A detailed examination of the studies indexed in the NIH database for clinical trials determined that there are currently only 7 studies involving transplantation of fetal tissue into patients (See Exhibit 9.4). Similarly, there are only 35 trials involving "stem cell lines" originally derived from human embryonic or fetal tissue (See Exhibit 9.4). Of these, a surprisingly large number (seven trials; 20%) have been withdrawn, suspended, or terminated—more than twice the rate seen for clinical studies using non-fetal stem cells.[1098] Together, these 42 fetal or embryonic stem-cell studies account for only 0.01% of all ongoing clinical trials. Clearly, the vast majority of scientists and physicians developing new treatments for human disease do not rely on either human fetal tissue or stem-cell lines derived from human fetuses.

Importantly, fetal tissue has been used in clinical research since the 1920s,[1099] yet in nearly 100 years of unrestricted research, *not a single clinical treatment has been developed from human fetal tissue*. Even worse, there are currently only a handful of studies investigating the use of fetal tissue or fetal-derived cells, most of which are in very early (phase I) clinical trials that have not yet shown any benefit to patients. Fetal tissue research has had ample time to prove itself clinically useful and has failed to do so. The evidence clearly indicates that *fetal tissue research is outdated technology that is largely ignored in by the clinical research enterprise because it has shown no benefit to patients.*

b) Non-fetal stem cells have consistently shown much greater clinical promise than fetal stem cells

As noted above, human fetal tissue has been the subject of clinical and scientific research since the 1920s, yet in modern research, fetal tissue is primarily used as a source of stem and progenitor cells. Similar cells exist in multiple adult and birth-related tissues, yet they have only recently become the subject of active clinical investigation. For example, while scientists appreciated the existence of stem cells in bone marrow as early as the 1930s,[1100] bone marrow

[1097] Based on the Clinical Trials website; Queried 11/22/2016; www.clinicaltrials.gov.

[1098] Overall, 8.1% of all studies listed in the Clinical Trials database have been terminated, suspended, or withdrawn (18,868 of 230, 631 as of 11/22/2016). A slightly higher number of studies involving non-fetal stem cells have been prematurely terminated (635 of 5805; 10.9%). Studies can be ended prematurely for a number of reasons, including insufficient recruitment of patients, futility (no positive results), clear benefit to patients or harm to patients. A recent analysis indicates that three factors (insufficient recruitment, futility and harm) account for 82% of premature terminations. *See* Premature trial discontinuation often not accurately reflected in registries: comparison of registry records with publications. Alturki R, Schandelmaier S, Olu KK, von Niederhäusern B, Agarwal A, Frei R, Bhatnagar N, Hooft L, von Elm E, Briel M. J Clin Epidemiol. 2016 Sep 7. pii: S0895-4356(16)30403-6

[1099] Op cit. Hurst AF, *Addison's Disease, 1922.*

[1100] Based on the PubMed database, the first paper with the phrase "stem cell" in the title or abstract was published in 1932; The production of osteogenic sarcomata and the effects on lymph nodes and bone marrow of intravenous infections of radium chloride and mesothorium in rabbits. Sabin FR, Doan CA, Forkner CE. J Exp Med. 1932 Jul 31;56(2):267-89.

from an unrelated donor was not used for a medical transplant until 1968,[1101] more than four decades after the first fetal tissue transplant. The first non-fetal stem cells from tissue other than bone marrow (satellite cells from muscle) were not isolated until 1986.[1102] Finally, multi-lineage progenitor cells were first isolated from adult adipose tissue in 2001,[1103] and these cells proved to be so medically promising, they were used in clinical trials a mere four years later.[1104] Despite the relatively recent isolation of non-fetal stem cells from bone marrow, fat and other tissues, they are currently being tested in over 5,800 clinical trials for a wide range of human disease, including diabetes, Parkinson's, multiple sclerosis, heart disease and cancer. Hundreds of studies using non-fetal stem cells have already advanced to phase II and phase III trials because they have shown clear benefit to patients.[1105]

c) Conclusion

In over 100 years of unrestricted research, fetal tissue has not proven to be useful for treating human disease. In contrast, although stem and progenitor cells from non-fetal tissues have only recently been discovered, they have rapidly yielded clinical treatments with ***proven benefit to patients***. The alarmist claims that restrictions on human fetal tissue research would somehow delay or prevent the development of cures are entirely unfounded.

7. Assertions that human fetal tissue is required for production of humanized mice that provide a model for human diseases with a restricted host range

Several universities (Baylor, Columbia, Dartmouth, Harvard, Hopkins, OHSU, Rockefeller, UCLA, UIC, UMN, UWM) claim that human fetal tissue is necessary to create "humanized mice" disease models. In the most extreme example of this research model, human fetal progenitors from blood, liver, and thymus are used to create a "BLT" mouse that reconstitutes many aspects of the immature human immune system.

However, humanized mice can be produced using a variety of more mature tissues, including progenitors from adult peripheral blood and from umbilical cord.[1106] Different methods of generating humanized mice have both advantages and disadvantages, with no single method being clearly superior.[1107] While there may be some scientific advantages to the use of human

[1101] Gatti RA, Meuwissen HJ, Allen HD, et al. Immunological reconstitution of sex-linked lymphopenic immunological deficiency. Lancet. 1968 Dec 28. 2(7583):1366-9.
[1102] Bischoff R. 1986. Proliferation of muscle satellite cells on intact myofibers in culture. Dev Biol. 115:129–139.
[1103] Zuk, P.A., Zhu, M., Mizuno, H., Huang, J., Futrell, J.W., Katz, A.J., Benhaim, P., Lorenz, H.P., and Hedrick, M.H. (2001). Multilineage cells from human adipose tissue: implications for cell based therapies. Tissue Eng 7, 211-228.
[1104] García-Olmo D, García-Arranz M, Herreros D, Pascual I, Peiro C, Rodríguez-Montes JA. A phase I clinical trial of the treatment of Crohn's fistula by adipose mesenchymal stem cell transplantation. Dis Colon Rectum. 2005;48(7):1416–1423.
[1105] A query of Clinical Trials website returns over 700 phase II and phase III trials involving non-fetal stem cells. Queried 10/28/2016; www.clinicaltrials.gov.
[1106] Reviewed in: Increasing hematopoietic stem cell yield to develop mice with human immune systems. Biancotti JC, Town T. Biomed Res Int. 2013;2013:740892.
[1107] Humanized mice for immune system investigation: progress, promise and challenges. Shultz LD, Brehm MA, Garcia-Martinez JV, Greiner DL. Nat Rev Immunol. 2012 Nov;12(11):786-98.; Improvements and Limitations of

fetal tissue in some experimental settings, fetal tissue is clearly not "required" for production of humanized mice. Moreover, this is a rapidly evolving technology, with many avenues as yet unexplored. For example, it is unclear whether fetal liver and thymus are required to produce "BLT" mice. Recent work indicates thymic tissue is functional throughout adult life, [1108] and postnatal thymic tissue has been used to reconstitute immune function in human patients,[1109] strongly suggesting that human fetal thymus may not be required for the BLT-mouse model.

8. Assertions that human fetal tissue is required to "validate" scientific findings obtained with human embryonic stem cells (hESCs) or human induced pluripotent stem cells (hiPSCs)

Several universities (Columbia, UCLA, Penn, and Yale) make this assertion, but it is unsupported by the scientific literature. Only a tiny fraction of all papers indexed in PubMed on the topic of cellular reprogramming also examine fetal tissue. Moreover, the use of iPSCs has grown dramatically since this technology was pioneered in 2007,[1110] yet despite the claim that human fetal tissue is required to "validate" iPSCs, there has been no corresponding growth in the use of human fetal tissue over this period.

Although the same assertions have been put forward by multiple institutions and individuals, these claims have no factual support. To date, the Panel has received *no evidence from scientific societies, medical societies, research universities, or individual scientists supporting the conclusion that human fetal tissue research provides unique scientific information or that this research is important for the development of new treatments for human disease.*

C. Response to the claim that "The Select Panel Has Thwarted Life-Saving Research"

The Minority report of the House Select Investigative Panel, dated December 5, 2016 (hereafter, "the Minority Report"), boldly states that "Select Panel Republicans have conducted an end-to-end attack on fetal tissue donation and research" (p. 12) and have "roundly rejected or ignored" the evidence for the value of this research, concluding:

> In reality, the Panel has received ***overwhelming evidence*** of the indispensable role that fetal tissue research plays in advancing our understanding and treatment of a staggering array of conditions that

Humanized Mouse Models for HIV Research: NIH/NIAID "Meet the Experts" 2015 Workshop Summary. Akkina R, Allam A, Balazs AB, Blankson JN, Burnett JC, Casares S, Garcia JV, Hasenkrug KJ, Kashanchi F, Kitchen SG, Klein F, Kumar P, Luster AD, Poluektova LY, Rao M, Sanders-Beer BE, Shultz LD, Zack JA. AIDS Res Hum Retroviruses. 2016 Feb;32(2):109-19.

[1108] The role of the thymus in immune reconstitution in aging, bone marrow transplantation, and HIV-1 infection. Haynes BF, Markert ML, Sempowski GD, Patel DD, Hale LP. Annu Rev Immunol. 2000;18:529-60.

[1109] Transplantation of thymus tissue in complete DiGeorge syndrome. Markert ML, Boeck A, Hale LP, Kloster AL, McLaughlin TM, Batchvarova MN, Douek DC, Koup RA, Kostyu DD, Ward FE, Rice HE, Mahaffey SM, Schiff SE, Buckley RH, Haynes BF. N Engl J Med. 1999 Oct 14;341(16):1180-9.

[1110] Human embryonic and induced pluripotent stem cell research trends: complementation and diversification of the field. Kobold S, Guhr A, Kurtz A, Löser P. Stem Cell Reports. 2015 May 12;4(5):914-25.

> afflict millions of people in this country and throughout the world. [emphasis added]

In support of this conclusion, the Minority Report identifies 10 medical conditions that it claims have benefited from human fetal tissue research. Yet for each of these conditions, the "overwhelming evidence" amounts to nothing more than unsupported assertions made by universities, scientific societies and individual scientists that have been uncritically repeated in the Minority Report, seemingly as an act of blind faith in scientific "authorities."

While appealing to authority can sometimes be a valid way to formulate an opinion, the views of individual scientists who personally conduct human fetal tissue research (and of the institutions that employ such individuals) are clearly subject to conflict of interest. When such views are also unaccompanied by any form of factual evidence, they have even less credibility. Yet when such personal opinions are also ***manifestly contradicted by the available evidence***, they must (at minimum) be dismissed as groundless, and (at worst) be seen as a deliberate attempt to distort the facts out of self-interest or ideological conviction.

We have already addressed in detail the false and misleading arguments put forward in letters to the panel (Chapter 9.B). Here, we specifically address the claims made in the Minority Report and demonstrate that publicly available evidence[1111] **clearly establishes the claims made in the report are false.** Below, we discuss each of these claims in light of the evidence and conclude by presenting factual data on the use of fetal tissue in NIH-funded disease research, FDA-approved clinical trials and in the peer-reviewed scientific literature.

1. Alzheimer's

The Minority Report begins by solemnly reminding us that Alzheimer's is a serious disease (p. 13). We agree. However, the report uncritically repeats the assertion made by Dr. Lawrence Goldstein that fetal tissue is the "gold standard" for Alzheimer's research. As noted in Chapter 9.B.5 of this report, the facts simply do not support Dr. Goldstein's opinion on this matter or justify the unquestioning faith the Minority Report appears to have placed in the veracity of his assertion. In reality, of the 1300 research grants investigating Alzheimer's awarded in 2014 and the over 1900 ongoing clinical trials testing possible treatments for Alzheimer's, ***not a single one uses fetal tissue***.[1112] While Dr. Goldstein may personally believe human fetal tissue is "the gold standard" for research, the vast majority of his scientific colleagues, as well as the NIH and the FDA clearly do not share this opinion.

[1111] Including: the funded grant database maintained by the National Institutes of Health (www.projectreporter.nih.gov), the clinical trials database maintained by the NIH and the Food and Drug Administration (www.clinicaltrials.gov), and the PubMed database of peer-reviewed scientific research maintained by the NIH and the National Library of Medicine (www.ncbi.nlm.nih.gov/pubmed).

[1112] A search of the NIH database of funded research (https://projectreporter.nih.gov) for 2014 using the NIH spending categories "Alzheimer's Disease" and "Human Fetal Tissue" returned two projects: one "core facility" (P50 award) that does not support a specific research program and one award that mentions Alzheimer's Disease, but is in fact focused on Down syndrome. A search of the clinical trials database (www.clinicaltrials.gov) for the term "fetal" and the medical condition "Alzheimer's" returned no studies.

2. Amyotrophic lateral sclerosis (ALS)

The Minority Report also reminds us that ALS is a serious disease (p. 13), and again, we agree. Just as for Alzheimer's, the report uncritically repeats assertions made by Johns Hopkins University and UCLA that fetal research is somehow important for developing a cure for ALS. Yet in reality, there is no evidence to support this assertion. Of the 360 ongoing clinical trials for ALS, only a single study involves transplantation of human fetal tissue (NCT01640067). This trial, completed in December of 2015, was an early, "phase I" study that has thus far neither advanced to a phase II trial nor published any results. Thus, despite the hyperbolic claim that "fetal tissue has already resulted in promising developments with regards to potential ALS treatments" (p. 14), there are no clinical findings in support of this claim.

The study of a new drug for ALS noted by Johns Hopkins is most likely to be the phase I trial of GM604, or Genervon's Master Regulator 604 (NCT01854294). The Minority Report repeats Johns Hopkins' glowing characterization of this research as "so promising for a potential ALS treatment that the FDA has approved an investigational new drug application for early stage clinical trials" (p. 14). Yet a comprehensive report on the GM604 trial by ALSUntangled (www.alsuntangled.com),[1113] a patient advocacy group and information resource, assigns this trial three "D" scores (the second lowest) and two "U" or "unranked" scores—indicating that there is insufficient information to make a valid judgment regarding the quality of the trial. They note that there is only a single "possibly relevant" publication using this drug in a mouse model of stroke (not ALS), with no peer-reviewed studies supporting the many claims made regarding GM604 on the Genervon web site. The report concludes:

> At this time, ALSUntangled finds no independently verifiable data supporting the efficacy or even the safety of GM604 in patients with ALS. We believe that independent peer review and replications are fundamentals of good science.

The Republican members of the Panel agree.

3. Diabetes Mellitus (DM)

Once again, the Minority Report reminds us that Diabetes is also a serious disease (p. 14). The report repeats the assertions of Harvard and Johns Hopkins Universities that fetal tissue is important for the study of DM and the complications of this disease, including diabetic retinopathy. Yet there is a difference between ***assertion*** and ***evidence***. Not only do Harvard and Johns Hopkins fail to report any evidence in support of their assertions; the objective facts largely contradict their conclusion. For example, in 2014, the NIH funded 2,332 research grants on the topic of diabetes and related diseases, and only 4 of these grants (less than 0.2%) involve human fetal tissue; one "exploratory" (R21) grant, a Postdoctoral fellowship award (F32) and two investigator initiated (R01) grants.[1114] While these projects report modest scientific results (an average of 1.2 scientific papers/grant/year), they are clearly not at the forefront of the field in

[1113] ALSUntangled No. 34: GM604. Amyotroph Lateral Scler Frontotemporal Degener. 2016 Oct - Nov;17(7-8):617-621.
[1114] Based on the NIH database: https://projectreporter.nih.gov/.

terms of productivity or impact. Based on the actual evidence, it is hard to see how the Minority Report's claim that human fetal tissue research makes a significant impact on DM is justified.

Similarly, of the *11,398 current clinical trials for childhood diabetes*, only one (NCT02239354) involves human fetal tissue.[1115] Similar to the GM604 trial discussed above, this DM study is an early, phase I trial with no reported results, and therefore the "promise" (or lack of promise) of this approach cannot be evaluated. However, the fact that fetal tissue contributes to only a single trial out of over 11-thousand clearly indicates that the overwhelming majority of physicians and scientists working to relieve diabetes patients "of the daily finger pricks and insulin injections they need to stay alive" (p. 14) simply do not share the opinion voiced by Harvard and Johns Hopkins that fetal tissue is important for basic and clinical research into this disease.

4. HIV/AIDS

The Minority Report quotes three institutions (the University of Minnesota, Oregon Health and Science University, and the International Society for Stem Cell Research), all of which assert that fetal tissue research has provided significant benefit to HIV patients. It also repeats an assertion made by Dr. Brooks Jackson of the University of Minnesota that fetal tissue was "critical in my research to develop an intervention to prevent mother-to-child transmission of HIV. That research alone has saved over 1 million infants in the last ten years while also reducing elective abortion in HIV positive women by more than half in this country." Dr. Jackson makes this assertion despite the fact that a query of the PubMed database[1116] does not return a single paper using fetal tissue that lists him as an author.

It is possible Dr. Jackson is merely asserting that human fetal tissue research contributed in some general way to HIV research, while his own research is responsible for saving over one million infants. Yet if this claim refers to the United States, it is *mathematically impossible*. The Centers for Disease Control and Prevention (CDC) report that "women represent 20%, (246,372) of the estimated 1,210,835 cumulative AIDS diagnoses in the United States from the beginning of the epidemic through the end of 2014."[1117] Even if every single woman in this country who had ever been infected with HIV had also been pregnant and had further been the beneficiary of Dr. Jackson's intervention, there are simply not enough HIV-positive women to have "saved over 1 million infant lives over the last 10 years" by preventing transmission of the virus from women to their children.

Alternatively, Dr. Jackson may be asserting that his research in other countries (presumably the HIVNET 012 clinical trial in Africa) has "alone" saved 1 million infants. It is true that global efforts to reduce HIV transmission from mothers to children have improved outcomes for women and children worldwide. AIDS.gov reports that there are approximately 1.8 million children living with HIV worldwide. In 2015, 77% of HIV-positive pregnant women had access to antiretroviral medicines to prevent transmission to their babies, with new HIV infections among children declining by 50% since 2010. This is an encouraging trend, yet there is no clear evidence that human fetal tissue was "critical" to either Dr. Jackson's research or to

[1115] Based on the Clinical trials database: www.clinicaltrials.gov.
[1116] https://www.ncbi.nlm.nih.gov/pubmed.
[1117] CDC, HIV Among Women, https://cdc.gov/hiv/group/gender/women/.

the development of antiretroviral drug treatments for HIV. Moreover, it is disingenuous to claim that the research of a single investigator has been responsible for the benefits provided by a global effort to combat HIV that (in the U.S. alone) has involved:

The Department of State[1118]
The Department of Health and Human Services[1119]
The Centers for Disease Control[1120]
The Food and Drug Administration[1121]
The Health Resources and Services Administration[1122]
The National Institutes of Health[1123]
The Substance Abuse and Mental Health Service Administration[1124]
The Department of Commerce[1125]
The Department of Defense[1126]
The Department of Labor[1127]
The Peace Corps[1128]
The U.S. Agency for International Development[1129]
27,398 NIH research grants on HIV/AIDS in the last five years[1130]
7946 ongoing clinical trials to treat HIV/AIDS[1131]

5. Infant and Childhood Leukemia

The Minority Report quotes two institutions (UCLA and CHOP) who assert that fetal tissue is important for treating childhood leukemia. Yet, as we have already noted, assertion is not evidence, and the facts do not support this assertion. Between 2010 and 2014, the NIH funded 887 grants on childhood leukemia, and ***not a single project used human fetal tissue***. Similarly, of the 750 ongoing clinical trials for childhood leukemia, ***not a single one involves fetal tissue***. While individual researchers and their institutions may "believe" without factual support that fetal tissue is important for the study and treatment of this disease, *it is not used for any successful, NIH-funded research programs or for any clinical trials designed to cure patients of childhood leukemia.*

[1118] http://www.pepfar.gov/about/agencies/c19390.htm.
[1119] http://www.pepfar.gov/about/agencies/c19401.htm.
[1120] http://www.cdc.gov/globalhivtb/index.html.
[1121] http://www.fda.gov/internationalprograms/pepfar/default.htm.
[1122] http://hab.hrsa.gov/global-hivaids-program.
[1123] https://aidsinfo.nih.gov/.
[1124] http://www.samhsa.gov/hiv-aids-viral-hepatitis.
[1125] http://www.pepfar.gov/about/agencies/c19398.htm.
[1126] http://www.pepfar.gov/about/agencies/c19397.htm.
[1127] http://www.pepfar.gov/about/agencies/c19400.htm.
[1128] http://www.pepfar.gov/about/agencies/c19402.htm.
[1129] https://www.usaid.gov/what-we-do/global-health/hiv-and-aids.
[1130] Grants on the topic of HIV/AIDS awarded between 2011-2015 (https://projectreporter.nih.gov).
[1131] www.clinicaltrials.gov.

6. Age-related Macular degeneration (AMD)

Harvard University and the University of Michigan assert that fetal tissue is important for the study of AMD *and adult-onset disease*. Go figure. While some researchers investigating AMD use fetal eyes, the relevance of this tissue to the disease is remote, especially given the many well-documented differences between fetal and adult neural tissue.[1132]

7. Preterm birth

The University of Illinois at Chicago reports that fetal tissue is "essential" for studying premature birth, but (again) this claim is difficult to reconcile with the facts. In 2014, the NIH funded 337 grants in the general area of "conditions affecting embryonic and fetal periods," and only one award employed human fetal tissue. Moreover, over a period of nine years, this project has only been modestly productive, yielding 11 papers, only 9 of which address basic biology and none of which appeared in top-ranked scientific journals. How this very modest level of productivity constitutes an "essential" contribution to the field is hard to imagine.

8. Spinal cord injury

The Minority Report again quotes Dr. Goldstein's assertion that research trials involving fetal tissue "are vital to pushing medical science forward" (p. 17), citing a single, phase I clinical trial using fetal-derived stem cells to treat spinal cord injury. What Dr. Goldstein fails to mention is that there are *over 900 clinical trials treating spinal cord injury*, including over 40 involving stem cells derived from adult tissue and over 100 that have advanced to phase II trials. How a single study with no published findings is "pushing medical science forward" in the wake of hundreds of promising treatments for spinal injury is hard to imagine.

9. Vaccine research

The Minority Report quotes Harvard, Yale, and the University of Wisconsin in asserting that human fetal tissue research has been vital to the development of vaccines. They falsely assert that "Panel Republicans acknowledge that the development of the polio vaccine relied on fetal tissue research," apparently having failed to read or at least failed to understand the interim report of the Republican members. As detailed above in Chapter 9.B.2-3, it is invalid to claim that vaccine research "would not have been possible without cells of fetal origin" (p. 17). This argument is as illogical as asserting, "vaccine research would not have been possible without automobiles," simply because automobiles were used by some vaccine researchers and may have facilitated research in some cases. While it is impossible to know how vaccine research might have unfolded without the use of fetal tissue, history *conclusively proves that it is entirely possible to develop vaccines without "cells of fetal origin."* For example, vaccines for Rabies, Diphtheria, Typhoid, Cholera, Plague, Tetanus, Pertussis and Bacille-Calmette-Guerin disease)

[1132] A survey of human brain transcriptome diversity at the single cell level. Darmanis S, Sloan SA, Zhang Y, Enge M, Caneda C, Shuer LM, Hayden Gephart MG, Barres BA, Quake SR. Proc Natl Acad Sci U S A. 2015 Jun 9;112(23):7285-90.

were all developed in the 1800s and early 1900s, well before the first use of fetal tissue in research. It is also an indisputable fact that the vaccines for Polio, Measles, Mumps and (the first) vaccine for Rubella were all developed using animal cell culture. Finally, of the nearly 75 vaccine formulations approved for use in the United States, *not a single vaccine is produced using fetal tissue* (see Exhibit 9.3).

10. Zika research

Again quoting the opinions of individuals and organizations, the Minority Report asserts that "fetal tissue is most needed in circumstances such as the Zika virus" (p. 18). Yet the published literature in this area simply does not support this assertion. As noted in Chapter 9.B.4 of this report, human fetal tissue research is not making a strong contribution to Zika research, with the major advances published in the most respected journals involving cell culture and animal models. Moreover, current clinical trials for a virus that causes brain defects very similar to Zika (the Cytomegalovirus) have clearly not relied on human fetal tissue research.

11. Objective Data on the contribution of fetal tissue to basic research, clinical research, and peer-reviewed scientific publications

It could possibly be the case that the institutions the Minority Report relied on simply erred in identifying diseases that benefit from human fetal tissue research; *i.e.*, if the institutions had focused on diseases arising during fetal life and/or affecting infants and children, human fetal tissue might play a greater role in this research. However, this is also not the case. Even for diseases arising during fetal life, human fetal tissue research plays little or no role in basic science investigations or clinical investigations and makes only a trivial contribution to the scientific literature (Table 1).

Below we present data on 1) grants that the NIH lists under specific disease funding areas that also use human fetal tissue, 2) clinical trials for specific diseases that also use human fetal tissue (Exhibit 9.4) and 3) publications indexed in the PubMed database that include both specific disease name and the terms "fetus" and "humans" as Medical Subject Headings (MeSH).

While the data on grants and clinical trials is comprehensive, the data on publications is informative but likely to be less comprehensive. The PubMed database is large, indexing over 20 million research papers. It is impossible to examine publications in detail, and searches of this database must rely on MeSH term indexing that does not specifically identify papers using human fetal tissue for research. Consequently, some publications using fetal tissue are not likely to be identified by this search (false negatives), and some publications that are identified do not actually use fetal tissue for research (false positives).

For example, a large proportion of the papers indexed under the MeSH terms "fetus" and "preterm birth" do not utilize fetal tissue for research, but rather examine aspects of fetal physiology (heart rate, response to interventions, etc.) in an attempt to either predict or prevent preterm delivery.[1133]

[1133] *See, e.g.*, Ultrasound Measurement of the Fetal Adrenal Gland as a Predictor of Spontaneous Preterm Birth. Hoffman MK, Turan OM, Parker CB, Wapner RJ, Wing DA, Haas DM, Esplin MS, Parry S, Grobman WA, Simhan HN, Myers S, Holder TE Jr, Rumney P, Litton CG, Silver RM, Elovitz MA, Peaceman AM, Emery S, Mercer

However, the relative contribution of all types of fetal research, including fetal tissue

Table 1: Contribution of human fetal tissue to disease research.

Diseases Identified in the Minority Report	Grants Awarded 2015			Clinical trials			Peer Reviewed Papers		
	Fetal	Total	%	Fetal	Total	%	"Fetus"	Total	%
Alzheimer's	0	1362	0.0%	0	1956	0.0%	109	75704	0.1%
Amyotrophic lateral sclerosis	0	152	0.0%	3	360	0.8%	33	14859	0.1%
Diabetes Mellitus	6	2382	0.3%	1	14807	0.01%	1486	353110	0.4%
HIV/AIDS	74	4935	1.5%	0	7950	0.0%	372	87756	0.4%
Infant and Childhood Leukemia	0	339	0.0%	0	750	0.0%	21	1996	1.1%
Age-related Macular degeneration	5	187	2.7%	10	1371	0.7%	15	18826	0.1%
Preterm birth*	4	355	1.1%	0	3375	0.0%	503	9006	5.6%
Spinal cord injury	0	249	0.0%	8	907	0.9%	49	41461	0.1%
Vaccine research	28	2509	1.1%	0	7024	0.0%	509	280174	0.2%
Zika/Brain Disorders**	158	52338	0.3%	0	18	0.0%	6	1926	0.3%
Diseases Arising in the Fetus and/or Affecting Children	**Grants Awarded 2015**			**Current clinical trials**			**Peer Reviewed Papers**		
	Fetal	**Total**	**%**	**Fetal**	**Total**	**%**	**"Fetus"**	**Total**	**%**
Attention Deficit Disorder	0	121	0.0%	0	1277	0.0%	23	23079	0.1%
Autism	2	506	0.4%	0	741	0.0%	43	17711	0.2%
Batten Disease	0	15	0.0%	0	23	0.0%	7	1761	0.4%
Epilepsy	2	397	0.5%	0	1404	0.0%	289	141397	0.2%
Hydrocephalus	0	15	0.0%	0	135	0.0%	275	21192	1.3%
Intellectual disabilities	10	1025	1.0%	0	541	0.0%	1255	86516	1.5%
Pediatric AIDS	0	467	0.0%	0	350	0.0%	8	1586	0.5%
Pediatric cancer	0	760	0.0%	0	1642	0.0%	302	56854	0.5%
Spinal muscular atrophy	0	34	0.0%	0	157	0.0%	15	1050	1.4%
Sudden Infant Death Syndrome	1	31	3.2%	0	89	0.0%	78	7094	1.1%

Grant data is from the NIH project reporter database. Clinical data is from the clinical trials database. Publication data is from the PubMed database (queried for disease name, "fetus" and "humans" as MeSH terms.

* The NIH does not have a spending category for preterm birth; grant data shown is for the broader category "Conditions affecting the embryonic and fetal periods," many of which result in preterm birth or fetal demise.

**The NIH does not have a spending category for Zika research; grant data shown is for the broader category "Brain Disorders," which includes a wide range of medical conditions.

research, to various diseases can be reasonably inferred from this data, and in all cases, ***fetal tissue makes a tiny contribution to disease research, if it contributes at all.***

BM,Koch MA, Saade GR; Nulliparous Pregnancy Outcomes Study: Monitoring Mothers-to-Be (nuMoM2b) Network.. Obstet Gynecol. 2016 Apr;127(4):726-34. Intra-Amniotic Administration of HMGB1 Induces Spontaneous Preterm Labor and Birth. Gomez-Lopez N, Romero R, Plazyo O, Panaitescu B, Furcron AE, Miller D, Roumayah T, Flom E, Hassan SS. Am J Reprod Immunol. 2016 Jan;75(1):3-7.

12. Conclusion

The assertions of the Minority Report are undocumented and unsupported by any of the publicly available evidence. Rather, this evidence clearly indicates that for all of the diseases held up as examples by the Minority Report, human fetal tissue makes little or no contribution to either research, clinical trials or the peer-reviewed scientific literature. ***There is no "overwhelming evidence" for the value of human fetal tissue research. In fact, there is no evidence at all.*** There is only what appears to be self-interested assertion from individuals and institutions engaged in human fetal tissue research that the Minority Report has naively accepted as "fact."

D. Analysis of currently funded long-standing human fetal-tissue research.

1. Goals of This Analysis

Many assertions have been made regarding the role of human fetal tissue in modern biomedical research, but to date, no factual evidence in support of these assertions has been provided. Moreover, publicly available evidence directly contradicts the claims made by universities, scientific societies and professional medical associations that are repeated in the Minority Report. We have presented considerable evidence that contradicts these claims. However, the data discussed thus far does not directly address three central questions regarding human fetal tissue research:

a. How many research projects rely on human fetal tissue?
b. How productive is human fetal tissue research, compared to non-fetal tissue research?
c. What is the impact of human fetal tissue research on the field, compared to non-fetal research; *i.e.*, how "important" is fetal research for the advance of science and medicine?

To answer these critical questions, the House Select Investigative Panel elected to conduct a neutral and objective examination of current human fetal tissue research.

2. Criterion for Grant Selection

It is important to note that grants utilizing human fetal tissue were <u>not</u> evaluated by the Panel for either the quality of the research or the competence of the investigator; <u>*i.e., it was assumed that the process of peer review is sufficient to identify meritorious research and successful scientists.*</u> Grants were examined <u>only</u> to determine the precise use of human fetal tissue and the impact of this research on the literature. To achieve these goals, grants were selected from the National Institutes of Health (NIH) grant database (https://projectreporter.nih.gov), using the following criteria.

a. To determine the use of human fetal tissue over an extended period, grants funded by the NIH over the last five years (2010-2014) were examined. A total of 329 grants using human fetal tissue were awarded during this period. **This represents approximately 0.2% of the total NIH-funded grant portfolio for these years**.

b. In order to determine the productivity and the impact of successful research programs involving human fetal tissue, established grants (*i.e.*, grants that had undergone competitive renewal and had been funded for 10 or more years) were further evaluated.
c. Several grant mechanisms were excluded from detailed analysis for the following reasons:
    i. Grants that are not directly responsible for generating scientific findings were not analyzed (*i.e.*, grants funding institutional "core" facilities or centers; P50, P30, PN2, R24, U54 and P01 cores).
    ii. Intramural grants to NIH researchers (ZIA) were excluded because they are awarded using criteria specific to internal NIH programs and therefore cannot be directly compared to external research grants.

3. Grant Classification

These criteria identified a total of 36, long-standing grants to individual researchers. A detailed inspection determined that only 34 of these projects involved primary human fetal tissue. These 34 projects were examined by a scientific reviewer to determine the proposed use of human fetal tissue relative to the research questions, as defined by the investigators themselves. The 34 grants investigate a range of scientific topics, but most address either basic mechanisms of biologic function or adult-onset disease. For example, twelve of the 34 grants investigate conditions arising in adults, while 15 are focused on basic biological processes that occur at all stages of life. Only a minority were focused on processes occurring during fetal life. Based on the research questions and the use of human fetal tissue proposed by the investigators, grants using fetal tissue were divided into three classes.

a. **Class 1:** Fetal tissue is required for the proposed study. There are no reasonable alternatives.
b. **Class 2:** Fetal tissue is not essential for the study. There are some scientific advantages to the use of fetal tissue, but alternatives exist.
c. **Class 3:** Fetal tissue is not essential for the study. There are no scientific advantages to the use of fetal tissue, and alternatives exist. In some cases, postnatal tissue is more relevant to the scientific question.

Of the 34 long-standing grants examined, 8 (approximately 24%) require human fetal tissue to accomplish the aims of the grant (*i.e.*, no reasonable alternatives exist). For 5 grants (approximately 15%), the use of human fetal tissue provides some advantage in terms of efficiency and/or relevance to human disease. However, these advantages are not critical to accomplish the goals of the proposed research, and reasonable alternatives exist; *i.e.*, the investigators themselves proposed multiple means to accomplish the same goals, most of which did not require human fetal tissue. For the remaining 21 grants (approximately 62%), human fetal tissue is not required to accomplish the goals of the proposed research, there are no advantages to the use of human fetal tissue, and superior alternatives exist. The nature of the studies and the proposed use of human fetal tissue are summarized in Exhibit 9.5, The Grant Classification Table. NB: To avoid any privacy concerns, the names of the grants and of the investigators that were included in the public database have been redacted.

4. Class 1 Grant Analysis

Eight Class 1 grants were identified. *This represents approximately 0.002% of the NIH research portfolio for this period (2010-14)*; *i.e.*, only 2 grants out of 100,000 are both long-standing and require human fetal tissue.

To obtain information on the relative productivity and impact of Class 1 grants, the publicly available information was further analyzed. The NIH database of funded research includes detailed information on publications resulting from each grant. Within the scientific profession, one of the most widely accepted means of determining the impact of a specific research paper is the number of citations that are made to that paper in the literature (*i.e.*, the "citation index"). Therefore, to determine the productivity and impact of human fetal tissue research, we examined both the number of papers resulting from each grant and the number of citations made to those papers by other researchers in the field.

Several factors must be taken into consideration when comparing research productivity and impact across different research groups and different scientific fields. First, the number of papers published varies considerably in different areas of research, depending on the amount of time necessary to conduct specific kinds of scientific investigations. Moreover, laboratories at well-endowed institutions can produce papers more rapidly, due to superior institutional support and facilities. Therefore, simply comparing the number of publications produced by different laboratories at different institutions can sometimes be misleading.

Similarly, the number of citations a specific paper receives can vary quite a bit from field to field. For example, some areas of research involve a large number of investigators, and papers in such areas receive a greater number of citations compared to papers of similar quality in research areas with fewer investigators.

To control for these factors, the productivity and relative impact of human fetal tissue research was determined by comparing publications that either did or did not involve human fetal tissue that were produced by the same research groups. A detailed examination of all publications resulting from the eight Class 1 grants identified above determined that seven of these research groups conducted both fetal and non-fetal research (as determined by a knowledgeable scientific reviewer), and therefore the productivity and impact of fetal and non-fetal research could be directly compared, with all other factors remaining constant.

A final factor taken into consideration was that the number of citations a paper receives is influenced by the date of publication in both positive and negative ways. Papers published earlier have more time to accumulate citations than recently published papers of similar quality. Conversely, papers published long ago using outdated technology tend not to be cited in the current literature unless they are of particular historic significance—regardless of the overall quality and impact of the research at the time of publication. Therefore, to fairly compare fetal and non-fetal research from the same laboratories, we considered papers published over the last 15 years (*i.e.*, from 2001 onward), ending with the most recently published paper involving human fetal tissue.

5. Productivity of Human Fetal Tissue Research and Impact on the Field

The number of citations for every publication listed in the NIH database for Class 1 grants was determined.[1134] From the seven Class 1 research groups that published both fetal and non-fetal research in this period, **there were 2.3x more publications not involving human fetal tissue** (Table 2)**.** This indicates that within the same scientific discipline and the same research laboratory, human fetal tissue research is far less productive than research not involving human fetal tissue.

Table 2: Class 1 Grant productivity and impact.

	Fetal	**Non-Fetal**
Productivity: Average number of papers	74	167
Impact: Average number of citations/paper	36	75

Similarly, **publications that did not involve fetal tissue received an average of 2.1x more citations/paper, compared to publications involving fetal tissue from the same research group.** This strongly suggests that human fetal tissue research is of lower quality compared to studies involving fetal tissue and has significantly less impact on the field.

Human fetal tissue is currently used by a very small number of scientists, representing less than 0.2% of the total NIH research portfolio. Detailed analysis of how human fetal tissue is used in 34 long-standing, successful research programs has determined that fetal tissue is actually required for only approximately 24% of these grants. For the remaining 76%, there are reasonable alternatives to the use of human fetal tissue and, in the majority of cases, these alternatives are superior scientific models. Based on these percentages, it is estimated that of the current 329 NIH-funded grants using human fetal tissue, only approximately 79 (or 0.08% of the 83,592 active projects), actually require the use of human fetal tissue. Thus, despite the repeated claim that human fetal tissue is "necessary" for modern biomedical research, only a tiny fraction of NIH funded research actually requires human fetal tissue. Moreover, even in cases where use of human fetal tissue is warranted (*i.e.*, Class 1 grants), this analysis indicates that **human fetal tissue research is less productive and has lower impact on the field, compared to studies from the same laboratories that do not involve human fetal tissue.**

In Conclusion: This analysis strongly indicates that, in contrast to repeated assertions, human fetal tissue research is an outdated and unproductive area of research that does not make a

[1134] Based on the citations identified using the "Google Scholar" search engine that is employed by the NIH: https://scholar.google.com/.

strong impact on the field. In over 100 years of unrestricted investigation, human fetal tissue research has had ample time to prove useful, yet it has failed to do so:

- Fetal tissue HAS NOT produced a single medical treatment.
- Fetal tissue WAS NOT used to cure polio, mumps, and measles.
- Fetal tissue IS NOT used for modern vaccine production or research.
- Fetal tissue IS NOT critical to study Zika or other diseases affecting brain development.
- Fetal tissue IS NOT required for the overwhelming majority of current research.
- Fetal tissue research is LESS PRODUCTIVE and has LOWER IMPACT when compared to non-fetal tissue research.

E. Recommendations for improving access to ethical and appropriate scientific models

The House Select Investigative Panel is firmly committed to supporting scientific research and helping it to advance as rapidly as possible towards effective and ethical treatments for human disease. Our detailed examination of how fetal tissue is currently used in successful, long-standing research programs (Chapter 9.D.3) revealed that in a surprising number of cases, human fetal tissue is not the most appropriate scientific model for the proposed experiments. For example, a number of grants focused on ***adult-onset*** neurological conditions employ human fetal neurons as a disease model, despite the well-known differences between fetal and adult neural cells.[1135] In some cases, investigators indicate that the choice of fetal tissue is dictated by economic reasons, including the cost and/or inconvenience of obtaining appropriate adult tissue (see Exhibit 9.5). Whether tissue procurement companies have artificially created a market for human fetal tissue by making diverse human fetal tissues readily available to researchers is difficult to determine. However, there are limited commercial options for obtaining living adult tissue and cells for research, and many companies providing this service focus on a limited number of cell types (primarily cells from blood). The difficulty and expense of obtaining appropriate adult tissue for research is likely to be a factor in the decision to use less scientifically relevant human fetal tissue that is readily available through tissue procurement companies.

Ideally, decisions about which experimental model to use for the study of a specific medical condition should be driven by scientific criteria, not by issues of convenience or cost. Here we make four recommendations for improving access to appropriate scientific models, including human fetal tissue when warranted, in order to promote the advance of science and the development of novel therapies.

1. Background for Recommendation 1: Establishing an ethically and scientifically superior source of human fetal tissue

Stem and progenitor cells present in developing human tissues have tremendous potential to expand scientific knowledge and treat human disease. Yet advances in both medicine and science have been limited by the lack of a consistent and high-quality source of donated human

[1135] A survey of human brain transcriptome diversity at the single cell level. Darmanis S, Sloan SA, Zhang Y, Enge M, Caneda C, Shuer LM, Hayden Gephart MG, Barres BA, Quake SR. Proc Natl Acad Sci U S A. 2015 Jun 9;112(23):7285-90.

cells. The current model of obtaining human cells and tissues from legal abortion is inadequate for three inherent reasons: 1) abortions do not represent the full range of human development and typically do not take place during periods where the most clinically relevant cells are present; 2) during an abortion, cells cannot be obtained in a sterile manner, and therefore these cells cannot be used clinically or in many research applications; and 3) serious ethical objections to abortion are likely to persist, making abortion an unreliable and inconsistent source of human cells.

In contrast, obtaining cadaveric donation of human cells and tissues from preterm and stillborn donors avoids all three of these limitations; *i.e.*, donations can be obtained in a clinically useful state across the full spectrum of human development without significant ethical controversy. The CDC estimates there are approximately 27,000 preterm deliveries and 24,000 stillbirths each year. Currently, there is only limited ability to use donated material from preterm and stillborn infants for conventional organ transplant. Expanding the opportunities to make a potentially life-saving donation for basic and clinical research following the tragic loss of a desired infant would provide a tremendous comfort to many grieving parents.

Currently, human fetal tissue is used in a very small number of research programs funded by the National Institutes of Health: approximately 0.2% of all funded research programs. Detailed examination of a selected sample of long-standing, successful awards indicates that only a quarter critically require human fetal tissue (Chapter 9.D.3); *i.e.*, no reasonable alternatives to the use of human fetal tissue exist. However, should a consistent, high-quality and ethically uncontroversial source of human fetal tissue exist, research in this area would undoubtedly expand enormously, advancing our understanding of human development and leading to potentially life-saving discoveries.

In addition to basic research, many human diseases could potentially be addressed by treatment with stem and progenitor cells. However, such regenerative-medicine approaches are limited due to the inherent difficulty of producing cells in the laboratory that have clinically useful properties; *i.e.*, cells that can be transplanted into patients and that restore normal function without forming tumors. Natural stem and progenitor cells that arise during human development would be an ideal source of material for clinical treatment of disease, if such cells could be obtained in a clinically appropriate and ethically uncontroversial manner.

Stakeholders in the effort to provide a consistent, high-quality and ethical source of human fetal tissue for research and therapies include:

a. The scientific community: The scope of research would greatly expand and the pace of discovery accelerate if a consistent source of human cells and tissues were available.

b. The medical community: Clinical application of human stem and progenitor cells would be nearly immediate, resulting in novel treatments and cures.

c. Patients suffering from untreatable disease: The rapid advance of both basic and clinical research would provide direct benefits to patients.

d. Parents who have tragically lost a desired infant: Contributing to life-saving research and medical treatments would provide great comfort to many grieving parents.

Recommendation 1: Congress will appropriate funding to the NIH for a competitive, multi-center trial of expanding the organ-donation network to include preterm and stillborn infant donors. Cadaveric tissues and cells would be made available to qualified scientists and physicians for basic and clinical research. Material from elective termination of pregnancy would be explicitly excluded from this program, both to restrict donation to clinically useful material and to avoid ethical controversy, thereby ensuring broad, bipartisan support for this program and providing a consistent source of high-quality donations for medicine and research.

2. Background for recommendation 2: Facilitating acquisition of adult tissue

Adult tissue (from either normal subjects or from individuals with specific medical conditions) is the most scientifically appropriate model for the study of many adult-onset diseases. Unfortunately, in many cases, adult tissue is not readily available for use by the research community. Consequently, researchers focus on animal models of disease and/or supplement this work using human fetal tissue, despite the known differences between adult and fetal cells. If primary adult human tissue were more readily available to the research community, it would facilitate development of appropriate research models with far greater relevance to human disease.

Recommendation 2: The NIH will undertake a study of research demand for adult human tissue and possible methods for facilitating the acquisition of adult cells and tissues for research, without impacting the supply of transplantable human organs. Possible sources of adult tissue include material from surgical procedures and cadaveric donation of tissue/organs that are not currently used for transplantation. One potential model may be an expansion of the National Disease Research Interchange (NDRI),[1136] an NIH-supported, non-profit organ and tissue donation network that has provided surgical and cadaveric biospecimens to researchers for over thirty years.

3. Background for recommendation 3: Establishing guidelines for the use of human fetal tissue

The process of scientific grant review evaluates the overall quality of the proposed research and the appropriateness of the scientific model. However, grant reviewers are not currently asked to consider whether the use of human fetal tissue is warranted by the experimental design, and there are no guidelines for making such a determination.

The use of animals in research provides a helpful model for the use of human fetal tissue. The NIH has a detailed instruction on animal use (Guide for the Care and Use of Laboratory Animals, hereinafter "the Guide").[1137] While supporting the value of animal research, the Guide acknowledges, "The decision to use animals in research requires critical thought, judgment, and

[1136] Information about NDRI is available at http://ndriresource.org/.
[1137] National Research Council, Guide for the Care and Use of Laboratory Animals (2011), https://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-use-of-laboratory-animals.pdf [hereinafter Guide].

analysis. Using animals in research is a privilege granted by society to the research community with the expectation that such use will provide either significant new knowledge or lead to improvement in human and/or animal well-being."[1138] Two central principles governing the use of animals are *Replacement* and *Reduction*, which are defined by the Guide as follows:

> **Replacement** refers to methods that avoid using animals. The term includes absolute replacements (i.e., replacing animals with inanimate systems such as computer programs) as well as relative replacements (i.e., replacing animals such as vertebrates with animals that are lower on the phylogenetic scale).
>
> **Reduction** involves strategies for obtaining comparable levels of information from the use of fewer animals or for maximizing the information obtained from a given number of animals (without increasing pain or distress) so that in the long run fewer animals are needed to acquire the same scientific information. This approach relies on an analysis of experimental design, applications of newer technologies, the use of appropriate statistical methods, and control of environmentally related variability in animal housing and study areas.[1139]

Similar to animal research, human fetal tissue research is controversial, with the majority of American citizens opposing the sale of human fetal body parts for research.[1140] Moreover, it is widely acknowledged that the use of human embryos/fetuses for research purposes warrants special consideration. For example, the 1994 NIH Report of the Human Embryo Research Panel produced under the Clinton administration states, "The Panel believes that because the preimplantation embryo possesses qualities requiring moral respect, research involving the ex utero preimplantation human embryo must be carefully regulated and consistently monitored."[1141] In light of the moral respect due to the human embryo/fetus, the decision to use human fetal tissue in research is also "a privilege granted by society to the research community with the expectation that such use will provide either significant new knowledge or lead to improvement in human . . . well-being."[1142] Consequently, just as for animal research, the decision to use human fetal tissue "requires critical thought, judgment and analysis,"[1143] with the

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[1138] *Id.* at 4.
[1139] *Id.* at 5.
[1140] A Rasmussen poll from 2015 indicates that 25% of likely voters support the sale of human fetal tissue, while 54% are opposed and 22% are undecided (http://www.rasmussenreports.com/public_content/politics/current_events/abortion/voters_balk_at_sale_of_fetal_body_parts). A Fox News poll from 2015 indicates that voters are evenly split on the use of fetal tissue for research, with 48% approving of such research, and 47% disapproving (http://www.foxnews.com/politics/2015/08/27/fox-news-poll-views-divided-over-issues-involving-abortion.html).
[1141] National Institutes of Health, Report of the Human Embryo Research Panel, vol. 1. 1994. Bethesda MD, https://repository.library.georgetown.edu/bitstream/handle/10822/559352/human_embryo_vol_1.pdf?sequence=1&isAllowed=y.
[1142] Guide at 5.
[1143] *Id.*

principles of *Replacement* and *Reduction* being applicable to all research programs using human fetal tissue.

Rigorous application of these principles would serve to limit the use of human fetal tissue to those proposals where this tissue is in fact required for the experimental question (*i.e.*, Class 1 proposals) and would reduce the overall use of such tissue to the minimum required for obtaining valid scientific results. Application of these principles would also serve as a vehicle for "critical thought, judgment and analysis" regarding what constitutes the most appropriate scientific model for a specific research question.

Recommendation 3: The NIH will establish guidelines for the use of human fetal tissue, modeled on the guidelines for animal research that include the principles of *Replacement* and *Reduction*. The NIH will mandate that these guidelines be applied to all grants proposing the use of human fetal tissue and that funding will be contingent on the investigator demonstrating that 1) human fetal tissue is required and appropriate for the proposed experiments, 2) there are no reasonable alternatives or replacements for the use of human fetal tissue, and 3) every effort has been made to reduce the amount of human fetal tissue employed in the proposed experiments.

4. Background for recommendation 4: Assuring continued availability of funding for research that requires human fetal tissue

The analysis of the House Select Investigative Panel indicates that, for a small number of research programs, human fetal tissue is the most appropriate scientific model (Class 1 grants). For a much larger number of research programs (Class 2 and Class 3), human fetal tissue is not the most appropriate model, and alternative models are available (Chapter 9.D.3). Application of the principles of *Replacement* and *Reduction* (See Recommendation 3, above) will serve to distinguish proposals that require human fetal tissue (Class 1) from proposals that do not. Appropriate classification of proposed research is required to assure continued funding for scientifically meritorious research that requires human fetal tissue.

Recommendation 4: The NIH will adopt a three-tiered classification system for proposals involving human fetal tissue as indicated below:

a. **Class 1:** Fetal tissue is required for the proposed study. There are no reasonable alternatives. These proposals will have met all of the requirements established by the NIH guidelines outlined in Recommendation 1 and will be fully eligible for funding, based on scientific merit and NIH funding priorities.
b. **Class 2:** Fetal tissue is not essential for the study. There are some scientific advantages to the use of fetal tissue, but alternatives exist. These proposals will have met some, but not all of the requirements established by the NIH guidelines outlined in Recommendation 1 and will be eligible for funding only under exceptional circumstances, as established by scientific merit and NIH funding priorities.
c. **Class 3:** Fetal tissue is not essential for the study. There are no scientific advantages to the use of fetal tissue, and alternatives exist. In some cases, postnatal tissue is more relevant to

the scientific question. These proposals will have failed to meet the requirements established by the NIH guidelines outlined in Recommendation 1 and will be ineligible for NIH funding.

5. Background for recommendation 5: Federal funding for fetal tissue research

Human fetal tissue is necessary for a limited number of research programs (Class 1 grants). Currently, tissue for these projects is only available from elective termination of pregnancy. Should a program for obtaining cadaveric fetal tissue donation from preterm and stillborn infants prove effective (Recommendation 1), this would provide a consistent source of human fetal tissue that is both ***scientifically*** and ***ethically*** superior to tissue obtained from induced abortion. If this is the case, fetal tissue donation should be expanded, and public research dollars should be restricted to a source of tissue that better serves the interests of basic and clinical research while simultaneously being ethically acceptable to all American citizens.

Recommendation 5: The NIH will report to Congress on the use of parent-donated tissue from natural demise of preterm children, anticipated by Recommendation 1 above, and Congress shall appropriate funds for an expansion of this program and disallow grants funded by federal dollars to utilize human fetal tissue obtained from induced abortion.

X. Recommendations

A. Recommendations for Direct Protection of Women and Infants

The Panel discerned a hardness and callousness toward women and infants, particularly after a clinic entered into a contractual relationship with a fetal tissue procurement business. The following recommendations focus on protections for women, preborn infants, and infants born alive during abortion procedures.

1) In keeping with the principles set forth in the Belmont Report, Congress should take appropriate measures to ensure that the informed consent provisions of 42 U.S.C. § 289g-1(b) & (c) protect all mothers, regardless of whether their donations of fetal tissue or the prospective research/use of donated fetal tissue is federally funded.

2) The Panel recommends that Congress pass legislation that expands and clarifies the definition of "changing the method of abortion" to ensure that abortion providers are not modifying the care of their patients, and potentially endangering patient health, to ensure that they can procure fetal tissue.

3) The Panel recommends that Congress take appropriate measures to ensure that the Department of Health and Human Services conducts greater oversight over:

    a. The use of fraudulent and misleading consent forms.

    b. Institutional Review Boards (IRB), to avoid the "mail-order" version of IRB's.

    c. Clinics found to have violated HIPAA.

    d. The training of abortion providers and clinic employees to care for infants born alive during abortion procedures (*i.e.*, protocols for calling 911 and providing life-sustaining treatment pending transfer to a hospital).

4) The Panel recommends that Congress take appropriate measures to ensure that the United State Department of Justice allocates resources for the prosecution of persons or entities that profit from the sale of fetal tissue. Additionally, Congress should prohibit any person from crossing state lines in order to obtain fetal tissue derived from an induced abortion when the law of the state in which the person is doing business prohibits the donation of such tissue.

5) Congress should pass a law providing that if the probable gestational age of the fetus is determined to be 20 or more weeks, the physician shall make his or her best reasonable efforts to deliver the infant alive. In such cases, no health care practitioner may use

digoxin or other feticide, and no physician may dismember the fetus unless it is necessary to protect the life of the mother.[1144]

6) Congress should enact a law, and the Department of Health and Human Services should promulgate detailed regulations requiring abortion providers to establish protocols for providing emergency care to infants born alive (as defined in 1 U.S.C. § 8 (b)) during abortions or attempted abortions, pending transfer to a hospital. The regulations should require, at a minimum, that all abortion providers are trained to preserve the life and resuscitate any infant who is born alive, and that abortion facilities are adequately equipped to care for infants born alive, pending transfer to a hospital. The regulations should require the presence of a health care practitioner dedicated to caring for infants born alive and to keeping precise records on methods of abortion, stages of gestation, and instances where infants show signs of life.

7) Congress should establish criminal penalties and other enforcement mechanisms to hold abortion providers accountable who fail to provide medical attention and care to infants born alive (as defined in 1 U.S.C. § 8 (b)) during an abortion or attempted abortion. At a minimum, abortion providers must ensure that a born-alive infant receives the same degree of care that is reasonably provided to any other child born at the same gestational age, and ensure that the child is immediately transferred to a hospital.[1145]

8) Legislation should also create an office in the Department of Justice, within the Criminal Division, to ensure the enforcement of the Partial-Birth Abortion Ban Act, Born-Alive Infants Protection Act, and other measures recommended in this report.

9) Legislation should ensure that that the statutory definition of cadaver uniformly includes human fetuses.

B. Recommendations for Stewardship of Taxpayer Funds

1) The Panel found that Planned Parenthood affiliates and clinics have repeatedly neglected their fiduciary duty requiring good stewardship of federal taxpayer dollars through the following: careless management and failed compliance with Medicaid billing procedures; violating federal laws and regulations pertaining to patient consent and the privacy rights of their patients; changing the method of abortion to increase procurement of fetal tissue for which they received a per tissue payment; and a general disinterest in clinical integrity. The Panel recommends that Planned Parenthood lose all federal funding, including reimbursements for Medicaid services. Further, grants no longer available to Planned Parenthood should be awarded to healthcare providers that provide comprehensive preventive healthcare for their patients, and that do not perform abortions, except:

[1144] *See* Pain-Capable Unborn Child Protection Act, H.R. 36, 114th Cong. (2015).
[1145] *See* Born-Alive Abortion Survivors Protection Act, H.R. 3504, 114th Cong. (2015).

> if the pregnancy is the result of an act of rape or incest;
>
> or
>
> in the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.

2) In keeping with the joint federal-state Medicaid program, the Panel recommends that Congress pass a law explicitly permitting states to exclude abortion providers from receiving Medicaid reimbursement (in response to narrow interpretations of current law by President Obama's Administration and the Seventh and Ninth Circuits).[1146]

3) The Panel also recommends that Congress pass a law overriding the Sept. 9, 2016, administrative rule restricting states' discretion in choosing subrecipients of Title X funding. Further, the new law should explicitly prohibit the federal government from contracting with anyone other than a state or a state's designee. That way, states will have the flexibility to ensure that Title X funds are used in a manner compatible with state public policy.

4) Taxpayer funding indirectly supports the practice of abortion when it funds institutions that provide or fund abortions, or when it funds research on tissue derived from aborted infants. Consistent with this principle, Congress should prohibit federal funding of research involving tissue derived from *induced* abortions. This should be enacted to become effective after establishment of a program that would fund alternative sources of fetal tissue (*i.e.*, fetal tissue from *spontaneous* abortions (miscarriages) or stillbirths) for research. See subsection C, below.

C. Recommendations to Improve Biomedical Research

The House Select Investigative Panel is firmly committed to supporting scientific research and helping it to advance as rapidly as possible towards effective and ethical treatments for human disease. Our detailed examination of how fetal tissue is currently used in successful, long-standing research programs (Chapter 9.D.3) revealed that in a surprising number of cases, human fetal tissue is not the most appropriate scientific model for the proposed experiments. For example, a number of grants focused on ***adult-onset*** neurological conditions employ human fetal neurons as a disease model, despite the well-known differences between fetal and adult neural cells.[1147] In some cases, investigators indicate that the choice of fetal tissue is dictated by economic reasons, including the cost and/or inconvenience of obtaining appropriate adult tissue

[1146] *See* Women's Public Health and Safety Act, H.R. 3495, 114th Cong. (2015).
[1147] A survey of human brain transcriptome diversity at the single cell level. Darmanis S, Sloan SA, Zhang Y, Enge M, Caneda C, Shuer LM, Hayden Gephart MG, Barres BA, Quake SR. Proc Natl Acad Sci U S A. 2015 Jun 9;112(23):7285-90

(see Exhibit 9.5). Whether tissue procurement companies have artificially created a market for human fetal tissue by making diverse human fetal tissues readily available to researchers is difficult to determine. However, there are limited commercial options for obtaining living adult tissue and cells for research, and many companies providing this service focus on a limited number of cell types (primarily cells from blood). The difficulty and expense of obtaining appropriate adult tissue for research is likely to be a factor in the decision to use less scientifically relevant human fetal tissue that is readily available through tissue procurement companies.

Ideally, decisions about which experimental model to use for the study of a specific medical condition should be driven by scientific criteria, not by issues of convenience or cost. Here we make four recommendations for improving access to appropriate scientific models, including human fetal tissue when warranted, in order to promote the advance of science and the development of novel therapies.

Background for Recommendation 1: Establishing an ethically and scientifically superior source of human fetal tissue. Stem and progenitor cells present in developing human tissues have tremendous potential to expand scientific knowledge and treat human disease. Yet advances in both medicine and science have been limited by the lack of a consistent and high-quality source of donated human cells. The current model of obtaining human cells and tissues from legal abortion is inadequate for three inherent reasons: 1) abortions do not represent the full range of human development and typically do not take place during periods where the most clinically relevant cells are present; 2) during an abortion, cells cannot be obtained in a sterile manner, and therefore these cells cannot be used clinically or in many research applications; and 3) serious ethical objections to abortion are likely to persist, making abortion an unreliable and inconsistent source of human cells.

In contrast, obtaining cadaveric donation of human cells and tissues from preterm and stillborn donors avoids all three of these limitations; i.e. donations can be obtained in a clinically useful state across the full spectrum of human development without significant ethical controversy. The CDC estimates there are approximately 27,000 preterm deliveries and 24,000 stillbirths each year. Currently, there is only limited ability to use donated material from preterm and stillborn infants for conventional organ transplant. Expanding the opportunities to make a potentially life-saving donation for basic and clinical research following the tragic loss of a desired infant would provide a tremendous comfort to many grieving parents.

Currently, human fetal tissue is used in a very small number of research programs funded by the National Institutes of Health: approximately 0.2% of all funded research programs. Detailed examination of a selected sample of long-standing, successful awards indicates that only a quarter critically require human fetal tissue (Chapter 9.D.3); *i.e.*, no reasonable alternatives to the use of human fetal tissue exist. However, should a consistent, high-quality and ethically uncontroversial source of human fetal tissue exist, research in this area would undoubtedly expand enormously, advancing our understanding of human development and leading to potentially life-saving discoveries.

In addition to basic research, many human diseases could potentially be addressed by treatment with stem and progenitor cells. However, such regenerative-medicine approaches are limited due to the inherent difficulty of producing cells in the laboratory that have clinically useful properties; *i.e.*, cells that can be transplanted into patients and that restore normal function without forming tumors. Natural stem and progenitor cells that arise during human development would be an ideal source of material for clinical treatment of disease, if such cells could be obtained in a clinically appropriate and ethically uncontroversial manner.

Stakeholders in the effort to provide a consistent, high-quality and ethical source of human fetal tissue for research and therapies include:

1. The scientific community: The scope of research would greatly expand and the pace of discovery accelerate if a consistent source of human cells and tissues were available.

2. The medical community: Clinical application of human stem and progenitor cells would be nearly immediate, resulting in novel treatments and cures.

3. Patients suffering from untreatable disease: The rapid advance of both basic and clinical research would provide direct benefits to patients.

4. Parents who have tragically lost a desired infant: Contributing to life-saving research and medical treatments would provide great comfort to many grieving parents.

Recommendation 1: Congress will appropriate funding to the NIH for a competitive, multi-center trial of expanding the organ-donation network to include preterm and stillborn infant donors. Cadaveric tissues and cells would be made available to qualified scientists and physicians for basic and clinical research. Material from elective termination of pregnancy would be explicitly excluded from this program, both to restrict donation to clinically useful material and to avoid ethical controversy, thereby ensuring broad, bipartisan support for this program and providing a consistent source of high-quality donations for medicine and research.

Background for recommendation 2: Facilitating acquisition of adult tissue. Adult tissue (from either normal subjects or from individuals with specific medical conditions) is the most scientifically appropriate model for the study of many adult-onset diseases. Unfortunately, in many cases, adult tissue is not readily available for use by the research community. Consequently, researchers focus on animal models of disease and/or supplement this work using human fetal tissue, despite the known differences between adult and fetal cells. If primary adult human tissue were more readily available to the research community, it would facilitate development of appropriate research models with far greater relevance to human disease.

Recommendation 2: The NIH will undertake a study of research demand for adult human tissue and possible methods for facilitating the acquisition of adult cells and tissues for research, without impacting the supply of transplantable human organs. Possible sources of adult tissue include material from surgical procedures and cadaveric donation of tissue/organs that are not currently used for transplantation. One potential model may be an expansion of the

National Disease Research Interchange (NDRI),[1148] an NIH-supported, non-profit organ and tissue donation network that has provided surgical and cadaveric biospecimens to researchers for over thirty years.

Background for recommendation 3: Establishing guidelines for the use of human fetal tissue. The process of scientific grant review evaluates the overall quality of the proposed research and the appropriateness of the scientific model. However, grant reviewers are not currently asked to consider whether the use of human fetal tissue is warranted by the experimental design, and there are no guidelines for making such a determination.

The use of animals in research provides a helpful model for the use of human fetal tissue. The NIH has a detailed instruction on animal use (Guide for the Care and Use of Laboratory Animals, hereinafter "the Guide").[1149] While supporting the value of animal research, the Guide acknowledges, "The decision to use animals in research requires critical thought, judgment, and analysis. Using animals in research is a privilege granted by society to the research community with the expectation that such use will provide either significant new knowledge or lead to improvement in human and/or animal well-being."[1150] Two central principles governing the use of animals are *Replacement* and *Reduction*, which are defined by the Guide as follows:

> **Replacement** refers to methods that avoid using animals. The term includes absolute replacements (i.e., replacing animals with inanimate systems such as computer programs) as well as relative replacements (i.e., replacing animals such as vertebrates with animals that are lower on the phylogenetic scale).
>
> **Reduction** involves strategies for obtaining comparable levels of information from the use of fewer animals or for maximizing the information obtained from a given number of animals (without increasing pain or distress) so that in the long run fewer animals are needed to acquire the same scientific information. This approach relies on an analysis of experimental design, applications of newer technologies, the use of appropriate statistical methods, and control of environmentally related variability in animal housing and study areas.[1151]

Similar to animal research, human fetal tissue research is controversial, with the majority of American citizens opposing the sale of human fetal body parts for research.[1152] Moreover, it is widely acknowledged that the use of human embryos/fetuses for research purposes warrants

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[1148] Information about NDRI is available at: http://ndriresource.org/

[1149] National Research Council, Guide for the Care and Use of Laboratory Animals (2011), https://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-use-of-laboratory-animals.pdf [hereinafter Guide].

[1150] *Id.* at 4.

[1151] *Id.* at 5.

[1152] A Rasmussen poll from 2015 indicates that 25% of likely voters support the sale of human fetal tissue, while 54% are opposed and 22% are undecided (Available: http://www.rasmussenreports.com/public_content/politics/current_events/abortion/voters_balk_at_sale_of_fetal_body_parts). A Fox News poll from 2015 indicates that voters are evenly split on the use of fetal tissue for research, with 48% approving of such research, and 47% disapproving (Available: http://www.foxnews.com/politics/2015/08/27/fox-news-poll-views-divided-over-issues-involving-abortion.html).

special consideration. For example, the 1994 NIH Report of the Human Embryo Research Panel produced under the Clinton administration states, "The Panel believes that because the preimplantation embryo possesses qualities requiring moral respect, research involving the ex utero preimplantation human embryo must be carefully regulated and consistently monitored."[1153] In light of the moral respect due to the human embryo/fetus, the decision to use human fetal tissue in research is also "a privilege granted by society to the research community with the expectation that such use will provide either significant new knowledge or lead to improvement in human . . . well-being."[1154] Consequently, just as for animal research, the decision to use human fetal tissue "requires critical thought, judgment and analysis,"[1155] with the principles of *Replacement* and *Reduction* being applicable to all research programs using human fetal tissue.

Rigorous application of these principles would serve to limit the use of human fetal tissue to those proposals where this tissue is in fact required for the experimental question (*i.e.*, Class 1 proposals) and would reduce the overall use of such tissue to the minimum required for obtaining valid scientific results. Application of these principles would also serve as a vehicle for "critical thought, judgment and analysis" regarding what constitutes the most appropriate scientific model for a specific research question.

Recommendation 3: The NIH will establish guidelines for the use of human fetal tissue, modeled on the guidelines for animal research that include the principles of *Replacement* and *Reduction*. The NIH will mandate that these guidelines be applied to all grants proposing the use of human fetal tissue and that funding will be contingent on the investigator demonstrating that 1) human fetal tissue is required and appropriate for the proposed experiments, 2) there are no reasonable alternatives or replacements for the use of human fetal tissue, and 3) every effort has been made to reduce the amount of human fetal tissue employed in the proposed experiments.

Background for recommendation 4: Assuring continued availability of funding for research that requires human fetal tissue. The analysis of the House Select Investigative Panel indicates that, for a small number of research programs, human fetal tissue is the most appropriate scientific model (Class 1 grants). For a much larger number of research programs (Class 2 and Class 3), human fetal tissue is not the most appropriate model, and alternative models are available (Chapter 9.D.3). Application of the principles of *Replacement* and *Reduction* (See Recommendation 3, above) will serve to distinguish proposals that require human fetal tissue (Class 1) from proposals that do not. Appropriate classification of proposed research is required to assure continued funding for scientifically meritorious research that requires human fetal tissue.

Recommendation 4: The NIH will adopt a three-tiered classification system for proposals involving human fetal tissue as indicated below:

[1153] National Institutes of Health, Report of the Human Embryo Research Panel, vol. 1. 1994. Bethesda MD, https://repository.library.georgetown.edu/bitstream/handle/10822/559352/human_embryo_vol_1.pdf?sequence=1&isAllowed=y.

[1154] Guide at 5.

[1155] *Id.*

Class 1: Fetal tissue is required for the proposed study. There are no reasonable alternatives. These proposals will have met all of the requirements established by the NIH guidelines outlined in Recommendation 1 and will be fully eligible for funding, based on scientific merit and NIH funding priorities.

Class 2: Fetal tissue is not essential for the study. There are some scientific advantages to the use of fetal tissue, but alternatives exist. These proposals will have met some, but not all of the requirements established by the NIH guidelines outlined in Recommendation 1 and will be eligible for funding only under exceptional circumstances, as established by scientific merit and NIH funding priorities.

Class 3: Fetal tissue is not essential for the study. There are no scientific advantages to the use of fetal tissue, and alternatives exist. In some cases, postnatal tissue is more relevant to the scientific question. These proposals will have failed to meet the requirements established by the NIH guidelines outlined in Recommendation 1 and will be ineligible for NIH funding.

Background for recommendation 5: Federal funding for fetal tissue research. Human fetal tissue is necessary for a limited number of research programs (Class 1 grants). Currently, tissue for these projects is only available from elective termination of pregnancy. Should a program for obtaining cadaveric fetal tissue donation from preterm and stillborn infants prove effective (Recommendation 1), this would provide a consistent source of human fetal tissue that is both ***scientifically*** and ***ethically*** superior to tissue obtained from induced abortion. If this is the case, fetal tissue donation should be expanded, and public research dollars should be restricted to a source of tissue that better serves the interests of basic and clinical research while simultaneously being ethically acceptable to all American citizens.

Recommendation 5: The NIH will report to Congress on the use of parent-donated tissue from natural demise of preterm children, anticipated by Recommendation 1 above, and Congress shall appropriate funds for an expansion of this program and disallow grants funded by federal dollars to utilize human fetal tissue obtained from induced abortion.