

Interim Update

To the U. S. House of Representatives

from the

Chairman and Majority Members of the Select Investigative Panel

on

The Transfer of Fetal Tissue

and Related Matters

July 14, 2016

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Preface

The Chairman and Majority Members of the Select Investigative Panel prepared the following *Interim Update* for the Leadership of the U.S. House of Representatives. The Panel was established by H. Res. 461 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 include 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 baby body parts 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 is concerned with a history of babies being born alive and the sale of baby body parts 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, will be part of the Panel's focus during the coming months.

Third, the Panel found evidence that some abortion providers altered abortion procedures in a manner that substitutes what is best for the patient 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 is critical to understanding the effectiveness of the current statute. This subject will also be the focus of the Panel's work in the coming months.

Fourth, the motive for profit sullies 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 endangers this system and threatens the future of finding cures. Thus, the Panel will continue to evaluate how to 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 some progress using the 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. Information is a critical tool for congressional deliberation, so in the coming months, the Panel will undertake initiatives to gain compliance with its subpoenas.

I. Congress Creates 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, 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 a dozen videos documenting the practices of local abortion clinics and other groups affiliated with the fetal tissue procurement industry. Daleiden supplemented the released video clips of conversations with the simultaneous release of the full, unedited versions. 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 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

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/>.

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,”*

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 of North Carolina managed the floor debate for H. Res. 461, a proposal for a centralized and comprehensive congressional investigation. During debate, Rep. Mimi Walters of California 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 of Tennessee 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

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:

Republican Members

Marsha Blackburn (Tennessee - 07), Chairman
Joseph Pitts (Pennsylvania - 16)
Diane Black (Tennessee - 06)
Larry Bucshon (Indiana - 08)
Sean Duffy (Wisconsin - 07)
Andy Harris (Maryland - 01)
Vicky Hartzler (Missouri - 04)
Mia Love (Utah - 04)

Democratic Members

Janice Schakowsky (Illinois - 09),
Ranking Member
Jerrold Nadler (New York - 10)
Diana DeGette (Colorado - 01)
Jackie Speier (California - 14)
Suzan DelBene (Washington - 01)
Bonnie Watson Coleman (New Jersey - 12)

<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, Feb. 27, 2015, at 13, <http://www.centerformedicalprogress.org/wp-content/uploads/2015/05/PPCAPSDVDfinal.pdf>.

⁸ Center for Medical Progress, Transcript, Mar. 18, 2015, at 12-13, 15, <http://www.centerformedicalprogress.org/wp-content/uploads/2015/05/PPCAPSDVDVRFinal.pdf>.

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

¹⁰ *Id.* at H6879.

II. Formation of the Investigative Plan—Applicable Laws, Regulations, and Commissions

The Panel's first task was to design an investigative plan. The Chairman directed that the Panel's inquiry should focus on two large questions: (1) How are women and children being treated? and (2) What are the business transactional questions that should be answered? The business transactional inquiry focused on how human fetal tissue is acquired, how is it transferred, what monetary exchanges are involved, and whether the revenues exceed the allowable costs. The Chairman stated that it was the duty of Congress to prevent the exploitation of women and children and to protect society's most vulnerable. Both questions are governed by federal regulations, statutes, and guidance.

A. Federal Laws that Address the Treatment of Women and Children

1. The Born-Alive Infant Protection Act

President George W. Bush signed the Born-Alive Infant Protection Act (BAIPA) (1 U.S.C. § 8) 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 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.

The Panel has tasked the Center for Disease Control to provide additional information about its statistics regarding children who survive abortions.

2. The Belmont Report

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, created on July 12, 1974, with the passage of the National Research Act (P.L. 93-348), 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).

In response to the Belmont Report, HHS and the FDA significantly revised their human subjects regulations in 1981 (454 C.F.R. § 46; 21 C.F.R. § 50).¹¹

During the Panel’s hearing on *Bioethics and Fetal Tissue*, Rep. Vicky Hartzler of Missouri 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.”¹² 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.”¹³ 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.”¹⁴

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.”¹⁵ 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.”¹⁶

A researcher invited by the minority to testify later during the hearing agreed, stating that the form would not have “made it past” his IRB.¹⁷ 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 of Utah 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

¹¹ 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).

¹² 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/>.

¹³ *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong. (unedited transcript 1708), (Mar. 2, 2016),

<http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-Transcript-20160302.pdf>.

¹⁴ *Bioethics and Fetal Tissue*, *supra* (Majority exhibit A-3),

<http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-20160302-SD030.pdf> (emphasis added).

¹⁵ *Bioethics and Fetal Tissue*, *supra* (unedited transcript 77).

¹⁶ *Id.* (testimony of Paige Cunningham).

¹⁷ *Id.* at 149 (testimony of Lawrence Goldstein).

that she is not being taken advantage of, to make sure that she is making the right decision.”¹⁸ 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?”¹⁹ Dr. G. Kevin Donovan, a witness, agreed that this presented a troubling problem.²⁰

3. Presidential Commissions

Since the **National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research** was created in 1974 in response to the Tuskegee Experiment scandal,²¹ “public national bodies” have had a decades-long 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.

The most important document to emerge from the first executive committee, mentioned above, was the **Belmont Report**.²² This seminal document identified three principles around which legislation could be crafted: respect for persons, justice, and beneficence. In other words, individuals are autonomous and entitled to protection, the costs and benefits of research should be weighed fairly, and human subjects of research should not be harmed in the process. These principles formed the basis for an approach to research since then. This first group also published a report called “Research on the Fetus” (1975),²³ in which they said their primary concern was “research on the fetus...before, during and after induced abortion.” While they did recommend “that use of the dead fetus, fetal tissue and fetal material for research purposes be permitted...” several members of the commission (those 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.”

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,”²⁴ which served as the basis for the Uniform Determination of Death Act subsequently enacted by most US states. Their report

¹⁸ *Id.* at 86-87.

¹⁹ *Id.*

²⁰ *Id.*

²¹ See The Tuskegee Timeline, CDC, <http://www.cdc.gov/tuskegee/timeline.htm>.

²² See Belmont Report, *supra*.

²³ 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.

²⁴ 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.

“Screening and Counseling for Genetic Conditions” (1983)²⁵ discussed in part the ethics of having abortions based on the knowledge of the sex or various disabilities of the fetus.

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.”²⁶

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 the controversial embryonic stem cell issue. 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.²⁷ 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.²⁸

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 training of attorneys or convictions under the statute.

²⁵ 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>.

²⁶ See Exec. Order No. 12975, “Protection of Human Research Subjects and Creation of National Bioethics Advisory Commission” (1995), available at <https://bioethicsarchive.georgetown.edu/nbac/about/eo12975.htm>.

²⁷ See *Reproduction and Responsibility: The Regulation of New Biotechnologies*, The President’s Council on Bioethics (2004), <https://bioethicsarchive.georgetown.edu/pcbe/reports/reproductionandresponsibility/>. These specific recommendations were to preserve a reasonable boundary between the human and the nonhuman in human procreation; respect for women and human pregnancy, preventing certain exploitative and degrading practices; respect for children conceived with the aid of assisted reproductive technologies, securing for them the same rights and human attachments naturally available to children conceived in vivo; setting some agree-upon boundaries on how embryos may be used and treated.

²⁸ Pub. L. No. 109-242; 42 U.S.C. § 289g-2.

4. 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).²⁹ 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.³⁰

A covered entity may not use or disclose an individual's PHI except as the Privacy Rule permits or requires,³¹ 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.³²

5. HHS Referral of StemExpress and Abortion Clinics

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.

These contracts produced a regime of cooperation between StemExpress and each clinic. In particular, 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 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.³³ 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.³⁴

²⁹ 45 C.F.R. § 160.103.

³⁰ 45 C.F.R. § 160.103.

³¹ 45 C.F.R. § 164.502(a).

³² Pub. L. No. 104-191; 42 U.S.C. §§ 1320d-5-1320d-6.

³³ See Clinic Procedures & Policies, produced by StemExpress.

³⁴ See Standard Operating Procedure, produced by StemExpress.

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.³⁵ 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.³⁶ StemExpress employees were handed a patient's medical chart by her healthcare provider in blatant violation of the HIPAA privacy rule.

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.

6. The Common Rule

Title 45 C.F.R. 46, the "Common Rule," was published in 1974 to regulate research conducted on human beings. Specifically, it was established in response to several research projects that had harmed human beings, such as the syphilis study in Tuskegee, Alabama. The Rule applies to research projects that receive funding from any 1 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.

7. IRB Regulations

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.³⁷ The rule lists several criteria for IRB approval, including the requirement that researchers obtain the informed consent from their research subjects.

³⁵ See 45 C.F.R. § 164.514(e).

³⁶ See 45 C.F.R. § 164.502(a)(1)(iii).

³⁷ 45 C.F.R. § 46.116.

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.³⁸

The 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.

³⁸ 45 C.F.R. § 116.

Additionally, documents produced by StemExpress demonstrate that tissue procurement technicians were engaging in real-time email correspondence with researchers while abortions were taking place, yet StemExpress employees already were promising to deliver “products of conception.” The emails quoted below 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 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 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.”⁴¹

The Panel has reviewed email exchanges between StemExpress and Harvard University and between StemExpress and its IRB “approval entity,” Biomed IRB. Harvard officials were concerned that the IRB approval form submitted by the StemExpress/BioMed IRB was out of date, and that the scope of the project had changed. The Harvard email asked that the change “makes us wonder if the change you made was reviewed and approved by Biomed [sic].”⁴² Harvard noted “it’s not generally acceptable to change an IRB approved document without the approval of the IRB.”⁴³ StemExpress replied: “Thank you for working with me on this and giving StemExpress the opportunity to procure tissue for you. We will use the BioMed IRB approved form . . . for any tissue that we procure for Harvard. This should clear up any concerns your IRB board may have.”⁴⁴

⁴¹ Emails produced by StemExpress (Stem.House.Select_0374-0377).

⁴² Emails produced by StemExpress, Jul. 17, 2012, at 8:00 p.m.

⁴³ Emails produced by StemExpress, Jul. 17, 2012, at 8:41 p.m.

⁴⁴ *Id.*

On Jul 17, 2012, at 8:00 PM, [Redacted] wrote:

Hi [Redacted]

One more question for you: The consent form attached . . . the 1001 version with the change from 450ml of blood collected to 10-60ml . . . was this change approved by Biomed? [Redacted] noted that the date on the bottom of the consent form is still 12/7/11, which makes us wonder if the change you made was reviewed and approved by Biomed. Though there clearly isn't any reason they wouldn't approve (since the change decreases the risk to the subjects), but it's not generally acceptable to change an IRB approved document without the approval of the IRB. If it was approved by Biomed, do you have an approval letter you could send to us?

Sorry to be such a pain in the neck about this. But it's these little details that make all the difference to our Committee.

[Redacted]

From: [Redacted] [mailto:[Redacted]@stemexpress.com]
Sent: Tuesday, July 17, 2012 5:41 PM
To: [Redacted]
Subject: IRB approval of consents for procurement for Harvard

Hello [Redacted]

Thank you for working with me on this and giving StemExpress the opportunity to procure tissue for you. We will use the BioMed IRB approved form 101-01 for any tissue that we procure for Harvard. This should clear up any concerns your IRB board may have.

Thank you,

[Redacted]

StemExpress

[Redacted]

778 Pacific St
Placerville, CA 95667
[Redacted]@stemexpress.com
stemexpress.com

**NOTE - StemExpress has moved as of Friday, June 15th!!
Our new address is 778 Pacific Street, Placerville, CA 95667.
Our phones numbers did NOT change!!**

This email message and any attached documents are for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original message. If you are the intended recipient, please be advised that the content of this message is subject to access, review and disclosure by the provider's Ethical System Administrator.

Please consider the environment before printing this e-mail.

<101-01 Informed Consent.pdf>

StemExpress-Harvard Email Exchange

StemExpress also informed Harvard that the original form was changed by BioMed IRB, not by them, and provided Harvard with several copies of previous IRB forms.⁴⁵ In its production, BioMed said it had no records related to StemExpress or to any IRB review of their procedures or business practices. In fact, the previous IRB forms were earlier versions of forms that Biomed IRB sells online.

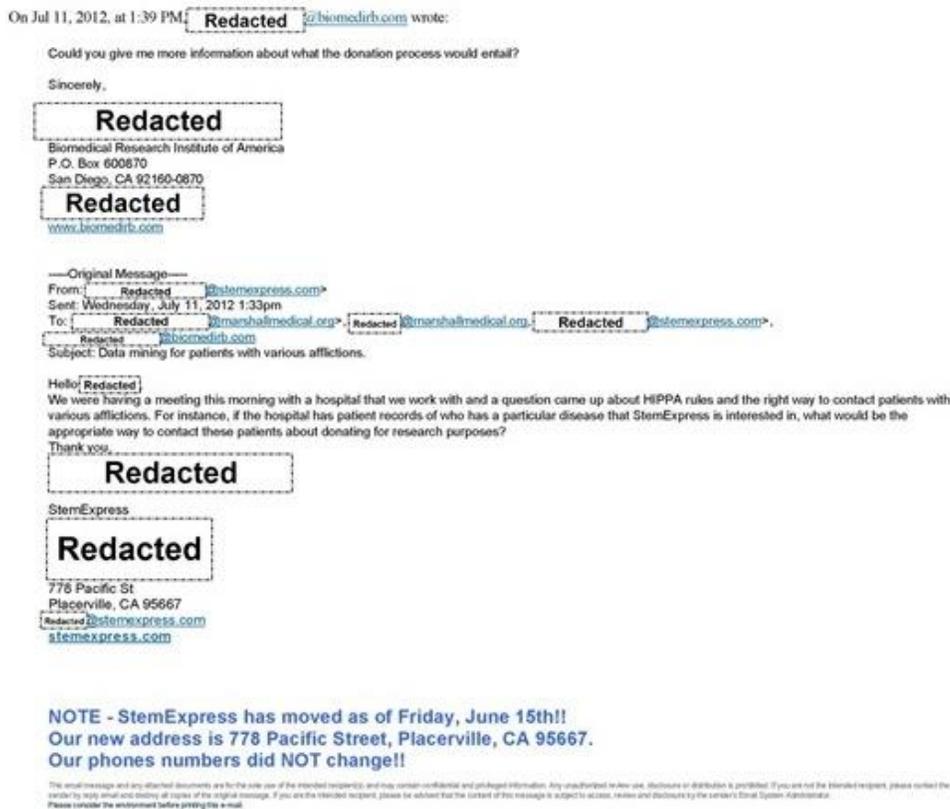
In another StemExpress email exchange, the firm sought to conduct “data mining for patients with various afflictions”⁴⁶ using the BioMed IRB approval form. On July 11, 2012, StemExpress wrote to unknown people at Marshall Medical Center and BioMed IRB that the firm was having a meeting with a “hospital that we work with and a question came up about the HIPAA rules and the right way to contact patients with various afflictions.”⁴⁷ It is clear from this

⁴⁵ Emails produced by StemExpress, Jul. 18, 2012, at 2:25 p.m.

⁴⁶ Email produced by StemExpress, Jul. 11, 2012, 1:33 p.m.

⁴⁷ *Id.*

email that StemExpress had concerns about possible HIPAA violations. StemExpress did not produce any further emails on this topic, so the outcome of the discussion and any possible decision is unclear.



Email Exchange between StemExpress and Biomed IRB on Data Mining for Patients with Various Afflictions

StemExpress advertised to researchers that its forms and procurement methodology had IRB approval. A StemExpress marketing brochure handed out at a NAF conference stated, “Our IRB approved protocols and consents protect you as well as donor’s privacy in accordance with HIPAA guidelines.”⁴⁸

StemExpress relied upon BioMed IRB as its Institutional Review Board. 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 research or transplantation of fetal tissue for which it issued an IRB approval.⁴⁹ BioMed IRB’s executive director informed the Panel on April 4, 2016, that, regarding StemExpress IRB records, “there are none.”⁵⁰

⁴⁸ Brochure (NAF-000003).

⁴⁹ Select Investigative Panel Subpoena to Biomedical Research Institute of America, Mar. 29, 2016.

⁵⁰ Email from [Redacted], Executive Director, Biomedical Research Institute of America, to Select Panel staff, Apr. 4, 2016.

In March of 2012, the Food and Drug Administration (FDA) issued a warning letter to BioMed IRB which detailed problematic behavior. This behavior included 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. As a result, the FDA ruled it “will withhold approval of all new studies subject to 21 C.F.R. Part 56 and reviewed by the IRB; and [n]o new subjects are to be enrolled in any ongoing studies subject to 21 C.F.R. Part 56 and approved by the IRB.”⁵¹ That ban was lifted in January 2013.⁵²

B. Federal Statutes Governing the Transfer of Human Fetal Tissue: Background and Application

1. The NIH Revitalization Act of 1993

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.”⁵³ Rep. Morella expressed her support for the legislation because “fetal tissue could not be sold.”⁵⁴ 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

⁵¹ 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 ██████████, Executive Director, Biomedical Research Institute of America dba BioMed IRB, Mar. 29, 2012.

⁵² 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 ██████████, Executive Director, Biomedical Research Institute of America dba BioMed IRB, Jan. 16, 2013.

⁵³ 139 Cong. Rec. H1099 (1993) (statement of Rep. John Edward Porter in support of the Waxman Amendment).

⁵⁴ *Id.* (statement of Rep. Connie Morella in support of H.R. 4 and the Waxman Amendment).

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.⁵⁵

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.”⁵⁶ 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.⁵⁷ The Committee Report adds, however, “Indeed the Committee has dealt with fetal tissue more restrictively”⁵⁸ 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.



2. The Statute Informed the Panel’s Investigative Plan

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 models currently operating in the market sector and one operating in the public sector. These are:

⁵⁵ *Id.* (statement of Rep. Henry Waxman).

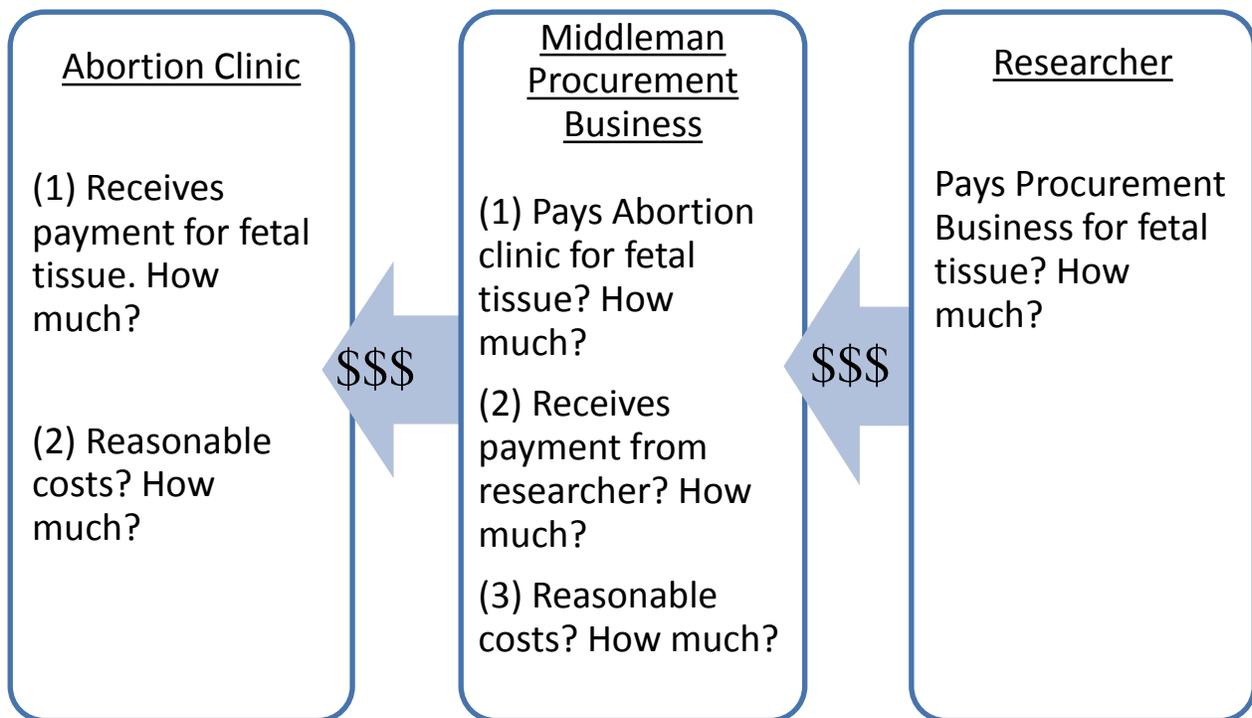
⁵⁶ H.R. Rep. No. 103-28 at 76 (1993).

⁵⁷ Pub. L. No. 98-507, 98 Stat. 2339 (1984).

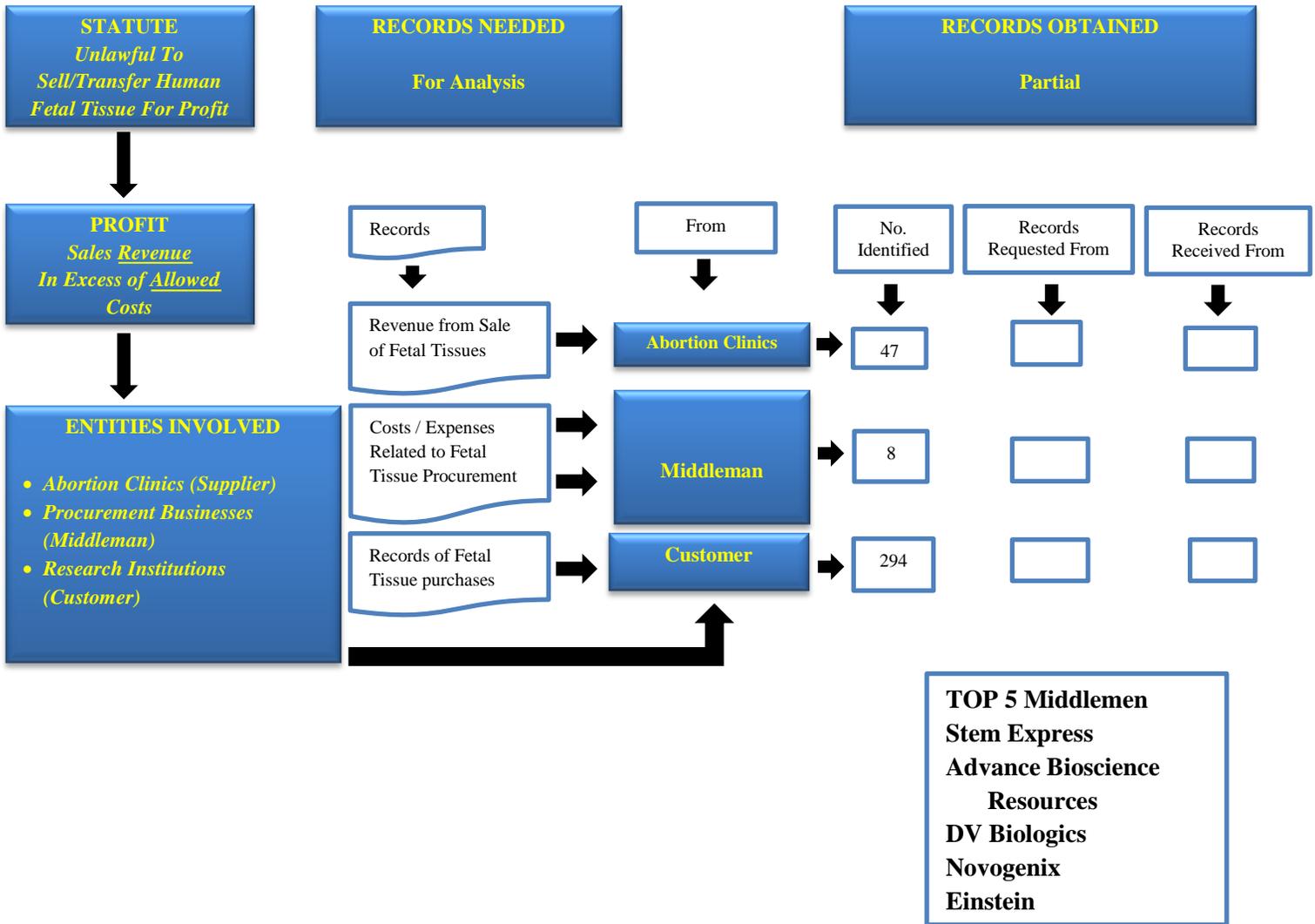
⁵⁸ H.R. Rep. No. 103-28 at 76 (1993).

- (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.
- (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.* The 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 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.



Middleman Investigative Work Plan Overview



3. Fetal Tissue Sales and Abortion Clinic Fiscal Problems

Abortion clinics began supplementing cash flow through the sale of human fetal tissue at a time when abortion clinics were declining in number and faced serious fiscal management issues.

Although abortion providers and abortion rights advocates have a long history of stating that they are driven by concerns for women’s reproductive health, not fiscal concerns, the Panel’s investigation has produced evidence that financial interests are increasingly driving management and clinical practice decisions.

In 1994, Planned Parenthood Federation of America (PPFA) created a “reinvention team” to address problems the National Federation saw in its affiliates. There was “a general concern

that the financial condition of the national organization had deteriorated.”⁵⁹ In short, net margins declined, smaller affiliates fared poorly, and private fundraising (20% of affiliate revenue) declined. The rise of managed care clinics also posed several threats to PPFAs, most importantly in the area of client composition. First, most managed care plans covered the reproductive services that Planned Parenthood offered. Planned Parenthood, therefore, needed to expand its services. Private physicians also began to serve more Medicaid patients, taking a chunk of Planned Parenthood’s customer base with them. But at the same time, the number of uninsured patients grew, increasing the demand at Planned Parenthood 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 two for-profit entities; and restructuring governance of the federation to add weight to the votes of clinics with more clients. But when the draft was reviewed, some complained that “abortion was mentioned only eight times in the entire, 123-page document.”⁶⁰ The second draft, therefore, “explicitly embraced protecting abortion rights as a key function.”⁶¹

Notably, even as many services at Planned Parenthood have declined and clinics have closed and consolidated, abortion as a percentage of revenue has seen a steady increase, along with Planned Parenthood’s revenue.

The following chart illustrates the steady decline in the number of clinics:

Source	Year	Affiliates	Clinics
HBS PPFA 2002	1994	163	938
http://www.frc.org/plannedparenthoodfacts	1995		938
HBS PPFA 1998	1997	150	900
	2000		875
HBS PFA 2008	2008	99	880
	2009	91	
NRLC State of Abortion 2016	2010	88	840
http://www.lifenews.com/2012/01/05/planned-parenthood-51-of-its-income-comes-from-abortions/	2011	86	785
ADF	2012	94	
NRLC State of Abortion 2016 and http://www.frc.org/plannedparenthoodfacts	2015	59	661

Throughout their reinvention process, PPFAs were careful to protect their most lucrative procedure. One former Planned Parenthood facility director emphasized the importance Planned Parenthood placed on abortion quotas. She received confirmation in 2014 that the Planned Parenthood of the Rocky Mountains gave an award to the Planned Parenthood of Aurora, Colorado “for exceeding abortion visits in the first half of FY12 compared to first half of FY13.”

⁵⁹ V. Kasturi Rangan and Elaine V. Backman, *Planned Parenthood Federation of America C*, Harv. Bus. Sch. Case Study No. 9-598-041 (1998).

⁶⁰ V. Kasturi Rangan and Elaine V. Backman, *Planned Parenthood Federation of America B*, Harv. Bus. Sch. Case Study No. 9-598-002 (1997).

⁶¹ *Id.*

She stated, “Planned Parenthood has responded and has confirmed that, YES, this is an award that was given out by them. And, YES, they will continue to “celebrate their progress and they always will.”⁶²

Furthermore, in 2010, affiliates were asked to ensure that at least one of their clinics perform abortions.⁶³ According to a Planned Parenthood fact sheet, for every adoption referral they make, they perform about 340 abortions. Similarly, abortion represented 97% of pregnancy-related services in 2009, despite the frequent claim that abortion is only 3% of its services. Based on PPFA’s own numbers, abortion accounts for about 30% of its annual income.⁶⁴

However, almost 15 years after the initial reinvention process, in 2008, PPFA faced 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. As 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.⁶⁵

4. StemExpress Enters the Marketplace

Around the time that Planned Parenthood was grappling with these financial woes, Cate Dyer was founding a tissue procurement business named StemExpress. She had previously worked at a similar company, Advanced Biosciences Resources (ABR), but left to start her own business. At a meeting with undercover investigators posing as biomedical researchers, Dyer explained that her start-up helps clinics supplement their income by purchasing the left-over body parts from abortions that would otherwise be thrown away. Dyer set up a helpful dichotomy for those who wish to understand the financial relationship between her fetal tissue procurement business and abortions clinics, like Planned Parenthood. Dyer said:

So [ABR] is a not-for-profit, and wasn’t paying any of the clinics, and was funding places in Hawaii for themselves, and all sorts of things. But I would go into clinics and they would say, “Oh you’re for profit? And you want to pay us?” And I’m like, “So *I* want to pay you, *she* [ABR employee] doesn’t want to.” And I’m like, “We’re *trying* to give money to you.” And they would say, “Yeah, that is kind of strange.” . . . So no tax, no payment [ABR’s agreement], tax and payment

⁶²See *Planned Parenthood Confirms It Gave Clinic Award For Killing More Babies In Abortions*, <http://www.lifenews.com/2014/07/18/planned-parenthood-confirms-it-gave-clinic-award-for-killing-more-babies-in-abortions/>.

⁶³ See *Planned Parenthood Plans To Expand Abortion Services Nationwide*, <http://dailycaller.com/2010/12/23/planned-parenthood-plans-to-expand-abortion-services-nationwide/>.

⁶⁴ *Planned Parenthood Federation of America Annual Report 2012-2013*, https://www.plannedparenthood.org/files/7413/9620/1089/AR-FY13_111213_vF_rev3_ISSUU.pdf, at 15.

⁶⁵ Grossman, Steenburgh, Mehler, Oppenheimer, *Planned Parenthood Federation of America in 2008*, Harv. Bus. Sch. Case Study No. 9-309-104 (2010).

[StemExpress’s agreement], you know? And they’d be like, “Okay, that makes sense”⁶⁶

5. Planned Parenthood’s Reliance on Medicaid

While federal funding sources for “family planning” services (e.g., Medicaid and Title X)⁶⁷ are not permitted to pay for most abortions, Planned Parenthood, which performs one third of the nation’s abortions, receives federal financial support for their most lucrative business venture. Abortion providers, such as Planned Parenthood, receive millions of dollars for “family planning” services. Seventy-five percent of U.S. public expenditures for family planning client services are through Medicaid—up from 20% in 1980.⁶⁸

While we know that Planned Parenthood receives millions of taxpayers’ dollars from the federal government, we don’t know exactly how much. Left unrestricted or unregulated, federal funding for family planning services can effectively and indirectly subsidize abortion providers by paying for costs, overhead, employee salaries, rent, utilities, and various other expenses. And as abortions at Planned Parenthood affiliates increase, so do the rates of government funding for the abortion giant.

Year	Total Gov funding (in millions)	Total Revenue (in millions)	Abortions
2006-2007	\$336.7 ⁶⁹	\$1017.9 ⁷⁰	2006: 289,750 ⁷¹
2007-2008	\$349.6 ⁷²	\$1038.1 ⁷³	2007: 305,310 ⁷⁴
2008-2009	\$363.2 ⁷⁵	\$1100.8 ⁷⁶	2008: 328,308 ⁷⁷
2009-2010	\$487.4 ⁷⁸	\$1048.2 ⁷⁹	2009: 332,278 ⁸⁰

⁶⁶ “Planned Parenthood Baby Parts Vendor ABR Pays Off Clinics, Intact Fetuses “Just Fell Out,” <https://www.youtube.com/watch?v=ndJMawjoyPc>.

⁶⁷ Grossman, *supra*. “In 1970, Congress passed and President Nixon signed into law Title X of the Public Health Services Act, which designated funding to provide access to contraceptive services, supplies and information to all who want and need them. Later, Congress broadened Title X’s mandate to provide community-based sex education programs and preventative services to unmarried teenagers at risk of pregnancy. This funding was essential as affiliates continued to expand and offer an increasing array of services.”

⁶⁸ See, e.g., *Publicly Funded Family Planning Services in the United States*, Guttmacher Institute Fact Sheet (Jul. 2015); Adam Sonfield & Rachel Benson Gold, *Public Funding for Family Planning, Sterilization, and Abortion Services, FY 1980-2010*, Guttmacher Institute (Mar. 2012).

⁶⁹ *Planned Parenthood Federation of America Annual Report 2006-2007*, <http://liveaction.org/research/wp-content/uploads/2011/06/2006-2007-Planned-Parenthood-Annual-Report.pdf>.

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² *Planned Parenthood Federation of America Annual Report 2006-2007*, http://www.mdrtl.org/files/PP_AnnualRpt08_vFinal.pdf.

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ Planned Parenthood, FactCheck.org, <http://www.factcheck.org/2011/04/planned-parenthood/>.

⁷⁶ *Planned Parenthood Federation of America Annual Report 2008-2009*, http://www.toomanyaborted.com/wp-content/uploads/2010/PDFs/PP_AR_011011_vF-1.pdf.

⁷⁷ *Id.*

2010-2011	\$538.5 ⁸¹	\$1219 ⁸²	2010: 329,445 ⁸³
2011-2012	\$542.4 ⁸⁴	\$1191.1 ⁸⁵	2011: 333,964 ⁸⁶
2012-2013	\$540.6 ⁸⁷	\$1210.4 ⁸⁸	2012: 327,166 ⁸⁹
2013-2014	\$528.4 ⁹⁰	\$1303.4 ⁹¹	2013: 327,653 ⁹²
2014-2015	\$553.7 ⁹³	\$1296.1 ⁹⁴	2014: 323,999 ⁹⁵

6. Evidence of Medicaid Fraud

The Houston affiliate of Planned Parenthood Gulf Coast (PPGC) paid the federal government \$4.3 million to resolve civil claims that it billed for items and services related to birth control counseling, STD testing, and contraceptives when they were not medically necessary or were not provided. In addition, PPGC agreed to pay the federal government \$1.4 million in a Medicaid fraud case.⁹⁶

Federal funding for abortion is generally prohibited by a patchwork of appropriations riders, including the *Hyde Amendment*, which applies to Medicaid funding. The Hyde Amendment permits federal funding for abortions when pregnancies result from rape or incest, or when the mother's life is in danger.

Despite those laws and Medicaid regulations, audits conducted by the Department of Health and Human Services Office of the Inspector General (OIG) found that Planned Parenthood in New Jersey routinely overbilled Medicaid. The OIG reported: "During our visits

⁷⁸ *Planned Parenthood Federation of America Annual Report 2009-2010*, https://issuu.com/actionfund/docs/ppfa_financials_2010_122711_web_vf?viewMode=doublePage&e=1994783/2039600.

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Planned Parenthood Federation of America Annual Report 2010-2011*, https://issuu.com/actionfund/docs/ppfa_ar_2011_110112_vf.

⁸² *Id.*

⁸³ *Id.*

⁸⁴ *Planned Parenthood Federation of America Annual Report 2011-2012*, https://issuu.com/actionfund/docs/ppfa_ar_2012_121812_vf.

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ *Planned Parenthood Federation of America Annual Report 2012-2013*, https://www.plannedparenthood.org/files/7413/9620/1089/AR-FY13_111213_vF_rev3_ISSUU.pdf.

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ *Planned Parenthood Federation of America Annual Report 2013-2014*, https://www.plannedparenthood.org/files/6714/1996/2641/2013-2014_Annual_Report_FINAL_WEB_VERSION.pdf.

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Planned Parenthood Federation of America Annual Report 2014-2015*, https://issuu.com/actionfund/docs/2014-2015_annual_report_final_20mb/1.

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ Department of Health and Human Services, Office of Inspector General, 2014: More News, <https://oig.hhs.gov/newsroom/podcasts/2013/news.asp>.

to family planning clinics throughout the State, many providers (especially Planned Parenthood providers) stated that they routinely billed all claims to Medicaid as ‘family planning.’ Officials at these clinics stated they believed that all of the services they provided were related to family planning.”⁹⁷ As a result, OIG recommended that New Jersey refund nearly \$600,000 to the federal government.⁹⁸

Across the Hudson River, in New York State, the OIG found that of 90 family planning Medicaid claims it sampled, 27 were for abortions.⁹⁹ Referring to those ineligible claims, the OIG reported, “[o]fficials at Planned Parenthood providers stated that they believed that nearly all the services they provide are related to family planning. However, the medical review determined that the providers improperly claimed, for example, services related to pregnant women, treatment for sexually transmitted diseases, and counseling visits unrelated to family planning services.” The OIG recommended that New York reimburse more than \$17 million to the federal government.¹⁰⁰

Another OIG audit, released last year, found that Planned Parenthood North Texas (PPNT) improperly billed Medicaid “for family planning services,” and “services [PPNT] claimed had a family planning purpose” due to record-keeping errors.¹⁰¹

At an Iowa affiliate of Planned Parenthood, (Planned Parenthood of the Heartland, Inc.) director Sue Thayer quit her job and filed a *qui tam* lawsuit after finding evidence of Medicaid fraud and abuse, in particular “false, fraudulent and/or ineligible claims for reimbursement.”¹⁰² She additionally revealed that her job required her to be “accountable for how many patients you see, and if you’re not seeing enough, why; and you need to have an action plan for [meeting the required number].” She stated that every center in Iowa (where she worked) “had a goal for how many abortions they needed to do.”¹⁰³

Because the federal government pays **90%** of the cost of family planning services, versus 50% to 75% for most other services,¹⁰⁴ states are not highly incentivized to investigate claims of Medicaid fraud.

⁹⁷ Department of Health and Human Services, Office of Inspector General, “Review of Outpatient Medicaid Claims Billed as Family Planning by New Jersey,” June 2008, A-02-06-01010, at 5, <https://oig.hhs.gov/oas/reports/region2/20601010.pdf>.

⁹⁸ *Id.* at 6.

⁹⁹ Department of Health and Human Services, Office of Inspector General, “Review of Clinic and Practitioner Claims Billed as Family Planning Services Under the New York State Medicaid Program,” Nov. 2008, A-02-07-01037, at 7, <https://oig.hhs.gov/oas/reports/region2/20701037.pdf>.

¹⁰⁰ *Id.* at 8.

¹⁰¹ Department of Health and Human Services, Office of Inspector General, “Texas Claimed Unallowable Federal Reimbursement for Some Family Planning Services,” Mar. 2005, A-06-11-00016, at ii, <https://oig.hhs.gov/oas/reports/region6/61100016.pdf>.

¹⁰² The United States of America and the State of Iowa, ex rel. Susan Thayer, *Qui Tam Plaintiff/Relator v. Planned Parenthood of the Heartland, Inc.*

¹⁰³ *Exposed: Former Planned Parenthood Director Says It Has Abortion Quotas*, <http://www.lifenews.com/2014/04/16/exposed-former-planned-parenthood-director-says-it-has-abortion-quotas/>.

¹⁰⁴ *See, e.g., Publicly Funded Family Planning Services in the United States*, Guttmacher Institute Fact Sheet (Jul. 2015), <https://www.guttmacher.org/fact-sheet/2015/publicly-funded-family-planning-services-united-states>.

III. The Ethics of 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 child parents, personalized medicine, organ cloning, chimeras, gene therapy and editing, and bioinformatics are all recent advances that the public has come to learn about and understand. 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.

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 of Illinois 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."¹⁰⁵

However, later in the hearing in an exchange with Dr. Goldstein, Rep. Andy Harris of Maryland, 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

¹⁰⁵ *Bioethics and Fetal Tissue, supra*, (unedited transcript 120).

months or even a year, can't it?"¹⁰⁶ 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."¹⁰⁷ 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.

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

<p>Common Ground</p> 	No one should profit from the sale of fetal tissue. ¹⁰⁸
	Inappropriate to get pregnant in order to donate fetal tissue for research. ¹⁰⁹
	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. ¹¹⁰
	No cures have been found that require fetal tissue. ¹¹¹
	Fetal tissue should not be used for cosmetics or taste testing. ¹¹²
	It is a moral decision for a woman to decide whether to make the fetal tissue donation. ¹¹³

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.

¹⁰⁶ *Id.* at 138.

¹⁰⁷ *Id.* at 139.

¹⁰⁸ *Bioethics and Fetal Tissue, supra* (unedited transcript 161).

¹⁰⁹ *Id.* at 37-8.

¹¹⁰ *Id.* at 149.

¹¹¹ *Id.*

¹¹² *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").

¹¹³ *Id.* at 140.

IV. Case Studies of the Fetal Tissue Industry

A. StemExpress

1. Executive Summary

The Panel's task is to compare documents it received from StemExpress, LLC, a for-profit business, to the applicable federal statute. StemExpress obtains fetal tissue from abortion clinics and offers it for resale to researchers. The documents show that StemExpress embedded employees within a group of abortion clinics to procure fetal tissue, and those employees then shipped the tissue to customers. StemExpress paid the abortion clinics a per-tissue fee for each tissue its employees procured, plus a per-tissue bonus to StemExpress employees.

The Panel compared StemExpress' methodology to HIPAA and Title 45 C.F.R. Part 46, the federal regulations governing IRBs.

2. StemExpress Business Model

As a middleman, StemExpress recruited abortion clinics from which to obtain fetal tissue and researchers to whom fetal tissue could be sold. StemExpress used its website and brochures distributed at a National Abortion Federation event to recruit abortion clinics.

As the screen capture below demonstrates, StemExpress recruited and screened clinics that were most likely to perform abortions that could produce saleable tissue to researchers. StemExpress sought information about the number of abortions it performed each week, the gestational age of fetuses scheduled to be aborted, the days the abortions were done, whether digoxin¹¹⁴ 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.

At hearings conducted by the Panel, both Rep. Black and Rep. Pitts called StemExpress "the Amazon.com of baby body parts."¹¹⁵ Researchers ordered tissue using StemExpress' website. The firm initially had a drop-down menu that allowed researchers to obtain various types of tissue. It later switched to another web-based system.

¹¹⁴ 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.

¹¹⁵ *Bioethics and Fetal Tissue, supra* (unedited transcript 55); *The Pricing of Fetal Tissue: Hearing Before the Select Investigative Panel of the H. Comm. on Energy and Commerce*, 114th Cong., Apr. 20, 2016 (unedited transcript 77).

StemExpress Website Recruitment Form for Abortion Clinics

7/5/2016

Form-2.png3.PNG (679x1600)

Clinic Name

Clinic Address

Street Address

Street Address Line 2

City State
Zip Code Country

First Name

Last Name

Office Phone Number
 -
Area Code Phone Number

Cell Phone Number
 -
Area Code Phone Number

E-mail *

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:

StemExpress Drop-Down Ordering Menu: “The Amazon.com of Baby Body Parts”

 Sign In Register My Account Create Wishlist Order 0 Items - \$0

Select Language ▼ 🔍

[home](#) [products & bioservices](#) [about stemexpress](#) [become a provider](#) [get involved](#) [news](#) [contact](#)

Tissue Order Form

Request Information

Have you placed this order previously? * Yes No

You have verified that your account address is up to date and current * Yes
If you need to check your address information, open your account page in a new window.

What days are you available to receive samples? * Every Day Monday Tuesday Wednesday Thursday Friday Saturday Sunday

What type of tissue would you like to order? * --- Organs and Tissues --- ▼ [\[SEE NEXT PAGE\]](#)

Number of Specimens *

Gestational Range Start * 4 wks ▼

Gestational Range End * 4 wks ▼

Add another tissue type? Yes

Shipping Options * Same Day Delivery: By Commercial Carrier/Hand Delivered *Available in select locations only
 FedEx First Priority Overnight: FedEx will deliver to your location roughly around 8 a.m. the day after procurement
 FedEx Priority Overnight: FedEx will deliver to your location roughly around 10:30 a.m. the day after procurement
 International Shipping: Will be arranged on a case-by-case basis

Transport Method * Refrigerated on Wet Ice Frozen on LN2 and Dry Ice Gel Ice Pack Ambient Temp

Media * Shipped on RPM1 ▼

Additional Notes

Not finding what you are looking for? Fill it in here.

Translate »

DOWNLOAD OUR CATALOG



Download our latest Product Catalog

SIGN UP FOR OUR NEWSLETTER

First Name * Translate »

E-mail *

Areas of Interest

- Peripheral blood
- Bone marrow
- Leuko Pak
- Maternal blood
- Umbilical cord blood
- Isolated cells
- MNC
- CD34+
- Other CD marker

BECOME A CUSTOMER



Become a Customer!

Become a StemExpress customer today to receive 10% off your first order up to \$1,000!

--- 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

3. Daily Work Schedule of StemExpress Embedded Tissue Technicians

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.¹¹⁶
- After an abortion, the technician collected the baby's remains and procured the body parts that were ordered, using her own supplies.¹¹⁷ 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.

¹¹⁶ BioMed IRB, Informed Consent, *supra*.

¹¹⁷ See Standard Operating Procedure, Jan. 24, 2011, at 1 ("The clinic staff will identify donors"), produced by StemExpress.

StemExpress Embedded Technician Pay Rates and Bonuses



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.



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

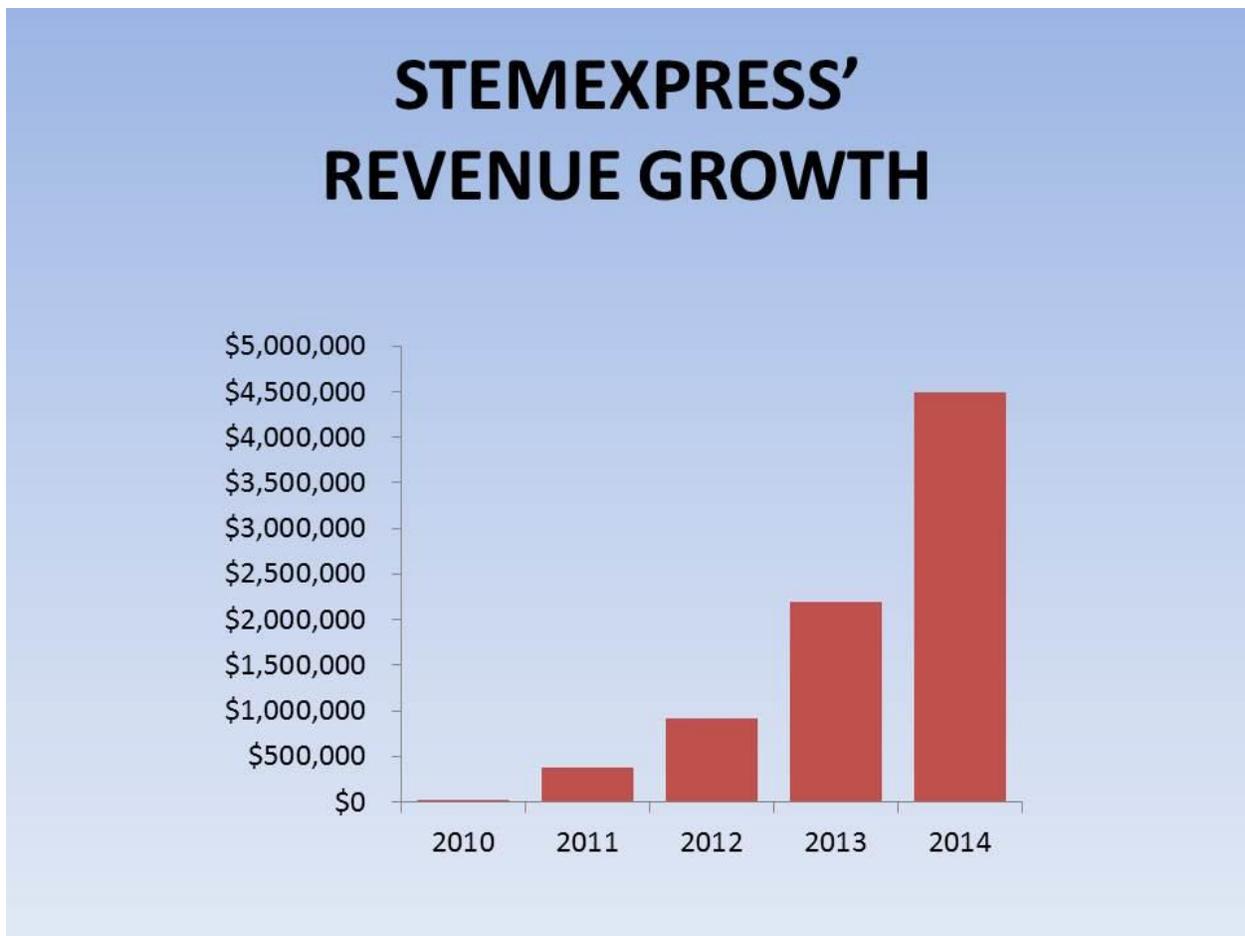
*Note: Blood Samples may be obtained with these specimens in which case Category C bonus does not apply

778 Pacific Street / Placerville CA 95667
T: 530-626-7000 F: 530-26-7900 / info@stemexpress.com / www.stemexpress.com

4. StemExpress' Revenue Growth

Press accounts reveal that Cate Dyer formed StemExpress in March 2010. Initially, she ran the firm out of her home. Within its first year of operation, the firm moved into a 1,500-square foot facility. By 2014, StemExpress was planning to open a branch in Washington, D.C., and “looking at the possibility of a site in Europe as well.”¹¹⁸

During the five years after its formation, StemExpress had stunning revenue growth: 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.¹¹⁹



¹¹⁸ *Cate Dyer, founder and CEO, Stem Express*, Sacramento Bus. J., Jul. 19, 2015, <http://www.bizjournals.com/sacramento/print-edition/2015/06/19/cate-dyer-founder-and-ceo-stem-express-llc.html>.

¹¹⁹ *The 500: Get to know the 500 fastest-growing privately held companies in America*, INC., Sept. 2014, at 137.

StemExpress Marketing Strategy

StemExpress' 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].”

StemExpress Brochure Distributed at NAF Conference



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.



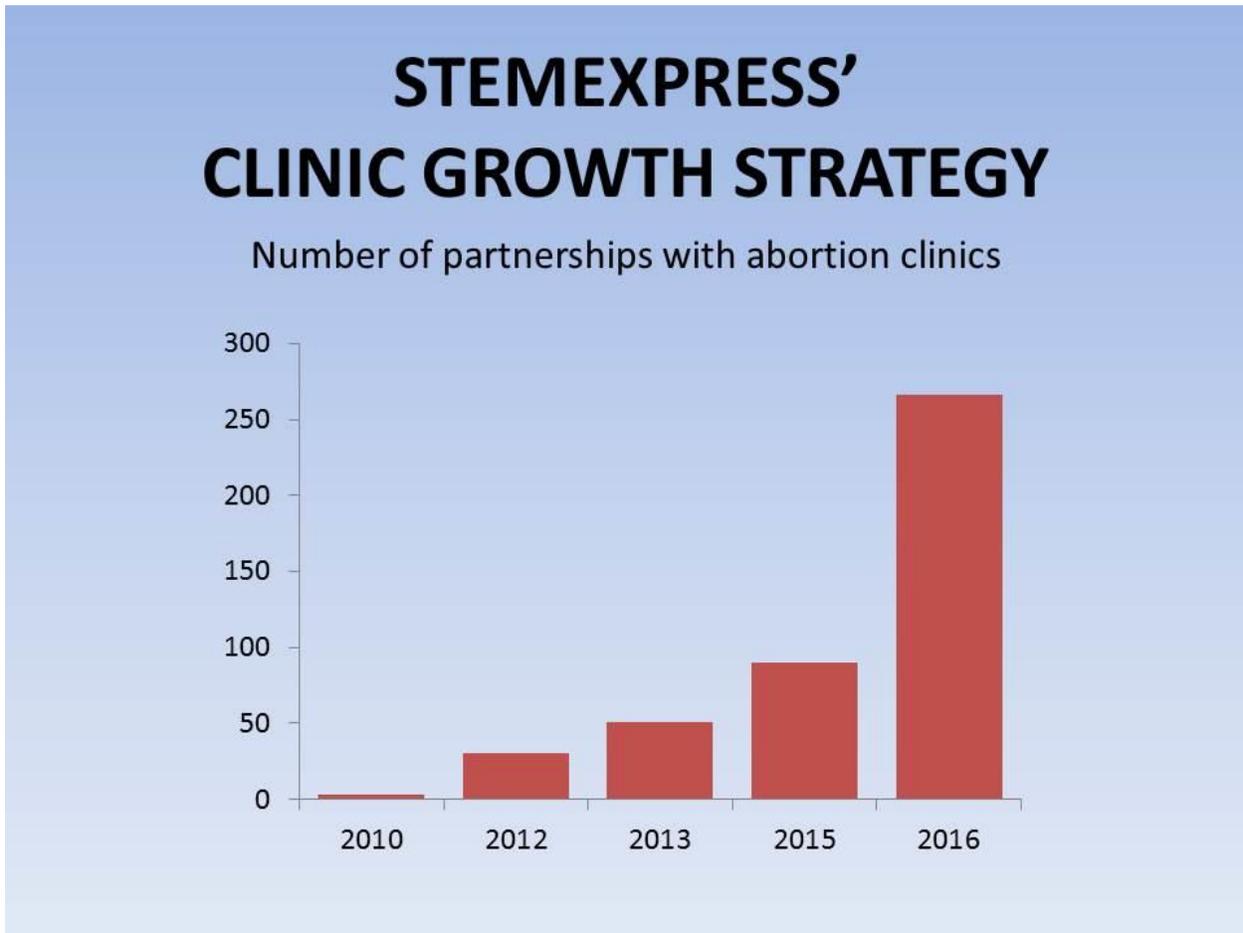
Easy to Implement Program + Financial Profits

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.

NAF-000003

5. StemExpress Expands from 4 Clinics to Nearly 300

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.”¹²⁰ 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.



StemExpress’ 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 obtained fetal tissue. StemExpress’ proposed contract [not ratified] with the National Abortion Federation reveals StemExpress intent to increase its supply of fetal tissue. Below are excerpts of the draft contract between StemExpress and the National Abortion Federation, dated March 25, 2015:

¹²⁰ Complaint at para. 17, StemExpress, LLC v. Center for Medical Progress, No. BC-589145 (L.A. Super. Ct. filed Jul. 27, 2015).

. . . 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 . . .

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.¹²¹

6. StemExpress' Profit and Loss

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 \$595 to \$910 per tissue or body part.

Payments from StemExpress to Abortion Clinics

CLINIC	DATE	ITEM	COST
Planned Parenthood Mar Monte: Fresno	September 5, 2012	POC	\$2,090.00
Planned Parenthood Mar Monte: Fresno	September 5, 2012	Bloods	\$490.00
Planned Parenthood Mar Monte: Fruitridge	September 5, 2012	POC	\$0
Planned Parenthood Mar Monte: Fruitridge	September 5, 2012	Bloods	\$0
Planned Parenthood Mar Monte: Mountain View	September 5, 2012	POC	\$0
Planned Parenthood Mar Monte: Mountain View	September 5, 2012	Bloods	\$0
Planned Parenthood Mar Monte: N. Highlands	September 5, 2012	POC	\$0
Planned Parenthood Mar Monte: N. Highlands	September 5, 2012	Bloods	\$0
Planned Parenthood Mar Monte: Eastland Plaza	September 5, 2012	POC	\$0
Planned Parenthood Mar Monte: Eastland Plaza	September 5, 2012	Bloods	\$40.00
Planned Parenthood Mar Monte: Sacramento	September 5, 2012	POC	\$3,740.00
Planned Parenthood Mar Monte: Sacramento	September 5, 2012	Bloods	\$800.00
Planned Parenthood Mar Monte: San Jose	September 5, 2012	POC	\$3,575.00
Planned Parenthood Mar Monte: San Jose	September 5, 2012	Bloods	\$630.00
Planned Parenthood Mar Monte: Seaside	September 5, 2012	POC	\$0

¹²¹ Draft Partnership Agreement between National Abortion Federation and StemExpress, LLC, Mar. 25, 2015 (NAF 000046-00005).

Planned Parenthood Mar Monte: Seaside	September 5, 2012	Bloods	\$0
Planned Parenthood Mar Monte: Stockton	September 5, 2012	POC	\$0
Planned Parenthood Mar Monte: Stockton	September 5, 2012	Bloods	\$0
TOTAL:			\$11,365.00
Planned Parenthood Mar Monte: Stockton	March 14, 2011	POC	\$55.00
Planned Parenthood Mar Monte: Stockton	March 14, 2011	Bloods	\$1,210.00
Planned Parenthood Mar Monte: Sacramento	March 14, 2011	POC	\$1,485.00
Planned Parenthood Mar Monte: Sacramento	March 14, 2011	Bloods	\$3,270.00
Planned Parenthood Mar Monte: Fresno	March 14, 2011	POC	\$660.00
Planned Parenthood Mar Monte: Fresno	March 14, 2011	Bloods	\$2,380.00
TOTAL:			\$9,060.00
Planned Parenthood Mar Monte: Fresno	February 17, 2014	POC	\$55.00
Planned Parenthood Mar Monte: Fresno	February 17, 2014	POC	\$175.00
Planned Parenthood Mar Monte: Fresno	February 17, 2014	Bloods	\$680.00
Planned Parenthood Mar Monte: Fruitridge	February 17, 2014	POC	\$0
Planned Parenthood Mar Monte: Fruitridge	February 17, 2014	Bloods	\$0
Planned Parenthood Mar Monte: Mountain View	February 17, 2014	POC	\$110.00
Planned Parenthood Mar Monte: Mountain View	February 17, 2014	Bloods	\$0
Planned Parenthood Mar Monte: N. Highlands	February 17, 2014	POC	\$0
Planned Parenthood Mar Monte: N. Highlands	February 17, 2014	Bloods	\$0
Planned Parenthood Mar Monte: Eastland Plaza	February 17, 2014	POC	\$0
Planned Parenthood Mar Monte: Eastland Plaza	February 17, 2014	Bloods	\$0
Planned Parenthood Mar Monte: Sacramento	February 17, 2014	POC	\$990.00

Planned Parenthood Mar Monte: Sacramento	February 17, 2014	POC	\$0
Planned Parenthood Mar Monte: Sacramento	February 17, 2014	Bloods	\$400.00
Planned Parenthood Mar Monte: San Jose	February 17, 2014	POC	\$1,375.00
Planned Parenthood Mar Monte: San Jose	February 17, 2014	POC	\$0
Planned Parenthood Mar Monte: San Jose	February 17, 2014	Bloods	\$740.00
Planned Parenthood Mar Monte: Seaside	February 17, 2014	POC	\$385.00
Planned Parenthood Mar Monte: Seaside	February 17, 2014	POC	\$0
Planned Parenthood Mar Monte: Seaside	February 17, 2014	Bloods	\$80.00
Planned Parenthood Mar Monte: Stockton	February 17, 2014	POC	\$715.00
Planned Parenthood Mar Monte: Stockton	February 17, 2014	POC	\$35.00
Planned Parenthood Mar Monte: Stockton	February 17, 2014	Bloods	\$270.00
TOTAL:			\$6,010.00

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
TOTAL:			\$2,230.00

Sample StemExpress Invoice to Customer

Redacted

PURCHASE ORDER

Winter Closure Warning: [Redacted] will be closed for 2 weeks from Monday, December 15, 2014 through January 4, 2015. [Redacted] will reopen on Monday, January 5, 2015. No staff will be here for deliveries during this closure unless they have made special arrangements with you to be here to receive this shipment. If you cannot deliver by Friday, December 19, 2014 please schedule your shipment to arrive as soon as possible on or after, Monday January 5, 2015.

DATE	PURCHASE ORDER NO.
16-DEC-2014	60858758
PAGE NO.	REVISION NO.
Page 1 of 1	0

To: **STEMEXPRESS LLC**
 778 Pacific St
 Placerville, CA 95667
 United States
 ATTN : [Redacted]

Ship To:

Redacted

ORDER PLACED WITH	FOB Destination	FREIGHT	VENDOR: If freight not included in price, prepay and add	DELIVERY DATE 17-DEC-2014	TERMS N30	
ITEM NUMBER	DESCRIPTION		QUANTITY	UNIT	UNIT PRICE	EXTENDED PRICE
1	FT0101F Human Fetal Tissue (Estimate 5251) - Gestation requirements: 17-18 weeks - - upper and lower limbs with hands and feet		1	EACH	890.00	890.00
2	FT0101F Human Fetal Tissue (Estimate 5251) - Calvarium - Matched to upper and lower limbs		1	EACH	595.00	595.00
TAXABILITY						
Exempt because items are for resale. California Sellers Permit: [Redacted]			Exempt as purchase on behalf of U.S. Government		Exempt because use is exempted.	
[Redacted]			[Redacted]		Authorized Signature: [Redacted]	
Direct questions to: [Redacted]					ESTIMATED TAX: 129.95	
TOTAL: 1,614.95					Chief Procurement Officer	
Unless specifically stated otherwise, [Redacted] is subject to Sales Tax. Suppliers should invoice for taxable items. If a Supplier does not have the authority to collect California Sales Tax, [Redacted] will accrue the tax and remit to the State Board of Equalization in the form of Use Tax.						
California Revenue and Taxation Code, Section 18662, require withholding for payments made to nonresidents of California for income earned in California related to independent contractor services, rent, and royalty distributions. For more information on this requirement reference https://www.ftb.ca.gov/forms/2012/19_1011.pdf .						

This Purchase Contract may be accepted only on the terms set forth herein. The complete Terms and Conditions can be found at: [Link](#). Terms in any acceptance by Seller which are in addition hereto or not identical with the terms hereof will not become a part of any Purchase Contract unless Buyer specifically and expressly agrees in writing that such other terms are accepted. By accepting this Purchase Contract or any part hereon, Seller agrees to and accepts all the provisions of the Purchase Contract.

INSTRUCTIONS
 Applicable unless otherwise stated

- A. Invoices** - Separate invoices for each purchase order. Show purchase order number on all documents. Mail invoices to Accounts Payable at:

Redacted

 If this order involves services and you have not advised [Redacted] of your tax status, please contact the Financial Support Center at [Redacted]. Failure to provide tax information may result in delayed payment. For more information, email [Redacted].

- B. Correspondence** - [Redacted]
- C. Transportation** - If freight is not included in price, prepay and state separately on invoice. Do not ship collect. Include a packing list with each shipment, and attach to outside (not inside) of container. Show purchase order number on outside of each container
- D. Late Shipment** - Advise at once if order will not reach destination on time.
- E. Terms and Conditions** - [Link](#).

CONFIDENTIAL / PROPRIETARY BUSINESS RECORDS

STEM.HOUSE.SELECT_ 0369

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 as expenses shipping, supplies, and infectious disease screenings. These were costs charged to researchers.

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 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.

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

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

B. Advanced Bioscience Resources, Inc.: A Case Study

1. Executive Summary

ABR, a non-profit, obtains fetal tissue from abortion clinics and offers it for resale to researchers. ABR’s business model is that of StemExpress. Notably, Dyer began her career in the fetal tissue industry as a tissue technician at ABR.

ABR obtains tissue from abortion clinics and generally pays them 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.

The Panel compared materials provided by ABR to Section 289g-2, which prohibits receipt of valuable consideration for fetal tissue, which excludes costs “associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.”¹²² 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.”¹²³ Only the

¹²² 42 U.S.C. § 289g-2(e)(3).

¹²³ Advanced Bioscience Resources, Inc., “ABR Overview: Key Points,” at 5 (SP000752).

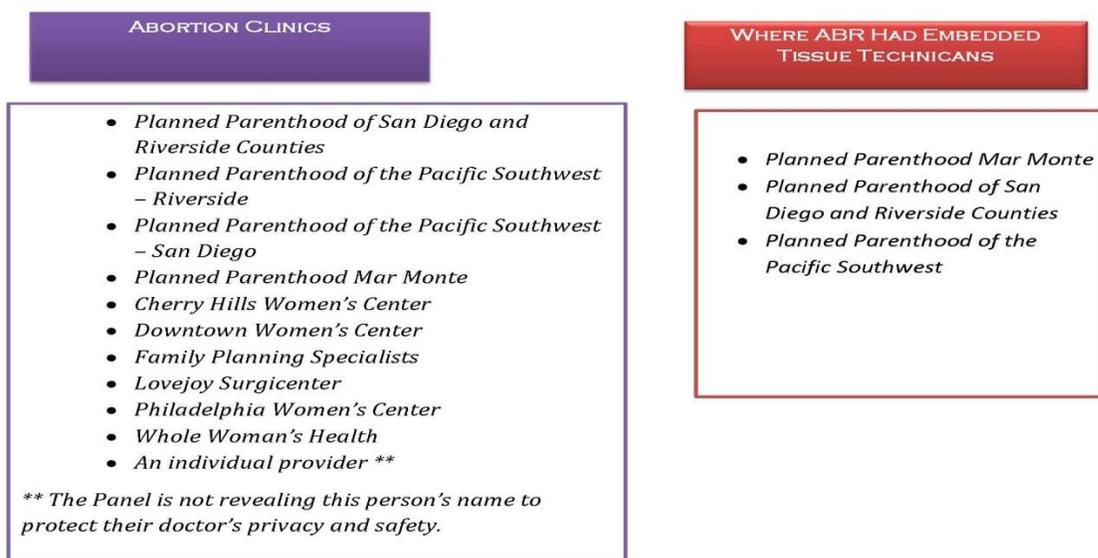
costs of transfer of fetal tissue can offset valuable consideration. The same ABR document states that its tissue technicians procure the tissue, package it, and ship it.¹²⁴ When the Panel asked ABR whether it prepares tissue for research, or modifies it into cell lines, the firm’s attorney stated “ABR does not provide any other services other than simple tissue procurement . . .”¹²⁵

2. ABR’s Business Model

ABR obtained fetal tissue from eleven abortion clinics or providers. It had embedded tissue technicians in at least three of those clinics. Due to ABR’s limited production, the Panel does not know whether the firm had embedded technicians in the remaining eight clinics.

ABR Clinics & Embedded Tissue Technicians

Advanced Bioscience Resources, Inc.



ABR “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 . . .”¹²⁶ The fees ranged from \$45 to \$60, depending upon the year and the clinic. The sole exception to that rule, as far as the Panel is aware, was at Planned Parenthood Pacific Southwest, where, starting in January, 2012, ABR paid for rented space two days a week for \$1,000; if ABR only used the space for one day, it paid \$500.

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 [REDACTED], the president. The review is

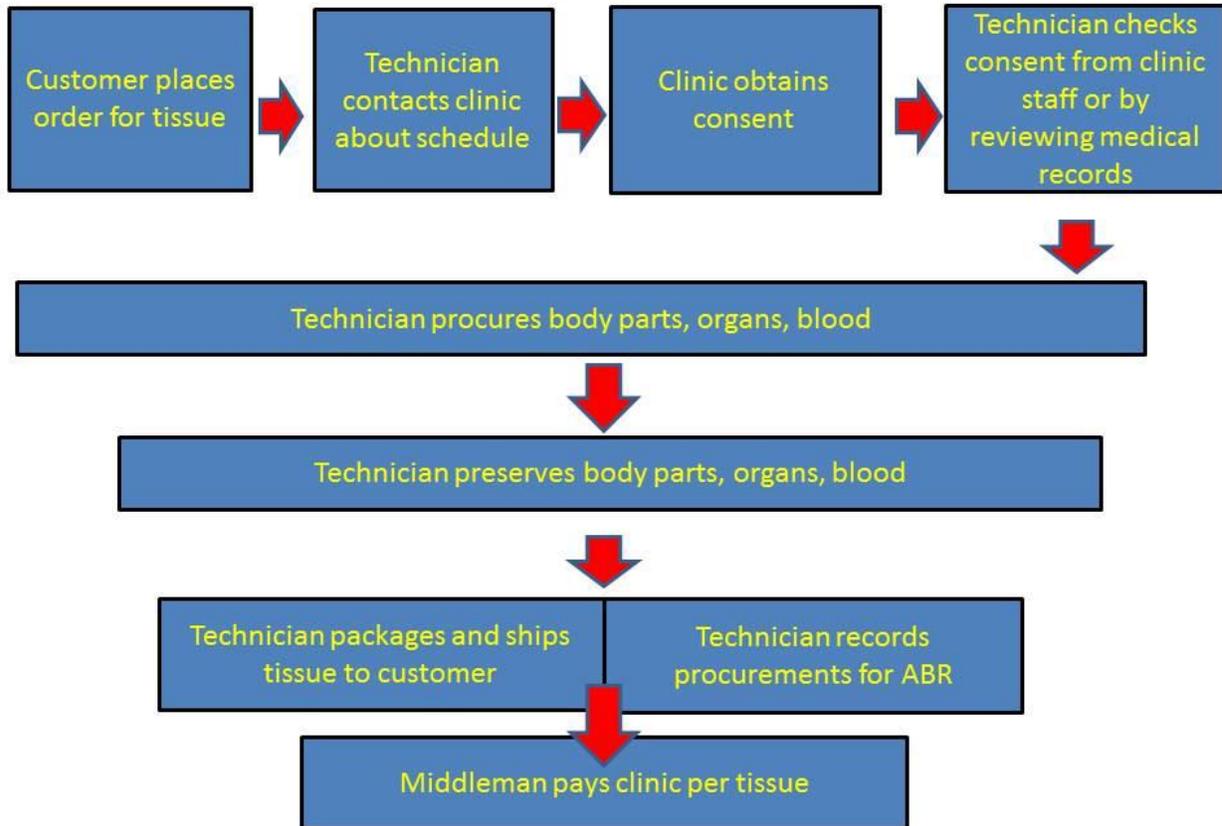
¹²⁴ *Id.* at 7 (SP000754).

¹²⁵ Letter from Jonathan F. Lopez, Orrick, Herrington & Sutcliffe, to Rep. Blackburn, Chairman, Select Investigative Panel, Feb. 24, 2016, at 2.

¹²⁶ ABR Overview: Key Points, *supra*, at 5 (SP000752).

focused on the scientific creditability and feasibility of their studies. Once approved, researchers send their specific tissue requests via facsimile, email, or phone call.

ABR Tissue Technicians' Workflow



3. Daily Work Schedule of ABR Embedded Tissue Technicians

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 then confirmed that the clinics have 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."¹²⁷

¹²⁷ "Permission for Donation of Tissue Obtained at the Time of Abortion" (HCEC000044).

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 also updated ABR on the tissue requests as they were fulfilled.
- 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.

4. ABR Payments to Abortion Clinics

During 2015, 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."¹²⁸

ABR Payments to Top 5 Abortion Clinics for Human Fetal Tissue for 2015

Family Planning Specialist	\$10,560
Cherry Hill Women's Center	\$10,812
Planned Parenthood (San Diego, CA clinic)	\$13,080
Lovejoy Surgicenter	\$22,940
Planned Parenthood: Riverside	\$23,460
Total	\$93,932

5. ABR Revenue from Customers

ABR produced only payments from a limited number of researchers to whom it transferred fetal tissue, covering invoices for a single year. However, researchers produced payments to ABR pursuant to document request letters. ABR's production of invoices presents an incomplete picture of their income, but their income tax forms report \$6.5 million in total revenue for the last five reporting years (2010-2014). The chart below lists the payments the top five researchers made to ABR during 2015.

ABR Human Fetal Tissue Revenue from Top 6 Customers for 2015

Chapel Hill	\$20,060
Sciencell Research Labs	\$21,840
Food and Drug Administration	\$24,890
National Institutes of Health	\$30,630
Vertex Pharmaceuticals	\$40,870
Mass General Hospital	\$53,694
Total	\$191,984

¹²⁸ ABR Overview: Key Points, *supra*, at 5 (SP000752).

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	

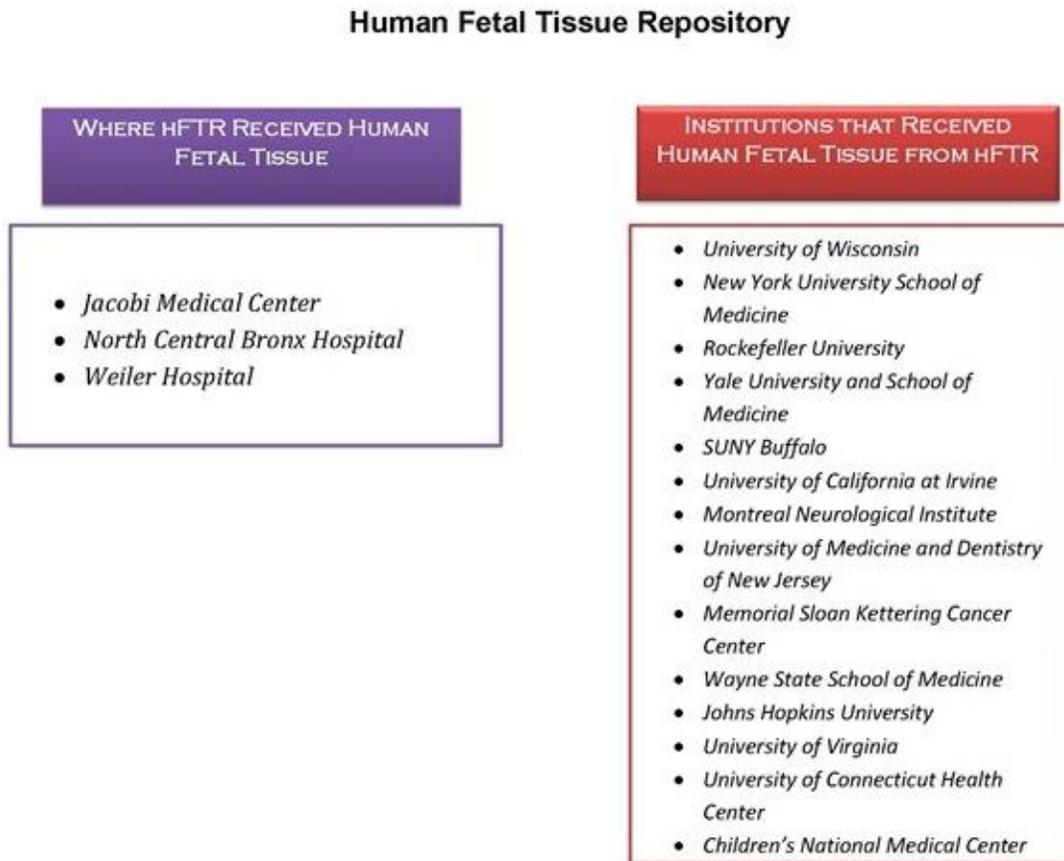
Summary total for top 5 customers.....\$61,600

C. Human Fetal Tissue Repository

The Human Fetal Tissue Repository (hFTR) presents a different case study. Unlike the other entities the Panel examined, hFTR effectively operated as a tissue bank for human fetal tissue. A university medical school ran the program, received human fetal tissue from three hospitals, and transferred the human fetal tissue to other colleges and hospitals for nominal fees. The dean of the college at which hFTR was housed said those payments defrayed the costs of operating hFTR.

The hFTR was operated by the Albert Einstein College of Medicine at Yeshiva University (Einstein) in the Bronx, a borough of New York City. It closed on March 2, 2015, after Einstein merged with the Montefiore Health System, another Bronx hospital. The closure occurred due to cash-flow issues at Einstein.

During its operations, hFTR received human fetal tissue from three New York City hospitals and transferred it to 14 different universities and hospitals. The hFTR paid no money for the human fetal tissue it obtained. It received “expenses” of \$100 from internal researchers and \$250 per human fetal tissue sample for external researchers “to defray the costs of operating hFTR.”¹²⁹ The following chart shows where hFTR received and transferred human fetal tissue:



¹²⁹ Letter from [REDACTED], Executive Dean, Albert Einstein College of Medicine of Yeshiva University, to Rep. Blackburn, Chair, Select Investigative Panel, Feb. 10, 2016, at 2.

D. The University/Clinic Model

This model comprises a research institution—usually a taxpayer-funded university—that has formed a close relationship with one or more abortion clinics and regularly acquires tissue from those clinics for research purposes. The research institution typically 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. 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 solicitation. Once available, the entities make arrangements to transfer the fetal organs and tissue from the clinic.

The Panel’s investigation into such a relationship in New Mexico illustrates this model. As discussed in more detail below, an employee of the University of New Mexico (UNM) has traveled to Southwestern Women’s Options (SWWO), a clinic that performs abortions through the third trimester, to procure human fetal organs or tissue an average of 39 times a year since 2010. Other partnerships between abortion clinics and researchers involve shipments or deliveries from the abortion clinic.

1. The University of New Mexico and Southwestern Women’s Options: A Case Study

a) 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 were often unwilling to participate.¹³⁰

UNM’s practice changed dramatically following the efforts of an abortion policy committee—largely spearheaded by *Doctor #1* and *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.¹³¹

¹³⁰ *Doctor #2, Doctor #1, “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*].

¹³¹ *Id.* at 84-88.

The doctors then pressed further, against additional resistance by administrators, until they successfully introduced surgical abortion into UNM clinics. To do this they overrode 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.”¹³² Today, UNM Hospital performs surgical abortions for any reason through 25 weeks gestation. At or beyond 24-25 weeks gestation, “pregnancy termination will be considered on a case-by-case basis for maternal or fetal reasons.”¹³³ UNM also refers patients to SWWO for late-term abortions.

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.¹³⁴ 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.¹³⁵

b) 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 *Doctor #3* at SWWO.¹³⁶

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.¹³⁷ 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.”¹³⁸ The sole UNM signatory to this contract was the director of the Fellowship in Family Planning, *Doctor #1*. Neither the 2012 nor the 2014 contract was signed by an official

¹³² *Id.* at 88.

¹³³ UNMHSC, Second Trimester Pregnancy Termination, D&E and induction of labor (UNM01685).

¹³⁴ The Susan Thompson Buffett Foundation 990-PF reports.

¹³⁵ You Can’t Do That, *supra*, at 85-86.

¹³⁶ UNM-SWWO agreement, June 2, 2014 (UNM03417-UNM03418) [2014 UNM-SWWO agreement].

¹³⁷ UNM-SWWO agreement signed Jan. 5 and Jan. 7, 2012 (UNM03419).

¹³⁸ 2014 UNM-SWWO agreement.

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.¹³⁹

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. *Doctor #1*, *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—activities in which UNM students are encouraged to participate. 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 *Doctor #1* 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.¹⁴⁰

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*.¹⁴¹ In a terse letter from *Doctor #1* to *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.¹⁴² 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. The following schedule generated by the Ob/Gyn department for the month of May 2016 details rotations at the clinic for staff physicians (names redacted) and serves as an illustration of UNM's relationship with Planned Parenthood:

¹³⁹ See University of New Mexico Regents' Policy Manual, Section 7.8: Signature Authority for Contracts; Administrative Policies and Procedures Manual, Section 5.2; University Business Policy 2010 Exhibit B2.

¹⁴⁰ 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., filed Jan. 15, 2016).

¹⁴¹ Colleen Heild, *UNMHSC Halts Training at Private Abortion Clinic*, *Albuquerque Journal*, Dec. 20, 2015, at A1.

¹⁴² Letter from *Doctor #1* to *Doctor #3*, Dec. 14, 2015 (UNM03429).

University of New Mexico-OB/GYN Department (May 2016)

	UNM Doctor	UNM Doctor	UNM Doctor	UNM Doctor	UNM Doctor	UNM Doctor	UNM Doctor	UNM Doctor
Su 1								
Mo 2								
Tu 3							Planned Parenthood AM	
We 4							Planned Parenthood PM	
Th 5								
Fr 6						Planned Parenthood AM		
Sa 7						Planned Parenthood PM		
Su 8								
Mo 9								
Tu 10		Planned Parenthood AM						
We 11		Planned Parenthood PM						
Th 12								
Fr 13		Planned Parenthood AM						
Sa 14		Planned Parenthood PM						
Su 15								
Mo 16								
Tu 17		Planned Parenthood AM						
We 18		Planned Parenthood PM						
Th 19								
Fr 20		Planned Parenthood AM						
Sa 21		Planned Parenthood PM						
Su 22								
Mo 23								
Tu 24		Planned Parenthood AM						
We 25		Planned Parenthood PM						
Th 26								
Fr 27		Planned Parenthood AM						
Sa 28		Planned Parenthood PM						
Su 29								
Mo 30								
Tu 31								

Source: <https://app.agenda.com/link/view?linkKey=e80f545e-3932-4e65-9068-b4fabebedf294&landingPageId=ef9020e4-2efe-466c-8362-b107767d864d>

c) 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 with titles such as clinical assistant professor or visiting instructor. 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.¹⁴³

As volunteer faculty, these SWWO doctors also are entitled to a list of benefits at UNM that includes access to numerous libraries and recreational facilities, discounts for athletic and cultural events, and membership in UNM’s credit union.¹⁴⁴ Apart from the UNM fellowship terminated at SWWO in December, the Panel is unaware that any of the UNM volunteer faculty members employed by SWWO provide any teaching or other academic services to UNM in exchange for the benefits provided by UNM. UNM does, however, continue to receive one substantial benefit from SWWO: fetal tissue.

¹⁴³ Volunteer Faculty Professional Liability Insurance Extension of New Mexico Tort Claims Act (UNM03399).

¹⁴⁴ UNM School of Medicine, Volunteer Faculty Benefits (SWWO001234-SWWO001235).

d) SWWO provides aborted infant tissue to UNM for research

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 asserts that “[t]he tissue is donated at no cost to UNMHSC and it is picked up at the clinic by UNMHSC staff.”¹⁴⁵ 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.”¹⁴⁶

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 2010.¹⁴⁷ 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; however, by July 2015, digoxin was only administered to infants “20wks+.”¹⁴⁸

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.¹⁴⁹ 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, *Doctor #3* of SWWO wrote a letter to UNM detailing a 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.”¹⁵⁰ The Panel has no information to suggest that SWWO has ceased providing aborted infant tissue to UNMHSC.

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.”¹⁵¹ The university claimed 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

¹⁴⁵ UNM Second Submission to House Select Panel, Feb. 16, 2016, at 1; UNM Document (UNM00560); UNM First Submission to House Select Panel, Jan. 29, 2016, at 1; UNM Response to House Select Panel Subpoena, Mar. 3, 2016, at 1; SWWO letter responding to document request, Feb. 12, 2016, at 1, Appendix A.

¹⁴⁶ UNM Study Document (UNM00790).

¹⁴⁷ See Procurement notes (UNM00004-UNM00052) (Approximation: 2010–43 days; 2011–25 days; 2012–45 days; 2013–49 days; 2014–41 days; 2015–33 days).

¹⁴⁸ *Id.* at UNM00049.

¹⁴⁹ *Id.* at UNM00019, UNM00041, UNM00024, UNM00006.

¹⁵⁰ May 5, 2015, Letter from *Doctor #3* to UNM (UNM01086).

¹⁵¹ UNM Second Submission, *supra*, at 2.

[redacted] and the providers at Southwest Women’s Options.”¹⁵² Documents provided to the Panel list 18 studies conducted in collaboration with SWWO since 1995.¹⁵³

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 tech wrote in May 2012 that someone from UNMHSC “asked clinic for digoxin treated tissue 24-28 weeks for methylation study + because [redacted] wants whole, fixed brains to dissect w/ summer camp students. Clinic est. 27 and 28 weeks.”¹⁵⁴

5-24-12 [redacted] 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. Smaller in amniotic/placenta

Excerpt from researcher’s notes

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.”¹⁵⁵ UNMHSC bears the cost for shipping tissue domestically; while for transactions in Canada, the Canadian researcher provides a Federal Express account number.

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).”¹⁵⁶

e) The Panel’s criminal referral of UNM and SWWO

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)*¹⁵⁷ established the state’s rules regarding anatomical gifts. The statute explicitly puts fetuses that result from abortion in a different category from those that are spontaneously miscarried or stillborn. It defines “decedent” as “a deceased individual whose body or part is or may be the source of an anatomical gift.” This “includes a stillborn infant and . . . a fetus **but [does] not includ[e] a fetus that is the subject of an induced abortion.**”¹⁵⁸ Moreover, the *Spradling Act* provides that the Act “applies to an

¹⁵² UNM Documents (UNM00560, UNM00812 & UNM01105).

¹⁵³ UNM Documents (UNM00768, UNM00815 & UNM01059).

¹⁵⁴ Procurement notes, *supra*, at UNM00024.

¹⁵⁵ UNM Second Submission to House Select Panel, at 1.

¹⁵⁶ Email from UNM to University of Edmonton (UNM00910).

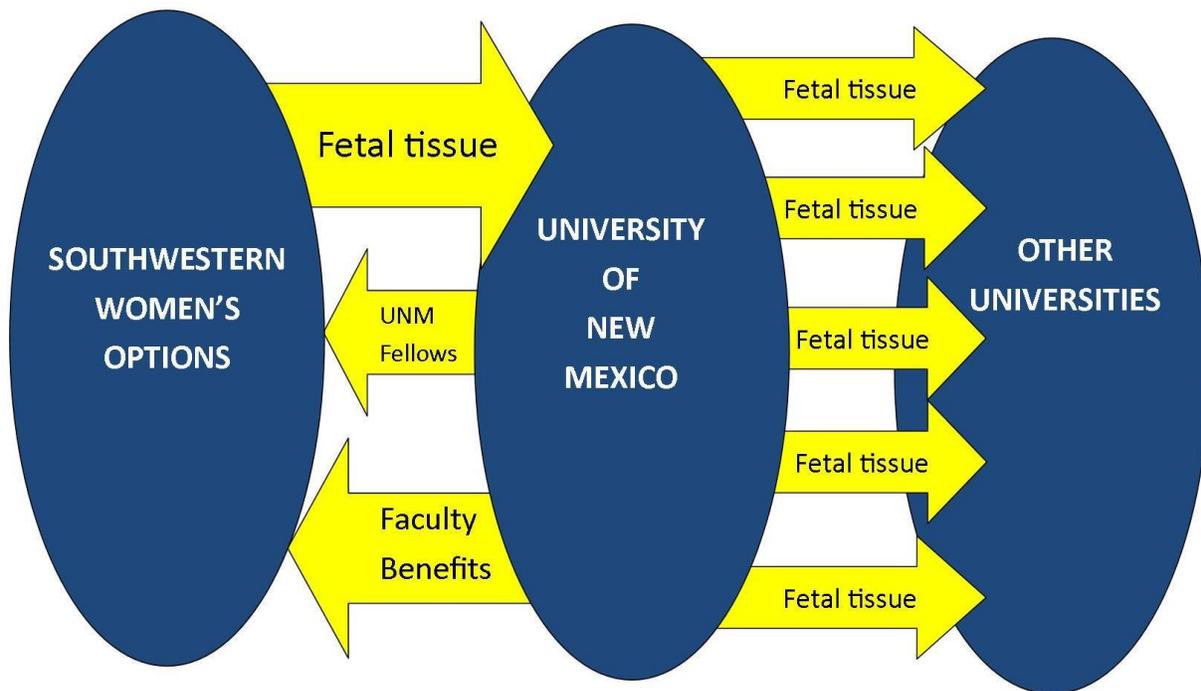
¹⁵⁷ N.M. Stat. Ann. § 24-6B-1, *et seq.*

¹⁵⁸ N.M. Stat. Ann. § 24-6B-2 (emphasis added).

anatomical gift or amendment to, revocation of or refusal to make an anatomical gift, whenever made.”¹⁵⁹ 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. SWWO’s provision and UNM’s acquisition of and research using aborted infant remains therefore appears to violate the *Spradling Act*.

42 U.S.C. § 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.

The operation of the university/clinic model in New Mexico is illustrated by the following chart:



¹⁵⁹ N.M. Stat. Ann. § 24-6B-3.

2. Further investigation of the university/clinic model

The following schools demonstrate other variations of the university/clinic model that call for further investigation. To date, the Panel has only had the opportunity to skim the surface of these relationships.

a) The University of Minnesota

The University of Minnesota's practices with respect to fetal tissue research and disposal were the subject of media and state legislative inquiry starting in 2015 and more recently evoked skepticism of its institutional candor. The university had initially denied to journalists that fetal tissue research occurred on campus, but after a news outlet uncovered receipts of fetal tissue purchases, its spokespeople reversed course and admitted that such research had taken place. The university reportedly made payments for fetal tissue since at least 2008 from the tissue procurement companies Advanced Bioscience Resources and StemExpress. They additionally received tissue from an abortion clinic, the Meadowbrook Women's Clinic of Minneapolis, that was used to conduct research on fetal brains. It is unclear whether payments were made for the latter transaction. The clinic still operates today under the banner of the Texas-based Whole Woman's Health Clinic.¹⁶⁰

The details of the university's relationship with the clinic merit further investigation, as do its fetal tissue practices generally. Independent of the question of what payments or other value were exchanged between the University of Minnesota and clinics or tissue procurement companies, its underlying 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."¹⁶¹ 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."¹⁶² 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."¹⁶³

The University of Minnesota 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.¹⁶⁴ The institution's decision to cross state lines to procure fetal tissue appears to be an effort to avoid criminal liability under Minnesota

¹⁶⁰ 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.

¹⁶¹ Minn. Stat. § 525A.02 subdiv. 5.

¹⁶² Minn. Stat. § 145.422 subdiv. 1 & 2.

¹⁶³ Minn. Stat. § 145.1621 subdiv. 3 & 4.

¹⁶⁴ See Olson, *supra*; Rddad, *supra*.

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.

b) Colorado State University

In addition to obtaining human fetal tissue from Tissue Procurement Businesses, researchers at Colorado State University (CSU) obtained tissue from Planned Parenthood of the Rocky Mountains.¹⁶⁵ Under the “Agreement for Transfer of Human Fetal Tissue” between Planned Parenthood and CSU, CSU 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.”¹⁶⁶ One invoice dated April 27, 2010, included a \$1,500 charge to the University for “Administrative Start Up.”¹⁶⁷ Another invoice charged \$1,600 for consent and processing for 10 specimens.¹⁶⁸ 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.¹⁶⁹

c) Planned Parenthood of the St. Louis Region and Southwest Missouri

The Majority Caucus of the Missouri State Senate announced on July 5, 2016, the initial results of their investigation into Planned Parenthood of the St. Louis Region and Southwest Missouri (PPSLR), reportedly the only clinic in that state that provides abortions. The medical director and at least one other physician at PPSLR have faculty positions at the Washington University School of Medicine. 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 the clinic’s pathologist to testify, invoking his Fifth Amendment privilege against self-incrimination. It 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.”¹⁷⁰ Given these findings, further investigation is warranted of abortion procedures and fetal tissue handling at PPSLR, including the clinic’s relationship with public universities in the area.

d) The University of Washington and other NIH-funded tissue banks

As will be noted below in greater detail, much fetal tissue research depends on financial support from the NIH, which issues grants to more than 50 universities. Given the symbiotic

¹⁶⁵ See CSU documents (CSU000002, CSU000019-22 & CSU000770).

¹⁶⁶ Panel document on file (CSU-1).

¹⁶⁷ Panel document on file (CSU-2).

¹⁶⁸ Panel document on file (CSU-3).

¹⁶⁹ CSU-1, *supra*.

¹⁷⁰ Missouri Senate Planned Parenthood Review Statement, Jul. 5, 2016, at 1, <http://www.senate.mo.gov/16web/wp-content/uploads/2016/07/Missouri-Senate-Planned-Parenthood-Review-Statement.pdf>.

relationship already observed between abortion clinics and public research institutions, it will be significant to discern how many similar relationships are fostered by federally funded programs. A contractual relationship between at least one abortion clinic and an NIH-funded tissue bank has already been acknowledged by the attorney general of Washington. The University of Washington School of Medicine manages and operates the Birth Defects Research Laboratory (UW BDRL), which contains the largest fetal tissue bank in the nation. The UW BDRL is funded by the NIH, and it has an agreement with at least one local abortion clinic to supply it fetal tissue—one of the nine clinics that comprise Planned Parenthood of Greater Washington and North Idaho (PPGWNI). While PPGWNI was not found by the attorney general to have received direct payment for fetal tissue, that office’s inquiry apparently ended there.¹⁷¹ In this and other cases involving similar entities, a full investigation includes asking broader questions as to whether other value was received from, or personnel shared with, the University of Washington.

e) Baylor College of Medicine

From September 2014 through November 2015, researchers at the Baylor College of Medicine (Baylor) attempted to obtain human fetal tissue from Planned Parenthood Gulf Coast (PPGC). Emails produced to the Panel by Baylor show that PPGC helped the researchers design a proposal that would be acceptable to the college’s Institutional Review Board. The issue of an outside entity assisting researchers with an IRB approval arose at the Panel’s first hearing, and the director of the Center for Clinical Bioethics at Georgetown University Medical Center said such activity would be wrong:

Rep. Harris. So, that if there were an instance where the application was, let us say, massaged a little bit, so that it was a little unclear what the source was, in an attempt to bypass that would really bypass the intention of an IRB. Is that right?

Dr. [G. Kevin] Donovan. Yes, you clearly know what you are talking about. And in fact, would that occur, the investigator would be in trouble with the IRB. They would be called in and questioned about it.¹⁷²

Researchers at Baylor believed they had a contract with PPGC for human fetal tissue. After the videos linking Planned Parenthood to the human fetal tissue industry were released, the Baylor researcher emailed the PPGC official with whom the researcher had been dealing, “In light of recent events, do we need to make changes to our contract?” The PPGC official responded by denying they had a contract, and stated that PPGC “will not commit” to providing human fetal tissue “at this time.” The PPGC official went on to state 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.”

¹⁷¹ Memorandum from Deputy Attorney General and Senior Assistant Attorney General to Attorney General of Washington, Nov. 12, 2015, at 2.

¹⁷² *Bioethics and Fetal Tissue*, *supra* (unedited transcript 69-70).

Planned Parenthood-Baylor Email Exchange

From: [REDACTED]@ppgulfcoast.org
Subject: RE: Pediatrics Research Proposal-[REDACTED]/Baylor College of Medicine- IRB Approval Obtained
Date: November 4, 2015 at 2:29 PM
To: [REDACTED]@bcm.edu
Cc: [REDACTED]@ppgulfcoast.org, [REDACTED]@ppgulfcoast.org

[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 fetal 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 publicly silent regarding their need for donated fetal tissue in research, yet have expectations that research collaboration with Planned Parenthood will remain intact.

[REDACTED]



[REDACTED]
Planned Parenthood
4600 Gulf Freeway
Houston, TX 77023
[REDACTED]

This message contains information which may be confidential and privileged. Unless you are the addressee (or authorized to receive for the addressee), you may not use, copy or disclose to anyone the message or any information contained in the message. If you have received the message in error, please advise the sender by replying and delete the message

From: [REDACTED]@bcm.edu]
Sent: Tuesday, October 13, 2015 2:59 PM
To: [REDACTED]
Subject: Re: Pediatrics Research Proposal-[REDACTED] Baylor College of Medicine- IRB Approval Obtained

Hello [REDACTED],

I hope you are well and had a great weekend.

In light of recent events, do we need to make changes to our contract?

I still very much believe in the value of my NIH funded studies, and would very much like to proceed if that is possible. Could you please let me know.

The following table summarizes what we know and still need to investigate regarding factors that reflect the university/clinic model at the above sampling of American universities:

University ¹⁷³	Clinic	Direct payment for fetal tissue	University doctor rotations at clinic	Faculty status for clinic personnel
U. of New Mexico	Southwestern Women's Options	N	Y	Y
U. of Minnesota	Meadowbrook Women's Clinic	?	?	?
Colorado State U.	Planned Parenthood of the Rocky Mountains	Y	?	?
Washington U.	PPSLR	?	?	Y
U. of Washington	PPGWNI	N	?	?

E. The Late-Term Abortion Clinic Model

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.¹⁷⁴ If the infant has not been administered feticide—typically intracardiac potassium chloride injection (KCl) or intrafetal/intra-amniotic digoxin injection¹⁷⁵—or if the feticide fails, infants are sometimes born alive.¹⁷⁶ 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.¹⁷⁷

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

¹⁷³ This chart excludes Baylor since the relationship it sought with a clinic was ultimately not consummated.

¹⁷⁴ See SFP Clinical Guidelines: *Cervical preparation for second-trimester surgical abortion prior to 20 weeks' gestation*, *Contraception* 89 (2014) 75-84, available at [http://www.contraceptionjournal.org/article/S0010-7824\(13\)00686-0/pdf](http://www.contraceptionjournal.org/article/S0010-7824(13)00686-0/pdf).

¹⁷⁵ See SFP Clinical Guidelines: *Induction of fetal demise before abortion*, *Contraception* 81 (2010) 462-473, available at [http://www.contraceptionjournal.org/article/S0010-7824\(10\)00019-3/pdf](http://www.contraceptionjournal.org/article/S0010-7824(10)00019-3/pdf).

¹⁷⁶ See SFP Clinical Guidelines: *Labor induction abortion in the second trimester*, *Contraception* 84 (2011) 4-18, available at [http://www.contraceptionjournal.org/article/S0010-7824\(11\)00057-6/pdf](http://www.contraceptionjournal.org/article/S0010-7824(11)00057-6/pdf).

¹⁷⁷ *Labor induction abortion in the second trimester*, *supra*.

involving an induced abortion; however, the CDC acknowledges that this could be an underestimate.¹⁷⁸

A careful investigation of late term abortion providers is necessary to ensure that entities are complying with the federal Born Alive Infant Protection Act,¹⁷⁹ 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.

¹⁷⁸ 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.

¹⁷⁹ 1 U.S.C. § 8.

V. Biomedical Research and Fetal Tissue

A. Development of Vaccines

Since the Panel's inception, several have claimed that use of human fetal tissue was critical for the development of vaccines, and for the polio vaccine in particular. The Panel's research found that the facts simply do not support this claim. Edward Jenner began vaccine research in the late 1700s, more than 100 years before the first published use of human fetal tissue for biomedical research.¹⁸⁰ Jenner developed a vaccine against smallpox in 1798, which ultimately led to the eradication of this devastating disease. In fact, vaccines against eight diseases (Rabies, Diphtheria, Typhoid, Cholera, Plague, Tetanus, Pertussis and Bacille-Calmette-Guerin disease) were all developed in the 1800s and early 1900s, well before the first use of fetal tissue in research.

1. Use of Fetal Cell Lines by Pharmaceutical Companies

Since the 1700s, vaccines have been developed against 26 different diseases.¹⁸¹ Vaccines for all but three of these diseases were developed without the use of human fetal tissue or human fetal cell lines. The three exceptions (Varicella, Hepatitis A and Zoster) were developed by pharmaceutical companies that routinely use the fetal cell lines MRC-5 and WI-38 for 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 use that method in order to avoid incurring new costs associated with "validating" the safety and efficacy of new procedures. Three major pharmaceutical companies (Merck, GlaxoSmithKline and Sanofi) adopted the fetal cell lines MRC-5 and WI-38 shortly after they were produced in the 1970s. They succeeded in gaining FDA approval for vaccines produced in these cells, and have used them since. However, today other pharmaceutical companies use existing viable alternatives (see Table 1).

Almost 75 specific vaccine formulations have been approved by the FDA for use in the United States (See Table 1 below) and not a single one has been produced using freshly isolated human fetal tissue. Eleven of these vaccines rely on fetal cell lines for historic reasons, yet all of them could be produced using animal cells.

2. Cells from Aborted Fetuses are not Used for Vaccine Production

For historical reasons, a handful of vaccines are still produced in cell lines (MRC-5 and WI-38) that were originally isolated in the 1960s from two aborted fetuses. And one strain of

¹⁸⁰ Hurst AF, Tanner WE, Osman AA., *Addison's Disease, with Severe Anaemia, treated by Suprarenal Grafting*, Proc. R. Soc. Med. 1922; 15 (Clin. Sect.):19-20.

¹⁸¹ Smallpox, Rabies, Diphtheria, Typhoid, Cholera, Plague, Tetanus, Pertussis, BCG, Influenza, Yellow fever, Polio, Measles, Mumps, Rubella, Meningococcus, Pneumococcus, Hepatitis B, Haemophilus influenza B, Varicella (Chickenpox), Hepatitis A, Rotavirus, Zoster, Papilloma, Influenza H5N1, Influenza H1N1.

Rubella (RA 27/3) was also isolated from an aborted fetus in the 1960s. But other than these three cases, not a single aborted fetus has contributed to the production of any vaccine anywhere in the world.

3. Fetal Cell Research is Outdated Technology

Beginning in the 1930s, viruses were propagated using fetal tissue and some laboratories continued to this method until the 1970s. During that time, scientists did not yet know how to work with more mature human cells, and fetal tissue was easier to grow in the laboratory. Science has now advanced beyond these earlier approaches. In short, human fetal tissue is outdated technology that is not necessary for modern vaccine research. For example, current vaccine research for HIV/AIDS, Cancer, Malaria and Ebola does not rely on fetal tissue (see Table 1 below).

4. The Nobel Prize was not Awarded for Curing Polio Using Fetal Tissue

The Noble Prize was awarded in 1954 to John Enders, Thomas Weller, and Fredrick Robbins for their work on the polio virus that used human fetal tissue. But human fetal tissue was not used to make the polio vaccine. Jonas Salk and Albert Sabin used monkey cells to produce the Polio vaccine—and vaccine manufacturing still uses monkey cells today.

Moreover, the work of Enders, Weller, and Robbins did not critically depend on the use of human fetal tissue; i.e. scientists could have learned everything they discovered using animal cells. Prior to the work of Enders, Weller and Robbins, people believed the polio virus only grew in 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 laboratory¹⁸² used human fetal brain tissue. Enders, Weller, and Robbins showed that the polio virus could be harvested from cultures of multiple fetal tissues and from cultures of human foreskin fibroblasts obtained from circumcision — a tissue that, unlike human fetal tissue, is still widely used today.

Importantly, the central discovery for which the Nobel Prize was awarded was not about the properties of human fetal cells. Rather, it was that the 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.

An often overlooked fact regarding vaccine research is that the very first Nobel Prize for Physiology and Medicine was awarded in 1901 to Emil von Behring for vaccine research that did not rely on fetal cells.

¹⁸² Sabin AB, Olitsky PK, *Cultivation of poliomyelitis virus in vitro in human embryonic nervous tissue*, Proc. Soc. Exp. Biol. Med. 1936; 34:357–359.

B. Zika and CMV Virus As Case Studies of Modern Virology Research

The Zika virus has received a lot of attention lately, with many characterizing it as a health crisis and calling for immediate action. Suggested steps to take include both expanding fetal tissue research to develop a vaccine and reducing restrictions on abortion to “treat” affected infants.

And Zika is indeed a frightening virus. The 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.¹⁸³ Adding to an already alarming picture, a recent study from Brazil¹⁸⁴ and a report by the CDC¹⁸⁵ 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 intensive research effort, with over 80 clinical and research articles published on the virus, most within the last few years.¹⁸⁶ **Of these, only two have involved the use of fetal tissue.**¹⁸⁷ The major advances in our understanding of the Zika virus, published in world-renowned scientific journals,

Figure 1: Microcephaly caused by CMV (top) and by Zika (bottom).



¹⁸³ Michael A. Johansson, Ph.D. et al, *Zika and the Risk of Microcephaly*, *New Eng. J. Med.* 375;1 (2016), available at <http://www.nejm.org/doi/pdf/10.1056/NEJMp1605367>.

¹⁸⁴ Patricia Brasil, M.D. et al, *Zika Virus Infection in Pregnant Women in Rio de Janeiro—Preliminary Report*, *New Eng. J. Med.* (2016), available at <http://www.nejm.org/doi/pdf/10.1056/NEJMoa1602412>.

¹⁸⁵ Centers for Disease Control and Prevention, *Morbidity and Mortality Weekly Report, Zika Virus Infection Among U.S. Pregnant Travelers—August 2015–February 2016*, (Mar. 4, 2016), <http://www.cdc.gov/mmwr/volumes/65/wr/mm6508e1.htm>.

¹⁸⁶ 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])).

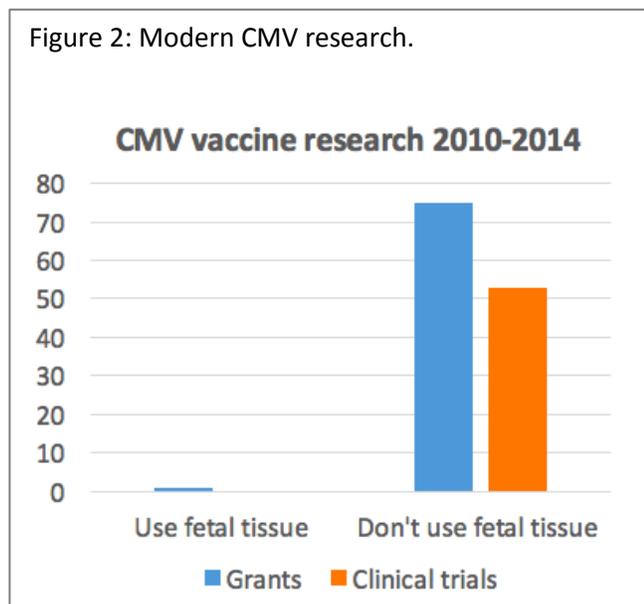
¹⁸⁷ Rita W. Driggers, M.D. et al, *Zika Virus Infection with Prolonged Maternal Viremia and Fetal Brain Abnormalities*, *New Eng. J. Med.* 374:2142-51 (2016), available at <http://www.nejm.org/doi/full/10.1056/NEJMoa1601824#t=article>; Fernanda R. Cugola et al, *The Brazilian Zika virus strain causes birth defects in experimental models*, *Nature* 534:267-71 (2016), available at <http://www.nature.com/nature/journal/v534/n7606/full/nature18296.html>.

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 is not the only virus that causes brain defects and miscarriage. A second virus that causes very similar problems is the Cytomegalovirus or CMV. Similarly 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).¹⁸⁸ Also similarly to Zika, the effects of CMV on adults are mild, making it difficult for a pregnant woman to be certain 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.¹⁸⁹ 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, or 5000 children each year, suffer permanent problems caused by CMV infection.¹⁹⁰ CMV is clearly a health crisis for women and 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. CMV was originally isolated in the 1950s,¹⁹¹ but researchers have been aware of its effects on unborn children since as early as 1881.¹⁹² 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 children with severe brain defects have been born, lived, and died, largely ignored by the media and by politicians.

Figure 2: Modern CMV research.



CMV is truly one of the darkest stories in modern medicine, but thankfully, a glimmer of hope has brightened the story. Several candidate vaccines have been developed and are currently

¹⁸⁸ S. Manicklal et al, *The "silent" global burden of congenital cytomegalovirus*, Clin Microbiol Rev. 26(1):86-102 (2013), available at <http://www.ncbi.nlm.nih.gov/pubmed/23297260>; M.J. Cannon, *Congenital cytomegalovirus (CMV) epidemiology and awareness*, J. Clin. Virol. 46 Suppl. 4:S6-10 (2009), available at <http://www.ncbi.nlm.nih.gov/pubmed/19800841>.

¹⁸⁹ Centers for Disease Control and Prevention, *Cytomegalovirus (CMV) and Congenital CMV Infection*, About CMV, <http://www.cdc.gov/cmvtrends-stats.html#affected>.

¹⁹⁰ *Id.*

¹⁹¹ H.D. Riley Jr., *History of the cytomegalovirus*, South Med J. 90(2):184-90 (1997), available at <http://www.ncbi.nlm.nih.gov/pubmed/9042169>.

¹⁹² *Id.*

being tested in clinical trials, with promising results.¹⁹³ After decades of disappointment, we may be close to preventing this devastating disease.

Has human fetal tissue research played a critical role in turning the tide on CMV after so many years of fruitless effort? **In fact, fetal tissue has made almost no contribution to modern CMV vaccine research. (Figure 2).** Between 2010 and 2014, NIH awarded over 75 grants focused on finding a vaccine to prevent CMV infection. Only one involved human fetal tissue.¹⁹⁴ Similarly, there are 53 ongoing clinical trials of CMV-vaccines, and not a single one involves the use of human fetal tissue.¹⁹⁵ The breakthrough on this devastating disease did not depend on human fetal tissue research at all.

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.¹⁹⁶ They later discovered that in women with natural immunity to CMV, this same complex was the target of antibodies that effectively neutralized the virus.¹⁹⁷ These findings led to successful vaccination experiments in animals¹⁹⁸ that have rapidly lead to similar human clinical trials.¹⁹⁹

What can we learn from CMV, a virus that is parallel in many ways to Zika? First, 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, 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 do not 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 any significant advantage in this fight. The ethical research tools we have in hand are

¹⁹³ S. Plotkin, *The history of vaccination against cytomegalovirus*, *Med. Microbiol. Immunol.* 204(3):247-54 (2015), available at <http://www.ncbi.nlm.nih.gov/pubmed/25791890>.

¹⁹⁴ 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.”

¹⁹⁵ Based on a search of the NIH clinical trials database (<https://www.clinicaltrials.gov>) for the terms “CMV vaccine” and “fetal tissue.”

¹⁹⁶ D.X. Liu et al, *Identification and expression of the human herpesvirus 6 glycoprotein H and interaction with an accessory 40K glycoprotein*, *J. Gen. Virol.* 74(Pt 9):1847-57 (1993), available at <http://www.ncbi.nlm.nih.gov/pubmed/8397282>.

¹⁹⁷ A. Macagno et al., *Isolation of human monoclonal antibodies that potently neutralize human cytomegalovirus infection by targeting different epitopes on the gH/gL/UL128-131A complex*, *J Virol* 84(2):1005-13 (2010), available at <http://www.ncbi.nlm.nih.gov/pubmed/19889756>.

¹⁹⁸ D.C. Freed et al., *Pentameric complex of viral glycoprotein H is the primary target for potent neutralization by a human cytomegalovirus vaccine*, *Proc. Natl. Acad. Sci. USA* 17;110(51):E4997-5005 (2013), available at <http://www.ncbi.nlm.nih.gov/pubmed/24297878>; www.ncbi.nlm.nih.gov/pubmed/23107592.

¹⁹⁹ E.g., NCT00722839; NCT00439803.

more than powerful enough to fight Zika, even if it proves to be as tenacious and confounding as CMV.

C. Fetal Tissue is not Mainstream Science

In 2014, the most recent year for which data is available,²⁰⁰ NIH funded a total of 76,081 research grants, only 160 of which (less than 1%) involved the use of human fetal tissue. In contrast, in the same year, NIH funded 1,136 grants using adult stem cells. The fact that fetal research is such a tiny fraction of all scientific research calls into serious question the claim that fetal research is vital and that science will not advance without it. In reality, use of human fetal tissue is increasingly an outdated and unnecessary scientific technology, used only by a handful of scientists.

While it is true that more than a half century ago in the 1950s and 1960s, a wide range of scientific investigations relied on fetal tissue, the use of fetal tissue has steadily declined as our knowledge of cell biology has advanced. For example, in 1960, we knew very little about how to culture human cells, and fetal cells were often employed because they were easier to maintain in the laboratory. Today, adult cells are routinely cultured and fetal cells are simply not required for most studies. Similarly, twenty years ago, cells isolated from human embryos were our only source of pluripotent stem cells, yet today pluripotent stem cells can be efficiently produced from adult human cells.

1. Alternatives to Fetal Tissue: Three False Arguments

Some have claimed²⁰¹ that fetal cells are “the gold standard” for scientific research, based on three false arguments.

- a) Cells derived from human fetuses are “necessary”

On March 2, 2016, in testimony before the Panel, Dr. Goldstein stated that fetal astrocytes are vital for his research on Alzheimer’s disease and cannot be replaced by astrocytes derived from non-fetal sources. However, only a tiny minority of scientists investigating Alzheimer’s disease employ fetal astrocytes. A query of NIH database of funded research²⁰² reveals that in 2014, a total of 1,304 grants investigating Alzheimer’s disease were awarded, yet only two employed human fetal tissue. Clearly, the vast majority of scientists studying Alzheimer’s disease do not agree that human fetal tissue is vital for their research.

- b) Fetal cells are important for clinical trials

Dr. Goldstein correctly notes that neural stem cells derived from fetuses are currently being tested in clinical trials, yet fails to mention that fetal tissue contributes to only a tiny fraction of

²⁰⁰ See NIH Research Portfolio Online Reporting Tools, <https://projectreporter.nih.gov/reporter.cfm>.

²⁰¹ *Bioethics and Fetal Tissue*, *supra* (testimony of Dr. Lawrence Goldstein), <http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-Wstate-GoldsteinL-20160302.pdf>.

²⁰² See NIH Research Portfolio Online Reporting Tools, *supra*.

such trials. A query of NIH database for clinical trials²⁰³ using the terms “fetal stem cells” or “fetal tissue transplant” returned only five studies involving transplantation of fetal tissue into patients. In contrast, there are currently over 5,300 clinical trials involving stem cells from non-fetal/embryonic sources, including 3,217 clinical trials using a patient’s own stem cells.

c) No alternative sources of cells with fetal-properties are available

Dr. Goldstein indicates that he is using fetal tissue in an attempt “to build new kidneys from stem cells,” because “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.” Yet substantial progress towards the goal of generating replacement organs has already been accomplished²⁰⁴ in other laboratories using stem cells from non-fetal sources.

Consistent with the view that there are no alternatives to fetal tissue, companies such as StemExpress market cells derived from fetal tissue²⁰⁵ as valuable scientific reagents. Yet all of the cell types marketed by StemExpress from fetal liver can be obtained from birth-related material (placenta, umbilical cord, and umbilical cord blood); including CD34+²⁰⁶, CD36²⁰⁷+, CD133+²⁰⁸ and stromal (mesenchymal)²⁰⁹ stem cells.

2. No Cures from Fetal Tissue

Fetal tissue has been used in biomedical research for over 90 years.²¹⁰ In this time, not a single medical cure has resulted from this research. While it is commonly claimed²¹¹ that fetal tissue was used to produce the polio vaccine, this is largely false. The polio vaccine was developed by Jonas Salk in 1955²¹² using a monkey cell line, and is still produced using monkey cells. In nearly 100 years of research, fetal tissue has not been directly linked to a single medical cure.

²⁰³ See ClinicalTrials.gov: A service of the U.S. National Institutes of Health, <https://clinicaltrials.gov/>.

²⁰⁴ Minoru Takasato et al, *Kidney organoids from human iPS cells contain multiple lineages and model human nephrogenesis*, *Nature* 526, 564-568 (2015) available at <http://www.nature.com/nature/journal/v526/n7574/full/nature15695.html>.

²⁰⁵ See StemExpress, Fetal Liver, <http://stemexpress.com/product-category/fetal-liver/>.

²⁰⁶ JN Mehrishi, *A novel method of CD34+ cell separation from umbilical cord blood*, *Transfusion* 53(11):2675-80 (2013), available at <http://www.ncbi.nlm.nih.gov/pubmed/23432618>.

²⁰⁷ X Huang, *Extensive ex vivo expansion of functional human erythroid precursors established from umbilical cord blood cells by defined factors*, *Mol Ther* 22(2):451-63 (2014), available at <http://www.ncbi.nlm.nih.gov/pubmed/24002691>.

²⁰⁸ E Solder, *Isolation and characterization of CD133+CD34+VEGFR-2+CD45- fetal endothelial cells from human term placenta*, *Microvasc Res* 84(1):65-73 (2012), available at <http://www.ncbi.nlm.nih.gov/pubmed/22480576>.

²⁰⁹ J Patel, *Novel isolation strategy to deliver pure fetal-origin and maternal-origin mesenchymal stem cell (MSC) populations from human term placenta*, *Placenta* 35(11):969-71 (2014), available at <http://www.ncbi.nlm.nih.gov/pubmed/25239220>.

²¹⁰ Charlotte Lozier Institute, *History of Fetal Tissue Research and Transplants* (Jul. 27, 2015), <https://lozierinstitute.org/history-of-fetal-tissue-research-and-transplants/>.

²¹¹ Heather D. Boonstra, *Fetal Tissue Research: A Weapon and a Casualty in the War Against Abortion*, *Guttmacher Policy Review* (Feb. 9, 2016), <https://www.guttmacher.org/about/gpr/2016/fetal-tissue-research-weapon-and-casualty-war-against-abortion>.

²¹² OM Kew, *Vaccine-derived polioviruses and the endgame strategy for global polio eradication*, *Annu Rev Microbiol* 59:587-635 (2005), available at <http://www.ncbi.nlm.nih.gov/pubmed/16153180>.

Some might object that while fetal tissue research has not directly resulted in medical cures, it has helped advance the overall body of scientific knowledge and thereby assisted in producing cures. It is impossible to determine whether this claim is true, and if so to what extent. Yet the fact is that no one can point to a single medical advancement that critically depended on the use of fetal tissue.

Vaccinations currently FDA-approved for use in the United States²¹³

	Product Name	Trade Name	Sponsor	FDA approval	Animal or other cells	Historic cell lines	Fetal tissue
1	Ebola virus	rVSV-ZEBOV-GP	New Link Genetics	2016	X		
2	HIV	RV144	Sanofi Pasteur	n/a	X		
3	Malaria	RTS,S and Pfs25-EPA	GlaxoSmithKline Biologicals	n/a	X		
4	Cancer	Sipuleucel-t (Provenge)	Dendreon Corporation	2010	X		
		Tumor antigens		n/a	X		
1	Adenovirus Type 4 and Type 7 Vaccine, Live, Oral	No Trade Name	Barr Labs, Inc.	2011		X	
2	Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine	Quadracel	Sanofi Pasteur Limited	2015	XXX	X	

²¹³ U.S. Food and Drug Administration, Complete List of Vaccines Licensed for Immunization and Distribution in the US, <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm>.

3	Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine	Pentacel	Sanofi Pasteur Limited	2008	XXXX	X	
4	Hepatitis A Vaccine, Inactivated	Havrix	GlaxoSmithKline Biologicals	2005		X	
5	Hepatitis A Vaccine, Inactivated	VAQTA	Merck & Co, Inc	1996		X	
6	Hepatitis A Inactivated and Hepatitis B (Recombinant) Vaccine	Twinrix	GlaxoSmithKline Biologicals	2007		X	
7	Measles, Mumps, and Rubella Virus Vaccine, Live	M-M-R II	Merck & Co, Inc	2008	XX	X	
8	Measles, Mumps, Rubella and Varicella Virus Vaccine Live	ProQuad	Merck & Co, Inc	2005	XX	XX	
9	Rabies Vaccine	Imovax	Sanofi Pasteur, SA	2011		X	
10	Varicella Virus Vaccine Live	Varivax	Merck & Co, Inc	1995		X	

11	Zoster Vaccine, Live, (Oka/Merck)	Zostavax	Merck & Co., Inc.	2006		X	
1	Anthrax Vaccine Adsorbed	Biothrax	Emergent BioDefense Operations Lansing Inc.	2010		X	
2	BCG Live	BCG Vaccine	Organon Teknika Corp LLC	2010		X	
3	BCG Live	TICE BCG	Organon Teknika Corp LLC	2010		X	
4	Diphtheria & Tetanus Toxoids Adsorbed	No Trade Name	Sanofi Pasteur, Inc	2003		XX	
5	Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed	Infanrix	GlaxoSmithKline Biologicals	1997		XXX	
6	Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed	DAPTACEL	Sanofi Pasteur, Ltd	2002		XXX	
7	Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed, Hepatitis B (recombinant) and Inactivated Poliovirus	Pediarix	GlaxoSmithKline Biologicals	2002		XXXXX	

	Vaccine Combined						
8	Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine	KINRIX	GlaxoSmithKline Biologicals	2008	XXXX		
9	Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)	PedvaxHIB	Merck & Co, Inc	2011	XX		
10	Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)	ActHIB	Sanofi Pasteur, SA	1996	XX		
11	Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)	Hiberix	GlaxoSmithKline Biologicals, S.A.	2009	XX		
12	Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) & Hepatitis B Vaccine	Comvax	Merck & Co, Inc	1996	XX		

	(Recombinant)						
13	Hepatitis B Vaccine (Recombinant)	Recombivax HB	Merck & Co, Inc	1999	X		
14	Hepatitis B Vaccine (Recombinant)	Engerix-B	GlaxoSmithKline Biologicals	1998	X		
15	Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant	Gardasil	Merck & Co, Inc.	2006	X		
16	Human Papillomavirus 9-valent Vaccine, Recombinant	Gardasil 9	Merck & Co., Inc	2014	X		
17	Human Papillomavirus Bivalent (Types 16, 18) Vaccine, Recombinant	Cervarix	GlaxoSmithKline Biologicals	2009	X		
18	Influenza A (H1N1) 2009 Monovalent Vaccine	No Trade Name	CSL Limited	2009	X		
19	Influenza A (H1N1) 2009 Monovalent Vaccine	No Trade Name	MedImmune LLC	2009	X		
20	Influenza A (H1N1) 2009 Monovalent Vaccine	No Trade Name	ID Biomedical Corporation of Quebec	2009	X		

21	Influenza A (H1N1) 2009 Monovalent Vaccine	No Trade Name	Novartis Vaccines and Diagnostics Limited	2009	X		
22	Influenza A (H1N1) 2009 Monovalent Vaccine	No Trade Name	Sanofi Pasteur, Inc.	2009	X		
23	Influenza Virus Vaccine, H5N1 (for National Stockpile)	No Trade Name	Sanofi Pasteur, Inc.	2007	X		
24	Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted	No Trade Name	ID Biomedical Corporation of Quebec	2013	X		
25	Influenza Vaccine, Adjuvanted	FLUAD	Novartis Vaccines and Diagnostics Limited	2015	X		
26	Influenza Virus Vaccine (Trivalent, Types A and B)	Afluria	CSL Limited	2008	X		
27	Influenza Virus Vaccine (Trivalent, Types A and B)	FluLaval	ID Biomedical Corp of Quebec	2008	X		
28	Influenza Vaccine, Live, Intranasal (Trivalent, Types A and B)	FluMist	MedImmune, LLC	2007	X		
29	Influenza Virus Vaccine (Trivalent, Types	Fluarix	GlaxoSmithKline Biologicals	2005	X		

	A and B)						
30	Influenza Virus Vaccine (Trivalent, Types A and B)	Fluvirin	Novartis Vaccines and Diagnostics Ltd	2005	X		
31	Influenza Virus Vaccine (Trivalent, Types A and B)	Agriflu	Novartis Vaccines and Diagnostics S.r.l.	2009	X		
32	Influenza Virus Vaccine (Trivalent, Types A and B)	Fluzone, Fluzone High-Dose and Fluzone Intradermal	Sanofi Pasteur, Inc	2002	X		
33	Influenza Virus Vaccine (Trivalent, Types A and B)	Flucelvax	Novartis Vaccines and Diagnostics, Inc.	2012	X		
34	Influenza Vaccine (Trivalent)	Flublok	Protein Sciences Corporation	2013	X		
35	Influenza Vaccine, Live, Intranasal (Quadrivalent, Types A and Types B)	FluMist Quadrivalent	MedImmune, LLC	2012	X		
36	Influenza Virus Vaccine (Quadrivalent, Types A and Types B)	Fluarix Quadrivalent	GlaxoSmithKline Biologicals	2012	X		
37	Influenza Virus Vaccine (Quadrivalent, Types A and	Fluzone Quadrivalent	Sanofi Pasteur, Inc	2013	X		

	Types B)						
38	Influenza Virus Vaccine (Quadrivalent, Types A and Types B)	FluLaval	ID Biomedical Corporation	2013	X		
39	Japanese Encephalitis Virus Vaccine, Inactivated, Adsorbed	Ixiaro	Intercell Biomedical	2009	X		
40	Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine	Menveo	Novartis Vaccines and Diagnostics, Inc.	2010	XX		
41	Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine	MenHibrix	GlaxoSmithKline Biologicals	2012	XXX		
42	Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine	Menactra	Sanofi Pasteur, Inc	2005	XX		
43	Meningococcal Group B Vaccine	BEXSERO	Novartis Vaccines and Diagnostics, Inc	2015	XX		

44	Meningococcal Group B Vaccine	TRUMENBA	Wyeth Pharmaceuticals, Inc.	2014	X		
45	Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined	Menomune-A/C/Y/W-135	Sanofi Pasteur, Inc	2009	X		
46	Pneumococcal Vaccine, Polyvalent	Pneumovax 23	Merck & Co, Inc	2008	X		
47	Pneumococcal 7-valent Conjugate Vaccine (Diphtheria CRM197 Protein)	Prevnar	Wyeth Pharmaceuticals Inc	2000	XX		
48	Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein)	Prevnar 13	Wyeth Pharmaceuticals Inc	2010	XX		
49	Poliovirus Vaccine Inactivated (Monkey Kidney Cell)	IPOL	Sanofi Pasteur, SA	2012	X		
50	Rabies Vaccine	RabAvert	Novartis Vaccines and Diagnostics	1997	X		
51	Rotavirus Vaccine, Live, Oral	ROTARIX	GlaxoSmithKline Biologicals	2008	X		
52	Rotavirus Vaccine, Live, Oral,	RotaTeq	Merck & Co., Inc.	2006	X		

	Pentavalent						
53	Smallpox (Vaccinia) Vaccine, Live	ACAM2000	Sanofi Pasteur Biologics Co.	2007	X		
54	Tetanus & Diphtheria Toxoids Adsorbed for Adult Use	No Trade Name	MassBiologics	2014	XX		
55	Tetanus & Diphtheria Toxoids Adsorbed for Adult Use	DECAVAC	Sanofi Pasteur, Inc	2014	XX		
56	Tetanus & Diphtheria Toxoids Adsorbed for Adult Use	TENIVAC	Sanofi Pasteur, Ltd	2003	XX		
57	Tetanus Toxoid Adsorbed	No Trade Name	Sanofi Pasteur, Inc	2005	XX		
58	Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed	Adacel	Sanofi Pasteur, Ltd	2005	XXX		
59	Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine,	Boostrix	GlaxoSmithKline Biologicals	2005	XXX		

	Adsorbed						
60	Typhoid Vaccine Live Oral Ty21a	Vivotif	Berna Biotech, Ltd	2013	X		
61	Typhoid Vi Polysaccharide Vaccine	TYPHIM Vi	Sanofi Pasteur, SA	2014	X		
62	Yellow Fever Vaccine	YF-Vax	Sanofi Pasteur, Inc	2008	X		

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<https://www.medicines.org.uk/emc/medicine/25927>

VI. Compliance with Congressional Subpoenas

A. Southwestern Women's Options

On January 6, 2016, the Panel requested documents from SWWO dated from January 1, 2010, including those documenting SWWO's relationship with UNM and other entities to which it transfers fetal tissue. SWWO did not reply to staff with any communication until January 28, the day before the production was due. Over the course of several telephone conferences and emails, SWWO's attorney suggested that her client may object to disclosing the requested names of individuals involved in abortion or fetal tissue procurement. Despite being repeatedly told by Panel staff that SWWO may make no redactions other than those established by HIPAA, SWWO redacted the requested names, disclosing only a list by letter of five physicians employed at the clinic, when it made its production on February 12, 2016.²¹⁴ The production also redacted the names and identifying information of anyone involved in abortion or fetal tissue, including apparently in some instances the five names disclosed in the letter. Without such names, the Panel could neither identify individuals to interview nor understand the nature of fetal tissue transactions—both of which are essential to the Panel completing its duties under H. Res. 461.

In the face of SWWO's repeated refusals to provide information, the Panel authorized a subpoena to SWWO on February 12, 2016. The subpoena demanded **unredacted** copies of documents created since January 1, 2011, with a production date of February 17, 2016.²¹⁵ Among the items required to be produced were documents referring or relating to abortion or the procurement of fetal tissue. This included documents "sufficient to show the identities of all Southwestern personnel whose responsibilities included procurement of fetal tissue, or disposing of fetal tissue, and the identity of any supervisory personnel under whom such individuals worked." Also among the subpoenaed documents were those sufficient to show personnel at UNM or elsewhere who participated in the abortion procedure or removed fetal tissue.²¹⁶

On February 17, 2016, SWWO's attorney reiterated the clinic's refusal to provide the information it previously refused to disclose, citing "objections and assertions of privacy rights."²¹⁷ Counsel also cited general objections based on the attorney-client or work-product privilege, First Amendment associational rights, and the scope of the Panel's jurisdiction.²¹⁸ SWWO made a supplemental production on March 7, 2016, containing communications with government officials or employees, but with names and often what appear to be dates and other information redacted.²¹⁹ In a telephone conference with staff the same day, SWWO's attorney stated the clinic was refusing to produce any more documents than it already had. A *New York Times* article published two days earlier quoted a co-director of SWWO as saying in reference to

²¹⁴ SWWO letter responding to document request, Feb. 12, 2016, at 1, Appendix C.

²¹⁵ Subpoena from the Select Investigative Panel to Southwestern Women's Options, Feb. 12, 2016, schedule.

²¹⁶ *Id.* at schedule items 2-3.

²¹⁷ SWWO letter responding to subpoena, Feb. 17, 2016, at 2, attachment (general and specific objections).

²¹⁸ *Id.* General Objections. The scattershot nature of counsel's objections is highlighted by its citation of HIPAA as a ground for objection, despite the fact that both the document request and the subpoena to SWWO had explicitly required HIPAA-protected information not to be produced.

²¹⁹ SWWO letters to Chairman Blackburn, Feb. 22, 2016, and May 11, 2016.

the subpoena, “I know that naming those names could be dangerous. So I won’t do it. No matter what.”²²⁰

B. University of New Mexico

On January 6, 2016, the Panel requested documents from UNM dated from January 1, 2010, including those documenting various UNM entities’ relationship with SWWO, and listing other locations where various UNM entities obtain or transfer fetal tissue. The Panel reached an agreement with UNM’s counsel permitting several modifications and clarifications of the request, as well as a rolling production. Nonetheless, UNM objected to several requests to identify those at UNM who participated in abortions or fetal tissue procurement, or personnel at abortion clinics whose liability insurance was covered by UNM.

Because UNM would not voluntarily withdraw its objections, on February 12, the Panel issued a subpoena to UNM demanding documents dated from January 1, 2011. The subpoena included a demand for documents or information “sufficient to show all entities and/or persons” from whom UNM received or to whom UNM provided fetal tissue and “[d]ocuments sufficient to show the identity, by name, of . . . UNM persons who removed fetal tissue from Southwestern Women’s Options.” Further, the subpoena requested all documents showing a “contractual relationship” between UNM and the director of SWWO, “including teaching schedules, medical malpractice insurance policies, and all remuneration or other benefits received directly or indirectly” by SWWO’s director from UNM.²²¹

UNM produced redacted documents on February 16 and March 2, which reflected its continued objection to producing “the names and identities of University physicians, students, lab technicians and/or other personnel.”²²² UNM also objected to some requests as beyond the scope of “the Select Panel’s investigative authority.”²²³ Some of the documents are so heavily redacted that it is impossible to understand their significance.²²⁴ Moreover, during its investigation, the Panel obtained documents from a private citizen that the individual received from UNM through the New Mexico Inspection of Public Records Act (IPRA).²²⁵ Numerous pages of the documents were identical to those produced by UNM to the Panel, except the documents obtained through IPRA did not include many of the redactions that were in the documents produced to the Panel.²²⁶ The following is a sample of UNM’s inconsistency:

²²⁰ Amanda Robb, *Abortion Witch Hunt*, New York Times, Mar. 5, 2016, at A23.

²²¹ Select Investigative Panel Subpoena to University of New Mexico, February 12, 2016.

²²² UNM Response to House Select Panel Subpoena, Feb. 19, 2016 at 1.

²²³ *Id.* at 4.

²²⁴ *See, e.g.*, UNM01082 (email related to research in which it is impossible to determine where the parties work).

²²⁵ NMSA 1978, §§ 14-2-1 *et seq.*

²²⁶ *See, e.g.*, UNM03122-UNM03136 versus IPRA Request 7830 documents, at 1-15.

Curriculum Vitae, Curtis Boyd, M.D.

1972- 12/1993 Curtis Boyd, M.D., P.C. of Santa Fe
Santa Fe, New M
Private practice specializing in abortion services

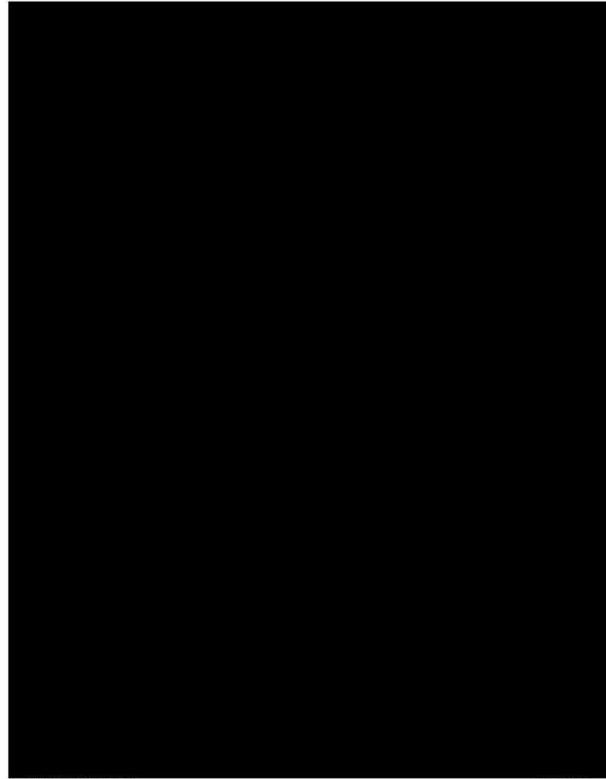
1964-1971 County Health Officer
Henderson, Texas

1964-1971 Curtis Boyd, M.D.
Private Family Practice
Athens, Texas

1962-1963 Nurse Intensive Care and Cardiac Surgery Unit
Texas Children's Hospital
Dallas, Texas

1958-1959 Biology Assistant
Texas A & M University

In the field of abortion technology, Dr Boyd has a national reputation for contributions in the areas of pain management, reduction of surgical risks, second trimester abortion methods and the establishment of guidelines and standard for abortion facilities. Dr. Boyd has served on the Boards of Directors of the National Abortion Federation and the Texas Family Planning Association.



Identical page produced by UNM for IPRA request (I) and congressional subpoena (r)

After this issue was raised with UNM's attorney, UNM sent a letter dated May 19 "reluctantly" re-producing the documents "in a form consistent with its IPRA productions."²²⁷ The newly produced documents were virtually free from redactions, even revealing names, and created a stark contrast with other heavily redacted documents produced to the Panel, which still remain redacted. UNM's heavy redactions hinder the Panel from completing its investigation into fetal tissue transfers between a prominent abortion clinic and university researchers.

Additionally, through the documents provided to the Panel by the private citizen's IPRA request (discussed *supra*), the Panel obtained contracts between UNM and Planned Parenthood covering the years 2012 and 2013. These "house officer affiliation agreements" 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. UNM should have produced these documents pursuant to the Panel's subpoena, which required the production of "[a]ll communications and documents directing personnel of UNM with respect to . . . the conduct of abortion procedures."²²⁸ The absence of these important documents from UNM's document productions raises the concern that other important documents are missing as well.

²²⁷ UNM letter to House Select Investigative Panel, May 19, 2016, at 2.

²²⁸ Subpoena to UNM, at 1.

C. Advanced Bioscience Resources

On December 17, 2015, Chairman Blackburn sent ABR a document request letter asking for, among other items, a list of all entities from which ABR receives or procures fetal tissue; a list of all entities to which ABR sells or donates fetal tissue; an organization chart of company personnel involved in the procurement of fetal tissue; all communications directing ABR personnel to procure fetal tissue; all accounting records related to the cost and pricing of fetal tissue; documents relating to rent or site fees paid to abortion clinics where ABR obtained fetal tissue; and all ABR banking and accounting records related to fetal tissue.

ABR's attorney replied that the firm had already provided to earlier congressional inquiries into the controversy surrounding the Planned Parenthood videos "substantially all of the information it can provide."²²⁹ After reviewing those productions, the Panel decided that ABR's representation was not accurate: the earlier productions did not include a list of customers, communications, a detailed organization chart, or the requested banking records.

The earlier productions did include a single-sheet of financial information, and a one-page document, apparently generated using a calculator.²³⁰ It is unclear how these documents were created or by whom. The first productions also included invoices from the clinics where ABR obtained its human fetal tissue.

The attorney represented that "ABR communicates with its staff, healthcare providers, and researchers predominantly via telephone and fax, and does not maintain records of these communications on a consistent basis. Accordingly, there are very few communications that ABR can produce to the Select Panel as part of this inquiry."²³¹ In addition, ABR's attorney represented that the firm "does not have any memoranda or other documented analysis of its fees and expenses . . ."²³² On April 29, 2016, the Panel issued a subpoena to ABR requiring the production of all the items listed in the original document request letter: a list of all entities from which ABR receives or procures fetal tissue; a list of all entities to which ABR sells or donates fetal tissue; a detailed organization chart, including the names of company personnel involved in the procurement of fetal tissue (so that Panel staff could interview and/or depose them); all communications directing ABR personnel to procure human fetal tissue; all accounting records related to the cost and pricing of fetal tissue; documents relating to rent or site fees paid to abortion clinics where ABR obtained human fetal tissue; invoices from the clinics where ABR obtained human fetal tissue, and from researchers to whom it transferred human fetal tissue; and all ABR banking and accounting records related to human fetal tissue, among other items,

Other than producing the list of abortion providers from which ABR obtained its human fetal tissue, and invoices from its top ten customers for 2015, ABR has not complied with the subpoena. The Panel was unable to determine what criteria ABR used to determine its top ten customers, or whether that list is accurate.

²²⁹ Letter from Jonathan E. Lopez, Orrick, Herrington & Sutcliffe LLP, to Chairman Blackburn, Jan. 8, 2016, at 1.

²³⁰ ABR "Financials" (HCEC000057; HCEC000058).

²³¹ Letter from Jonathan E. Lopez, Orrick, Herrington & Sutcliffe LLP, to Chairman Blackburn, Feb. 24, 2016, at 1.

²³² *Id.* at 2.

D. StemExpress

On December 17, 2015, Chairman Blackburn sent StemExpress a document request letter asking for, among other items, a list of all entities from which StemExpress receives or procures fetal tissue; a list of all entities to which StemExpress sells or donates fetal tissue; an organization of company personnel involved in the procurement of fetal tissue; all communications directing StemExpress personnel to procure fetal tissue; all accounting records related to the cost and pricing of fetal tissue; documents relating to rent or site fees paid to abortion clinics where StemExpress obtained fetal tissue; and all StemExpress banking records related to fetal tissue.

Other than to list abortion clinics that it had previously produced to a Senate committee, StemExpress did not provide the names of any additional clinics. Citing non-disclosure agreements, StemExpress did not provide the names of its non-public customers. StemExpress did not produce the detailed organization chart, or the accounting and banking records.

As a result, the Panel issued a February 12, 2016, subpoena to StemExpress requiring the production of, among other items, the names of employees involved in the procurement of fetal tissue, so staff could interview and/or depose them. Citing safety and security concerns, the firm refused to produce the names. Yet a recent article about the company in *The Washington Post* identifies an individual StemExpress employee by name, and the article contains numerous photographs of workers, including one which clearly shows an employee's face.²³³

The Panel's first subpoena also demanded the production of all banking and accounting records relating to fetal tissue. StemExpress only produced accounting summaries created by their attorneys. After months of non-compliance on the accounting records, the Chairman wrote a letter to StemExpress that listed accounting documents covered under the first subpoena, demanding the production of those records, and stating that failure to produce would leave the Panel with no choice but to pursue all means necessary to compel compliance. The attorney for StemExpress stated it would not produce the accounting documents unless and until a new subpoena is issued.

On March 29, 2016, the Panel then issued a second subpoena, this one to Catherine "Cate" Dyer, StemExpress' founder and chief executive officer, requiring the production of the names of the firm's finance director, finance manager, or account manager. StemExpress refused to comply with that requirement. That subpoena also required for the second time the production of accounts payable and receivable. StemExpress has not produced those documents.

Without enforcing the subpoenas to StemExpress and Ms. Dyer, the Panel will be unable to determine whether StemExpress complied with or violated Section 289g-2.

²³³ See Danielle Paquette, A Tiny Firm Caught In Abortion War, Wash. Post, May 29, 2016, at G1.

E. Compliance Chart

Entity Subpoenaed or Document Requested	Full Compliance Y/N	Redacted Production Y/N	No Response	Refusal to Comply in Writing Y/N
Advanced Bioscience Resources	N	N		Y
Albert Einstein College of Medicine	N	N		
All Cells				
American Academy of Pediatrics	Y- they answered our letter but did not produce any documents			
American Association of the Advancement of Science	Y- they answered our letter but did not produce any documents			
American College of Obstetricians and Gynecologist			To our knowledge	
American Type Culture Collection	Y	N		
Anatomic Gift Foundation				
Association of American Medical Colleges	Y- they answered our letter but did not produce any documents			
Asterias	Y	N		
Baylor College of Medicine	Y	N		
Bioarray Therapeutics	N		N	
Biomedical Research	N		N	
Buffalo Biosciences	N		N	
Butler Medical Transport	Y	N		
Camelback Family Planning	Y	N		
Capital Biosciences	Y	N		
Carhart, Leroy	N	Y		Y
Carr, Shannon	N	N		Y
Cedar River Clinics	Y	N		
Children's Hospital of Philadelphia	Y	N		
City of Hope	Y	N		
Colorado State University	Y	N		
Columbia University	Y	N		
Dartmouth University	Y	N		
Drexel University	Y	N		
DV Biologics	Y	N		
Dyer, Cate	N			Y
Espey, Eve	N	Y		Y
Family Planning Specialists Medical Group	Y	N		
Five Star Bancorp	N	N		
Ganogen	N	Y		

Germantown Reproductive Health Services	N	Y		Y
Harvard	Y			
Heuston, Sara Lee	N			Y
HHS	N	N		
Holy Cross Germantown Hospital	Y	N		
Independent Women's Clinic				
Invivo	N	N		
Johns Hopkins				
Maryland Board of Physicians	N	Y		Y
Massachusetts General Hospital				
Montgomery County Department of Fire and Rescue Services	N	Y		
Montgomery County Department of Police	Y	N		
Montgomery County Emergency Communications Center	N	Y		
National Abortion Federation	Y			
Neuralstem	N		N	
Neurona				
National Institute of Health	Y	N		
Northland Family Planning	Y			
Novartis	Y	N		
Novogenix Labs	N	N		
Ohio State University				
Ohls, Robin	N	Y		Y
Oregon Health Sciences	Y	N		
Pfizer	Y			
Presidential Women's Options	Y	N		
Q Therapeutics	N	N		
Saneron	Y	N		
Scikon	N		N	
Scinto	N			Y
Southwestern Womens Options	N	Y		Y
Stanford University	Y			
Stem Cell Innovations	N		N	
Stemcells Inc	Y	N		
StemExpress	N	Y		Y
Shady Grove Medical Center	N	N		
SUNY Upstate	Y	N		
Thermo Scientific	N		N	
Trade Group Letters				
University of California Los Angeles	Y	N		
University of California San Diego	Y	N		
University of California- Keck School of Medicine	Y	N		
University of Colorado	N	N		
University of Connecticut	Y	N		

University of Illinois Chicago	Y	N		
University of Michigan	N	N		
University of Minnesota	Y	N		
University of New Mexico	N	Y		Y
University of North Carolina- Chapel Hill	Y	N		
University of Pennsylvania	Y	N		
University of Texas	Y	N		
University of Washington	N	N		
University of Wisconsin	Y	N		
US Department of Justice (2)				
Women's Health Specialist	Y	N		
Yale	N	N		
Zyagen				