

114TH CONGRESS }
2nd Session }

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**HUMAN FETAL TISSUE RESEARCH:
CONTEXT AND CONTROVERSY**

MAJORITY STAFF REPORT

PREPARED FOR THE USE OF THE

**COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE**

**ONE HUNDRED FOURTEENTH CONGRESS
SECOND SESSION**



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EXECUTIVE SUMMARY

***Note:** On July 14, 2015, an organization called the Center for Medical Progress (CMP) began releasing a series of undercover videos regarding transfers of fetal tissue obtained from abortions. Those CMP videos and the resulting public concern were the impetus for the Committee's investigation. However, the Committee's analyses and findings do not rely on the CMP videos. Rather, this report is based on documents and information the Committee independently obtained in the course of its investigation directly from the relevant organizations involved in fetal tissue transfers, from the relevant government agencies, and from an examination of legislative history. Accordingly, criticism of the CMP videos or of the techniques CMP used to create them are generally irrelevant to this report.*

As part of this Committee's investigation, Chairman Grassley sent a series of letters requesting documents and information from the Planned Parenthood Federation of America, all of the Planned Parenthood affiliates nationwide, StemExpress, Advanced Bioscience Resources, Novogenix, CMP, the Department of Health and Human Services, and the Department of Justice. Investigative counsel for the Committee then engaged with counsel for the respective organizations involved in transferring fetal tissue. In response to the Chairman's requests for information, the Committee received and reviewed roughly 20,000 pages of documents provided voluntarily by the parties, including contracts, invoices, cost calculations, internal medical standards and guidelines, technician compensation policies, and tissue procurement logs.

The activities of those involved in the fetal tissue transfer industry potentially implicate a number of federal laws, including: alteration of abortion procedures in order to obtain fetal tissue, a potential violation of 42 U.S.C. § 289g-1; performing partial-birth abortions, a violation of 18 U.S.C. § 1531; obtaining organs from still-living aborted fetuses, a violation of 42 U.S.C. § 289g and 18 U.S.C. § 1111; and receiving or paying valuable consideration for fetal tissue, a violation of 42 U.S.C. § 289g-2. However, the Department of Health and Human Services informed the Committee that there has been no research subject to 42 U.S.C. § 289g-1 since 2007. Further, investigations of violations of 18 U.S.C. § 1531, 18 U.S.C. § 1111, and 42 U.S.C. § 289g would involve identifying the particular abortions and/or tissues obtained, and would likely require review of medical records and testimonial evidence from the participants. That is beyond the resources, capabilities, expertise, and legislative fact-gathering purpose of this Committee. In light of all this, the Committee's investigation was limited in scope to issues involving the buying and selling of fetal tissue in violation of 42 U.S.C. § 289g-2, a law created by the NIH Revitalization Act of 1993. For a broader examination of all the implicated laws, please refer to the work of the House Select Investigative Panel on Infant Lives.

1. The NIH Revitalization Act of 1993 Was a Bipartisan Approach to Address the Controversy Surrounding Human Fetal Tissue Research. The Law was Explicitly Premised on the Enforcement of Safeguards to Prevent the Commodification of Human Fetuses.

Since shortly after the Supreme Court's *Roe v. Wade* decision in 1973, there has been substantial public debate about the ethics and legality of research involving aborted human fetuses. After multiple rounds of congressional hearings, partially relevant laws, and government-created panels, Congress in 1993 passed the NIH Revitalization Act. That Act

authorized the government to fund research on therapeutic fetal tissue transplants, subject to several safeguards proposed by a government panel.

Those safeguards were intended to prevent a market for fetal tissue from developing and to prevent fetal tissue research from incentivizing abortion. Chief among the safeguards was a prohibition making it “unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce.” This prohibition applies to all fetal tissue transfers, not just ones related to government-funded research on therapeutic transplantation. This ban on buying or selling fetal tissue also has what was intended to be a narrow exception that “‘valuable consideration’ does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.”

As the government panel had stated: “Certain precautions are paramount if such research is to be permitted. Prevention of any commercialization in obtaining the fetal tissue would seem to be an absolute requirement.” The legislative history demonstrates that many members of Congress supported the Act based on their belief that the safeguards would be enforced and function as intended, preventing a market for fetal tissue from developing.

2. Despite the Clear Legislative History of the 1993 NIH Revitalization Act, the Executive Branch across Multiple Administrations Has Failed to Enforce the Law’s Safeguards.

Unfortunately, the executive branch, across multiple administrations, has failed to enforce the law’s safeguards. The portion of the Act addressing federally-funded research on the use of fetal tissue for therapeutic transplantation contained several documentary requirements intended to safeguard against such research incentivizing abortion. The required documents were to be made available for audit by the Secretary of the Department of Health and Human Services (HHS), who would exercise oversight to ensure the safeguards were functioning. However, during the 14 years that the government funded research covered by this section of the law, HHS never conducted a single audit.

Similarly, although the law’s ban on buying or selling fetal tissue contains criminal penalties, the Justice Department has never initiated a single prosecution for violating the law since its enactment in 1993. Indeed, the Department has only undertaken two investigations during this 23-year period. Those investigations were undertaken after a bipartisan Congressional request to do so. The Justice Department declined to bring charges in either investigation, and refused to provide the Committee with the documents explaining the decisions. Accordingly, the Committee cannot assess whether the Justice Department prosecutors involved believed that the exception to the ban on payments is too broad or vague to allow for enforcement, or if other factors led to these decisions.

3. In the Absence of Any Enforcement, Companies Engaged in Transferring Fetal Tissue Have Interpreted the Exception to the Ban on Payments so Broadly as to Undermine the Purpose of the Safeguard.

With no executive branch oversight and no meaningful risk of prosecution, the companies involved in transferring fetal tissue have been free to receive substantial payments with impunity. The companies that are the subject of this investigation apparently did not attempt to contemporaneously determine their actual costs when setting their prices. In response to undercover videos casting doubts about the propriety of these practices, the companies have since relied on broad *post hoc* interpretations of the exception to the ban on payments in attempts to justify millions of dollars in revenue. Although they claimed that they were only recovering allowable costs, they admitted failing to actually track and document these costs when setting their prices. Even after being contacted by the Committee, the companies failed to provide meaningful cost analyses that would justify the amounts received. Some have attempted to rely on vague, expansive, and undefined indirect costs and general overhead to justify the payments received. However, these categories are so broad that to allow them would be inconsistent with the law's clear intent to prevent the buying and selling of fetal tissue, since prohibited payments could simply be re-categorized and falsely justified by amorphous general overhead or indirect costs.

4. Since 2010, Three Companies - Advanced Bioscience Resources, Inc.; StemExpress, LLC; and Novogenix Laboratories, LLC - Have Paid Planned Parenthood Affiliates to Acquire Aborted Fetuses, and Subsequently Sold the Fetal Tissue to Their Respective Customers at Substantially Higher Prices than Their Documented Costs.

Committee investigators received numerous records from the companies, each of which charged its customers hundreds of dollars for each fetal tissue specimen obtained. Novogenix has since gone out of business, and the Committee's review of the intermediary companies focused on Advanced Bioscience Resources (ABR) and StemExpress. A review of ABR's and StemExpress's records show that each received payments for fetal tissue specimens far in excess of their demonstrated costs of the allowable categories, and that neither apparently sought to contemporaneously determine these relevant costs when setting prices.

5. ABR's Records Seem to Show It Received Payments for Fetal Tissue Specimens Far in Excess of Costs for "the Transportation, Implantation, Processing, Preservation, Quality Control, or Storage of" the Tissue, a Likely Violation of the Ban on Selling Fetal Tissue.

A sample of ABR's fetal tissue procurement and distribution demonstrates its business model. For example, according to ABR's records, on one day in June of 2014, an ABR technician obtained a 20-week-old fetus at a Planned Parenthood clinic, for which it paid the clinic \$60. From that one fetus, ABR sold its brain to one customer for \$325; both of its eyes for \$325 each (\$650 total) to a second customer; a portion of its liver for \$325 to a third customer;

its thymus for \$325 and another portion of its liver for \$325 to a fourth customer; and its lung for \$325 to a fifth customer. However, those fees are merely the “service fees” for the specimens themselves. In addition, ABR also separately charged each customer for shipping, disease screening, cleaning, and freezing, as applicable. Moreover, because the company does not store or implant the tissues, its fees cannot plausibly be based on those exempted categories. So, from that single fetus, for which ABR paid Planned Parenthood a mere \$60, ABR charged its customers a total of **\$2,275** for tissue specimens, plus additional separate charges for shipping and disease screening.

ABR procured the 20-week old fetus described above at 9:00am and shipped to its customers all the specimens obtained from it, as well as those from three more fetuses obtained that morning, at 1:00pm. During the four hours the ABR technician worked at the Planned Parenthood clinic that day, he or she obtained, processed, and shipped a total of 20 specimens from four procured fetuses. As a result, ABR charged its customers total specimen service fees of **\$6,825** stemming from that four-hour procurement session. Once again, that is the total for only the specimen service fees; shipping, disease testing, cleaning, and freezing (where applicable) were subject to separate fees. Pursuant to ABR’s contract with the clinic, it paid the clinic a total of \$240 for procuring those four fetuses. At ABR’s stated \$15 an hour wage for its technician, it paid the technician \$60 for the four-hour session. Thus it appears the total direct costs incurred by ABR would have been \$240 to the clinic, \$60 to its technician, plus possible small amounts for the technician’s mileage reimbursement, supplies, and paperwork. This example is representative of the ABR’s usual business operation.

In short, for ABR to justify the \$6,825 in income received in connection with these fetal tissue samples, for which it incurred roughly \$300 in direct costs, ABR must demonstrate \$6,525 in other costs that were apparently not directly related to the transactions but yet somehow still allowable under the law’s narrow exception allowing reasonable payments for “the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.” There is no evidence that the company attempted to contemporaneously determine its costs for these categories when setting its prices. Nor has the company provided the Committee any justification for such costs for any one of its fetal tissue transactions. Rather, it has relied on broader assertions about the overall profitability, or lack thereof, of the company. That is largely irrelevant. In short, it is implausible that the income ABR received can be justified under the categories within the narrow exception to the ban on buying and selling fetal tissue. Without any enforcement of the law, though, there are no consequences for such an improperly broad interpretation.

6. StemExpress's Records Also Seem to Show It Received Payments for Fetal Tissue Specimens Far in Excess of Costs for "the Transportation, Implantation, Processing, Preservation, Quality Control, or Storage of" the Tissue, a Likely Violation of the Ban on Selling Fetal Tissue.

An example of StemExpress's transactions also raises similar concerns. According to StemExpress's records, in August of 2012, a StemExpress technician obtained a 19-week-old fetus at a Planned Parenthood clinic, for which it paid the clinic \$55. From that one fetus, StemExpress sold its brain for \$250 to one customer; its liver for \$250, its thymus for \$250, and its torso skin for \$250 to a second customer. Those fees are merely the service fees for the specimens themselves; StemExpress also separately charged each of its customers for shipping/delivery, disease screening, cleaning, and freezing, as applicable. So, from that single fetus, for which StemExpress paid the clinic \$55, StemExpress charged its customers a total of \$1,000 for tissue specimens. At its current prices, StemExpress would make \$2,380 for the four specimens. According to records StemExpress provided the Committee, the procuring technician was presumably paid \$15 an hour, plus \$200 in bonuses for the four specimens obtained. Thus, in relation to the \$1,000 it made from this fetus, it appears the total direct costs incurred by StemExpress would have been \$55 to the clinic, \$215 to its technician, plus possible small amounts for the technician's mileage reimbursement, supplies, and paperwork.

As with ABR, there is no evidence that StemExpress attempted to contemporaneously determine its costs for the allowable categories within the exception when setting its prices, despite its current reliance on those purported costs to justify its prices. The company also has not provided the Committee any justification for such costs for any of its fetal tissue transactions, but rather provided a broader explanation of the overall profitability, or lack thereof, of the segment of its business involving fetal tissue transfers. That explanation has several flaws, and is largely irrelevant. Once again, it is implausible that the income StemExpress received can be justified under the narrow exception to the ban on buying and selling fetal tissue. Certainly, margins like this do not appear consistent with the stated Congressional intention to prevent the commodification of human fetuses.

7. The Planned Parenthood Federation of America (PPFA) Had Policies in Place to Ensure Its Affiliates with Paid Fetal Tissue Programs Were Not Breaking the Law. The Affiliates Did Not Follow Those Policies. When PPFA Learned of This Fact in 2011, It Curtailed its Oversight of Affiliates' Paid Fetal Tissue Programs Rather Than Exercise Oversight to Bring the Affiliates Back into Compliance.

According to Planned Parenthood's representations to the Committee, four Planned Parenthood affiliates have had paid fetal tissue programs since 2010: Planned Parenthood Mar Monte; Planned Parenthood of the Pacific Southwest; Planned Parenthood Northern California; and Planned Parenthood Los Angeles. In 2001, PPFA issued a memorandum on fetal tissue programs to its affiliates, which had specific instructions regarding compliance with the ban on buying and selling fetal tissue. Specifically, PPFA instructed its affiliates that they could either

(1) recover no costs at all in connection with transferring fetal tissue, or (2) “employ an independent auditor to conduct a credible and good faith analysis of the actual costs incurred by the affiliate in the transportation, implantation, processing, preservation, quality control, or storage of the fetal tissue.” The memorandum further stated that PPFA’s accreditation reviews would confirm that any affiliate involved in a fetal tissue program complied with this requirement. Moreover, Planned Parenthood’s Manual of Medical Standards and Guidance (Manual) similarly stated that affiliates initiating a fetal tissue transfer program must request approval for the service, and reasserted that PPFA would monitor the programs as part of the affiliate recertification process.

Despite this framework, in January of 2011, PPFA learned that some of its affiliates were receiving payments for fetal tissue transfers without having gone through the required PPFA procedures to ensure compliance with the law. In response, PPFA initially decided to resend the 2001 memorandum to the affiliates who were already participating in paid fetal tissue programs, that a PPFA attorney would call the affiliates that needed additional guidance, and that the 2001 memorandum would be discussed with the PPFA accreditation personnel. However, shortly thereafter, PPFA instead deleted the Manual’s requirement that PPFA monitor the affiliates’ fetal tissue programs as part of the recertification process. Therefore, it appears as though PPFA intentionally turned a blind eye after it discovered affiliates had violated the policies it had in place to ensure compliance with the law, and facilitated the continuation of those practices. In fact, from 2011 to 2015, it is difficult to see what, if any, effective controls PPFA had on affiliate fetal tissue payment programs.

In May of 2015, a few weeks before the undercover videos were released, PPFA changed its guidance on fetal tissue programs, removing it from its Manual altogether, placing it on an intranet site, and adding a new section to address fetal tissue payments. After the undercover videos were released, the president of PPFA, Ms. Cecile Richards, repeatedly cited this guidance in Planned Parenthood’s defense, without noting how recently that guidance had been issued.

8. The Cost Analyses Planned Parenthood Affiliates Created in Response to the Committee’s Investigation Rely on an Unreasonably Broad Interpretation of Costs for “the Transportation, Implantation, Processing, Preservation, Quality Control, or Storage of” Fetal Tissue. Accordingly, the Planned Parenthood Affiliates’ Paid Fetal Tissue Transfers were Likely in Violation of the Ban on Selling Fetal Tissue.

Committee investigators brought the information above to the attention of Planned Parenthood’s attorneys. In a letter to them, Chairman Grassley referenced the 2001 PPFA memorandum requiring affiliates to use independent auditors if they wanted to receive payments, and asked whether any such auditors’ reports existed for the four affiliates that had paid fetal tissue programs since 2010. He also requested copies of any accreditation reviews that evaluated those paid fetal tissue transfer programs. Eventually, Planned Parenthood’s attorneys acknowledged that its affiliates had apparently failed to follow the procedures PPFA had put in place to ensure affiliate fetal tissue programs comply with the law. They wrote: “We have

determined that these four affiliates either did not conduct or cannot locate contemporaneous cost analyses, or secure independent audit opinions as articulated by PPFA's then-existing guidance."

Despite PPFA's constant statements to the media that the affiliates had merely been recovering their costs, the attorneys also stated that the affiliates had only actually tried to determine their costs after-the-fact and at the insistence of the Committee: "In response to your October 26 [2015] letter . . . the affiliates have each performed a good-faith accounting of their costs associated with facilitating fetal tissue donation." Around that time, Planned Parenthood announced it would no longer accept any payments in connection with its fetal tissue transfer programs.

The *post-hoc* cost analyses the affiliates created in response to the Committee's investigation attempted to shoehorn a vast array of unrelated, indirect, or tenuously related costs into the law's exception for reasonable payments for "the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue." It includes attempting to attribute several thousands of dollars in costs to an amorphous category, "General Administrative & Medical Overhead." Simply put, an interpretation of the exception that is this broad would clearly be at odds with the primary purpose of the safeguard, as demonstrated by the legislative history. It thus appears that the affiliates' payments may have violated the ban on buying and selling fetal tissue. In addition, the actions of PPFA and its affiliates after PPFA learned of the affiliates' violation of PPFA's fetal tissue policies suggest the possibility of a violation of the federal criminal conspiracy law, 18 U.S.C. § 371.

9. Conclusion

Much of the Congressional support for the 1993 NIH Revitalization Act was premised on the idea that the ban on buying or selling fetal tissue would be a safeguard against the development for a market for human fetuses. Tragically, the executive branch has either failed or simply refused to enforce that safeguard. As a result, contrary to the intent of the law, companies have charged thousands of dollars for specimens removed from a single aborted fetus; they have claimed the fees they charged only recovered acceptable costs when they had not, in fact, conducted any analysis of their costs when setting the fees; and their *post hoc* accounting rationalizations invoked indirect and tenuously-related costs in an attempt to justify their fees. With no executive branch oversight or enforcement of the law, there are no consequences to these actions. Unless there is a renewed emphasis on enforcement or changes in the law to clarify the exception to the ban on payments, the problem is likely to continue. Accordingly, the Justice Department should fully investigate the fetal tissue practices of Planned Parenthood Federation of America; the individual Planned Parenthood affiliates involved in paid fetal tissue transfers; Advanced Bioscience Resources, Inc.; StemExpress, LLC; and Novogenix Laboratories, LLC in order to enforce this law.

* * * * *

I. THE INITIAL PUBLIC DEBATE ABOUT FETAL TISSUE RESEARCH

In the United States, public controversy over research involving electively-aborted fetuses began in earnest shortly after the Supreme Court's *Roe v. Wade* decision in January of 1973. In April of that year, a reporter for a medical newsletter, *OB-GYN News*, recorded and published portions of a meeting at the National Institutes of Health (NIH) addressing proposals on fetal tissue research.¹ The *Washington Post*, having learned of the recording prior to the newsletter's publication, first reported on the NIH discussions.² The *Washington Post*'s article described research, sometimes financially supported by NIH, conducted immediately after abortions on still-living aborted fetuses.³ The article further described the debate within NIH about whether federal funds should be used in such research.⁴ That *Washington Post* article is credited with "introduc[ing] the topic of fetal research to the American public."⁵

In reaction to the strong public response to the article, NIH a few days later made the claim that it would not, and did not as of that time, financially support research on live aborted human fetuses.⁶ At the time, NIH reportedly financed nearly half of all U.S. medical research, and the NIH official qualified his denial by stating that NIH was "dealing with 14,000 grants" so it was not funding such research "insofar as we know."⁷ NIH also sought to differentiate between fetal tissue research in which procedures were done during the minutes or hours while some aborted fetuses were still alive or could be kept alive, and procedures done on aborted fetuses to obtain cells and organs that could be kept alive in a laboratory.⁸ NIH only claimed not to support the former.⁹

However, in the days and weeks following NIH's assertion, a number of press reports describing particular fetal tissue studies seemed to undermine NIH's claims. The reports described studies that appeared to involve NIH-funded scientists performing research on living aborted fetuses. The reports also described studies that seemed to show that the NIH's purported distinction between the two types of fetal tissue research was, in connection with at least one method of abortion used at the time, much blurrier than NIH had implied. On April 15, 1973, two days after publishing a story on NIH's statement, the *Washington Post* reported on two such fetal tissue studies:

An intense scientist named Dr. Gerald Gaull in periodic trips to Finland injects a radioactive chemical into the fragile umbilical cords of fetuses freshly removed from their mothers' wombs in abortions. The fetus in each case is too young to survive, but in the brief period that its heart is still beating, Gaull – chief of pediatrics research at the New York State Institute for Basic Research in Mental Retardation on Staten Island – then operates to remove its brain, lung, liver and kidneys for study. . . . Dr. Robert Schwartz, chief of pediatrics at Cleveland Metropolitan General Hospital, goes to Finland for a similar purpose. After a fetus is delivered, while it is still linked to its mother by the umbilical cord, he takes a blood

sample. Then, after the cord is severed, he “as quickly as possible,” he states, operates on this aborted being to remove other tissues and organs. . . . Schwartz . . . works with NIH funds. Gaull works abroad with his own money, he reports, but in the United States is funded by New York state with help from an NIH grant.¹⁰

The article went on to describe the work of another NIH grantee at the University of Pittsburgh Children’s Hospital:

“We used to do research on the intact fetus,” he said. “Now we take tissues – the brain has stopped functioning but the tissues are still alive.” . . . Other scientists do not believe that some tissues are really “alive” enough if the brain has stopped working. . . . This is one reason some scientists have preferred to work while the fetus is still attached to the mother.¹¹

Similar stories appeared in other leading publications around this time. For example, in May of 1973, the *New York Times* published an article describing a study conducted by American scientists from NIH and Case Western University with Finnish doctors.¹² The scientists injected the rubella vaccine into 35 pregnant women who were scheduled to have abortions.¹³ Rubella can cause birth defects, and the purpose for these injections was to determine whether the live virus in the vaccine would harm the fetuses.¹⁴ The fetuses were later aborted, their tissues examined, and “[t]he study strengthened evidence that [the vaccine] would not be safe for the fetus.”¹⁵

In June of 1973, *Medical World News* published an article describing experiments conducted by Dr. Peter A.J. Adam, a professor of pediatrics at Case Western University, with colleagues in Finland.¹⁶ To determine whether glucose and D-beta hydroxyl butyrate could serve equally well as energy sources in brain metabolism, Dr. Adam and his colleagues experimented on 12 fetuses, from 12 to 20 weeks gestation, obtained via hysterotomy – the procedure used for Caesarian births.¹⁷ They then decapitated the fetuses, attached tubes to the arteries feeding their brains, and circulated a solution into the arteries containing the energy sources and oxygen.¹⁸ Dr. Adam dismissed ethical concerns regarding fetal research, stating: “[O]nce society has declared the fetus dead and abrogated its rights, I don’t see an ethical problem. . . . Whose right are we going to protect when we’ve already decided the fetus won’t live?” Dr. Adam’s experiments were reportedly supported by NIH funds.¹⁹

In the wake of such articles describing fetal tissue research, the issue became “a subject of great controversy[.]”²⁰ Some argued that research on aborted fetuses, including on still-living aborted fetuses, was necessary for the advancement of medical knowledge and obtaining future treatments for diseases. Others argued that, regardless of any scientific benefit, the practices were unethical and violations of human dignity.

II. CONGRESSIONAL RESPONSE TO THE FETAL RESEARCH DEBATE

In response, the 93rd Congress held hearings in which numerous witnesses testified, and each chamber passed bills addressing the issue of fetal tissue research.²¹ House and Senate negotiators met to resolve differences between the two chambers' competing bills, and the final version, entitled the National Research Act, was enacted on July 12, 1974.²²

This 1974 statute established a new, 11-member commission and tasked it with recommending permanent fetal research rules by May 1, 1975.²³ The new law also barred the United States Department of Health, Education, and Welfare (HEW) from conducting or supporting fetal research "before or after induced abortion" until the commission's recommendations were issued.²⁴ Although the ban was limited to fetal research directly or indirectly supported by HEW, at the time HEW reportedly supported the majority of all health-related research in the United States.²⁵

Numerous witnesses testified before this panel, entitled the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, before it issued the required report and recommendations to HEW.²⁶ Some witnesses cited the benefits derived from past fetal research and argued "that banning medical research on living fetuses would deny freedom from disease to millions of future children."²⁷ Others voiced ethical concerns, detailing past experiments in which aborted fetuses were purposely kept alive outside the womb for up to 22 hours using oxygen and other methods in order to conduct experiments on them.²⁸

In May 1975, the Commission issued its "Report and Recommendations: Research on the Fetus," which recommended lifting the ban on research on living fetuses, before or after abortion, subject to several conditions:

Research had to be directed at the health needs of the fetus or the mother, could pose no added risk to the fetus and could not involve terminating the heartbeat or respiration of the non-viable fetus. Artificially maintaining the vital functions of living, non-viable fetuses was also prohibited. The regulations required a separation between the persons performing the abortion and the persons removing the tissue from live fetuses. And the regulations prohibited any inducements, monetary or otherwise, and any change in abortion procedures that would hurt either the fetus or the pregnant woman.²⁹

The adoption of these recommendations as regulations in July of 1975 substantially circumscribed HEW-supported research on living fetuses, whether before or after abortion. But neither the commission's recommendations nor the regulations extensively addressed the use of tissue from dead aborted fetuses:

The one clear requirement in the regulations was that research involving dead fetuses had to conform to any applicable state or local laws. Otherwise, it was a matter of uncertainty and dispute whether the other procedural provisions – such as the ban on payment or the mandatory separation between the abortion and the personnel using the tissue – applied to research involving dead fetuses.³⁰

Some doctors apparently interpreted the regulations as inapplicable to dead fetuses: in February of 1976, a *Washington Post* investigation revealed that D.C. General Hospital had sold fetuses from late-term elective abortions to Flow Laboratories, a Maryland firm that used fetal organs and other fetal tissue to produce cell cultures, which it in turn sold to medical pharmacological researchers and firms.³¹ The hospital had not sought or received the permission of the women receiving the abortions, and the department involved had kept the money it received in a special, unauthorized fund.³² A federal grand jury was impaneled to review the matter – not for a violation of the fetal tissue regulations, but rather for a potential violation of a law that made it illegal for District of Columbia employees to receive outside compensation for work undertaken during working hours.³³

In later years, Congress passed a few additional laws relevant to these issues. In 1984, the National Organ Transplant Act (NOTA) was enacted.³⁴ NOTA criminalized the exchange of valuable consideration for human organs for use in human transplantation, if the transfer affects interstate commerce.³⁵ NOTA did not provide a statutory definition of the phrase “valuable consideration,” but it did clarify that the phrase “does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.”³⁶ In 1988, Congress amended NOTA to explicitly include fetal organs, but, consistent with the original NOTA, the 1988 ban on buying or selling fetal organs was limited to the context of human transplantation.³⁷

In 1985, the Health Research Extension Act was enacted.³⁸ The relevant portions of the Act modified the Public Health Act, essentially codifying some of the recommendations made a decade earlier by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research regarding the use of fetuses in research or experimentation. The Act stated:

The Secretary may not conduct or support any research or experimentation, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation —

- (1) may enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or

(2) will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.³⁹

Moreover, regarding research on fetuses in utero, the Act stated that: “the Secretary shall require that the risk standard . . . be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.”⁴⁰ Thus, by the mid-1980s, the government had established a partial legal framework to address fetal tissue research, but many areas were unclear or unresolved.

III. THE RETURN OF THE FETAL TISSUE DEBATE IN THE LATE 1980S

In the late 1980s, public debate regarding fetal tissue research arose once again. In 1987, NIH scientists requested approval to transplant fetal tissue cells obtained from an induced abortion into the brain of a patient with Parkinson’s disease.⁴¹ In October of that year, the Director of NIH, James Wyngaarden, sought the approval of Assistant Secretary for Health and Human Services (HHS) Robert Windom to fund the proposed research “because of the broad scientific and ethical implications surrounding this area of research.”⁴²

The HHS Assistant Secretary responded in March of 1988, announcing a temporary ban on all NIH funding of research on fetal tissue transplantation, pending the recommendations of an advisory committee that was to be created to study the issue.⁴³ Specifically, Assistant Secretary Windom instructed NIH to “convene one or more special outside advisory committees that would examine comprehensively the use of human fetal tissue from induced abortions for transplantation and advise us on whether this kind of research should be performed, and, if so, under what circumstances.”⁴⁴

A. The Human Fetal Tissue Transplantation Research Panel

In response, the NIH Director created the Human Fetal Tissue Transplantation Research Panel (the Panel) and charged it “with reviewing the ethical, legal, and scientific issues surrounding the use of human fetal tissue derived from induced abortions in transplantation research.”⁴⁵ The Panel held a series of meetings in late 1988, during which it heard “public testimony from over 50 experts in the fields of science, law, and ethics.”⁴⁶ As with the earlier debate on fetal tissue research, some argued that the research was essential to develop new treatments for diseases, with the emphasis largely placed on the potential of fetal tissue transplants to treat Parkinson’s disease, diabetes, spinal cord injuries, and Alzheimer’s disease. Others raised ethical objections to treating human beings as commodities and using tissue from fetal humans who were inherently incapable of consenting to such experiments.

In December of 1988, the Panel presented its final report to NIH.⁴⁷ A majority of the NIH-appointed Panel stated:

It is of moral relevance that human fetal tissue for research has been obtained from induced abortions. However, in light of the fact that abortion is legal and that the research in question is intended to achieve significant medical goals, the panel concludes that the use of such tissue is acceptable public policy.⁴⁸

Within that Panel's majority, some members believed that supporting fetal tissue transplantation research was acceptable public policy because "the source of the tissue posed no moral problem," while others felt "the immorality of its source could be ethically isolated from the morality of its use in the research" by means of safeguards that would serve as "insulating measures."⁴⁹ Regardless, the Panel as a whole "believe[d] strongly that we should keep transplantation and research on fetal tissue from encouraging abortion"⁵⁰ and proposed a number of specific measures intended to do so, including:

- A requirement "that informed consent for an abortion precede informed consent or even the provision of preliminary information for tissue donation" in an attempt to prevent the potential benefits of fetal tissue research from serving as an inducement to choose to abort. "Ideally, permission to use tissues from the aborted fetus would not even be sought until the abortion itself had been performed."⁵¹
- A prohibition preventing the pregnant woman from designating the transplant-recipient of the fetal tissue, so as to avoid women becoming pregnant in order to direct the aborted fetal tissue to be used in treating a sick family member or friend.⁵²

Importantly, the Panel's report stated:

- "Certain precautions are paramount if such research is to be permitted. Prevention of any commercialization in obtaining the fetal tissue would seem an absolute requirement. . . . Payments and other forms of remuneration and compensation associated with the procurement of fetal tissue should be prohibited, except payment for reasonable expenses occasioned by the actual retrieval, storage, preparation, and transportation of the tissues. . . . [C]lear guidelines about what constitutes procurement expenses [are] essential . . ."⁵³

The Panel emphasized the importance of the "strict adoption" of these "safeguards that would eliminate or at least radically reduce profit motives and tendencies toward commercialization."⁵⁴ These safeguards against commercialization were both intended to

prevent research on fetal tissue from encouraging abortion, and to prevent any interests in obtaining usable fetal tissue from influencing clinical decisions affecting the health of the woman. To that end, the Panel further recommended that “the timing and method of abortion should not be influenced by the potential uses of fetal tissue for transplantation for medical research.”⁵⁵ The Panel also recommended that “NIH conduct periodic reviews to ensure that the concerns expressed in this report, as well as other concerns that arise as research progresses, are carefully safeguarded.”⁵⁶ The Advisory Committee to the NIH Director accepted the Panel’s report and recommendations, and the NIH Director then recommended to HHS that it lift the ban on funding fetal tissue transplantation research.⁵⁷

B. The George H.W. Bush Administration Rejects the Panel’s Recommendations

The Panel’s report came at the end of the Reagan administration, and several months passed before the Bush administration’s newly-appointed Secretary of HHS, Louis Sullivan, passed judgment on NIH’s pending recommendation.⁵⁸ In November of 1989, Secretary Sullivan announced that he was rejecting the NIH panel’s recommendations and would instead keep the ban on federal funding of fetal tissue research in place indefinitely.⁵⁹ He explained his rationale as follows:

It is clear that research involving the use of fetal tissue from induced abortions for human transplantation could potentially produce health benefits, and I do not in any way discount the importance of this fact. . . . But this is an issue which requires careful consideration not only of the potential benefits and hazards of such research, but also profound consideration of the moral and ethical elements. I am particularly convinced by those who point out that most women arrive at the abortion decision after much soul searching and uncertainty. Providing the additional rationalization of directly advancing the cause of human therapeutics cannot help but tilt some already vulnerable women toward a decision to have an abortion.⁶⁰

In short, Secretary Sullivan did not believe that the Panel’s proposed safeguards could truly prevent fetal tissue research from incentivizing abortion.

C. Congressional Efforts to Overturn the Ban and Codify the Panel’s Recommendations

In 1991, Congressman Henry Waxman (D-CA), introduced the National Institutes of Health Revitalization Amendments of 1991, H.R. 2507, which sought to override the continuing HHS ban on federal funding of fetal tissue transplantation research and enact the NIH Panel’s recommended safeguards.⁶¹ In Congressional debates, proponents of fetal tissue research again stated that such research could lead to new treatments for Alzheimer’s disease, Parkinson’s

disease, diabetes, and spinal cord injuries. Congressman Waxman and others extolled the potential medical gains to be obtained from fetal tissue transplantation research, and adamantly reassured their pro-life colleagues that the proposed safeguards would prevent the commercialization of fetal tissue and prevent the transfers from incentivizing abortion.

During the House debate on the bill, Congressman John Cox (D-IL) similarly argued that the safeguards would prevent a market for fetal tissue:

Understandably, there are concerns that lifting the ban will create a free market with people buying and selling fetuses for profit. This bill embodies several ethical safeguards to assure that these fears will not become reality. Consent for the abortion must be obtained prior to and separate from the decision to donate the fetal tissue. The sale of fetal tissue is prohibited. The legislation makes it a Federal crime to sell or solicit human tissue punishable by fines and imprisonment. The ethical concerns having been addressed, the decision should be uncomplicated.⁶²

Congresswoman Connie Morella (R-MD) similarly stated:

The legislation includes important safeguards to ensure that any future research is conducted in an ethical manner. For example, fetal tissue could not be sold nor could donations be targeted to any particular individual. As a result of these protections, ethical concerns have been addressed.⁶³

Some Senators also grappled with the issue, weighing the potential benefits to medical research against ethical concerns. Senator John McCain (R-AZ), stated:

I have lost sleep struggling with this very question. My abhorrence for the practice of abortion is unquestionable. Yet, my abhorrence for these diseases and the suffering they cause is just as strong. . . . I would never support lifting the ban if I thought it would result in the creation of a market for fetal tissue. The idea of such a market is barbaric, and the safeguards placed in the bill, and the criminal penalties for such violations, are necessary to prevent this from occurring. **Only my strong belief that these safeguards are sufficient permit me to vote in favor of lifting this ban.**⁶⁴

The prospect that fetal tissue transplantation research could lead to several life-saving treatments, coupled with assurances that the Act's safeguards would prevent a market for fetal tissue and insulate the research from incentivizing abortion, effectively persuaded Congress. The

House passed the bill, by a vote of 274 to 144, with 40 Republicans voting in favor.⁶⁵ The Senate version passed by a vote of 87 to 10.⁶⁶

However, in June of 1992, President George H.W. Bush vetoed the bill, noting that it “is unacceptable to me on almost every ground: ethical, fiscal, administrative, philosophical, and legal.”⁶⁷ He added: “I believe this moratorium is important in order to prevent taxpayer funds from being used for research that many Americans find morally repugnant and because of its potential for promoting and legitimizing abortion.”⁶⁸ He argued that the benefits of fetal tissue research likely still could be obtained by using fetal tissue that had not been acquired from elective abortions, such as from miscarriages and tubal pregnancies, and proposed policies toward that end.⁶⁹ He similarly did not believe that the purported safeguards would prevent fetal tissue research from incentivizing abortion.⁷⁰ A congressional attempt to override the veto failed, and the ban thus endured throughout his presidency.⁷¹

D. President Clinton Lifts the Ban and Congress Codifies the Panel’s Recommendations

President Clinton did not share his predecessor’s view on fetal tissue research, and on his third day in office, he ended the ban on federal funding of fetal tissue transplantation research via executive action.⁷² Meanwhile, Senator Ted Kennedy (D-MA) introduced the National Institutes of Health Revitalization Act of 1993 (S. 1) to codify this executive action and institute the safeguards recommended by the NIH Panel.⁷³ The Committee Report accompanying this bill, authored by Senator Kennedy’s staff, again touted the scientific potential of fetal tissue research, stating:

Fetal tissue transplantation research holds greatest immediate promise for the development of therapies and treatments for people who suffer from diabetes, Parkinson’s disease, and spinal cord injury. Many other chronic disorders including Alzheimer’s disease, genetic disorders, cancer, and AIDS may eventually benefit from the research.⁷⁴

The report also expressly tied the bill’s requirements to the NIH Panel’s recommendations, stating:

The bill requires the Secretary to establish safeguards for the conduct or support of research on the transplantation of human fetal tissue for therapeutic purposes . . . as recommended by the 1988 NIH Human Fetal Tissue Transplantation Research Panel. These requirements include, among others, the prohibition of the purchase or sale of human fetal tissue . . . and the subjecting of violators to a fine and/or imprisonment. . . . It contains safeguards, recommended by the NIH panel, to remove any potential incentives for abortion. . . . [T]he measure makes it a criminal offense, in both the public and private sectors, to purchase human fetal tissue With these safeguards,

the committee believes that any potential incentives for abuse will be removed. . . . [I]t is the committee's intent that the guidelines in this bill be promulgated uniformly in both public and private sectors and monitored by the NIH.⁷⁵

The bill also required the Government Accounting Office to conduct a compliance review of research on fetal tissue transplantation conducted or supported by HHS.⁷⁶ The bill passed the Senate by a vote of 93 to 4.⁷⁷

In the House, Congressman Waxman again pointed to the bill's supposed safeguards, arguing that the legislation would "prevent the sale of fetal tissue for any purpose" not just in connection with NIH-funded research on therapeutic transplantation.⁷⁸ He explained: "It would be abhorrent to allow for a sale of fetal tissue and a market to be created for that sale."⁷⁹

Some in the House opposed the bill, expressing skepticism about the efficacy of its purported safeguards. As Congressman Thomas Bliley (R-VA) stated:

I cannot, in good conscience, support the decision to allow such [fetal tissue] research to move forward with Federal funds. . . . I also believe that, over time, the safeguards against allowing such research to become an inducement for abortion will prove to be meaningless.⁸⁰

Congressman Robert Dornan (R-NY) similarly stated:

While S. 1 supporters claim it will guard against abuses in fetal tissue research by prohibiting the sale of fetal tissue, do not believe for a second that that is going to be firm law. It will be violated regularly, as it has been for decades, with aborted babies sold to medical labs after they are dead.⁸¹

Nonetheless, the bill passed the House by a vote of 290 to 130 and President Clinton signed it in June of 1993.⁸² Congress and the executive branch had thus agreed on a broader legal framework for fetal tissue research.

IV. THE NIH REVITALIZATION ACT OF 1993

A. The Terms of 42 U.S.C. § 289g-1

The NIH Revitalization Act of 1993 (Pub. L. No. 103-43) amended the Public Health Services Act, 42 U.S.C. § 289 *et seq.*, creating a section addressing federal funding of fetal tissue transplantation research. That section, 42 U.S.C. § 289g-1, authorizes the HHS Secretary to "conduct or support research on the transplantation of human fetal tissue for therapeutic purposes." It also includes documentation requirements related to the safeguards recommended

by the NIH panel. Specifically, it requires that the woman providing the fetus demonstrate her informed consent by signing a statement declaring that she donates the tissue for use in therapeutic fetal tissue transplantation research, without any restrictions on, or knowledge of, who the tissue recipient will be.

The law also requires the attending physician to sign a written statement confirming that, in the case of tissue obtained through an induced abortion, the woman's consent for the abortion was obtained prior to her consent for the tissue donation; no alteration of the timing, method, or procedures used to terminate the pregnancy was made solely for the purposes of obtaining the tissue; the abortion was performed in accordance with applicable state law; and the woman signed a statement evidencing her informed consent to the tissue donation. The law also requires the physician to declare that full disclosure was provided to the woman regarding the physician's interest, if any, in the research to be conducted with the tissue and any known additional medical or privacy risks that might be associated with the fetal tissue donation.

The law further requires those with primary responsibility for conducting the fetal tissue research to sign statements declaring that they are aware that: the tissue in question is human fetal tissue; the tissue may have been obtained pursuant to an abortion or a stillbirth; and the tissue was donated for research purposes. The signed statement must also declare that the primary researcher has provided this same information to other individuals involved in the research, and will require the advance, written acknowledgement of such information by the recipient of a fetal tissue transplantation prior to obtaining that individual's consent to tissue transplantation. Lastly, the primary researcher's statement must declare that he or she has had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy made solely for the purposes of research.

Moreover, the law requires that the head of the agency or entity conducting the fetal tissue research certify to the HHS Secretary that all these required statements will be available for audit by the Secretary, and requires that any such audits by the Secretary are conducted in a confidential manner. The law requires HHS to submit an annual report to relevant House and Senate Committees describing all activities carried out under this section during the previous fiscal year.

B. The Terms of 42 U.S.C. § 289g-2

The NIH Revitalization Act of 1993 limits the requirements of 42 U.S.C. § 289g-1 to federally-funded research on the transplantation of fetal tissue for therapeutic purposes. However the Act also created 42 U.S.C. § 289g-2,⁸³ which much more broadly criminalizes the transfer of human fetal tissue for valuable consideration if the transfer affects interstate commerce. Under 42 U.S.C. § 289g-2, the purpose of the tissue transfer is irrelevant (*i.e.*, it need not occur as part of federally funded research): “[i]t shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce.” Consistent with the NIH panel's

recommendation, “[t]he term [‘]valuable consideration[’] does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.” The penalties for violating the ban include imprisonment for up to 10 years as well as fines no less than twice the amount of the valuable consideration received.

C. GAO Verification Report

The 1993 Act also required the General Accounting Office (GAO) to conduct an audit to determine the extent to which federally-funded research into therapeutic fetal tissue transplants has been conducted in accordance with the requirements set forth in 42 U.S.C. § 289g-1.⁸⁴ The Act also instructed the GAO audit to address the extent to which there have been violations of 42 U.S.C. § 289g-2, but only within the narrow context of federally funded research on the transplantation of fetal tissue for therapeutic purposes, *i.e.*, research that was also subject to 42 U.S.C. § 289g-1.⁸⁵ So, despite 42 U.S.C. § 289g-2’s wide applicability to all transfers of fetal tissue, the 1993 Act only instructed the GAO to evaluate a specific subset of transfers.⁸⁶ The GAO was to complete its audit and provide a report to Congress by no later than May 19, 1995.⁸⁷

On March 10, 1997, the GAO submitted its report to Congress.⁸⁸ In the eight-page report, the GAO noted that NIH had spent roughly six million dollars funding five projects involving therapeutic human fetal tissue research from fiscal years 1993 to 1996.⁸⁹ The GAO report noted that HHS had not complied with its annual Congressional reporting obligations, and had only submitted in 1997 a combined report covering 1993 through 1995.⁹⁰ To verify compliance with the documentary requirements - forms memorializing the informed consent of the donor, the attending physician statement, the principal researcher statement, and the informed consent of the recipient - the GAO checked for the inclusion of the required statements on the forms used by two of the projects, and verified that the properly executed forms were in the project files.⁹¹ The GAO found that the documentation for both of the projects it checked complied with the legal requirements.⁹² It also found that the institutions involved had submitted assurances to NIH that all the required documents were available for audit, and that the institutions involved had submitted assurances to NIH stating that they were in compliance with state law.⁹³ There is no indication that the GAO in any way sought to independently verify the projects’ compliance with state law.

In evaluating whether anyone had violated the prohibition in 42 U.S.C. § 289g-2 on transferring fetal tissue for valuable consideration, GAO merely asked NIH and the funded institutions’ review boards whether any violations had been detected or reported.⁹⁴ GAO claimed “[n]o violations had been reported.”⁹⁵ However, GAO noted that NIH had not conducted any audits on fetal tissue projects, and the review boards rely on self-reporting by the parties involved.⁹⁶ Thus it is unsurprising that no one had detected any violations; no one had looked.

In short, the scope of GAO’s review was quite narrow and the methodology largely relied on self-reporting by those being investigated. GAO undertook no independent analysis of the

projects' compliance with state law, nor did it undertake any efforts to independently verify that any payments involved were not prohibited valuable consideration but rather allowed reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.

Moreover, given that it did not in any way review monetary payments subject to 42 U.S.C. § 289g-2 for transfers that were not also subject to 42 U.S.C. § 289g-1, *i.e.*, it was limited to five federally-funded fetal tissue transplantation research projects and ignored all other fetal tissue transfers in the country, the GAO report cannot reasonably be considered a full review of compliance with 42 U.S.C. § 289g-2, nor of the law's efficacy in general. Accordingly, the report did not provide adequate evidence to determine whether the codified NIH safeguards had actually worked as promised to prevent the development of a market for fetal tissue.

D. Proposed Modification of 42 U.S.C. § 289g-2 to Require Reporting

During Senate debates in October of 1999 about the then-proposed Partial Birth Abortion Act, Senator Bob Smith, (R-NH), raised doubts as to whether 42 U.S.C. § 289g-2 effectively safeguarded against a market for fetal tissue, as intended, or whether its structure functionally created a largely unverifiable loophole allowing for that very result. He had proposed an amendment to require organizations engaged in fetal tissue transfers involving payments to submit documentation to the government in an effort to achieve greater transparency and accountability.⁹⁷ On the floor of the Senate, Senator Smith read 42 U.S.C. § 289g-2's prohibition on transferring fetal tissue for valuable consideration, and said:

It is against the law, ladies and gentlemen, my fellow Americans, and colleagues, it is against the law to do this. . . . But the lawyers went to work, as only lawyers can do. They found a loophole: How can we sell this tissue, make a profit at the expense of this poor woman victim, and get it to research, and hide it all by calling it research? How do we do that without getting caught and getting our tails thrown in jail? That was the question. So they found it in section D(3) which: . . . allows reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue. That is the loophole The wholesaler's technician harvests the organs. Then the clinic "donates" fetal body parts to the wholesaler/harvester, who in turn pays the clinic a "site fee" for access to the aborted babies. Then the wholesaler/harvester "donates" the fetal body parts to the buyer. The buyer then "reimburses" the wholesaler/harvester for the cost of retrieving the fetal body parts. . . . [B]ecause there is no documentation, no disclosure, no government oversight, this section has become a gigantic loophole to allow this industry to engage in the illegal trafficking of body parts of fetal tissue without any

prosecution. . . . [T]he consulting firm of Frost & Sullivan recently reported that the worldwide market for sale in tissue cultures brought in nearly \$428 million in 1996, and they predict that market will continue to expand and will grow at an annual rate of 13.5 percent a year, and by 2002 will be worth nearly \$1 billion. That is a whole lot of money⁹⁸

To address these concerns, Senator Smith proposed an amendment requiring detailed disclosures to the government by the parties involved in fetal tissue transfers:

This amendment allows HHS to track these transfers to enforce current law. . . . It protects the privacy of all women undergoing abortions and the doctors providing them. But this is something that is occurring within the industry. It is a very elaborate network of abortion providers getting those body parts to a wholesaler who then in turn is selling those body parts to universities and other research institutions. [The amendment] simply lets the light in.⁹⁹

Senator Barbara Boxer, (D-CA), who opposed Senator Smith's amendment in the end, had tried to work with him to reach an accommodation to address her concern that disclosure of the clinics involved could lead to violence against those clinics:

I tried very hard to work with my colleague. There is one very serious flaw in his legislation which I fear could escalate the violence at health care clinics all over this country. Now it is illegal in any way to sell fetal tissue. We all support that ban. We have voted on that ban. You cannot sell fetal tissue. The Senator is concerned that this sale, nonetheless, is taking place. He wants certain disclosure as it relates to this issue. . . . [H]e has amended his legislation to deal with some of my problems The one area we couldn't reach agreement on had to do with the identity of the health care facility in which the woman had her legal and safe abortion. That will be subject to disclosure. Anyone could find out through a Freedom of Information request where that clinic is. There have been 33 instances of violence against health care facilities since 1987. . . . I am very fearful [the amendment] could escalate the violence.¹⁰⁰

Senator Smith lost the vote on his amendment, 46 to 51.¹⁰¹

V. **MEDIA AND CONGRESSIONAL INVESTIGATIONS INTO VIOLATIONS OF 42 U.S.C. § 289G-2 IN THE YEAR 2000**

A. **Call for Congressional Investigation**

In November of 1999, the House of Representatives adopted a resolution calling upon Congress to conduct an investigation into whether human fetuses and fetal tissue were being bought and sold in violation of 42 U.S.C. § 289g-2.¹⁰²

The resolution was based on information that came to the attention of Congress indicating that at least one commercial fetal tissue broker had developed a price list for the sale of various fetal body parts, with prices that did not appear on their face to be reflective of differing cost structures and in some cases seemed unreasonably high This price list was for a company named Opening Lines, an entity that acquires human fetal tissue and then provides it to the research community.¹⁰³

After the House resolution was passed, the House Committee on Commerce launched an investigation into whether parties involved in procuring or transferring fetal tissue were operating in compliance with the law.¹⁰⁴ In an apparent reference to the concerns that some in Congress had expressed during the debate over the NIH Revitalization Act of 1993—namely, that the Act’s purported safeguards would not adequately prevent the commercialization of fetal tissue—Representative Tom Coburn, (R-OK), stated: “[T]his is exactly the slippery slope we said we would be going down.”¹⁰⁵

B. **20/20 Hidden-Camera Fetal Tissue Investigation**

On March 8, 2000, the ABC news program *20/20* aired a story about two organizations, Opening Lines and the Anatomic Gift Foundation, both of which obtained fetal tissue from abortion clinics and transferred fetal tissue specimens to researchers.¹⁰⁶ The story featured a hidden-camera investigation, in which a producer for *20/20* posed as a prospective investor and surreptitiously recorded a conversation he had over dinner with the owner of Opening Lines, Dr. Miles Jones.¹⁰⁷ The story also featured two former employees of the companies raising allegations about the companies’ practices.¹⁰⁸

20/20 reported that Dr. Jones had stated he paid an average of \$50 per fetus, plus overhead, but that he could make \$2500 transferring tissue obtained from a single fetus.¹⁰⁹ The hidden-camera recording contained the following exchanges:

20/20 Producer: What does a brain go for? What does a kidney or liver go for?
 Dr. Jones: **It's market force.** It's what can you sell it for.
 ...
 Dr. Jones: That one fetus – the cost of procuring it is the same – whether you get one kidney or you get two kidneys; a lung; a brain; a heart. It's the same cost that you've put into it.
 20/20 Producer: But you keep charging?
 Dr. Jones: Each researcher gets charged.
 20/20 Producer: And each time, that's just money in the bank?
 Dr. Jones: Mmm-hmm.¹¹⁰

The report further stated that Dr. Jones expressed a desire to open his own abortion clinic in Mexico, where he could get a greater supply of fetal tissue by offering cheaper abortions.¹¹¹ On the video, he was shown explaining: "If you can control the flow, it's probably the equivalent of the assembly line."¹¹²

The two former employees raised allegations that the abortion procedures were modified to acquire fetal tissue, that the prices were set to maximize profit rather than recoup legitimate expenses, and that tissue was taken from fetuses even when the women having the abortions had not consented.¹¹³ Although one of the former employees, Dean Alberty, admitted he had been paid \$10,000 by a pro-life group, Life Dynamics, he told 20/20: "I will stand behind my words until I die. I will go in front of Congress, if I have to, and testify under oath."¹¹⁴

C. Hearing by the House Subcommittee on Health

The next day, March 9, 2000, the Subcommittee on Health and the Environment of the House Committee on Commerce held a hearing on the issue titled: "Fetal Tissue: Is It Being Sold in Violation of Federal Law?"¹¹⁵ Dr. Jones had been subpoenaed, but failed to attend and the Committee subsequently unanimously approved a report on contempt against him.¹¹⁶ Among the other witnesses were medical professionals and Mr. Alberty, one of the former employees featured in the 20/20 report.¹¹⁷

The hearing began with seemingly bipartisan affirmation of the importance of pursuing violators of 42 U.S.C. § 289g-2. Congressman Waxman stated:

In 1993, Congress passed important legislation authorizing Federal support of fetal tissue transplantation research. . . . It also established strong criminal penalties for the transfer of any fetal tissue for valuable consideration, whether that tissue was used in either the public or private sector. . . . Where that has occurred, we are all in agreement that the abuses should be stopped and the law should be enforced. We stand ready to join with our colleagues to ask Federal and State authorities to do their job.¹¹⁸

Congresswoman Lois Capps, (D-CA), similarly stated:

If third-party fetal tissue procurement businesses are making a profit from their transactions in clear violation of the law, they must be held accountable and they must be punished. No one on this committee would disagree with that. I would say compelling opening statements attest to our bipartisan and unanimous conviction.¹¹⁹

Congressman Eliot Engel, (D-NY), stated:

[W]e must not confuse the issue before us today. Fetal tissue research must not be compromised because of those who seek to abuse the system. We have laws that need to be enforced, and we have research that needs to be done. Those in violation of the law must be prosecuted, and those conducting research must have access to the tools that allow them to combat the illnesses that afflict so many. I want to commend this Committee for its investigation into the wrongdoings of those seeking to profit from the need for fetal tissue research and reiterate the importance that this research be continued.¹²⁰

The Republican Chairman of the House Committee on Commerce, Science, and the Environment, Congressman Thomas Bliley, (R-VA), stated:

Congress' objectives in this area were threefold: to ensure that fetal tissue could be made available for valuable research purposes, while at the same time preventing the development of a market for such tissue and ensuring that the health of the women undergoing abortions would not be put at risk simply to acquire the tissue. Yet, over the last 7 years, since this bill became the law of the land, there has been no government oversight of any type concerning whether this important law is being followed. We contacted the National Institutes of Health, and it informed us that since the law was passed the agency has not reviewed at all whether the law is being complied with. We contacted the Department of Justice, and their representatives told us the same thing, even though the 1993 law is a criminal statute with criminal enforcement provisions.¹²¹

However, the hearing quickly descended into chaos.¹²² Mr. Alberty had made statements in a documentary video created by Life Dynamics and to *20/20* in which he alleged that his former employer had illegally profited from selling fetal tissue and that abortion procedures were modified to obtain fetal tissue.¹²³ As noted above, he went so far as to tell *20/20* that, even

though he had been paid by the pro-life group: “I will stand behind my words until I die. I will go in front of Congress, if I have to, and testify under oath.”¹²⁴ Yet, when Congressman Waxman confronted Mr. Albery with a sworn affidavit Albery had made, in which he explicitly stated that he had no personal knowledge of any of his former employers receiving compensation in violation of fetal tissue laws and had no knowledge of instances in which a doctor was asked or otherwise decided to perform a different type of abortion procedure solely for the purposes of obtaining fetal tissue, Mr. Albery recanted his allegations.

Mr. Waxman: So your statements under oath seem to contradict your statements that you gave for purposes of a propaganda piece in which you appeared and were paid for appearing by an anti-abortion group. Is that an accurate statement?

Mr. Albery: That is an accurate statement. When I was under oath I told the truth. Anything I said on the video when I’m not under oath, that is a different story.¹²⁵

Mr. Albery stated that he had accepted payment from the pro-life group to make the video because he “needed the money” and that he had told them what he did because “I think that’s what they wanted to hear.”¹²⁶ In response, Congressman Richard Burr, (R-VA), told Mr. Albery: “I found there to be so many inconsistencies in your testimony between that and tapes and testimonies prior to this, whether they were under oath or not under oath, your credibility, as far as this member is concerned, is shot.”¹²⁷

Congressman Waxman stated that the evidence of purported wrongdoing gathered for the hearing was tied to Dr. Jones, who did not attend, and to Mr. Albery, who had recanted.¹²⁸ Thus the Subcommittee did not have adequate information to make an informed decision.¹²⁹ As Congressman Bart Stupak, (D-WI), stated:

[I]t is important to note that the subcommittee has not conducted a whole or proper investigation of this matter. We should be able to easily determine whether companies have made a profit on these transactions. One should be able to acquire their financial records and compare their cost to the amounts that they received for the tissue and determine whether or not they made a profit. It is my understanding that the subcommittee has not received any information about the financial status of Opening Lines or the Anatomic Gift Foundation.¹³⁰

On the morning of the hearing, Congressman Fred Upton spoke with the Deputy Attorney General, Eric Holder, to ask about the Justice Department’s enforcement of the ban on receiving valuable consideration for transferring fetal tissue.¹³¹ The Justice Department reportedly responded that it had not “received any information meeting [its] standards for triggering a formal investigation.”¹³² A bipartisan group of Representatives then wrote to the Justice

Department “requesting that the Justice Department and the Federal Bureau of Investigation conduct a full investigation of Opening Lines, its principals and its current and former employees” to determine if fetal tissue laws had been violated.¹³³ The Justice Department subsequently did investigate Dr. Jones, as well as the Anatomic Gift Foundation, but declined to bring any prosecutions.¹³⁴ While this Committee sought the investigative files relating to these investigations from the Justice Department and FBI in order to understand the respective facts and legal analyses, the Department refused to provide them, except for one FBI document that relayed the Anatomic Gift Foundation’s claim that its indirect costs justified the payments it received.¹³⁵

D. Another Proposed Modification of 42 U.S.C. § 289g-2 to Require Reporting

A week after the hearing, Congressman Coburn introduced the Human Fetal Tissue Reporting and Disclosure Act of 2000.¹³⁶ Similar to Senator Smith’s failed amendment, the bill sought to modify 42 U.S.C. § 289g-2 to require organizations obtaining fetal tissue to make a disclosure statement to the HHS Secretary, while protecting the confidentiality of the women who had the source abortions and the doctors involved.¹³⁷ The bill was referred to the Subcommittee on Health and Environment, where nothing came of it.¹³⁸

E. 2000 GAO Report on Fetal Tissue Research

That same year, the Senate Subcommittee on Labor, Health and Human Services, and Education, a subcommittee of the Committee on Appropriations, asked the GAO to provide information on a number of questions related to fetal tissue research, including: which federal agencies under the Subcommittee’s jurisdiction sponsored biomedical research using human fetal tissue; the costs associated with acquiring human fetal tissue; the extent to which federal human fetal tissue acquisition policies adhered to federal law; and how federal agencies ensured that federally-funded researchers comply with human fetal tissue law.¹³⁹

In response, the GAO reported that the NIH was the only agency under the Subcommittee’s jurisdiction funding fetal tissue research, and that it had spent approximately 17 million dollars on research grants using fetal tissue in fiscal year 1999.¹⁴⁰ GAO’s evaluation of “the costs associated with acquiring human fetal tissue” solely consisted of sending a survey to the relevant recipients of NIH grants to ask how much they paid suppliers for the fetal tissue used in their studies.¹⁴¹ GAO did not attempt to determine whether the organizations from which the grant recipients received the fetal tissue were only charging to recoup their allowed expenses under the statute or whether they were illegally receiving valuable consideration for the fetal tissue.¹⁴²

The GAO report’s opening summary states: “We found that federal human fetal tissue procurement policies and guidance are consistent with federal law.”¹⁴³ However, the basis for this assertion was sparse. The report noted that because neither 42 U.S.C. § 289g-1 nor g-2 have

implementing regulations, “NIH addresses the importance it attaches to these statutory requirements and the criminal penalties that the prohibitions carry through its guidance to its grantee researchers.”¹⁴⁴ The report did not state what that existing guidance was; it merely noted that NIH was going to provide a “forthcoming policy statement” that would emphasize that “the scientific and ethical challenges associated with research utilizing human fetal tissues make it imperative that researchers and their institutions be clearly aware of and in compliance with federal requirements.”¹⁴⁵ Moreover, even assuming that the report had accurately found that the federal policies and guidance are consistent with the law, it failed to evaluate whether actual practices were consistent with those policies and guidance.¹⁴⁶

In addressing how federal agencies ensure compliance with fetal tissue law, the report stated that “[r]eview boards that are established at each institution performing HHS-funded biomedical research have the primary responsibility for ensuring that the procedures for acquiring human fetal tissue comply with federal, state, and local law.”¹⁴⁷ Those review boards rely on self-reported assurances from the researchers involved that they are not violating the law.¹⁴⁸

In short, the 2000 GAO report did not address in any meaningful way whether 42 U.S.C. § 289g-2’s prohibition on transferring fetal tissue for valuable consideration was effectively preventing the commodification of fetal tissue, nor did it address whether any suppliers of fetal tissue were violating the law. Like the 1997 GAO report, it was a fairly superficial and cursory evaluation that did not substantively address the key questions regarding compliance with the law or the law’s efficacy vis-à-vis its intended function.

F. Summary

To sum up the relevant history: the NIH panel’s recommendation that government funding of fetal tissue research would be acceptable public policy was premised on the idea that proposed safeguards could mitigate the attendant ethical issues. Chief among those safeguards was the requirement that it would be illegal to transfer fetal tissue for valuable consideration. Congress codified the NIH recommendations under the explicit understanding that the strict enforcement of the safeguards would prevent the development of a market in fetal tissue. However, in the years after the law passed, NIH conducted no audits of fetal tissue activities subject to 42 U.S.C. § 289g-1 and the Department of Justice pursued no prosecutions under 42 U.S.C. § 289g-2. It did not even conduct any investigations, except for the two referred to it by a bipartisan group of Congressman.

Congressional critics of the law raised two separate but related concerns. The first was that the law was simply not being enforced. The second was that the parties involved could use accounting shenanigans to apply the exception to the prohibition on valuable consideration, which allows for reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue, in such a way that it became a loophole so large as to render the prohibition meaningless. Both of these issues would

have the same effect, entirely undermining the intended purpose of § 289g-2 and erasing the rationale on which many pro-life legislators had predicated their support of fetal tissue transfers. Subsequent legislative attempts to resolve the problem failed, and the situation has remained unresolved to the present.

VI. THE RECENT CONTROVERSY

On July 14, 2015, a pro-life organization called the Center for Medical Progress (CMP) began releasing a series of undercover videos of encounters with personnel from the Planned Parenthood Federation of America (PPFA), various Planned Parenthood affiliates, StemExpress, and ABR regarding fetal tissue transfers.¹⁴⁹ CMP describes itself as “a group of citizen journalists dedicated to monitoring and reporting on medical ethics and advances” who are opposed to “any interventions, procedures, and experiments that exploit the unequal legal status of any class of human beings.”¹⁵⁰ The series of videos, which also featured interviews with a former StemExpress employee, seemed to raise issues as to whether parties obtaining and transferring fetal tissue were illegally receiving valuable consideration, altering abortion procedures to facilitate fetal tissue acquisition, failing to obtain informed consent, performing partial-birth abortions, and obtaining fetal organs from still-living aborted fetuses.¹⁵¹ Critics subsequently alleged that the videos had been deceptively edited, although a forensic analysis conducted for Planned Parenthood at the direction of its counsel “found no evidence that CMP inserted dialogue not spoken by Planned Parenthood staff.”¹⁵²

The Senate Judiciary Committee began its investigation on July 15, 2015, and Chairman Grassley subsequently sent a series of letters to PPFA, all of the Planned Parenthood affiliates nationwide, StemExpress, ABR, Novogenix, CMP, HHS, and the Department of Justice, seeking more information. Investigative counsel for the Committee then engaged in numerous conversations and meetings with counsel for the respective organizations involved in transferring fetal tissue. In response to the Chairman’s requests for information, the Committee received and reviewed roughly 20,000 pages of documents, including contracts, invoices, cost calculations, internal medical standards and guidelines, technician compensation policies, and tissue procurement logs.¹⁵³

The CMP videos were the impetus for the Committee’s investigation. However, cognizant of the issues surrounding the House Subcommittee on Health’s reliance on undercover videos and former employee statements in 2000, the Committee’s analyses and findings do not rely on the CMP videos, but rather on the documents and information obtained directly from PPFA, Planned Parenthood affiliates, StemExpress, ABR, Novogenix, HHS, and the Department of Justice.¹⁵⁴ Accordingly, criticism of the CMP videos or of the techniques CMP used to create them are generally irrelevant to this report.

A. The Scope of the Committee's Investigation

1. Laws Potentially Violated or in Need of Modification

The potential issues implicated by the activities of those obtaining and transferring fetal tissue, both before and after the CMP videos, implicate a number of laws, including:

- alteration of abortion procedures in order to get fetal tissue, a potential violation of 42 U.S.C. § 289g-1;
- performing partial-birth abortions, a violation of 18 U.S.C. § 1531;
- obtaining organs from still-living aborted fetuses, a violation of 42 U.S.C. § 289g and 18 U.S.C. § 1111; and
- receiving or paying valuable consideration for fetal tissue, a violation of 42 U.S.C. § 289g-2 and possibly § 274e.

However, as noted above, the requirements of 42 U.S.C. § 289g-1 only apply to federally-funded research on the *transplantation* of human fetal tissue for therapeutic purposes. In response to an inquiry from the Committee, HHS informed the Committee that it has not funded or supported any such research since 2007.¹⁵⁵ So, § 289g-1 would not have been applicable to recent fetal tissue transfers. Additionally, proving partial-birth abortions occurred in violation of 18 U.S.C. § 1531 or proving that organs were obtained from still-living aborted fetuses in violation of 42 U.S.C. § 289g and 18 U.S.C. § 1111 would require identifying the particular abortions and/or tissues obtained, and would likely require testimonial evidence from the participants. Pursuing that question is beyond the resources, capabilities, expertise, and legislative fact-gathering purpose of this Committee. As far as 18 U.S.C. § 274e, that law's prohibition on receiving valuable consideration for fetal organs only applies to transfers for transplantation. By contrast, 42 U.S.C. § 289g-2's similar prohibition of transferring fetal tissue for valuable consideration applies regardless of whether the transfer is for transplantation.

Accordingly, the Committee's focus in its investigation was on matters related to 42 U.S.C. § 289g-2, namely, whether the parties involved had received or paid valuable consideration for fetal tissue. Given the centrality of legislators' broad and bipartisan concerns regarding the development of a market for fetal tissue in the history of fetal tissue laws, this seemed an appropriate focus in order to evaluate the efficacy of the existing law and its enforcement or lack of enforcement by the executive branch.

2. Parties Involved

The Committee focused on gathering information from Planned Parenthood and the intermediary tissue companies that acquire fetal tissue from it. Chairman Grassley asked PPFA and all Planned Parenthood affiliates to identify which affiliates had participated in fetal tissue transfers since 2010. In a November 2015 letter, Planned Parenthood's attorneys¹⁵⁶ responded:

During the last five years [2010-2015], four Planned Parenthood affiliates facilitated their patients' donation of fetal tissue for research, and accepted reasonable payments associated with the costs incurred to facilitate such donations. Two others also facilitated these donations but did so while foregoing any reimbursement for their expenses.¹⁵⁷

The attorneys later disclosed a third affiliate that had transferred tissue without payments within the relevant period.¹⁵⁸

The four affiliates Planned Parenthood identified as accepting payments in connection with transferring fetal tissue were:

- Planned Parenthood Mar Monte;
- Planned Parenthood of the Pacific Southwest (formerly Planned Parenthood of San Diego and Riverside Counties);
- Planned Parenthood Northern California (formerly Planned Parenthood Shasta Pacific); and
- Planned Parenthood Los Angeles.

The companies that obtained fetal tissue from these affiliates were:¹⁵⁹

- Advanced Bioscience Resources, Inc.;
- StemExpress, LLC; and
- Novogenix Laboratories, LLC.

The Committee's investigation thus focused on these companies, these Planned Parenthood affiliates, and PPFA.¹⁶⁰

B. Advanced Bioscience Resources, Inc.

Advanced Bioscience Resources, Inc. (ABR) describes itself as "a non-profit corporate foundation established in 1989 under California law to provide biomedical researchers with access to human tissues."¹⁶¹ ABR "specializes in the procurement, preservation, and distribution of both human fetal tissue and full umbilical cord blood for research."¹⁶² ABR does not perform any lab work on fetal tissue, such as stem cell isolation, but rather merely obtains and transfers "unaltered" fetal tissue to its customers.¹⁶³

For the period covering 2005 to the present, ABR informed the Committee that it obtained fetal tissue from two Planned Parenthood affiliates, as well as from seven other independent clinics.¹⁶⁴ Each Planned Parenthood affiliate is itself comprised of a number of individual clinics, and ABR operated at multiple clinics within each affiliate. ABR further claimed to provide fetal tissue specimens to roughly 125 researchers, 40 to 50 of whom it

estimated receive NIH funds.¹⁶⁵ While ABR provided the Committee with its contracts with the Planned Parenthood affiliates, it did not provide the actual signed contracts with its other suppliers, nor did it reveal their identities. ABR did provide what it termed a “Template Healthcare Provider Agreement,” which it claimed was the basis of its contracts with non-Planned Parenthood abortion providers.¹⁶⁶

1. Contracts with Planned Parenthood Affiliates

ABR had contracts for the acquisition of fetal tissue with Planned Parenthood Mar Monte (PPMM) from 1997 to 2010.¹⁶⁷ The first of these contracts was in force from 1997 to 2007, the second from 2007 to 2010.¹⁶⁸ PPMM abruptly terminated the contract in 2010 without explanation.¹⁶⁹ ABR has had similar contracts since 1999 with Planned Parenthood of San Diego and Riverside Counties, which changed its name to Planned Parenthood of the Pacific Southwest (PPPSW) in 2010.¹⁷⁰ One version of ABR’s contracts with PPPSW was in force from 1999 to 2005, another from 2005 to 2010, and a third from 2010 to 2015.¹⁷¹

The contracts set forth the basic framework ABR used to obtain fetal tissue from the Planned Parenthood affiliates. All of ABR’s contracts with the Planned Parenthood affiliates define the term “product of conception” (POC) to mean “any fetal organ or other fetal or placental material taken from the human uterus during an abortion.”¹⁷² The contracts with both affiliates contained the following clause setting forth the basic terms of the agreement:

Planned Parenthood Mar Monte [or Planned Parenthood of the Pacific Southwest, as applicable] will provide, and ABR will pay reasonable costs for, services and facilities (hereinafter collectively “services”) associated with obtaining consents and with the removal of fetal organs from POCs, and their processing, preservation, quality control, transportation, and storage; including appropriate space in which ABR employees can work, disposal services for non-used portions of cadaveric materials, and for seeking consent for donation of tissues and organs from appropriate donors, and maintaining records of such consents so that verification of consent can be supported.¹⁷³

The 1997 version of the contract with PPMM set the payment terms as follows: “The charge to ABR for the services specified in this Agreement in connection with each POC provided to ABR shall be forty-five dollars (\$45.00).”¹⁷⁴ That amount rose to \$55 in the 2007 version of the contract.¹⁷⁵ The 1999 version of ABR’s contract with PPPSW also set the payment at \$45 per POC, which rose to \$55 in the 2005 version, and \$60 in the 2010 version.¹⁷⁶

Although the definition of “POC” in the contract could seem to be interpreted as applying to each individual organ obtained from a given fetus, ABR’s attorneys represented to the

Committee that in performing transfers pursuant to these contracts, ABR paid a flat-fee per aborted fetus, regardless of how many organs or other fetal tissues were obtained, stating:

ABR reimbursed PPMM and PPSW for costs associated with each consenting donor who provided ABR with fetal tissue, maternal blood, cord blood, or a combination of those. The amount reimbursed did not change based on the number or type of fetal tissue specimens or blood obtained from each consenting donor.¹⁷⁷

Thus ABR would pay, for example, \$60 for a single aborted fetus in 2014 regardless of whether it obtained from that fetus one tissue specimen to transfer to its customers or half a dozen.

In addition to these contracts, ABR provided the Committee with a 2012 Addendum to its contract with PPSW.¹⁷⁸ The addendum was to apply to “Regulated Tissue Acquisition” (RTA) and stated that RTA “requires a 2-consecutive-day commitment,” the first of which would involve ABR staff identifying potential candidates for RTA, the second for the actual surgery, acquisition of tissues, and distribution thereof.¹⁷⁹ ABR would require a “clean space” in the clinic as part of the process.¹⁸⁰ The addendum set a fee substantially higher than the normal contract: “The charge to ABR for the services specified in this Addendum in connection for each 2-day RTA Component shall be \$1,000 (one thousand dollars).”¹⁸¹ The contract stated it could be executed in counterparts, and the version provided to the Committee by ABR contained only the ABR official’s signature.¹⁸²

ABR’s attorneys could not confirm to the Committee whether the contract was ever executed, stating: “We explained at the September 3, 2015 meeting that we were unclear whether PPSW executed the January 2012 Addendum as we only had a version executed by [ABR]. However, we confirmed to you that nothing was undertaken under that January 2012 Addendum.”¹⁸³ For its part, PPSW never provided a version of the contract to the Committee.

Moreover, when asked to explain what ABR meant by “Regulated Tissue Acquisition,” ABR’s attorneys responded: “As used in the January 2012 Addendum, Regulated Tissue Acquisition is the same process described at 42 U.S.C. sec. 289g-1.”¹⁸⁴ However, as noted above, NIH asserted to the Committee that there has not been any such § 289g-1 research since 2007 – five years before this addendum.¹⁸⁵ As such, ABR’s explanation of its addendum offering PPSW an additional \$500 a day for tissue acquisition is unconvincing.

A few months after CMP began releasing videos, Planned Parenthood announced it would no longer accept any payments in connection with its fetal tissue transfer programs.¹⁸⁶ As a result, Planned Parenthood presumably no longer accepts payments from ABR for fetal tissue transfers.

2. ABR's Fetal Tissue Technicians

ABR technicians working at the Planned Parenthood clinics obtain the fetuses from the Planned Parenthood staff and then harvest and immediately ship the fetal tissue specimens.¹⁸⁷ The fetal tissue is never stored or otherwise in the possession of ABR.¹⁸⁸ As ABR's attorneys explained: "ABR procurement technicians package and ship all materials obtained from a health care center on the day they are procured. ABR does not engage in cell isolation."¹⁸⁹

Specifically, ABR's technicians are to:

1. Maintain professional contact with medical facility to report daily to ABR the number of potential cases for tissue procurement, surgery start times & other pertinent information
2. Set up for procurement at the medical facilities, review ABR tissue procurement schedule requests
3. At the completion of each surgery, identify and remove requested tissues, place in appropriate media and package according to researcher protocols
4. Prepare shipping boxes for local and out-of-state tissue shipment, according to established protocols
5. Draw blood from appropriate donors, complete lab requisitions for testing
6. Document all information on appropriate forms
7. Maintain frequent communication with medical facility and ABR personnel regarding procurement
8. Assure delivery of packages to FedEx for shipment to various research facilities
9. Fax completed forms as required to ABR
10. Clean up procurement work area before leaving facility¹⁹⁰

As ABR's attorneys stated: "For purposes of actual procurement, ABR's employees primarily work at a counter in each affiliate's laboratory and are able to access various instruments and supplies from the assigned cabinets and/or refrigerators in the lab, or from the basement. ABR personnel may also access common areas as well as the recovery room to draw blood, as necessary."¹⁹¹ As described in greater detail below, the process of obtaining the tissue specimens from the fetus is generally a quick one; it appears a technician can process several fetuses and ship the obtained specimens within a few hours.

ABR pays its technicians by the hour, with no additional bonuses based on obtaining particular fetal tissue specimens.¹⁹² The "Procurement Specialist/Technician Job Description" form ABR provided to the Committee states that the technicians receive "hourly pay [of] \$15" as well as mileage reimbursement and benefits.¹⁹³ In correspondence with the Committee, ABR attorneys wrote: "We again confirm that ABR's procurement technicians are paid an hourly rate,

and that no ABR employee is compensated based on the number or type of fetal tissue or maternal blood collected.”¹⁹⁴

3. Contracts with ABR’s Customers

While ABR declined to provide the Committee copies of executed contracts with its customers, it did provide a sample contract, its fee schedules from 2010 through 2015, and all invoices ABR sent to its customers for fetal tissue specimens in June of 2014. These documents provide substantial, though not complete, information regarding its usual business practices.

ABR’s sample contract language includes a number of assurances to its customers.¹⁹⁵ ABR states: “Any fetal tissues provided to the Facility will be taken from a dead fetus only, i.e., a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.”¹⁹⁶ ABR further includes boilerplate representations that it “will make no payments to anyone for any tissue transferred in connection with this agreement, and . . . all tissue (and any information about the tissue) will be collected and disclosed to the Facility in compliance with applicable laws and regulations.”¹⁹⁷

The sample contract and fee schedules set forth the basic payment structure, at least nominally framing the payments as reimbursements for costs.¹⁹⁸ The initial contract states that the customer “agrees to pay ABR a fee for costs incurred by ABR in providing services in connection with the acquisition of each sample of tissue requested by Facility, to be mutually agreed upon by ABR and Facility in writing upon approval of this agreement.”¹⁹⁹ As detailed in the fee schedules provided to the Committee, ABR charges its customers a “service fee” per specimen, the amount of which varies according to the trimester of the sample. Importantly, ABR separately charges fees for: tissue cleaning; tissue freezing; case report form completion; infectious disease screening; and delivery.²⁰⁰ None of those factors are included in the separate service fee charged for the specimen itself.

As demonstrated by its fee schedules, ABR’s fee per specimen substantially increased from 2010 to 2015:

Trimester	Fee per Specimen ²⁰¹						
	Jan. 2010	Jan. 2011	Jan. 2012	Jan. 2013	Sept. 2013	Jan. 2014	Jan. 2015
2 nd Trimester (13-24 weeks)	\$200	\$220	\$230	\$275	\$300	\$325	\$340
1 st Trimester (8-12 weeks)	\$420	\$450	\$450	\$515	\$515	\$525	\$550

ABR offered no explanation as to why its fees to its customers rose so steeply from 2010 to 2015 despite no corresponding increases in the wages it paid its technicians or in the fees it paid the Planned Parenthood affiliates.

4. Fetal Tissue Transaction Examples

Examining a few sample transactions helps demonstrate how ABR's business operates. In addition to providing the Committee with its contracts with Planned Parenthood affiliates, information about technician pay, customer fee schedules, and all invoices it sent to its customers for fetal tissue specimens in June of 2014, ABR also provided copies of its procurement logs for specimens collected from PPPSW in June of 2014. Both the logs and the invoices include specimen identification numbers. The procurement logs note all the specimens obtained from each fetus, as well as the time at which the fetus was provided to the technician and the time at which the specimens were shipped. As such, cross-referencing all of these materials provides a detailed account of how the fetal tissue transfer process was conducted. The results are illuminating.

For example, on one day in June of 2014, the ABR technician obtained a 20-week-old fetus at a PPPSW clinic.²⁰² From that one fetus, ABR sold its brain to one customer for \$325;²⁰³ both of its eyes for \$325 each (\$650 total) to a second customer;²⁰⁴ a portion of its liver for \$325 to a third customer;²⁰⁵ its thymus for \$325 and another portion of liver for \$325 to a fourth customer;²⁰⁶ and its lung for \$325 to a fifth customer.²⁰⁷ Those fees are merely the service fees for the specimens themselves; ABR separately charged each customer for shipping, disease screening, cleaning, and freezing, as applicable.²⁰⁸ So, from that single fetus, for which ABR paid PPPSW a mere \$60, ABR charged its customers a total of \$2,275 for tissue specimens, plus additional charges for shipping and disease screening.

Fetal Tissue Specimens ABR Transferred From PPPSW 20-Week Fetus (No. xxx201)		
Customer Number	Specimen	Specimen Service Fee
0564	Brain	\$325
0237	Eyes (2)	\$650
0446	Liver	\$325
	Thymus	\$325
0666	Liver	\$325
0159	Lung	\$325
TOTAL:		\$2,275

The procurement logs also document the time of the fetus procurement and the time when the ABR technician shipped the specimens.²⁰⁹ ABR procured the 20-week old fetus described above at 9:00am, and shipped the specimens obtained from it, as well as those from three more fetuses obtained that morning, at 1:00pm.²¹⁰ In fact, during the four hours the ABR technician worked at the PPPSW clinic that day, he or she also obtained, processed, and shipped a total of 20 specimens from four procured fetuses.²¹¹ As a result, ABR charged its customers total specimen service fees of **\$6,825** stemming from that four-hour procurement session.²¹² Once again, that is the total for only the specimen service fees; shipping, disease testing, cleaning, and freezing (where applicable) were subject to separate fees.²¹³ Pursuant to ABR's contract with PPPSW, it paid PPPSW a total of \$240 for procuring those four fetuses.²¹⁴ At ABR's stated \$15 an hour wage for its technician, it paid the technician \$60 for the four-hour session. Thus it appears the total direct costs incurred by ABR would have been \$240 to PPPSW, \$60 to its technician, plus possible small amounts for the technician's mileage reimbursement, supplies, and paperwork.

That fetus was not an isolated example. For instance, on another day in June of 2014, ABR procured a 19-week old fetus from a PPPSW clinic.²¹⁵ From this fetus, ABR sold its brain for \$325 to one customer;²¹⁶ both of its legs for \$650 total to a second customer;²¹⁷ and its thymus and liver for \$325 each to a third customer.²¹⁸ ABR accordingly charged \$1,625 total in specimen service fees for the specimens obtained from this one fetus, which it had paid PPPSW \$60 to procure.

Fetal Tissue Specimens ABR Transferred From PPPSW 19-Week Fetus (No. xxx502)		
Customer Number	Specimen	Specimen Service Fee
0564	Brain	\$325
0613	Lower Limbs (2)	\$650
0673	Liver	\$325
	Thymus	\$325
TOTAL:		\$1,625

Indeed, ABR procured six fetuses from the PPPSW clinic that same morning beginning at 9:00am, and shipped all the specimens obtained from them by 12:30pm.²¹⁹ In total, from the six fetuses processed during those three-and-a-half hours, ABR transferred 16 specimens for total specimen service fees of \$5,200.²²⁰ Again, those specimen service fees do not include fees for shipping, disease testing, cleaning, and freezing, which were separate fees.²²¹ For the six fetuses procured from PPPSW, ABR paid \$360.²²² ABR would have paid its technician \$52.50 for the three-and-a-half hour session.²²³

ABR's procurement model was not limited to the Planned Parenthood clinics with which it worked. ABR similarly processed fetal tissue specimens from its non-Planned Parenthood suppliers.²²⁴ For example, from a 21-week-old fetus with Down Syndrome, which ABR procured in June of 2014 from a non-Planned Parenthood clinic, ABR sold its brain for \$325 to one customer;²²⁵ a portion of its liver for \$325 to a second customer;²²⁶ both of its eyes for \$650 to a third customer;²²⁷ and its leg for \$325, its thymus for \$325, another portion of its liver for \$325, and its skin for \$325 to a fourth customer.²²⁸ In total, ABR charged \$2,600 in specimen service fees to its customers for specimens obtained from this single fetus. While the Committee does not have the underlying contract ABR had with this clinic, ABR's attorneys asserted to the Committee that its fees-per-POC range from \$50 to \$68 with non-Planned Parenthood clinics.²²⁹

Fetal Tissue Specimens ABR Transferred From 21-Week Fetus (No. xxx602)		
Customer Number	Specimen	Specimen Service Fee
0376	Brain (Trisomy 21)	\$325
0477	Liver	\$325
0237	Eyes (2)	\$650
0553	Lower Limb	\$325
	Thymus	\$325
	Liver	\$325
	Skin	\$325
TOTAL:		\$2,600

5. ABR's Purported Cost Justification

The sample transactions above appear to show ABR charging thousands of dollars in fees beyond the actual direct costs it incurred in acquiring, processing, and transferring the fetal tissue. Although ABR's contracts ostensibly framed the payments it received as reimbursements for costs,²³⁰ the Committee learned that ABR did not conduct any actual contemporaneous analysis of its costs in order to determine the justifiable amounts of reimbursement it could charge its customers as fees. In short, it is unrealistic for the company to claim it only received payments to cover its costs, given that it did not even attempt to determine its actual relevant costs at the time it set the rates for those payments. Its attempts to justify the fees after being challenged appear to be *post hoc* rationalizations in an attempt to avoid criminal liability.

In Chairman Grassley's initial letter to ABR in July of 2015, he asked ABR for "a detailed accounting of the costs incurred by ABR" in its transfers of fetal tissue, in an attempt to evaluate ABR's compliance with 42 U.S.C. § 289g-2.²³¹ If the company's fees were actually established only to recover legitimate costs incurred, then ABR should have easily been able to provide the cost analysis it used to determine its fee rates. Yet, as late as September of that year, ABR's attorneys informed Committee investigators that they did not yet have a cost analysis.²³² In fact, ABR subsequently never provided the Committee with any analysis of its costs as related

to individual fetal tissue transfers. Nor did it provide the Committee with an analysis of its costs related to its fetal tissue transfer program as a whole.

Rather, ABR only provided the Committee with an overview of the company's overall annual profits, or lack thereof, from 2009 to 2013.²³³ During those years, ABR's attorneys represented that the company received from \$602,000 to \$666,000 per year in income from tissue transfers, which was roughly half of its total reported income.²³⁴ The attorneys also relayed to the Committee ABR's total annual revenue and its total business costs.²³⁵ ABR's attorneys conceded that ABR had made a profit in 2012, but relayed that ABR had operated slightly in the red from 2009 through 2011 and in 2013.²³⁶ They provided no data for 2014.²³⁷

However, this attempt to use aggregated financial data of the company as a whole to demonstrate compliance with 42 U.S.C. § 289g-2 is invalid. Under that section, *each individual transfer* is subject to the ban on valuable consideration, and the exceptions accordingly apply in regard to the costs of that individual transfer. Aggregated financial data is of limited utility, if any, in attempting to demonstrate that any particular fetal tissue transaction was lawful. The sample fetal tissue transactions above seem to show that ABR received prohibited valuable consideration; ABR has failed to rebut this implication.

C. StemExpress, LLC

StemExpress was founded in 2010 as a for-profit company and describes itself "as a small life sciences company that supports leading research institutions in the United States and internationally—including medical schools, pharmaceutical companies, and federal agencies—to provide stem cells and other human tissue critical to medical research."²³⁸ In three years, the company had impressive revenue growth of more than 1300 percent.²³⁹ According to the company, the majority of its business "involves isolating and purifying cells derived from donated adult tissue and blood."²⁴⁰ StemExpress estimates that "approximately 10 percent [of its business] involves fetal tissue and isolated cells that are manufactured using fetal tissue."²⁴¹ It further claims that "less than one percent of StemExpress's business in 2014 dealt with unaltered fetal tissue."²⁴² Expressing a lack of concern regarding that fact that the company's work raises ethical questions, StemExpress's founder, Cate Dyer, described the company's work in procuring aborted fetuses and transferring fetal tissue as follows: "We're collecting biohazardous waste, discarded waste. [StemExpress technicians] go to a hospital or to a facility that does terminations and collect tissues from those waste products."²⁴³

StemExpress informed the Committee that it acquired fetal tissue from two Planned Parenthood affiliates: Planned Parenthood Mar Monte (PPMM) and Planned Parenthood Northern California (PPNC, previously known as Planned Parenthood Shasta Pacific).²⁴⁴ It also acquired fetal tissue from five independent clinics, located in Arkansas, Arizona, California, Florida, and Washington.²⁴⁵ In response to Committee requests, StemExpress's attorneys provided the Committee with its contracts with the Planned Parenthood affiliates, a range of invoices it received from the affiliates, invoices StemExpress sent its customers, procurement

logs, procurement technician compensation policies, estimates of costs, and other information. Because of the technical aspects of manufactured isolated cells, the Committee's inquiry regarding StemExpress focused on its business in transferring unaltered fetal tissue.

1. Contracts with Planned Parenthood Affiliates

StemExpress's contracts with the Planned Parenthood affiliates set forth the basic framework for its acquisition of fetal tissue from them.²⁴⁶ The company's contracts with both PPMM and PPNC defined "product of conception" as "any fetal organ or other fetal or placental material taken from the human uterus during an abortion."²⁴⁷ The contracts stated:

Planned Parenthood Mar Monte [or PPNC, as applicable] will provide, and StemExpress will pay the reasonable costs for, services and facilities at mutually agreed upon health centers (hereinafter collectively referred to as "services") associated with the following: the removal of fetal organs from POCs; the processing, preservation, quality control, and transportation of the fetal organs; appropriate space in which StemExpress representatives and employees may work; disposal services for non-used portions of cadaveric materials; obtaining maternal bloods; seeking consent for donation of fetal organs and maternal bloods from appropriate donors, and; maintaining records of such consents so that verification of consent can be supported. . . . The reasonable costs associated with the services specified in this Agreement shall be fifty-five dollars (\$55.00) per POC determined in the clinic to be usable, and ten dollars (\$10.00) per maternal blood.²⁴⁸

As with ABR's contracts with Planned Parenthood, the definition of "POC" and the terms of the contract seem to imply that StemExpress might pay \$55 per fetal organ specimen to the clinics. However, StemExpress's attorneys represented to the Committee: "StemExpress was not invoiced by PPSM [sic] and PPMM per specimen. Rather, the PP clinics invoiced StemExpress per POC, which includes placental, cord, or fetal tissue, that are procured for use in medical research."²⁴⁹ Accordingly, similar to ABR, StemExpress would purportedly pay \$55 for a single "useable" aborted fetus regardless of the number of specimens it obtained from the fetus and transferred to its customers. StemExpress reported to the Committee that its payments to Planned Parenthood pursuant to these contracts as of July 2015 were as follows:²⁵⁰

StemExpress Payments to Planned Parenthood Mar Monte Affiliate Clinics For Blood and Tissue Collection Costs (2013 - 2015 YTD)			
	2013	2014	2015 YTD
Annual Payments for Blood	\$ 13,105.00	\$ 14,000.00	\$ 2,600.00
Annual Payments for Tissue	\$ 20,175.00	\$ 24,425.00	\$ 12,370.00
Annual Payments Total	\$ 33,280.00	\$ 38,425.00	\$ 14,970.00

StemExpress Payments to Planned Parenthood Shasta Pacific Affiliate Clinics For Blood and Tissue Collection Costs (2013 - 2015 YTD)			
	2013	2014	2015 YTD
Annual Payments for Blood	\$3,820.00	\$2,550.00	\$30.00
Annual Payments for Tissue	\$2,420.00	\$4,290.00	\$715.00
Annual Payments Total	\$6,240.00	\$6,840.00	\$745.00

After the CMP videos were released, StemExpress ended its business relationship with Planned Parenthood.²⁵¹

2. StemExpress's Payments to Its Technicians

As with ABR's technicians, StemExpress's technicians working at Planned Parenthood were located onsite to obtain fetal tissue specimens from procured fetuses.²⁵² Unaltered fetal tissues were packaged and shipped on the same day they were collected.²⁵³ At the clinics, "StemExpress personnel were typically provided with access to (1) an office and/or work room to perform their administrative functions, including paperwork related to procurement and shipping; and (2) a counter space made available in the clinic laboratory to procure POCs after termination procedures."²⁵⁴

StemExpress paid its technicians \$15 an hour.²⁵⁵ Unlike ABR, StemExpress also provided technicians "\$50 for the first tissue procured from any given POC" and \$25 per tissue for any additional ones from the same fetus.²⁵⁶ Prior to September 1, 2012, they received \$50 per tissue specimen obtained.²⁵⁷ These bonus payments appear to be valuable consideration paid to the technician for acquiring the fetal tissue and do not appear to be tied to any additional expenses accrued in the process.

3. Example of a StemExpress Fetal Tissue Transaction

Evaluating a sample StemExpress fetal tissue transfer process helps demonstrate StemExpress's business operation. In addition to providing its contracts with Planned Parenthood affiliates and information about its technicians' pay, StemExpress provided the Committee with procurement logs and invoices sent to its customers for sample periods. Unlike ABR, StemExpress's procurement logs do not document the length of time the technician spent obtaining the specimens. However, cross referencing the procurement logs, the customer invoices, and the underlying contracts with Planned Parenthood still provides key information.

For example, in August of 2012, a StemExpress technician obtained a 19-week-old fetus at a PPMM clinic.²⁵⁸ From that one fetus, StemExpress sold its brain for \$250 to one customer;²⁵⁹ its liver for \$250, its thymus for \$250, and its torso skin for \$250 to a second customer.²⁶⁰ Those fees are merely the service fees for the specimens themselves; StemExpress separately charged each of its customers for shipping/delivery, disease screening, cleaning, and freezing, as applicable.²⁶¹ So, from that single fetus, for which StemExpress paid PPMM \$55, StemExpress charged its customers a total of \$1,000 for tissue specimens. The procuring technician was presumably paid \$15 an hour, plus \$200 in bonuses for the four specimens obtained.²⁶² Indeed, within the sample range of procurement logs and invoices the Committee obtained, StemExpress's fee per fetal tissue ranged from \$250 to \$595.²⁶³ But StemExpress reportedly now charges \$595 per sample,²⁶⁴ so at today's prices the total for the specimens obtained from the sample fetus would be \$2,380.

Fetal Tissue Specimens StemExpress Transferred From PPMM 19-Week Fetus (No. 0807120602)		
Invoice Number	Specimen	Specimen Service Fee
1710	Brain	\$250
1701	Liver	\$250
	Thymus	\$250
	Torso Skin	\$250
TOTAL:		\$1,000

4. StemExpress's Purported Cost Justification

As with ABR, the example fetal tissue transfers seem to show StemExpress charging specimen fees far in excess of its actual direct costs. While StemExpress similarly claimed that its payments were only allowable reimbursements for its incurred costs, it also had apparently

not conducted any contemporaneous cost analysis when setting its fee structure. In response to the Committee's request that StemExpress provide a detailed accounting of the costs it incurred in transferring unaltered fetal tissue, StemExpress responded, stating:

StemExpress's modest accounting system does not allow for immediate reporting of revenue or line-item expenses associated with particular types of tissues. . . . StemExpress had manually reviewed records for 2014 and determined that unaltered fetal tissue procured from Planned Parenthood affiliates generated approximately \$50,000 in gross (pre-tax) revenue against expenses in excess of \$75,000. StemExpress charges researchers a fee of roughly \$500 to \$600 for unaltered tissues, but incurs directly associated expenses of approximately \$750 to \$1000 for each procurement. Part of those expenses include the roughly \$30,000 paid to two Planned Parenthood clinics for reasonable costs and expenses Other expenses include compensation paid to StemExpress's tissue procurement personnel and costs associated with training, packaging and ordering supplies, overnight shipping charges, infectious disease screening, and general overhead²⁶⁵

There are several problems with this purported explanation. First, StemExpress's purported breakdown of expenses for each individual transfer is cursory; StemExpress has provided the Committee no evidence to support these conclusory claims. Second, StemExpress stated that fetal tissue transfers constitute 10% of its business, and that unaltered fetal tissue transfers constitute only 1%.²⁶⁶ Yet in subtracting costs from the revenue it gained from transfers of unaltered fetal tissue, it attempts to subtract the entire \$30,000 it paid to Planned Parenthood – an amount that presumably covers costs for both unaltered fetal tissue transferred and fetal tissue used for manufactured isolated cells. If the breakdown of fetal tissue obtained from Planned Parenthood mirrors that of the company's obtained fetal tissue in general – 10% fetal tissue transferred unaltered and 90% used for manufacturing isolated cells – then StemExpress should only count ten percent of the \$30,000 in fees paid to Planned Parenthood, \$3,000, against its income. Third, StemExpress claims that the fees it charges for fetal tissue specimens cover expenses for “overnight shipping [and] infectious disease screening.”²⁶⁷ Yet, the invoices provided clearly show that StemExpress separately charged customers for overnight shipping and infectious disease screening; those were not part of the specimen fee.²⁶⁸ Lastly, StemExpress's attempted aggregation to its entire unaltered fetal tissue transfer business is subject to the same problems as the aggregation approach used by ABR.

D. Novogenix Laboratories, LLC

Novogenix Laboratories, LLC was incorporated in February 2010.²⁶⁹ The company's attorney informed the Committee that from its creation until 2015, it had contracts with 102 clients, all but three of which were labs and academic institutions.²⁷⁰ Beginning in March 2010,

Novogenix had a contract with Planned Parenthood Los Angeles (PPLA) to obtain fetal tissue.²⁷¹ That contract stated:

PPLA agrees to provide Novogenix aborted pregnancy tissue which consists of raw, unmanipulated or unprocessed, biological material/cells (“Specimen” or “Specimens”) from PPLA clients who have undergone an elective abortion during the first or second trimester, are at least 18 years of age or older, and have signed the Donation Consent Form. . . . Novogenix shall use Specimens for cell and stem cell research only. The intended “scope of use” for the Specimens is described in Novogenix’s Research Summary . . . and generally provides that Novogenix will isolate cell types and Specimens and use the sorted cell types to culture organ-specific cell and stem cell lines. . . . Novogenix will reimburse PPLA for reasonable administrative costs associated with the identification of potential donors, as well as the obtaining of informed consent. This amount will be \$45 per donated specimen.²⁷²

Novogenix’s counsel first responded to the Committee’s request for information about the costs it incurred in fetal tissue transfers by generally reporting to the Committee that, overall, the company had operated at a loss from 2012 to 2014.²⁷³ Novogenix counsel later provided a spreadsheet he had produced that was intended to document the costs.²⁷⁴ That spreadsheet clearly applied to the costs Novogenix incurred for manufactured isolated cells rather than just those incurred for transfers of unaltered fetal tissue.²⁷⁵ When the Committee wrote Novogenix’s attorney to request “procurement logs, invoice(s) to Novogenix from PPLA, and invoice(s) to Novogenix’s customers from Novogenix[.]” Novogenix’s attorney informed the Committee that the company had gone out of business, and subsequently produced a spreadsheet that did not include useful specimen identifying information.²⁷⁶ Because Novogenix’s business model focused primarily on stem cell development, rather than on the transfer of unaltered fetal tissue, and because of the difficulties associated with obtaining information from a defunct company, the Committee focused its efforts elsewhere.

E. Planned Parenthood

In contrast to the thousands of dollars in specimen fees ABR and StemExpress charged per aborted fetus, Planned Parenthood’s fees were in the comparably modest range of \$45 to \$60 per aborted fetus.²⁷⁷ As noted in the contract sections quoted above, those fees were purportedly intended to cover the reasonable costs for services and facilities associated with:

- the removal of fetal organs from POCs;
- the processing, preservation, quality control, and transportation of the fetal organs;

- appropriate space in which company representatives and employees may work;
- disposal services for non-used portions of cadaveric materials;
- seeking consent for donation of fetal organs from appropriate donors; and
- maintaining records of such consents so that verification of consent can be supported.²⁷⁸

Moreover, in contrast to ABR, which derives half of its income from tissue transfers, the payments received by Planned Parenthood affiliates are a relatively small fraction of their overall income. As Planned Parenthood reported to the Committee in reference to fetal tissue payments in the first part of 2015²⁷⁹:

- At Planned Parenthood Los Angeles, cost reimbursements to facilitate patients' tissue donation amounted to \$15,750 for the relevant year, as compared to total revenues of \$59,717,927. These payments represented less than 0.027% of PPLA's total revenue.
- At Planned Parenthood Mar Monte, cost reimbursements to facilitate patients' tissue donation amounted to \$18,955 for the relevant year, as compared to total revenues of \$94,422,729. These payments represented less than 0.021% of PPMM's total revenue.

- At Planned Parenthood Northern California, cost reimbursements to facilitate patients' tissue donation amounted to \$1,375 for the relevant year, as compared to total revenues of \$47,268,637. These payments represented less than 0.003% of PPNorCal's total revenue.
- At Planned Parenthood of the Pacific Southwest, cost reimbursements to facilitate patients' tissue donation amounted to \$18,960 for the relevant year, as compared to total revenues of \$57,357,352. These payments represented less than 0.034% of PPSW's total revenue.

Nonetheless, whether Planned Parenthood affiliates broke the law is not dependent on how much of their revenue was derived from fetal tissue. Given Planned Parenthood's key role in transferring aborted fetuses to ABR and StemExpress, and facilitating the fetal tissue transfer industry in general, it is important to evaluate Planned Parenthood's justification for its payments as well.

After the CMP videos were released, Ms. Cecile Richards, the President of the Planned Parenthood Federation of America, repeatedly stated in interviews that the Planned Parenthood affiliates participating in paid fetal tissue transfer programs were only recovering their costs.²⁸⁰ On July 15, 2015, Chairman Grassley wrote to the Planned Parenthood Federation of America, specifically requesting "[a] detailed accounting of the costs incurred by Planned Parenthood's provision of fetal tissue."²⁸¹ A few days later, Chairman Grassley wrote to each of the Planned

Parenthood affiliates nationwide, requesting “[a] detailed accounting of the costs incurred by [the affiliate’s] provision of fetal tissue, including a specific breakdown of costs associated with tissue collection, preparation, storage, and transportation.”²⁸²

The documents the Committee received in the following months revealed important facts Ms. Richards had omitted from her public defense of Planned Parenthood’s involvement in paid fetal tissue transfers. Specifically, to ensure compliance with the law, PPFA had put in place a policy requiring affiliates to use an independent auditor to conduct an analysis of the actual costs incurred if the affiliates wanted to accept payments for fetal tissue transfers. The policy also stated that the affiliates were required to obtain PPFA’s advance approval for such programs, and that PPFA would monitor the programs as part of the affiliates’ re-certification process. However, the documents provided also showed that the affiliates ignored the policy. When PPFA discovered this in 2011, it curtailed its oversight of affiliates’ paid fetal tissue programs rather than exercise that oversight to bring the affiliates back into compliance. In May of 2015, just as it was likely learning of the CMP videos and anticipating the ensuing controversy, PPFA reissued policy guidance to its affiliates to ensure compliance with the law.

1. PPFA’s 2001 Fetal Tissue Policy

In overseeing Planned Parenthood affiliates’ involvement in fetal tissue transfers, PPFA developed a memorandum in 2001 for the affiliates, titled “Federal Regulations for Aborted Pregnancy Tissue Donation Programs.”²⁸³ This 2001 memorandum, which had specific instructions to the affiliates regarding compliance with 42 U.S.C. § 289g-2 and other fetal tissue laws on payments, gave the affiliates two options.²⁸⁴ To ensure their compliance with the law, they could either:

- 1) “recover no costs associated with any aspect of participation in a fetal tissue program,” or
- 2) “employ **an independent auditor to conduct a credible and good-faith analysis of the actual costs** incurred by the affiliate in the transportation, implantation, processing, preservation, quality control, or storage of the fetal tissue.”²⁸⁵

As further explained in that memorandum, affiliates choosing the second option “must maintain careful records of actual tissue donations and of payments received from the researcher or tissue-gathering entity” and “must be able to demonstrate that the payments do not exceed the actual costs of the actual tissue donations.”²⁸⁶

The 2001 memorandum also explained the key role played by PPFA in reviewing Planned Parenthood affiliates’ fetal tissue payment arrangements:

PPFA accreditation reviews will confirm . . . that one of these two ways [*i.e.*, accepting no payments or having costs determined by an

independent auditor] has been employed by any affiliate that chooses to participate in aborted pregnancy tissue donation programs.²⁸⁷

Similarly, as noted in the 2004 version of Planned Parenthood's Manual of Medical Standards and Guidance (PPFA Manual), affiliates initiating a fetal tissue program must request approval from PPFA to do so, and once approved, PPFA "[m]onitoring of affiliate abortal tissue donation programs will take place as part of the affiliate recertification process."²⁸⁸

2. Developments in 2011

The 2001 memo set out affiliates' payment options for fetal tissue programs. As explained in the 2005 version of the PPFA Manual, "[a]ffiliates initiating an abortal tissue donation program **must** request approval for a new service," and:

The wording in the consent for donation of abortal tissue for research has been adopted from federal statute. The consent form language cannot be altered in any way other than to add the affiliate name, address and phone number or other demographic information.²⁸⁹

However, notes from a PPFA meeting on "Aborted Tissue Programs" that took place on January 5, 2011, imply that Planned Parenthood affiliates may have been taking actions relating to their fetal tissue programs without PPFA's advance knowledge.²⁹⁰ According to the notes of this meeting, which was attended by PPFA's legal representatives and medical services department staff:

We recently learned that some affiliates:

1. Are including blood samples along with the aborted tissue
2. Made alterations to the PPFA CHC [the consent form]
3. **Are receiving payments** to cover administrative costs associated with the program²⁹¹

It further appears from the notes that the PPFA personnel in the meeting then gave *post hoc* approval for the inclusion of blood samples and the alteration of the consent forms, stating in listed "follow-up steps" to the meeting that "[i]n the future, [the PPFA attorney] will review aborted tissue CHCs altered by affiliates."²⁹² But there is no mention of PPFA approval of the payments or any indication that the 2001 memorandum was followed. Instead, among the other "next steps" listed are that the 2001 memorandum covering acceptable payments would be "resent to the affiliates that are currently participating in aborted tissue programs" and that the PPFA attorney "will call affiliates that need additional guidance."²⁹³ Moreover, the 2001 memo was to be discussed with the PPFA accreditation personnel.²⁹⁴

In keeping with this, later in January of 2011, Dr. Deborah Nucatola from PPFA, who had attended the meeting, sent an email attaching the 2001 memo to all of the affiliates, “remind[ing] affiliates about the federal law relating to payment for participation in [fetal tissue] programs” to ensure “continuing compliance with the statutes.”²⁹⁵ As noted above, that 2001 memo required the affiliates to either accept no payments or use an independent auditor to prove costs. Moreover, the PPFA Manual required affiliates to get PPFA’s approval to initiate a fetal tissue transfer program. Both the 2001 memo and the PPFA Manual further required PPFA to review and monitor the affiliates’ fetal tissue payment programs as part of the recertification process. But rather than doing so, PPFA seems to have instead changed its Manual in June of 2011.

3. PPFA Stops Monitoring Affiliate Fetal Tissue Programs in Accreditation Reviews

Shortly after Dr. Nucatola sent her letter reminding the affiliates of the need to comply with the law, and after PPFA personnel in the January 2011 meeting stated they would discuss the 2001 memo with PPFA accreditation personnel, PPFA *deleted* the Manual’s requirement that PPFA monitor the affiliates’ fetal tissue programs as part of their recertification process.²⁹⁶ That appears to have been a substantial change in PPFA’s policy on monitoring affiliate fetal tissue payments. In light of the apparent decision to remove PPFA evaluation of affiliates’ fetal tissue payments from the recertification process, it is difficult to see what, if any, effective controls Planned Parenthood had from 2011 to 2015 on affiliate fetal tissue payment programs. In fact, it appears that PPFA not only turned a blind eye to the affiliates’ violations of the fetal tissue policy, but that PPFA altered its own oversight procedures in a way that facilitated the continuation of those affiliates’ practices.

While this report does not rely on the CMP videos, and they are not necessary in order to draw any conclusions, statements by some of the Planned Parenthood personnel in them are consistent with the information described above from Planned Parenthood documents. To be clear, conclusions about this matter were independently drawn from the documents Planned Parenthood provided. Nonetheless, the following exchanges are worth noting. For example, in one of the videos released by CMP, purportedly taken in 2014, CMP asked Dr. Nucatola about the PPFA policy:

CMP: “You don’t by any chance have on you like the PPFA guidelines on tissue procurement or anything like that-”
 Deborah Nucatola, PPFA: “There are no guidelines. . . . No. There are guidelines on research, but there are not guidelines on tissue procurement . . . and there will never be guidelines. . . . There are mechanisms by which contracts can be reviewed and things like that, but there are no guidelines. This is something that the national office is not involved in. For the first few years that it happened, it was treated as research, and then we realized that that was kind of

overkill . . . it just didn't fit into our framework, so we just kind of backed off of that.”

CMP: “Even in terms of compensation and stuff like that?”

Nucatola: “Nothing is written. There's nothing in stone. . . . **We don't have a policy per se, and that is by choice.**”²⁹⁷

A CMP video purportedly taken in February of 2015 also contains the following exchange on fetal tissue programs:

CMP: “What I understand from Deborah is there's not a set PPFA national policy right now? . . .”

Deb Vanderhei, PPFA: “**We are absent a policy and that's relatively intentional**, and the policy that we do have suggests that you just really think about what you're doing, vet your procurement service. . . . If you do decide that you want to engage in remuneration, that you really need to, like, think that through . . . and think ‘*New York Times* headline’ when you're creating your policy.”²⁹⁸

And in another CMP video, purportedly taken in late April of 2015, Ms. Vanderhei confirmed that PPFA does not monitor affiliate fetal tissue program compliance as part of accreditation reviews:

CMP: “I was just thinking in terms of what would work best for everybody and maybe like the safest model to move toward in order to avoid the ‘*New York Times* headline.’ . . .”

Deb Vanderhei, PPFA: “But the truth is, is that some might want to do it for- to increase their revenues, and we can't stop them. So, we only have carrots and sticks.”

CMP: “Really, that's the only control mechanism?”

Deb Vanderhei, PPFA: “Well, we have medical standards and guidelines, and if they want to maintain their, um, you know, **if they want to be a PP [Planned Parenthood], if they want to maintain a franchise, the PP [Planned Parenthood] stamp of approval, they have to comply with the medical standards and guidelines, which tissue donation is not²⁹⁹ part of, and they have to comply with some other things** about, you know, revenue cycles and board diversity and how many people need to be on a board and bylaws and that. **And they get, they have a visit, an accreditation visit, every three years** and they have to comply with those things. **But tissue donation and tissue- tissue donation in particular will never be one of those indicators.**”³⁰⁰

4. Policy Changes in May 2015

Then, in May of 2015, just a few weeks before CMP began releasing its undercover videos, PPFA changed its guidance on fetal tissue programs, removing it from its Manual altogether, placing it on an intranet site, and adding a new section to address fetal tissue payments.³⁰¹

Federal law prohibits the payment or receipt of money or any other form of valuable consideration for fetal tissue, regardless of whether the program to which the tissue is being provided is federally funded or not. There are limited exceptions that allow reimbursement for actual expenses (e.g. storage, processing, transportation, etc.) of the tissue. If an affiliate chooses to accept reimbursement for allowable expenses, it must be able to demonstrate the reimbursement represents its actual costs. PPFA recommends that an affiliate consult with CAPS about steps to take to documents and demonstrate actual costs.³⁰²

After CMP released its videos and the current controversy erupted, the president of PPFA, Ms. Cecile Richards, repeatedly cited this May 2015 guidance to the media to assert—in the present tense—that Planned Parenthood affiliates only receive payments for their actual costs. In a letter Ms. Richards sent to Congressional leadership, she also cited to this May guidance, noting “federal law restricts the reimbursement that Planned Parenthood can receive” for fetal tissue and stating that the PPFA “guidance to [Planned Parenthood] affiliates reflects this,” without noting how recently that guidance was issued.³⁰³ Moreover, her letter did not reference any independent auditors determining these costs, nor did it mention any PPFA accreditation reviews to verify compliance, nor the apparent removal of fetal tissue program review from the PPFA accreditation review process. Rather, her letter merely stated that “the affiliates report” that the payments they received “were intended to recover only their costs.”³⁰⁴

Committee investigators brought all of this to the attention of Planned Parenthood’s attorneys. In an October 2, 2015 letter to them, Chairman Grassley referenced the 2001 PPFA memorandum requiring affiliates to use independent auditors if they wanted to receive payments, and asked whether any such auditors’ reports existed for PPMM, PPNC, PPLA, and PPSW.³⁰⁵ He also noted the referenced role of accreditation reviews in monitoring affiliates’ fetal tissue transfer programs, and asked for copies of those accreditation reviews that evaluated the fetal tissue transfer programs.³⁰⁶

In response, after nearly four months of the Committee seeking Planned Parenthood’s cost documentation, its attorneys acknowledged that its affiliates had apparently failed to follow the procedures PPFA had put in place to ensure affiliate fetal tissue programs comply with the law.³⁰⁷ They wrote: “We have determined that these four affiliates either did not conduct or cannot locate contemporaneous cost analyses, or secure independent audit opinions as articulated

by PPFA’s then-existing guidance.”³⁰⁸ Indeed, the attorneys stated that the affiliates had only actually tried to determine their costs at the insistence of the Committee: “In response to your October 26 letter . . . the affiliates have each performed a good-faith accounting of their costs associated with facilitating fetal tissue donation.”³⁰⁹ A little over a week after Chairman Grassley sent his October 2, 2015 letter, and well before Planned Parenthood substantively responded to it, Planned Parenthood announced it would no longer accept any payments in connection with its fetal tissue transfer programs.³¹⁰

5. Planned Parenthood’s *Post Hoc* Cost Calculations Created in Response to the Committee’s Inquiry

Unsurprisingly, those affiliates’ *post hoc* accounting of their costs associated with facilitating fetal tissue argued that they had done nothing improper.³¹¹ They include a laundry list of purported expenses. While § 289g-2 only allows for reasonable payments associated with “the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue,” Planned Parenthood has sought to invoke that narrow exception to cover the following universe of purported costs:³¹²

NIH Panel’s Recommended Exception to the Ban on Fetal Tissue Payments	289g-2’s Statutory Exception to the Ban on Fetal Tissue Payments
“payment for reasonable expenses occasioned by actual retrieval, storage, preparation, and transportation of the tissues”	“reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue”
Planned Parenthood’s Purported Costs Invoked to Justify the Fetal Tissue Payments it Received	
<p>PPLA: staff time preparing surgical list and internal coordination - front desk, registered nurse; staff time coordinating with Novogenix representative – center manager, front desk, medical assistant; staff time attending morning meetings’ discussion of donation program – center manager, clinician, front desk, licensed vocational nurse, medical assistant, registered nurse, surgical technician; staff time managing and overseeing tissue donation program – medical director, vice president of patient services; supplies/equipment – disposable gloves, disposable masks, laundry, shoe covers, underpads coordination tissue collection and processing – management and general overhead; staff time discussing program with patients, obtaining consent or declination – clinician, medical assistant, registered nurse; staff time preparing, processing, and photocopying consent forms – front desk; registered nurse; supplies and equipment – photocopies, printing, slipsheets; obtaining patient consent for donation – management and general overhead; staff time transferring tissue to Novogenix representative – surgical technician; staff time disposing of unused tissue – surgical technician; staff time invoicing company – administrative assistant for patient services; staff time revising electronic health records – nurse informatics; transportation, preservation, quality control and storage – management and general overhead; use of space by company representative – dedicated work areas, utilities, taxes, depreciation, repairs and maintenance; shared common areas; use of facility space – management and general overhead.³¹³</p>	

PPMM: staff time coordinating and managing patient flow – health services specialist, abortion coordinator; staff time supervising/coordinating with StemExpress Representative – center manager, chief medical office; tissue collection and processing supplies/equipment – disposable gloves, flush solutions, gauze, band-aids; tissue collection and processing operations costs – telephone usage, postage, office supplies, other direct costs; **general administrative and medical overhead;** staff time interpreting consent forms – health services specialist; staff time verifying and signing consent forms – clinician; staff time scanning consent forms – check-out specialist; obtaining patient consent supplies and equipment – photocopies; obtaining patient consent – operations costs; obtaining patient consent - **general administrative and medical overhead;** **transportation,** staff time cleaning StemExpress equipment – health services specialist; staff time invoicing StemExpress – assistant lab manager, accountant; transportation, preservation, quality control, and storage - shipping labels; operations costs, **general administrative and medical overhead;** use of space by StemExpress representative – dedicated work areas, utilities, taxes, depreciation, repairs and maintenance; storage areas.³¹⁴

PPNC: staff time supervising/coordinating with StemExpress Representative – vice president of medical services, center director, abortions services coordinator; coordinating tissue collection and processing operations costs – telephone usage, postage, office supplies, other direct costs; coordinating tissue collection – **general administrative and medical overhead;** staff time verifying and signing consent forms – medical director; staff time scanning consent forms – flow coordinator; obtaining patient consent – **general administrative and medical overhead;** staff time coordinating courier service for StemExpress representative – flow coordinator; staff time screening donated tissue – medical director; staff time invoicing StemExpress – medical services manager; transportation, supplies and equipment – autoclave sterilization indicator tape, autoclave sterilization indicator strip, tubing for sterile instrument transportation; transportation, preservation, quality control, and storage – operation costs, general administrative and medical overhead; use of space by StemExpress representative – dedication work areas, utilities, taxes, depreciation, repairs and maintenance; storage areas; **general administrative and medical overhead.**³¹⁵

PPPSW: staff time communicating with ABR representative prior to collection – front desk, center manager, flow coordinator, medical assistant; staff time supervising/coordinating with ABR representative – center manager, flow coordinator, medical assistant, supplies/equipment for coordinating tissue collection and processing – chucks, disposable gloves, Ziploc bags; **general administrative and medical overhead;** staff time discussing programs with patients, obtaining consent – medical assistant; staff time preparing consent forms, whiteboard, and anonymized consent list – front desk, medical assistant, manager, flow coordinator; staff time sending consent forms to administrative office – front desk; supplies and equipment for obtaining patient consent – photocopies; obtaining patient consent, **general administrative and medical overhead;** extra tissue examination time – medical assistant, flow coordinator; staff time transferring tissue to ABR representative – medical assistant, flow coordinator; staff time managing deliveries, moving boxes, and discarding documents for ABR representative – center manager, medical assistant, front desk; staff time coordinating courier service for ABR representative – front desk, medical assistant, center manager; staff time installing shelf for ABR representative – maintenance; shelf for ABR representative; transportation, preservation, quality control, and storage – **general administrative and medical overhead;** use of space by ABR representatives – dedicated work areas, utilities, taxes, depreciation, repairs, and maintenance; shared common areas; use of facility space – general administrative and medical overhead.³¹⁶

In short, Planned Parenthood has attempted to shoehorn a vast array of indirect or tenuously related costs into § 289g-2's exception, including attributing several thousands of dollars in costs to amorphous "General Administrative & Medical Overhead." As noted above, interpreting § 289g-2's exception this broadly would clearly be at odds with the primary purpose of the law, which is apparent from the legislative history. Any company could simply shift

unrelated costs into such categories to hide actual profits obtained from the transactions - the very scenario Senator Smith described when trying to resolve the issue in 1999.

Accordingly, there is reason to question whether Planned Parenthood fully complied with federal requirements relating to fetal tissue transfer payments. As noted above, when PPFA learned that its affiliates had failed to comply with the policies it had in place to prevent breaking the law, PPFA reportedly contacted the affiliates and then modified PPFA accreditation reviews in a manner that facilitated the continuation of those fetal tissue payments. PPFA's and the affiliates' actions may implicate the federal criminal conspiracy statute, 18 U.S.C. § 371.

F. Continued Lack of Oversight and Enforcement

In 2000, Congressman Bliley referenced the fetal tissue laws within NIH Revitalization Act of 1993, lamenting:

[O]ver the last 7 years, since this bill became the law of the land, there has been no government oversight of any type concerning whether this important law is being followed. We contacted the National Institutes of Health, and it informed us that since the law was passed the agency has not reviewed at all whether the law is being complied with. We contacted the Department of Justice, and their representatives told us the same thing, even though the 1993 law is a criminal statute with criminal enforcement provisions.³¹⁷

Unfortunately, the situation has not changed much since then. While the GAO did nominally conduct reviews in 1997 and 2000, they were cursory and fundamentally too limited to be meaningful evaluations.³¹⁸

Moreover, 42 U.S.C. § 289g-1 required substantial documentation in order to implement the NIH Panel's recommended safeguards for fetal tissue transplantation research. That documentation was to be kept available for audit by the HHS Secretary. As part of this investigation, Chairman Grassley asked HHS how many times the HHS Secretary had exercised his or her authority to conduct audits.³¹⁹ In response, HHS informed the Committee that from the time the law was passed in 1993 through 2007—the last year it applied to any ongoing HHS research—the Secretary *never* conducted a *single* audit.³²⁰

Chairman Grassley also contacted the Department of Justice and FBI to ask how many investigations of possible violations of 42 U.S.C. §§ 289g-1 and g-2 they had undertaken since the laws' enactments, how many of those investigations led to prosecutions, and how many of those prosecutions led to convictions.³²¹ In response, the Justice Department wrote that, since their enactments in 1993, there have been no prosecutions brought under either law.³²² As best as the Department could tell, there had only ever been two investigations for violations of § 289g-2.³²³ Those investigations were related to the companies at issue in the undercover 20/20 video in 2000: one was of the Anatomic Gift Foundation and the other was of Dr. Jones, the

owner of Opening Lines.³²⁴ Chairman Grassley asked for the respective investigative files, to better understand how the Justice Department views the interpretation and enforcement of these laws.³²⁵ While the Justice Department identified two documents relating to the investigation of Dr. Jones, it refused to provide them to the Committee, citing “the Department’s confidentiality interests in internal attorney work product regarding prosecutorial decisions.”³²⁶ The Justice Department had not located any documents from the U.S. Attorney’s office relating to the investigation of the Anatomic Gift Foundation, but included a related FBI document which relayed the company’s purported assertion of its costs, including indirect costs, which it claimed justified the fetal tissue payments it had received.³²⁷

VII. CONCLUSION

The debate in this country over fetal tissue research has been long and contentious, but legislators on both sides of the debate seemed to reach a limited compromise with the NIH Revitalization Act of 1993. When the NIH Panel offered its recommendation about fetal tissue research in 1988, it predicated its recommendation that the government allow such research on the enactment and strict enforcement of particular safeguards, which were intended to address the ethical problems presented:

Prevention of any commercialization in obtaining the fetal tissue would seem an absolute requirement. . . . Payments and other forms of remuneration and compensation associated with the procurement of fetal tissue should be prohibited, except payment for reasonable expenses occasioned by the actual retrieval, storage, preparation, and transportation of the tissues. . . . [C]lear guidelines about what constitutes procurement expenses [are] essential³²⁸

It further recommended that “NIH conduct periodic reviews to ensure that the concerns expressed in this report, as well as other concerns that arise as research progresses, are carefully safeguarded.”³²⁹ And when the Senate moved to pass the bill codifying in part the Panel’s recommendations, the Committee report stated “it is the committee’s intent that the guidelines in this bill be promulgated uniformly in both public and private sectors and monitored by the NIH.”³³⁰ Many legislators voted to support fetal tissue research based on their faith that the safeguards would work; the ban on valuable consideration would be enforced and thus prevent the creation of a market for fetal tissue. As Senator McCain stated: “Only my strong belief that these safeguards are sufficient permit me to vote in favor of lifting this ban.”³³¹ This was the framework the law attempted to establish.

But in the years since, there has been substantial evidence that the executive branch agencies involved have failed to monitor the industry and failed to actively investigate potential criminal violations. During the 14 years when the requirements of 42 U.S.C. § 289g-1 were applicable, the HHS Secretary did not conduct a single audit of the parties involved.³³² For the entire 23 years the prohibition in 42 U.S.C. § 289g-2 on transferring fetal tissue for valuable

consideration has been law, the Department of Justice has only acknowledged two investigations of potential violations – and those only occurred after bipartisan pressure from Congress to do so.³³³

With no executive branch oversight and no meaningful risk of prosecution, the companies involved in transferring fetal tissue have been free to receive substantial payments with impunity, relying on an expansive interpretation of the exception to the ban on buying or selling fetal tissue. Moreover, there is substantial evidence that this unreasonably broad interpretation of the exception to “valuable consideration” has effectively acted as a loophole so wide that it has prevented the law from functioning in accordance with its intended purpose. Unfortunately, because the Department has thus far refused to share the relevant prosecutorial documents from its investigations, the Committee cannot assess whether the Justice Department believes that the cost loophole is too broad to allow any prosecutions under § 289g-2.

The recent controversy appears to confirm the critics’ concerns about the law: companies have charged thousands of dollars for specimens removed from a single aborted fetus; they have claimed the fees they charged only recovered acceptable costs when they had not, in fact, conducted any analysis of their costs when setting the fees; and their *post hoc* accounting rationalizations invoked a bevy of indirect and tenuously related costs in an attempt to justify their fees. To date, the Justice Department has failed to indict any of the parties involved.

In short, legislators who voted for the law based on their belief that the safeguards would function as promised have not seen that faith vindicated. Absent a renewed emphasis on enforcement, or changes in the law itself, the situation is likely to continue. To address this, the Department of Justice should investigate the fetal tissue practices of the Planned Parenthood Federation of America; all the Planned Parenthood affiliates that have engaged in paid fetal tissue transfers within the statute of limitations; Advanced Bioscience Resources, Inc.; Novogenix Laboratories, LLC; and StemExpress, LLC.

¹ JOHANNA SCHOEN, *ABORTION AFTER ROE 75-77* (University of North Carolina Press) (2015).

² Victor Cohn, *Live-Fetus Research Debated: Use of Fetus from Abortion for Research is Debated*, WASHINGTON POST, Apr. 10, 1973, at A1; see SCHOEN, *supra* note 1, at 76. The Los Angeles Times also ran a similar story that day, which noted that the NIH proposal under consideration would allow for funding studies in which aborted fetuses were kept alive for three or four hours by artificial means for scientific experiments. *Keeping Fetuses Alive for Tests Proposed*, LOS ANGELES TIMES, Apr. 10, 1973, at A4.

³ Cohn, *supra* note 2.

⁴ *Id.*

⁵ SCHOEN, *supra* note 1, at 76.

⁶ Victor Cohn, *NIH Vows Not to Fund Fetus Work*, WASHINGTON POST, Apr. 13, 1973, at A1.

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ Victor Cohn, *Scientists and Fetus Research: NIH Ruling May Halt What Some Deem Critical*, WASHINGTON POST, Apr. 15, 1973, at A1.

¹¹ *Id.*

¹² Harold M. Schmeck Jr., *What Price Research?*, NEW YORK TIMES, May 6, 1973, at 18.

¹³ *Id.*

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- ¹⁴ *Id.*
- ¹⁵ *Id.*
- ¹⁶ *Post-Abortion Fetal Study Stirs Storm*, MEDICAL WORLD NEWS, June 8, 1973, at 21.
- ¹⁷ *Id.*
- ¹⁸ *Id.*
- ¹⁹ *Id.*
- ²⁰ Harold M. Schmeck Jr., *Conferees Agree to Ban Research on Live Fetus*, NEW YORK TIMES, June 8, 1974, at 1.
- ²¹ *E.g., Fetal Research, 1974: Examination of the Varying and Somewhat Controversial Issues Involved in Regard to the Ban on Fetal Research Contained in the National Research Act: Hearing Before the Subcommittee on Health of the Senate Committee on Labor and Public Welfare*, 93rd Cong. (1974).
- ²² National Research Act, Pub. L. No. 93-348, 88 Stat. 342 (1974); see Schmeck, *supra* note 12.
- ²³ *Id.*
- ²⁴ National Research Act, Pub. L. No. 93-348, 88 Stat. 342 (1974); see Kenneth Jost, *Fetal Tissue Research: Should We Permit Research on Fetal Tissue Transplants?* CONGRESSIONAL QUARTERLY RESEARCHER, Aug. 16, 1991.
- ²⁵ Schmeck, *supra* note 20.
- ²⁶ See THE NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, DHEW PUB. NO. (OS) 76-127, RESEARCH ON THE FETUS: REPORT AND RECOMMENDATIONS (1975) (hereinafter COMMISSION REPORT).
- ²⁷ Victor Cohn, *Fetal Research Ban Scored*, WASHINGTON POST, Feb. 15, 1975, at A8.
- ²⁸ Victor Cohn, *Research on Living Fetuses Soars, Panel Told*, WASHINGTON POST, Feb. 16, 1975, at A31.
- ²⁹ Jost, *supra* note 24; see COMMISSION REPORT, *supra* note 26.
- ³⁰ *Id.*
- ³¹ D.B. Colen, *Hospital Got Cash for Fetuses: Parents Unaware D.C. General Got Money for Fetuses*, WASHINGTON POST, Feb. 29, 1976, at B1.
- ³² *Id.*
- ³³ Timothy S. Robinson and D.B. Colen, *Jury Probes Sales of Dead Fetuses, Mother's Milk*, THE WASHINGTON POST, Dec. 13, 1976, at B3.
- ³⁴ National Organ Transplant Act, Pub. L. No. 98-507, 90 Stat. 2339 (1984).
- ³⁵ *Id.*
- ³⁶ *Id.*
- ³⁷ Health Omnibus Programs Extension of 1988, Pub. L. No. 100-607, 102 Stat. 3048 (1988).
- ³⁸ Health Research Extension Act of 1985, Pub. L. No. 99-158, 99 Stat. 820 (1985).
- ³⁹ *Id.*
- ⁴⁰ *Id.*
- ⁴¹ REPORT OF THE ADVISORY COMMITTEE TO THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH: HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH I (1988).
- ⁴² *Id.*
- ⁴³ *Id.* at 1-2.
- ⁴⁴ *Id.*
- ⁴⁵ *Id.* at 2.
- ⁴⁶ *Id.*
- ⁴⁷ CONSULTANTS TO THE ADVISORY COMMITTEE TO THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH, REPORT OF THE HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH PANEL (1988) (hereinafter NIH CONSULTANTS' REPORT).
- ⁴⁸ *Id.* at 1.
- ⁴⁹ *Id.* at 2.
- ⁵⁰ *Id.* at 4.
- ⁵¹ *Id.* at 4, 10.
- ⁵² *Id.* at 3.
- ⁵³ *Id.* at transmittal letter, 9.
- ⁵⁴ *Id.* at 10.
- ⁵⁵ *Id.* at 4.
- ⁵⁶ *Id.* at transmittal letter.
- ⁵⁷ COMM. ON LABOR AND HUMAN RESOURCES, REPORT: NATIONAL INSTITUTES OF HEALTH REVITALIZATION ACT OF 1993, S. REP. NO. 103-2, at 13 (1993) (hereinafter NIH ACT COMM. REPORT).
- ⁵⁸ *Id.*
- ⁵⁹ Gary Silverman, *Sullivan Extends Ban on Fetal Tissue Research*, UPI, Nov. 2, 1989.

- ⁶⁰ *Id.*
- ⁶¹ NIH Revitalization Amendments of 1991, H.R. 2507, 102nd Cong. (1991).
- ⁶² 138 Cong. Rec. H3842-02 (1992) (statement of Rep. John Cox).
- ⁶³ *Id.* (statement of Rep. Connie Morella).
- ⁶⁴ 138 Cong. Rec. S4759-02 (1992) (statement of Sen. John McCain).
- ⁶⁵ NIH Revitalization Amendments of 1991, H.R. 2507, 102nd Cong. (1991) (Roll Call Vote No. 229).
- ⁶⁶ *Id.* (Record Vote No. 66).
- ⁶⁷ *Bush Vetoes Fetal Tissue Research Bill*, ASSOCIATED PRESS, June 24, 1992.
- ⁶⁸ *Id.*
- ⁶⁹ *See id.*
- ⁷⁰ *See id.*
- ⁷¹ NIH Revitalization Amendments of 1991, H.R. 2507, 102nd Cong. (1992) (Roll Call Vote No. 229).
- ⁷² *See* President's Memorandum for the Secretary of Health and Human Services: Federal Funding of Fetal Tissue Transplantation Research, 58 Fed. Reg. 7457 (Jan. 22, 1993); *see also* Karen Tumulty and Marlene Cimons, *Clinton Revokes Abortion Curbs: President Ends Ban on Fetal Tissue Research*, LOS ANGELES TIMES, Jan. 23, 1993 (Exhibit 1).
- ⁷³ NIH Revitalization Act of 1993, S. Res. 1 (1993) (enacted).
- ⁷⁴ NIH ACT COMM. REPORT, *supra* note 57, at 14-15.
- ⁷⁵ *Id.* at 2, 15, 23.
- ⁷⁶ NIH Revitalization Act of 1993, S. Res. 1 (1993) (enacted).
- ⁷⁷ *Id.* (Record Vote No. 15).
- ⁷⁸ 139 Cong. Rec. H1099-02 (1993) (statement of Rep. Henry Waxman).
- ⁷⁹ *Id.*
- ⁸⁰ 139 Cong. Rec. H2731-01 (1993) (statement of Rep. Thomas Bliley).
- ⁸¹ *Id.* (statement of Rep. Robert Dorman).
- ⁸² NIH Revitalization Act of 1993, S. Res. 1 (1993) (Roll Call Vote No. 178); *see Clinton Signs Bill Allowing Research with Fetal Tissue*, ST. LOUIS POST-DISPATCH, June 12, 1993.
- ⁸³ 42 U.S.C. § 289g-2 was later amended by the Fetus Farming Prohibition Act of 2006, Pub. L. No. 109-242 (2006). The additions made in 2006 are not particularly relevant to this report, however, they did result in the reordering of some of the lettered subsections of the original version. Accordingly, references to the same sections before and after the amendment may cite different letters.
- ⁸⁴ NIH Revitalization Act of 1993, Pub. L. No. 103-43 (1993).
- ⁸⁵ *Id.*
- ⁸⁶ *Id.*
- ⁸⁷ *Id.*
- ⁸⁸ U.S. GOV'T ACCOUNTING OFFICE, GAO/HEHS-97-61, REPORT TO THE CHAIRMEN AND RANKING MINORITY MEMBERS, COMMITTEE ON LABOR AND HUMAN RESOURCES, U.S. SENATE, AND COMMITTEE ON COMMERCE, HOUSE OF REPRESENTATIVES: NIH-FUNDED RESEARCH - THERAPEUTIC HUMAN FETAL TISSUE TRANSPLANTATION PROJECTS MEET FEDERAL REQUIREMENTS (1997) (hereinafter 1997 GAO REPORT) (Exhibit 2).
- ⁸⁹ *Id.* at 3.
- ⁹⁰ *Id.* at 6.
- ⁹¹ *Id.*
- ⁹² *Id.*
- ⁹³ *Id.*
- ⁹⁴ *Id.*
- ⁹⁵ *Id.*
- ⁹⁶ *Id.*
- ⁹⁷ S. 1692, 106th Cong. (1999) (Proposed Amendment 2324).
- ⁹⁸ 145 Cong. Rec. S12904-01 (1999) (statement of Sen. Bob Smith).
- ⁹⁹ 145 Cong. Rec. S12972-01 (1999) (statement of Sen. Bob Smith).
- ¹⁰⁰ *Id.* (statement of Sen. Barbara Boxer).
- ¹⁰¹ S. 1692, 106th Cong. (1999) (Proposed Amendment 2324) (Record Vote No. 338).
- ¹⁰² H. Res. 350, 106th Cong. (1999); *see* H.R. Rep. No. 106-527 (2000).
- ¹⁰³ H.R. Rep. No. 106-527, at 2 (2000).
- ¹⁰⁴ *Id.* at 2-5.
- ¹⁰⁵ 145 Cong. Rec. H11723-02 (1999) (statement of Rep. Tom Coburn).

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- ¹⁰⁶ 20/20 (ABC News television broadcast Mar. 8, 2000) (Exhibit 3).
- ¹⁰⁷ *Id.*
- ¹⁰⁸ *Id.*
- ¹⁰⁹ *Id.*
- ¹¹⁰ *Id.*
- ¹¹¹ *Id.*
- ¹¹² *Id.*
- ¹¹³ *Id.*
- ¹¹⁴ *Id.*
- ¹¹⁵ *Fetal Tissue: Is It Being Sold in Violation of Federal Law? Hearing before the H. Subcomm. on Health and Environment of the Committee on Commerce*, 106th Cong. (2000) (hereinafter *2000 Fetal Tissue Hearing*); see Alissa J. Rubin, *House to Open Hearing on Fetal Tissue Research Sales: Accusations of Selling Body Parts to Highest Bidder Trouble Mary, Including Legitimate Scientists*, LOS ANGELES TIMES, Mar. 9, 2000.
- ¹¹⁶ *Id.*; see H.R. Rep. No. 106-1047, at 161-62 (2000), (“The Full Committee on Commerce unanimously approved this Report on Contempt against Dr. Miles Jones on March 15, 2000. Dr. Jones subsequently agreed to testify before the Committee, so the Chairman did not forward the Report on Contempt to the full House of Representatives for consideration. However, due to concerns raised by the Federal Bureau of Investigation (FBI)—which launched a criminal inquiry into Dr. Jones’ activities as a result of the Committee’s oversight—the Committee did not re-call Dr. Jones to testify.”)
- ¹¹⁷ *2000 Fetal Tissue Hearing*, *supra* note 115.
- ¹¹⁸ *Id.* (statement of Rep. Henry Waxman).
- ¹¹⁹ *Id.* (statement of Rep. Lois Capps).
- ¹²⁰ *Id.* (statement of Rep. Eliot Engel).
- ¹²¹ *Id.* (statement of Rep. Thomas Bliley).
- ¹²² See Stacey Zolt, *Fetal Tissue Hearing Thrown Into Chaos*, ROLL CALL, Mar. 13, 2000.
- ¹²³ *2000 Fetal Tissue Hearing*, *supra* note 115.
- ¹²⁴ 20/20 (ABC News television broadcast Mar. 8, 2000) (Exhibit 3).
- ¹²⁵ *2000 Fetal Tissue Hearing*, *supra* note 115 (statements of Rep. Henry Waxman and Mr. Dean Albery).
- ¹²⁶ *Id.* (statement of Mr. Dean Albery).
- ¹²⁷ *Id.* (statement of Rep. Richard Burr).
- ¹²⁸ *Id.* (statement of Rep. Henry Waxman).
- ¹²⁹ *Id.*
- ¹³⁰ *Id.* (statement of Rep. Bart Stupak).
- ¹³¹ *Id.* (statement of Rep. Fred Upton).
- ¹³² *Id.*
- ¹³³ *Id.* (statement of Rep. Diane DeGette, introducing the letters into the record).
- ¹³⁴ See Letter from Chairman Grassley, U.S. Senate Committee on the Judiciary, to Attorney General Lynch and FBI Director Comey (Aug. 27, 2015) (hereinafter Chairman Aug. DOJ Letter) (Exhibit 4); Letter from Assistant Attorney General Kadzik to Chairman Grassley, U.S. Senate Committee on the Judiciary (Nov. 5, 2015) (hereinafter DOJ Nov. Letter) (Exhibit 5); Letter from Chairman Grassley, U.S. Senate Committee on the Judiciary, to Attorney General Lynch and FBI Director Comey (Jan. 22, 2016) (hereinafter Chairman Jan. DOJ Letter) (Exhibit 6); Letter from Assistant Attorney General Kadzik to Chairman Grassley, U.S. Senate Committee on the Judiciary (Mar. 18, 2016) (hereinafter DOJ Mar. Letter) (Exhibit 7).
- ¹³⁵ *Id.*
- ¹³⁶ Human Fetal Tissue Reporting and Disclosure Act of 2000, H.R. 3980, 106th Cong. (2000).
- ¹³⁷ *Id.*
- ¹³⁸ *Id.*
- ¹³⁹ U.S. GOV’T ACCOUNTING OFFICE, GAO-01-65R, HUMAN FETAL TISSUE: ACQUISITION FOR FEDERALLY FUNDED BIOMEDICAL RESEARCH 1 (2000) (hereinafter 2000 GAO REPORT).
- ¹⁴⁰ *Id.* at 2.
- ¹⁴¹ *Id.* at 3, 5-6.
- ¹⁴² See *id.*
- ¹⁴³ *Id.* at 2.
- ¹⁴⁴ *Id.* at 7.
- ¹⁴⁵ *Id.*
- ¹⁴⁶ See *id.*

¹⁴⁷ *Id.* at 8.

¹⁴⁸ See 1997 GAO REPORT, *supra* note 88 (Exhibit 2).

¹⁴⁹ See Sandhya Someshekhar and Danielle Paquette, *Undercover Video Shows Planned Parenthood Official Discussing Fetal Organs Used for Research*, WASHINGTON POST, July 14, 2015, available at https://www.washingtonpost.com/politics/undercover-video-shows-planned-parenthood-exec-discussing-organ-harvesting/2015/07/14/ae330e34-2a4d-11e5-bd33-395c05608059_story.html.

¹⁵⁰ THE CENTER FOR MEDICAL PROGRESS – ABOUT US, <http://www.centerformedicalprogress.org/about-us/> (last visited Oct. 2016).

¹⁵¹ See THE CENTER FOR MEDICAL PROGRESS – HUMAN CAPITAL, <http://www.centerformedicalprogress.org/human-capital/> (last visited Oct. 2016).

¹⁵² FUSION GPS, ANALYSIS OF CENTER FOR MEDICAL PROGRESS VIDEOS 2 (2015) (Exhibit 8).

¹⁵³ Although investigative counsel for the Committee met with CMP personnel on one occasion and the Chairman wrote to CMP requesting all the documents and materials CMP created and obtained during its investigation, CMP did not provide any documents to the Committee, citing concerns about ongoing litigation.

¹⁵⁴ In reference to one conclusion drawn from obtained documents, the report does cite to a series of statements within the CMP videos that seem to provide context to the information in the documents. However, the findings stand based on the documents, regardless of whether one credits the video comments.

¹⁵⁵ Letter from Jim R. Esquea, Assistant Secretary for Legislation, U.S. Department of Health and Human Services, to Chairman Ron Johnson, U.S. Senate Committee on Homeland Security and Governmental Affairs I (Nov. 17, 2015) (Exhibit 9); see Letter from Jim R. Esquea, Assistant Secretary for Legislation, U.S. Department of Health and Human Services, to Chairman Chuck Grassley, U.S. Senate Committee on the Judiciary (Aug. 14, 2015) (Exhibit 10).

¹⁵⁶ The Planned Parenthood Federation of America and all the individual Planned Parenthood affiliates are represented by K. Lee Blalack II and his colleagues at O'Melveny & Meyers LLP.

¹⁵⁷ Letter from K. Lee Blalack II, Counsel for Planned Parenthood, to Chairman Grassley, U.S. Senate Committee on the Judiciary (Nov. 9, 2015) (Exhibit 11).

¹⁵⁸ Letter from K. Lee Blalack II, Counsel for Planned Parenthood, to Chairman Grassley, U.S. Senate Committee on the Judiciary (Feb. 26, 2016) (Exhibit 12).

¹⁵⁹ A university also made payments in connection with obtaining fetal tissue from one of the affiliates. However, unlike the companies doing business with the affiliates, the university's payments were not fees numerically tied to the provision of fetuses. Rather, the university paid a portion of the wages for an affiliate employee, who then spent a percentage of his or her time obtaining and transferring tissue. After reviewing the details of the arrangement provided by Planned Parenthood and assessing the likelihood that the arrangement could violate 42 U.S.C. § 289g-2, investigative counsel for the Committee decided not to contact the university to further pursue the matter.

¹⁶⁰ To be sure, this investigation does not constitute a full evaluation of all the parties involved in making or receiving payments in connection with transferring fetal tissue, which is likely a vastly larger network of organizations. Indeed, the Orange County district attorney's office has brought a prosecution against two of the companies that had received fetal tissue from a Planned Parenthood affiliate without making any payments to the affiliate. See Christopher Goffard and Soumya Karlamangla, *Orange County Prosecutors File Suit Against Biological Suppliers, Alleging Unlawful Pricing of Fetal Tissue*, LOS ANGELES TIMES, Oct. 13, 2016, available at <http://www.latimes.com/local/lanow/la-me-ln-fetal-tissue-charges-orange-county-20161012-snap-story.html>.

¹⁶¹ SJC000038 (Exhibit 13).

¹⁶² *Id.*

¹⁶³ Letter from Jonathan E. Lopez, Counsel for ABR, to Chairman Grassley, U.S. Senate Committee on the Judiciary (Nov. 23, 2015) (hereinafter Nov. ABR Letter) (Exhibit 14).

¹⁶⁴ Meeting between Counsel for ABR and Investigative Counsel for the Judiciary Committee (Sept. 3, 2015) (hereinafter ABR Meeting).

¹⁶⁵ *Id.*

¹⁶⁶ SJC00040-41 (Exhibit 15); ABR Meeting, *supra* note 164.

¹⁶⁷ SJC000001-22 (Exhibit 16). The Committee asked ABR for “[a]ll contracts that ABR has had since 2005 with any clinic, entity, or individual relating to the procurement, preparation, and transportation of fetal tissue.” Letter from Chairman Grassley, U.S. Senate Committee on the Judiciary, to Ms. Linda Tracy, President, Advanced Bioscience Resources, Inc. (July 29, 2015) (Exhibit 17). Thus ABR provided the two contracts with PPMM, one from 1997-2007, the other from 2007-10. Whether ABR had a contractual relationship with PPMM prior to the 1997 contract was beyond the scope of this investigation.

¹⁶⁸ SJC000001-22 (Exhibit 16).

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- ¹⁶⁹ SJC000022 (Exhibit 16).
¹⁷⁰ SJC000023-34 (Exhibit 18).
¹⁷¹ *Id.*
¹⁷² *E.g.*, SJC000001 (Exhibit 16).
¹⁷³ *Id.*; SJC000031 (Exhibit 18).
¹⁷⁴ SJC000001 (Exhibit 16).
¹⁷⁵ SJC000004 (Exhibit 16).
¹⁷⁶ SJC000024; SJC000027; SJC000032 (Exhibit 18).
¹⁷⁷ Nov. ABR Letter, *supra* note 163 (Exhibit 14).
¹⁷⁸ SJC000034. (Exhibit 18).
¹⁷⁹ *Id.*
¹⁸⁰ *Id.*
¹⁸¹ *Id.*
¹⁸² *Id.*
¹⁸³ Nov. ABR Letter, *supra* note 163 (Exhibit 14).
¹⁸⁴ *Id.*
¹⁸⁵ Letter from Jim R. Esquea, Assistant Secretary for Legislation, U.S. Department of Health and Human Services, to Chairman Ron Johnson, U.S. Senate Committee on Homeland Security and Governmental Affairs 1 (Nov. 17, 2015) (Exhibit 19).
¹⁸⁶ SJC000231 (Exhibit 20).
¹⁸⁷ *See* Nov. ABR Letter, *supra* note 163 (Exhibit 14).
¹⁸⁸ *Id.*
¹⁸⁹ *Id.*
¹⁹⁰ SJC000045 (Exhibit 21).
¹⁹¹ Letter from Jonathan E. Lopez, Counsel for ABR, to Chairman Grassley, U.S. Senate Committee on the Judiciary (Feb. 25, 2016) (Exhibit 22).
¹⁹² SJC000045 (Exhibit 21).
¹⁹³ *Id.*
¹⁹⁴ Nov. ABR Letter, *supra* note 163 (Exhibit 14).
¹⁹⁵ SJC000049 (Exhibit 23).
¹⁹⁶ *Id.*
¹⁹⁷ *Id.*
¹⁹⁸ *Id.*
¹⁹⁹ *Id.*
²⁰⁰ SJC000050-56 (Exhibit 24).
²⁰¹ *Id.*
²⁰² SJC000330 (Exhibit 25). The procurement log has the date listed in two places. One is printed, which reads "June," and the other is handwritten, which appears to state "JAN." Because the document was provided to the Committee among sequentially dated June logs, the listed donor IDs correspond to June specimen shipments, and the printed date states "June," the Committee staff assesses that the "JAN" handwritten date is an error.
²⁰³ SJC000479 (Exhibit 26).
²⁰⁴ SJC000472 (Exhibit 27).
²⁰⁵ SJC000470 (Exhibit 28).
²⁰⁶ SJC000476 (Exhibit 29).
²⁰⁷ SJC000477 (Exhibit 30).
²⁰⁸ SJC000050-56 (Exhibit 24).
²⁰⁹ *See, e.g.*, SJC000330 (Exhibit 25).
²¹⁰ *Id.*
²¹¹ *Id.*, SJC000470-80 (Exhibits 26-36).
²¹² *Id.*
²¹³ SJC000050-56 (Exhibit 24).
²¹⁴ *See* SJC000031-33 (Exhibit 37).
²¹⁵ SJC000327 (Exhibit 38).
²¹⁶ SJC000464 (Exhibit 39).
²¹⁷ SJC000455 (Exhibit 40).
²¹⁸ SJC000463 (Exhibit 41).

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- ²¹⁹ SJC000327 (Exhibit 38).
- ²²⁰ *See id.*, SJC000455 (Exhibit 40), SJC000458-64 (Exhibits 39, 41-42). The total would have been higher, but there was apparently a shipping error with one fetal liver specimen. SJC000457 (Exhibit 43).
- ²²¹ SJC000050-56 (Exhibit 24).
- ²²² *See* SJC000031-33.
- ²²³ *See* SJC000045 (Exhibit 21).
- ²²⁴ The limited documentation ABR provided the Committee showed it obtaining fetal tissue specimens from fetuses as old as 24-weeks. SJC000488-89 (Exhibit 44).
- ²²⁵ SJC000520 (Exhibit 45).
- ²²⁶ SJC000523 (Exhibit 46).
- ²²⁷ SJC000522 (Exhibit 47).
- ²²⁸ SJC000521 (Exhibit 48).
- ²²⁹ ABR Meeting, *supra* note 164.
- ²³⁰ SJC000049 (Exhibit 23).
- ²³¹ Letter from Chairman Grassley, U.S. Senate Committee on the Judiciary, to Linda Tracy, President, Advanced Bioscience Resources, Inc. (Jul. 29, 2015) (Exhibit 17).
- ²³² Call between Counsel for ABR and Investigative Counsel for the Judiciary Committee (Sept. 2, 2015).
- ²³³ ABR Meeting, *supra* note 164.
- ²³⁴ *Id.*
- ²³⁵ *Id.*
- ²³⁶ *Id.*
- ²³⁷ *Id.*
- ²³⁸ STEM.JUD00000009-11 (Exhibit 49).
- ²³⁹ Denise Grady and Nicholas St. Fleur, *Fetal Tissue From Abortions for Research is Traded in a Gray Zone*, THE NEW YORK TIMES, Jul. 27, 2015, available at <http://www.nytimes.com/2015/07/28/health/fetal-tissue-from-abortions-for-research-is-traded-in-a-gray-zone.html>.
- ²⁴⁰ STEM.JUD00000010 (Exhibit 49).
- ²⁴¹ *Id.*
- ²⁴² *Id.*
- ²⁴³ Grady, *supra* note 239.
- ²⁴⁴ STEM.JUD00000024-25 (Exhibit 50).
- ²⁴⁵ STEM.JUD00000001-6 (Exhibit 51).
- ²⁴⁶ *Id.*
- ²⁴⁷ *Id.*
- ²⁴⁸ *Id.*
- ²⁴⁹ STEM.JUD00000129-131 (Exhibit 52).
- ²⁵⁰ STEM.JUD00000007 (Exhibit 53).
- ²⁵¹ Jennifer Haberkorn, *Human Tissue Firm Cuts Ties with Planned Parenthood*, POLITICO, Aug. 14, 2015, available at <http://www.politico.com/story/2015/08/planned-parenthood-fetal-tissue-company-cuts-ties-videos-121371>.
- ²⁵² STEM.JUD00000130 (Exhibit 52).
- ²⁵³ *Id.*
- ²⁵⁴ STEM.JUD00000132-33 (Exhibit 54).
- ²⁵⁵ STEM.JUD00000596-98 (Exhibit 55).
- ²⁵⁶ *Id.*
- ²⁵⁷ STEM.JUD00000598 (Exhibit 55).
- ²⁵⁸ STEM.JUD00000292 (Exhibit 56); STEM.JUD00000316 (Exhibit 57).
- ²⁵⁹ STEM.JUD00000144 (Exhibit 58).
- ²⁶⁰ STEM.JUD00000140 (Exhibit 59).
- ²⁶¹ *See, e.g.*, STEM.JUD00000140 (Exhibit 59); STEM.JUD00000144 (Exhibit 58).
- ²⁶² From August 6, 2012 to September 1, 2012, technicians received bonuses of \$50 per tissue. STEM.JUD00000598 (Exhibit 60). That policy was then changed to \$50 for the first tissue specimen from an individual fetus and \$25 for each additional tissue specimen from that same fetus. STEM.JUD00000596 (Exhibit 60).
- ²⁶³ *See* STEM.JUD00000167 (Exhibit 61).

²⁶⁴ Danielle Paquette, *'We Lose Money Doing This': Tiny Company Caught In Abortion Debate Takes on Congress*, WASHINGTON POST, May 27, 2016, available at <https://www.washingtonpost.com/news/wonk/wp/2016/05/27/critics-say-theyre-selling-baby-body-parts-they-say-theyre-saving-lives>.

²⁶⁵ STEM.JUD0000009-11 (Exhibit 49).

²⁶⁶ *Id.*

²⁶⁷ *Id.*

²⁶⁸ *See, e.g.*, STEM.JUD00000140 (Exhibit 59); STEM.JUD00000144 (Exhibit 58).

²⁶⁹ Letter from Joshua Levy, Counsel for Novogenix, to Chairman Grassley, U.S. Senate Committee on the Judiciary (Aug. 14, 2015) (hereinafter Novogenix Aug. 14 Letter) (Exhibit 62).

²⁷⁰ *Id.*

²⁷¹ Novo-000009-15 (Exhibit 63).

²⁷² *Id.*

²⁷³ Novogenix Aug. 14 Letter, *supra* note 269 (Exhibit 62).

²⁷⁴ *See* Letter from Joshua Levy, Counsel for Novogenix, to Chairman Grassley, U.S. Senate Committee on the Judiciary (Aug. 24, 2015) (Exhibit 64).

²⁷⁵ *Id.*

²⁷⁶ Letter from Joshua Levy, Counsel for Novogenix, to Chairman Grassley, U.S. Senate Committee on the Judiciary (Mar. 4, 2016) (Exhibit 65).

²⁷⁷ Letter from Cecile Richards, President of Planned Parenthood Federation of America, to Congressional Leadership 5 (Aug. 27, 2015) (hereinafter Richards Letter) (Exhibit 66).

²⁷⁸ *E.g.*, STEM.JUD00000001 (Exhibit 16).

²⁷⁹ Letter from K. Lee Blalack II, Counsel for Planned Parenthood, to Chairman Charles Grassley, U.S. Senate Committee on the Judiciary (Nov. 9, 2015) (hereinafter PPFA Nov. Letter) (Exhibit 67).

²⁸⁰ *E.g.*, *This Week with George Stephanopoulos* (ABC News television broadcast July 29, 2015) (Ms. Richards stated the payments are "actually just the cost of transmitting the material to research institutions").

²⁸¹ Letter from Chairman Grassley, U.S. Senate Committee on the Judiciary, to Cecile Richards, Planned Parenthood Federation of America (July 15, 2015) (Exhibit 68).

²⁸² *E.g.*, Letter from Chairman Grassley, U.S. Senate Committee on the Judiciary, to Planned Parenthood of Los Angeles (July 23, 2015) (Exhibit 69).

²⁸³ PPFA-SEN_JUD-000540-41 (Exhibit 70).

²⁸⁴ *Id.*

²⁸⁵ *Id.* (emphasis added).

²⁸⁶ *Id.*

²⁸⁷ *Id.*

²⁸⁸ PPFA-SEN_JUD-000523-24 (Exhibit 71). The 2005 version similarly stated: "Affiliate aborted tissue donation programs will be monitored as part of the affiliate recertification process." PPFA-SEN_JUD-000529-30 (Exhibit 72).

²⁸⁹ PPFA-SEN_JUD-000529-30 (Exhibit 72).

²⁹⁰ PPFA-SEN_JUD00768 (Exhibit 73).

²⁹¹ *Id.*

²⁹² *Id.*

²⁹³ *Id.*

²⁹⁴ *Id.*

²⁹⁵ PPFA-SEN_JUD-000539-41 (Exhibit 74).

²⁹⁶ *Compare* PPFA-SEN_JUD-000537-38 (Exhibit 75) *and* PPFA-SEN_JUD-00041-42 (Exhibit 76) *with* PPFA-SEN_JUD000529-30 (Exhibit 72).

²⁹⁷ Center for Medical Progress, *Full Footage: Planned Parenthood Uses Partial-Birth Abortions to Sell Baby Parts* (July 14, 2015), <https://www.youtube.com/watch?v=H4UjIM9B9KQ>; Center for Medical Progress, *Top Planned Parenthood Exec: Baby Parts Sales "A Valid Exchange," Can Make "A Fair Amount of Income"* (Sept. 15, 2015), https://www.youtube.com/watch?v=c9EU_02c5bM.

²⁹⁸ Center for Medical Progress, *Full Footage: PPCAPS Deb VanDerhei* (Sept. 15, 2015), <https://www.youtube.com/watch?v=2m7VbmHXwcU>.

²⁹⁹ It is unclear whether Ms. Vanderhei says "not" or "now," which would have different meanings about the status of fetal tissue programs in the PPFA Manual at the time of the video. As explained above, the Manual was apparently modified to remove the section on fetal tissue programs around the time the video was reportedly taken.

Regardless, she then states that monitoring of affiliate tissue donation programs is not part of the PPFA accreditation review.

³⁰⁰ GotNews, *Planned Parenthood Rep Admits Affiliates Can't Stop Harvesting* (Oct. 20, 2015),

https://www.youtube.com/watch?v=_4P3oHI7KFQ

³⁰¹ PPFA's guidance on fetal tissue programs was previously part of Planned Parenthood's Manual of Medical Standards and Guidelines, but was moved in May of 2015 to the PPFA Consortium of Abortion Providers Intranet site. PPFA-SEN_JUD000053-54 (Exhibit 77).

³⁰² PPFA-SEN_JUD000055-56 (emphasis added) (Exhibit 78).

³⁰³ Richards Letter, *supra* note 277 at 5 (Exhibit 66).

³⁰⁴ *Id.* at 6.

³⁰⁵ Letter from Chairman Grassley, U.S. Senate Committee on the Judiciary to Planned Parenthood Federation of America (Oct. 2, 2015) (Exhibit 79).

³⁰⁶ *Id.*

³⁰⁷ PPFA Nov. Letter, *supra* note 279 (Exhibit 67).

³⁰⁸ *Id.* at 3.

³⁰⁹ *Id.*

³¹⁰ Maria L. La Ganga and Michael Muskal, *Planned Parenthood Makes Shift: Group Stops Accepting Payment for Fetal Tissue Used by Medical Researchers*, LOS ANGELES TIMES, Oct. 14, 2015.

³¹¹ See PPFA Nov. Letter, *supra* note 279 (Exhibit 67); PPNC-SEN_JUD-000705-06 (Exhibit 80); PPPSW-SEN_JUD-000129-30 (Exhibit 81); PPLA-SEN_JUD-000159-60 (Exhibit 82); PPMM-SEN_JUD-000408-09 (Exhibit 83).

³¹² *Id.*

³¹³ PPLA-SEN_JUD-000159-60 (Exhibit 82).

³¹⁴ PPMM-SEN_JUD-000408-09 (Exhibit 83).

³¹⁵ PPNC-SEN_JUD-000705-06 (Exhibit 80).

³¹⁶ PPPSW-SEN_JUD-000129-30 (Exhibit 81).

³¹⁷ *2000 Fetal Tissue Hearing*, *supra* note 115 (statement of Rep. Thomas Bliley).

³¹⁸ See 1997 GAO REPORT, *supra* note 88 (Exhibit 2); 2000 GAO REPORT, *supra* note 139.

³¹⁹ Letter from Chairman Grassley, U.S. Senate Committee on the Judiciary, to Sylvia Matthews Burwell, Secretary of the U.S. Department of Health and Human Services (Feb. 22, 2016) (Exhibit 84).

³²⁰ Letter from Jim R. Esquea, HHS Assistant Secretary for Legislation, to Chairman Grassley, U.S. Senate Committee on the Judiciary (Feb. 29, 2016) (Exhibit 85).

³²¹ Chairman Aug. DOJ Letter, *supra* note 134 (Exhibit 4); see Chairman Jan. DOJ Letter, *supra* note 134 (Exhibit 6).

³²² DOJ Nov. Letter, *supra* note 134 (Exhibit 5); DOJ Mar. Letter, *supra* note 134 (Exhibit 7).

³²³ *Id.*

³²⁴ *Id.*

³²⁵ Chairman Jan. DOJ Letter, *supra* note 134 (Exhibit 6).

³²⁶ DOJ Mar. Letter, *supra* note 134 (Exhibit 7).

³²⁷ *Id.*

³²⁸ NIH CONSULTANTS' REPORT, *supra* note 53.

³²⁹ *Id.*

³³⁰ NIH ACT COMM. REPORT, *supra* note 57, at 23.

³³¹ 138 Cong. Rec. S4759-02 (1992) (statement of Sen. John McCain).

³³² Letter from Jim R. Esquea, HHS Assistant Secretary for Legislation, to Chairman Grassley, U.S. Senate Committee on the Judiciary (Feb. 29, 2016) (Exhibit 85).

³³³ DOJ Nov. Letter, *supra* note 134 (Exhibit 5); DOJ Mar. Letter, *supra* note 134 (Exhibit 7).