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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

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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 consequence 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 hy 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 money . . . .[98]

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. Alberty with a sworn affidavit Alberty 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. Alberty 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. Alberty: 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. Alberty 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. Alberty: "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. Alberty, 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 attorneys[156] 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 PPPSW 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 PPPSW.[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 PPPSW 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, PPPSW 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 PPPSW 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 facility[190]

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*
2nd Trimester (13-24 weeks)	$200	$220	$230	$275	$300	$325	$340
1st 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 overhead . . . .[265]

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 2015[279]:

- 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 PPPSW'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 CIIC [the consent form]
> 3. **Are receiving payments** to cover administrative costs associated with the program[291]

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 CIICs 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 not**[299] **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 PPPSW.[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 eannot 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	
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]	

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] essential . . . ."[328]

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.

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[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.*

[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 1 (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 Dornan).
[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).

[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 Many, 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 Alberty).
[126] *Id.* (statement of Mr. Dean Alberty).
[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 tbe 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 1 (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).

[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).

[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).

NOTE:

Many of the exhibits included in this report were obtained from the Planned Parenthood Federation of America, individual Planned Parenthood affiliates, StemExpress, ABR, or Novogenix. The versions of the documents these organizations provided to the Committee contained some redactions. Committee staff made additional redactions to many of the documents in an attempt to protect the privacy of people involved. Committee staff also notified the organizations which of the documents they had provided were being considered for release and offered an opportunity to propose additional redactions. With the exception of one organization that proposed fully redacting all information in all of its documents, the proposed additional redactions were made as requested by the organizations. Accordingly, the enclosed exhibits contain more redactions than the versions originally provided by the organizations and reviewed by the Committee investigators.

Exhibit 1

58 FR 7457, 1993 WL 13149867(Pres.)
Memorandum

Federal Funding of Fetal Tissue Transplantation Research

January 22, 1993

Memorandum for the Secretary of Health and Human Services

On March 22, 1988, the Assistant Secretary for Health of Health and Human Services ("HHS") imposed a temporary moratorium on Federal funding of research involving transplantation of fetal tissue from induced abortions. Contrary to the recommendations of a National Institutes of Health advisory panel, on November 2, 1989, the Secretary of Health and Human Services extended the moratorium indefinitely. This moratorium has significantly hampered the development of possible treatments for individuals afflicted with serious diseases and disorders, such as Parkinson's disease, Alzheimer's disease, diabetes, and leukemia. Accordingly, I hereby direct that you immediately lift the moratorium.

You are hereby authorized and directed to publish this memorandum in the **Federal Register.**

WILLIAM CLINTON

THE WHITE HOUSEWashington, January 22, 1993.

Editorial note: The Secretary of Health and Human Services is publishing a document relating to this memorandum in Part V of this issue. For the President's remarks on signing this memorandum, see p. 85 of the *Weekly Compilation of Presidential Documents.*

End of Document

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Exhibit 2

United States General Accounting Office

GAO

Report to the Chairmen and Ranking Minority Members, Committee on Labor and Human Resources, U.S. Senate, and Committee on Commerce, House of Representatives

March 1997

NIH-FUNDED RESEARCH

Therapeutic Human Fetal Tissue Transplantation Projects Meet Federal Requirements

GAO/HEHS-97-61

Exhibit 2

Exhibit 2

GAO

United States
General Accounting Office
Washington, D.C. 20548

Health, Education, and
Human Services Division

B-276018

March 10, 1997

The Honorable James M. Jeffords
Chairman
The Honorable Edward M. Kennedy
Ranking Minority Member
Committee on Labor and Human Resources
United States Senate

The Honorable Thomas J. Bliley, Jr.
Chairman
The Honorable John D. Dingell
Ranking Minority Member
Committee on Commerce
House of Representatives

Therapeutic human fetal tissue transplantation is a promising area of research that may have application for a broad range of diseases, such as juvenile diabetes and leukemia. Current federally funded research projects use fetal tissue—cells from electively aborted fetuses—to treat patients with Parkinson's disease. Although this research holds promise for treating diseases, concerns have been raised about the acceptance of fetal tissue transplantation; that is, some women might choose to conceive for the sole purpose of aborting their fetuses, so that tissue could be provided to treat family members or to supply fetal material for financial gain.

In March 1988, the Department of Health and Human Services (HHS) imposed a moratorium on the use of federal funds for research projects on therapeutic human fetal tissue transplantation until a panel, appointed by HHS, could study the ethical issues involved.[1] In the fall of 1988, the panel concluded that the use of human fetal tissue in research is acceptable public policy, but the moratorium remained until the President ordered it lifted in January 1993. At the same time, the Secretary, HHS, directed the National Institutes of Health (NIH) to develop interim guidelines for the support and conduct of such research projects "to ensure that federal funding of human fetal tissue transplantation research does not encourage the choice of abortion." In June 1993, the NIH Revitalization Act of 1993 (P.L. 103-43) was enacted, a part of which establishes the conditions under which federally funded therapeutic human fetal tissue transplantation research can take place.[2]

[1]During the moratorium, private funding was used for therapeutic transplantation studies.

[2]The NIH interim guidelines were withdrawn when P.L. 103-43 was enacted.

Exhibit 2

The NIH Revitalization Act of 1993 requires us to carry out a compliance review of research on fetal tissue transplantation conducted or supported by HHS. Specifically, the act requires that we (1) determine compliance with informed consent and other documentation and (2) report on any violations occurring in the acquisition of human fetal tissue for use in transplantation.

To determine compliance with the requirements of the act, we met with federal officials and with project personnel at two institutions awarded grants for federally funded research on therapeutic human fetal tissue transplantation. The federal officials gave us information from NIH's Office for Protection from Research Risks (OPRR),[3] Office of Science Policy, and the National Institute of Neurological Disorders and Stroke (NINDS). This information included project funding and status, as well as institutional procedures for ensuring protection for human subjects.

We visited the project personnel at the University of Colorado Health Sciences Center in Denver, Colorado, and the Mount Sinai Medical Center in New York City, as well as its affiliated site at the University of South Florida in Tampa, Florida.[4] We spoke with the principal investigators and the chairs of the institutional review boards.[5] In addition, we examined documents used for the research projects, including consent forms and statements of the attending physicians. In reviewing such documents, we were mindful of the confidentiality granted to the project participants and of the integrity of the double-blind research methodology. These double-blind research projects were designed so that neither the recipients nor the researchers who evaluate the outcome of the transplant surgery knew which patients were in the experimental group and which in the control group. In our workpapers, we did not record the names of the donors or recipients, nor any of the dates on which the transplantations took place. We reviewed the relevant documents to ensure that the proper number of forms were present and that consent had been obtained on or before the dates that transplantations were performed.

[3]OPRR has the responsibility for ensuring that institutions awarded grants for research on fetal tissue transplantation comply with the act's requirements for informed consent and other human subject protection.

[4]The University of South Florida is "affiliated" because it receives funding from Mount Sinai's NIH award. We needed to visit South Florida because it had relevant documents.

[5]Institutional review boards are responsible for examining research proposals and ongoing studies in order to ensure protection of human subjects from risks. These boards, composed mainly of scientists at institutions doing the research, are required to report to the NIH any violations or unanticipated problems involving risks to subjects.

We conducted our review from October 1996 to December 1996 in accordance with generally accepted government auditing standards.

Results in Brief

In general, the requirements of the act are being complied with. The act's documentation requirements—pertaining to informed consent of donors and "donees" (recipients) and compliance statements made by institutions, researchers, and attendiug physicians—were met. HHS did not submit annual reports on the program's activities, however, as required by the act. But the agency did submit a combined report on January 29, 1997, describing the activities from fiscal years 1993 through 1995.

There have been no reported violations in the acquisition of human fetal tissue for use in transplantation, according to NIH and our verification efforts.

Background

Between fiscal years 1993 and 1996, NIH awarded over $6 million for five extramural projects involving therapeutic human fetal tissue research. Two projects—at the University of Colorado Health Sciences Center and the Mount Sinai Medical Center—involved actual transplantation of fetal tissue. These projects accounted for about $5.9 million of the funds. Both were funded by NINDS, which expects to continue funding these projects in fiscal year 1997. The remaining three projects—at Yale University School of Medicine, University of Colorado Health Sciences Center, and Columbia University College of Physicians and Surgeons—totaling about $280,000, were funded through NIH's National Center for Research Resources (NCRR) grants at General Clinical Research Center (GCRC) sites. For these three projects, funds were not spent to transplant fetal tissue, but to clinically observe Parkinson's patients before and after transplant surgery. (For more detailed funding information, see app. I).

No intramural projects involving therapeutic human fetal tissue transplantation have been funded. At the time of our review, no new projects on therapeutic human fetal tissue transplantation were being proposed for funding by January 1997.

Ongoing Projects Have Complied With the Requirements of the Act

The act contains the following eight requirements for research on human fetal tissue transplantation:

(1) Informed consent of the donor: The woman providing the tissue must make a signed written statement, declaring that she is donating fetal tissue for research, without any restrictions on, or awareness of, who the tissue recipient will be.

(2) Attending physician statement: The physician responsible for obtaining the tissue from the woman involved must make a signed written statement declaring that

- in the case of tissue obtained through an induced abortion, consent for the abortion preceded consent for the tissue donation, the timing of the abortion was not solely for purposes of obtaining the tissue, and the abortion was performed in accordance with state law;
- the woman gave informed consent, as described in (1) above; and
- the donor was given full disclosure of any interest the physician has in the research use of the tissue and any known medical risks and privacy risks associated with the tissue donation.

(3) Principal researcher statement: The individual with the principal responsibility for conducting the research must make a signed written statement indicating awareness that the tissue obtained is human tissue, that it may have been obtained through a spontaneous or induced abortion or a stillbirth,[6] and that it was donated for research purposes. The statement also must indicate that the researcher

- has provided such information to others with responsibilities for the research,
- will obtain written acknowledgment from the tissue recipient of the receipt of such information, and
- has not been involved in the timing of, or method used, in the abortion.

(4) Informed consent of the recipient: The individual to be a recipient of a transplantation of tissue must provide written acknowledgment, as described in (3) above.

[6]Due to concerns about the quality of the tissue, only tissue obtained from induced abortions is used in research on therapeutic human fetal tissue transplantation.

(5) Availability of statements for audit: The head of each agency or entity conducting the research must certify to the Secretary of HHS that the required statements (1 to 4) will be available for audit by the Secretary.

(6) Compliance with state law: The recipients of funding for research on fetal tissue transplantation must agree to conduct research in accordance with applicable state law.

(7) HHS annual report: HHS is required to submit annual reports to the House Committee on Commerce and the Senate Committee on Labor and Human Resources, describing the fetal tissue transplantation activities carried out during the preceding fiscal year and discussing whether those activities were carried out in accordance with the law.

(8) Tissue purchase and donation restrictions: The purchase of human fetal tissue is prohibited. In addition, donated tissue can not be transplanted into a recipient specified by the donor, such as a relative of the donor, nor can a person acquiring tissue pay costs associated with the abortion. Violators are subject to fines or imprisonment or both.

In general, the research projects we reviewed were in compliance with the requirements of the act. See table 1 for a summary of our methodology and findings, which verify compliance.

Table 1: GAO Verification of Compliance With Requirements of the Act

Requirement of the act	Methodology and findings
(1) Informed consent of donor (2) Attending physician statement (3) Principal researcher statement (4) Informed consent of recipient	We checked for the inclusion of the required statements on the forms used by the projects,[a] and verified that the required forms were in the project files and were properly executed. **Documentation for both projects met the requirements of the law.**
(5) Availability of statements for audit	We checked whether the institutions involved in this research had submitted institutional assurances to NIH that covered the audit requirements. **Each institution involved had submitted such an assurance.**
(6) Compliance with state law	We checked whether the institutions involved in this research had submitted institutional assurances to NIH that covered the state law requirements. **Each institution involved had submitted such an assurance.**
(7) HHS annual report	We checked on HHS submission of reports to the Congress. **HHS was not in compliance with the annual requirement. The agency submitted a combined report covering fiscal years 1993-95 in January 1997.**
(8) Tissue purchase and donation restrictions	We checked with NIH's OPRR and the funded institutions' institutional review boards. **No violations had been reported or detected.**

[a]Each project had several participating institutions, but only one institution for each project was listed as the funded institution.

We found that the two research projects on fetal tissue transplantation adhered to the documentation requirements for the protection of human subjects. Our examination of the four forms used by each of the two projects conducting fetal tissue transplantation research indicated that the requirements of the law were met. During our visits to the project sites, we also verified that the forms had been appropriately executed for each project. All of the forms that were required were present, signed, dated, and witnessed.

To date, NIH's OPRR has not performed audits on the two projects conducting fetal tissue transplantation research because there have been no complaints reported. According to OPRR, NIH funds approximately 15,000 studies involving human subjects and OPRR can only carry out about five compliance site visits each year. Therefore, site visits tend to be made to institutions with some indication of problems.

We also found that the Secretary, HHS, had not submitted annual reports to your Committees as required. NIH prepared draft annual reports for fiscal

years 1993, 1994, and 1995 and forwarded them to the Secretary in May 1994, June 1995, and August 1996, respectively. HHS submitted a combined report, covering fiscal years 1993 through 1995, on January 29, 1997.

Agency Comments

A draft of this report was reviewed by NIH officials. They agreed with our findings related to therapeutic human fetal tissue transplantation research. Based on these officials' technical comments, we changed the report where appropriate.

We are sending copies of this report to other interested Members of Congress, and will make copies available to others on request. Please call me on (202) 512-7119 if you or your staff have any questions about the issues discussed above. Other major contributors include Rosamond Katz, Erwin Bedarf, Ann White, and Robert Crystal.

Bernice Steinhardt
Director, Health Services Quality
and Public Health Issues

Exhibit 2

Appendix I

NIH Funding of Award Institutions for Research on Fetal Tissue Transplantation, FYs 1993-96

Award institution	NIH sponsor	FY 1993	FY 1994	FY 1995	FY 1996[a]	Total NCRR FYs 1993-96	Total NINDS FYs 1993-96	Total FYs 1993-96
Yale University School of Medicine								**$213,357**
	NCRR (GCRC)	$97,325	$76,693	$36,007	$3,332	$213,357	[b]	
University of Colorado Health Sciences Center[c]								**3,855,445**
	NINDS	[d]	1,019,956	1,326,627	1,507,573	[b]	3,854,156	
	NCRR (GCRC)	[d]	[d]	1,289	[d]	1,289	[b]	
Columbia University College of Physicians and Surgeons								**66,890**
	NCRR (GCRC)	[d]	[d]	26,424	40,466	66,890	[b]	
Mount Sinai Medical Center[c,e]								**2,028,049**
	NINDS	[d]	[d]	952,070	1,075,979	[b]	2,028,049	
Total		**$97,325**	**$1,096,649**	**$2,342,417**	**$2,627,350**	**$281,536**	**$5,882,205**	**$6,153,741**

[a]Only preliminary information was available for FY 1996.

[b]Total not applicable here.

[c]These funds were used for a research project involving transplant surgery.

[d]No funding.

[e]The University of South Florida was funded through this award.

Source: Office of Science Policy, NIH.

Exhibit 2

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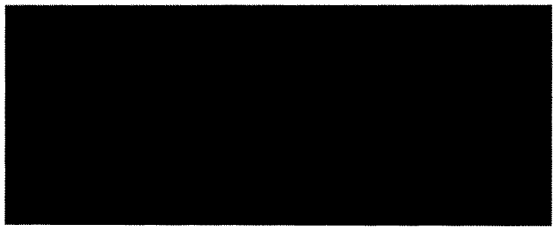

Exhibit 3

FOCUS - 1 of 1 DOCUMENT

Copyright 2000 American Broadcasting Companies, Inc.
ABC NEWS

SHOW: 20/20 WEDNESDAY (10:00 PM ET)

March 8, 2000, Wednesday

TYPE: Profile

LENGTH: 2170 words

HEADLINE: PARTS FOR SALE; PEOPLE MAKE THOUSANDS OF DOLLARS OFF THE SALE OF FETAL BODY PARTS

ANCHORS: CONNIE CHUNG; CHARLES GIBSON

REPORTERS: CHRIS WALLACE

BODY:

PARTS FOR SALE

CONNIE CHUNG, co-host:

Now, a story we guarantee most of you have never heard before. The subject is highly charged and controversial. Behind the scenes of some promising medical research, big money is being made from the sale of fetal body parts. Chief correspondent Chris Wallace has been investigating this story. Chris:

CHRIS WALLACE reporting:

Connie, our hidden camera investigation has found evidence that some businessmen are trafficking in fetuses. One has even put out a price list. And there are claims that some are selling fetuses that women have not even given for research. Here's what can happen when something that is supposed to be used to spur medical breakthroughs is used instead to make money.

(VO) It's a moment too painful to imagine--after getting radiation treatments for cancer, Cindy Smith, a mother of five, learned she was pregnant with twins.

Ms. CINDY SMITH: They basically told me that my children were dying inside me, that I was the only thing keeping them living.

WALLACE: (VO) Cindy decided to end her pregnancy. She says her only comfort came from signing this consent form, giving the fetuses to medical researchers, looking into cures for terrible diseases.

Exhibit 3

Ms. SMITH: What I wanted to do was make something positive out of a horrible situation.

WALLACE: (VO) What she didn't know is that this man would be making money off her twins.

Dr. MILES JONES: If you have a guy that's desperate for, let's say, a heart, then he'll pay you whatever you ask.

WALLACE: (VO) His name is Dr. Miles Jones, and he says he can make big bucks selling human fetuses to researchers.

Dr. JONES: Let's say someone needs feet. Feet are real common. They are not hard to get.

WALLACE: A 20/20 hidden camera investigation has found a thriving industry in which aborted fetuses women donate to help medical research are being marketed for hundreds, even thousands of dollars. We showed what we found undercover to Arthur Caplan, director of the University of Pennsylvania Center for Bioethics.

Mr. ARTHUR CAPLAN: That's trading in body parts, there's no doubt about it.

WALLACE: Turning human fetuses into a commodity.

Mr. CAPLAN: Into a product.

WALLACE: (VO) There's a demand for fetal tissue, because doctors believe it may be the key to medical breakthroughs, cures for Alzheimer's and Parkinson's disease, diabetes and other illnesses. Some researchers use fetal cells, others need whole organs or limbs.

But no one on either side of the abortion debate wants fetal research to become an incentive for abortions. So laws have been passed to draw a clear line. A woman must decide to have an abortion before she's approached to donate the fetus. Abortions can't be altered to get better specimens. And above all, tissue can't be sold for profit. Despite all that, some businessmen have slipped in and turned human fetuses into dollars.

Mr. DEAN ALBERTY: This is purely for profit. Everything was about money.

WALLACE: (VO) Dean Alberty worked for two companies that acted as middle men, getting the fetuses from abortion clinics and shipping tissue to researchers.

Mr. ALBERTY: When I got the fetus, I'd already have a checklist telling me what specific organs they were looking for.

WALLACE: (VO) The law allows tissue companies to recover their costs. This government agency charges $ 100 per shipment. But take a look at what one private company is demanding. Opening Lines put out this price list: $ 325 for a spinal cord, $ 550 for a reproductive organ, $ 999 for a brain. Alberty says he helped put together the price list.

Is there any way to justify these prices?

Mr. ALBERTY: No. There is not.

WALLACE: So what does this price represent?

Mr. ALBERTY: That represents greed.

WALLACE: (VO) Who runs Opening Lines? Dr. Miles Jones, the Missouri pathologist whose company handled Cindy's fetuses. Last year Jones not only mailed out the price list, but also this brochure.

"Fresh fetal tissue harvested and shipped to your specifications where and when you need it."

Exhibit 3

Mr. ALBERTY: That's correct.

Dr. JONES: Pleased to meet you.

Unidentified Woman #1: Nice to meet you.

WALLACE: (VO) We wanted to find out for ourselves how these companies do business. So posing as a prospective investor, a 20/20 producer met with Dr. Jones, who wanted to talk over dinner.

Unidentified 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?

WALLACE: (VO) Over lobster bisque and roast duck, Dr. Jones explained the business of selling human fetuses.

Dr. JONES: We had projections of $ 50,000 a week. And you know, some weeks you can hit that and some weeks you can't. It's just a matter of being able to match supply and demand.

WALLACE: (VO) Dr. Jones said the average specimen costs him just $ 50 plus overhead, but that he charges an average of $ 250. The law only talks about recovering costs. But on a single fetus, Jones said he can make $ 2500.

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.

Producer: But you keep charging?

Dr. JONES: Each researcher gets charged.

Producer: And each time that's just money in the bank?

Dr. JONES: Mm-hmm.

Mr. CAPLAN: It's flat out buying and selling, flat out profiteering. It's flat out saying, 'I'm going to charge you whatever you're going to pay me.'

Dr. JONES: You can't kill the golden goose but you can certainly keep it well fed and it will lay lots of eggs for you.

WALLACE: A human fetus as a golden goose. I know you've been studying this business a long time, but does that shock even you?

Mr. CAPLAN: That kind of blatant, 'I'm going to get the maximum value of mining a fetus,' is--is--it's shocking.

Ms. SMITH: Just from a human standpoint, that's horrific.

WALLACE: (VO) When we told Cindy Smith about Dr. Jones, she also was upset.

Ms. SMITH: I did not donate that thinking ever that someone was going to profit. And that just really bothers me because that's not what I intended at all.

WALLACE: (VO) Alberty says some tissue companies went even further to boost their revenue. He says both companies he worked for, Opening Lines, and this firm, Anatomic Gift Foundation or AGF pressured him to get as much tissue as possible. And at times even told him to take it from fetuses women had not donated for research.

Exhibit 3

Mr. ALBERTY: Miles told me if they're not looking, they're not looking. Why don't you grab that pancreas? Even though it wasn't consented for.

WALLACE: And did you do it?

Mr. ALBERTY: Yes I did.

WALLACE: (VO) That's not all. Alberty alleges that abortions were altered to get better tissue. He says this clinic in Overland Park, Kansas, normally did early abortions with a suction machine. But when the fetus was being donated he says this special syringe was used which experts say puts women through longer more uncomfortable abortions. Where did the clinic get the syringes?

AGF was supplying these special syringes to the clinics?

Mr. ROSS CAPS: That's correct.

WALLACE: (VO) Ross Caps (ph) also worked for AGF. He and nurses who worked at the clinic confirm that women donating fetuses were given different abortions.

If the woman didn't consent, they wouldn't use the special syringe?

Mr. CAPS: No. They only used a special syringe if they knew I wanted the specimen.

WALLACE: (VO) Again, the law says abortions can't be altered to get tissue. Alberty who says he was originally pro-choice, was finally so disturbed by what he saw that he contacted Life Dynamics, a Texas pro-life group that paid him $ 10,000 to be an informant, while he continued to work in the tissue business. But Alberty denies making up stories to push a political agenda.

Why should people believe you? Why shouldn't we believe that there are just some things that you've said that are part of this movement?

Mr. ALBERTY: I will stand behind my words until I die. I will go in front of Congress if I have to and testify under oath.

WALLACE: (VO) But Alberty's allegations are only part of the story. Some of the most troubling evidence we found came from our undercover conversation with Dr. Jones. Here he explains how easy it is to talk a woman into donating a fetus.

Dr. JONES: You can do something that's got all the legal mumbo-jumbo in it and they'll sign it anyway. If you have someone trained to ask properly you can get 80, 90 percent consent rates.

WALLACE: (VO) His dream, he said, is to run bis own clinic in Mexico where he could get a greater supply of fetal tissue by offering cheaper abortions.

Dr. JONES: You can control the flow. It's probably the equivalent of the invention of the assembly line.

WALLACE: (VO) We showed Dr. Jones' comments to Congressman Thomas Bliley, chairman of the House Commerce Committee.

Mr. THOMAS BLILEY: Terrible. Just absolutely terrible.

WALLACE: (VO) After hearing allegations of illegal activity Bliley's committee is now investigating four companies. He says he's found evidence that tissue is being sold for profit.

Exhibit 3

Mr. BLILEY: We are interested in that the people who do this recover their legitimate costs. It appears that it's more than that, that it comes down to trafficking in tissue parts, in body parts.

WALLACE: (VO) Bliley is pro-life, but even the most ardent pro-choice advocates, like Planned Parenthood president, Gloria Feldt, are disturbed by what we found.

Ms. GLORIA FELDT: It seems inappropriate. Totally inappropriate. Where there is wrongdoing, it should be prosecuted. People who are doing that kind of thing should be--should be brought to justice.

WALLACE: (VO) We wanted to talk with some of these fetal tissue businessmen. When we called Dr. Jones for an interview, he hung up on us. But James Bartsly (ph) of AGF, said his nonprofit company recently got out of the business. He maintained his fees, which were lower than Jones', were reasonable and that AGF never asked anyone to take tissue without consent. And he suggested Alberty is angry because AGF sued him over a business dispute.

Did AGF ever encourage doctors to alter the way they did abortions to get specimens?

Mr. JAMES BARTSLY: No. First of all, that would be illegal.

WALLACE: (VO) But wasn't AGF supplying those special syringes to get better tissue?

Mr. BARTSLY: Yeah. That's--that's--that's the logical conclusion that you would draw. I don't believe that was altering the abortion technique.

WALLACE: Doesn't this special syringe add as much as 15 minutes to the length of the abortion?

Mr. BARTSLY: I don't know.

WALLACE: Oh, sure you did.

Mr. BARTSLY: In some cases, perhaps. It takes longer.

WALLACE: (VO) Bartsly later sent us this letter saying the Kansas clinic already used syringes and that AGF provided special ones just to keep tissue sterile. The clinic finally severed its ties with AGF and later Opening Lines, but that came too late for Cindy Smith. All she thinks about is what happened to her twins.

Ms. SMITH: It's just wrong for someone to be making money off the dead. I didn't want somebody to profit off of my heartache. It makes me almost feel like the one good thing I did really wasn't that good after all.

WALLACE: Tomorrow, a congressional subcommittee will hold a hearing on fetal tissue trafficking. And Dean Alberty, the whistleblower from inside the business, will be the star witness. As for Dr. Miles Jones, he's been subpoenaed to testify but has not responded. Investigators say if he fails to show up, Jones could be held in contempt of Congress. Charlie:

CHARLES GIBSON, co-host:

Chris, if there are laws on the books on this subject, why is it still going on? Why hasn't something been done?

WALLACE: It's a question we kept asking in this investigation. We couldn't find anyone in the federal government enforcing those laws which is why tomorrow's hearing is such an important first step.

GIBSON: All right, Chris Wallace thank you very much.

And we'll be right back.

Exhibit 3

Announcer: A car, lights out, speeding the wrong way down the highway. Headed towards certain collision.

Unidentified Woman #2: He's all the way in the left lane. He's traveling the opposite way.

Announcer: But even more outrageous was the mystery of who was driving and who was blamed for the crash. Chief investigative correspondent Brian Ross with suspicions of a cover-up. When 20/20 continues.

(Commercial Break)

Announcer: Strangely different accounts of a deadly head-on crash. Two brothers died. This FBI agent survived and blamed them. But who was speeding the wrong way down the highway that night, were police guilty of a cover up? When 20/20 continues, after this from our ABC stations.

(Commercial Break)

LANGUAGE: English

LOAD-DATE: March 9, 2000

Exhibit 4

CHARLES E. GRASSLEY, IOWA, CHAIRMAN

ORRIN G. HATCH, UTAH
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RICHARD BLUMENTHAL, CONNECTICUT

KOLAN L. DAVIS, Chief Counsel and Staff Director
KRISTINE J. LUCIUS, Democratic Chief Counsel and Staff Director

United States Senate

COMMITTEE ON THE JUDICIARY

WASHINGTON, DC 20510-6275

August 27, 2015

VIA ELECTRONIC TRANSMISSION

The Honorable Loretta Lynch
Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530

The Honorable James B. Comey, Jr.
Director
Federal Bureau of Investigation
935 Pennsylvania Avenue, NW
Washington, DC 20535

Dear Attorney General Lynch and Director Comey:

Over the last two months, the Center for Medical Progress has released a series of videos suggesting that a number of organizations, including Planned Parenthood, have violated laws relating to the acquisition and sale of fetal tissue, as well as the ban on partial-birth abortion. On July 15, 2015, I wrote to Attorney General Lynch regarding the Department's efforts to ensure compliance with the Partial-Birth Abortion Ban Act, 18 U.S.C. § 1531, and I received a generally unresponsive reply letter from Assistant Attorney General Kadzik on August 4, 2015. Today I write regarding the Department's enforcement of 42 U.S.C. § 289g-1 and g-2.

Enacted in 1993, 42 U.S.C. § 289g-2(a) states that "[i]t shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce." The criminal penalties for violating this statute include fines and up to 10 years imprisonment. Also enacted in 1993, 42 U.S.C. § 289g-1 applies to a narrower category of fetal tissue activities than § 289g-2, namely to research conducted or supported by the Department of Health and Human Services relating to the transplantation of human fetal tissue for therapeutic purposes. Within that category, the statute prohibits the "alteration of the timing, method, or procedures used to terminate the pregnancy [if

Exhibit 4

it] was made solely for the purposes of obtaining the tissue" and requires written consent of the patient and a certification by the attending physician.

The Judiciary Committee has initiated an inquiry into the alleged violations of these statutes and the government's enforcement efforts. To assist in the inquiry, please provide the following information by September 3, 2015:

1. Since 1993, how many investigations of possible violations of 42 U.S.C. § 289g-2 have the FBI or other components of the Justice Department initiated? Please provide copies of any such investigative files.

    a. How many of these investigations led to prosecutions? Please provide copies of all prosecution memoranda prepared as a result of any such investigation as well as any related documents deciding whether or not to initiate a prosecution.

    b. How many of these prosecutions resulted in convictions? Please provide the relevant case names and numbers.

2. Since 1993, how many investigations of possible violations of 42 U.S.C. § 289g-1 have the FBI or other components of the Justice Department initiated?

    a. How many of these investigations led to prosecutions? Please provide copies of all prosecution memoranda prepared as a result of any such investigation as well as any related documents deciding whether or not to initiate a prosecution.

    b. How many of these prosecutions resulted in convictions? Please provide the relevant case names and numbers.

3. In March of 2000, an ABC news report on fetal tissue sales featured an undercover video of Dr. Miles Jones, the head of a company that acquired fetal tissue from clinics and resold it to researchers, in which he appeared to discuss over dinner how his business profited from fetal tissue sales. Shortly thereafter, the FBI and the U.S. Attorneys' offices in Kansas and Missouri publicly announced an investigation of the matter, purportedly addressing alleged violations of 42 U.S.C. § 289g-I and 2.[1] In September of 2001, the acting U.S. Attorney for Kansas announced that the investigation was complete and that authorities had determined "there was no violation of federal statutes."[2] Dr. Jones died in 2013.[3]

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[1] *FBI Probes Fetal Tissue Removal at Kansas Clinic*, THE WASHINGTON POST, Mar. 12, 2000.
[2] *Investigation into Marketing of Fetal Tissue Ends*, JEFFERSON CITY NEWS-TRIBUNE, Sep. 2, 2001.
[3] *Obituaries*, THE KANSAS CITY STAR, Feb. 17, 2013.

Exhibit 4

a. Please provide a copy of all materials related to this investigation, including all FD-302s, other witness statements, financial and transactional records obtained, the prosecution memorandum, and all records relating to the decision not to initiate a prosecution.

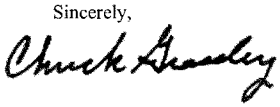
4. Since 1993, how many times have the FBI or other components of the Justice Department received a referral, complaint, or tip alleging possible violation of 42 U.S.C. § 289g-1 or 2?

5. Do the FBI or other components of the Justice Department have any internal guidance documents relating to investigations or prosecutions of violations of 42 U.S.C. § 289g-1 and g-2? If so, please provide copies of any such guidance in existence since 1993.

6. Are the FBI or other components of the Justice Department currently engaged in any active investigations of alleged violations of 42 U.S.C. § 289g-1 or 2? If so, how many, and when was each investigation initiated?

If you have any questions about this request, please contact Patrick Davis of my Committee staff at (202) 224-5225. Thank you for your attention to this important matter.

Sincerely,



Charles E. Grassley
Chairman

Exhibit 5

U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General *Washington, D.C. 20530*

November 5, 2015

The Honorable Charles E. Grassley
Chairman
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

This responds to your letter to the Attorney General dated August 27, 2015, which requested information and documents relating to the Department of Justice's (the Department) law enforcement efforts pursuant to provisions of the Public Health Service Act, set forth in 42 U.S.C. §§ 289g-1 and g-2. We apologize for our delay in responding to your letter.

In response to your request, we have not identified in our case management systems any publically charged case under the provisions of the Public Health Service Act identified in your letter since their enactment in 1993.[1] Please note that our case management systems do not have reliable records of referrals, complaints or tips alleging possible violations of § 289g-2 dating back to 1993. However, we have identified two matters that were investigated pursuant to § 289g-2, but not prosecuted, over a decade ago. One of these matters pertained to the now-deceased individual identified in your letter. After review of the evidence, prosecution was declined in both matters. In response to your request, we are currently processing the available records pertaining to these two matters, and will supplement this response as soon as those efforts are completed.

We have not located any internal guidance documents relating to investigations or prosecutions of 42 U.S.C. §§ 289g-1 or 289g-2. Finally, we are not in a position to answer your question about active investigations that the Department has not previously placed into the public record. This is consistent with the long-standing Department policy that protects the integrity of the criminal justice process, including the confidentiality and privacy interests that are important to our law enforcement efforts.

[1] Though the Public Health Service Act was originally enacted in 1944, its prohibitions regarding human fetal tissue were added to the statute in 1993. Section 289g-1 is titled "Research on Transplantation of Fetal Tissue" and the criminal provisions pertinent to our law enforcement efforts are set forth in 289g-2, which is titled "Prohibitions Regarding Human Fetal Tissue."

Exhibit 5

We hope this information is helpful. Please do not hesitate to contact this office if we may provide additional assistance regarding this or any other matter.

Sincerely,

Peter J. Kadzik
Assistant Attorney General

cc: The Honorable Patrick J. Leahy
Ranking Member

Exhibit 6

CHARLES E. GRASSLEY, IOWA, CHAIRMAN

ORRIN G. HATCH, UTAH
JEFF SESSIONS, ALABAMA
LINDSEY O. GRAHAM, SOUTH CAROLINA
JOHN CORNYN, TEXAS
MICHAEL S. LEE, UTAH
TED CRUZ, TEXAS
JEFF FLAKE, ARIZONA
DAVID VITTER, LOUISIANA
DAVID A. PERDUE, GEORGIA
THOM TILLIS, NORTH CAROLINA

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CHRISTOPHER A. COONS, DELAWARE
RICHARD BLUMENTHAL, CONNECTICUT

KOLAN L. DAVIS, Chief Counsel and Staff Director
KRISTINE LUCIUS, Democratic Chief Counsel and Staff Director

United States Senate

COMMITTEE ON THE JUDICIARY

WASHINGTON, DC 20510-6275

January 22, 2016

VIA ELECTRONIC TRANSMISSION

The Honorable Loretta Lynch
Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530

The Honorable James B. Comey, Jr.
Director
Federal Bureau of Investigation
935 Pennsylvania Avenue, NW
Washington, D.C. 20535

Dear Attorney General Lynch and Director Comey:

On August 27, 2015, I wrote to inquire about the Department of Justice's (DOJ) enforcement of 42 U.S.C. § 289g-1 and g-2, which are laws relating to the transfer of human fetal tissue. Among other things, I asked how many investigations of violations of those laws FBI or other DOJ components had undertaken since the laws were enacted in 1993. I asked for copies of any such investigative files, copies of all prosecution memoranda, as well as any related documents deciding whether or not to initiate a prosecution.

On November 5, 2015, I received a response from Assistant Attorney General Kadzik that stated that DOJ had identified two matters that were investigated pursuant to § 289g-2, but not prosecuted, over a decade ago. I had referenced one of those investigations, which pertained to Dr. Miles Jones, in my original letter. The response letter further stated that, in response to my request, DOJ was processing the available records pertaining to these two matters and would supplement the response as soon as those efforts were completed.

However, five months after I sent my original letter, and two months after DOJ's initial response, I have yet to receive any of the requested documents. Section 9-27.270 of the U.S. Attorneys' Manual requires that "[w]henever the attorney for the government declines to commence or recommend Federal prosecution, he/she should ensure that his/her decision and the reasons therefore are communicated to the investigating agency involved and to any other interested agency, and are reflected in the office files." Accordingly, by DOJ's own rules, these files should exist and be easily obtainable in the respective office files.

Exhibit 6

In light of this, please respond to the following by no later than February 5, 2016:

1. Did anyone from the U.S. Attorney's Office or any other component of DOJ ever seek authorization to initiate a prosecution stemming from the two above-mentioned investigations? If so, please provide all records relating to that request.

2. Did anyone from the U.S. Attorney's Office or any other component of DOJ ever prepare a prosecution memorandum relating to either of the two above-mentioned investigations? If so, please provide a copy of that memorandum.

3. Who made the decision not to initiate a prosecution relating to the two above-referenced investigations? As stated in Section 9-27.270 of the U.S. Attorneys' Manual, decisions to decline to commence or recommend federal prosecution, and the reasons therefore, are to be maintained in the office files. Please provide all records related to the decision not to initiate prosecution and the reasons therefore.

If you have any questions about this request, please contact Patrick Davis of my Committee staff at (202) 224-5225. Thank you for your attention to this important matter.

Sincerely,

Charles E. Grassley
Chairman
Senate Committee on the Judiciary

cc: The Honorable Patrick J. Leahy
Ranking Member
Senate Committee on the Judiciary

Exhibit 7

U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General *Washington, D.C. 20530*

March 18, 2016

The Honorable Charles E. Grassley
Chairman
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

This responds to your letter to the Attorney General and Director of the Federal Bureau of Investigation (FBI) dated January 26, 2016, which requested documents and other information relating to the Department of Justice's (the Department) law enforcement efforts pursuant to provisions of the Public Health Service Act, set forth in 42 U.S.C. §§ 289g-1 and g-2, in two matters.

In our letter dated November 5, 2015, we informed you that we had identified two matters that were investigated pursuant to § 289g-2, but not prosecuted, over a decade ago. Prosecution was declined by the relevant United States Attorney's Offices in both matters after review of the evidence. In our review of the available records for both matters, we have not found any record indicating that a United States Attorney's Office (USAO) or any other component asked to initiate a criminal prosecution.

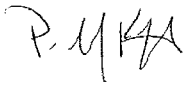
Enclosed is a 2003 FBI communication, which includes the FBI's explanation of the evidence developed in the investigation, and indicates that the USAO for the District of Colorado intended to decline prosecution. The document bears redactions to protect individual privacy and other law enforcement interests, as described in the enclosed redaction code list. We have not located a document in the USAO relating to this decision.

In the matter pertaining to the now-deceased individual identified in your letter, we have located two documents, both of which implicate the Department's confidentiality interests in internal attorney work product regarding prosecutorial decisions. While we are not prepared to disclose those documents, we can advise you that, consistent with the *Principles of Federal Prosecution*, the matter was declined in 2001, based upon the USAO's conclusion that the evidence did not establish a violation of federal law.

Exhibit 7

We hope this information is helpful. Please do not hesitate to contact this office if we may provide additional assistance regarding this or any other matter.

Sincerely,



Peter J. Kadzik
Assistant Attorney General

Enclosure

cc: The Honorable Patrick J. Leahy
Ranking Member

Exhibit 7

REDACTION CODES

E. INFORMATION, THE DISCLOSURE OF WHICH WOULD TEND TO IDENTIFY A SOURCE OF INFORMATION, WHERE CONFIDENTIALITY IS EXPRESSED OR IMPLIED.

F. ADMINISTRATIVELY DESIGNATED FBI FILE NUMBERS, PHONE/FACSIMILE NUMBERS, AND ADMINISTRATIVE NOTATIONS WHICH REPRESENT INDIVIDUALS OR MATTERS WHICH ARE NOT THE SUBJECT OF THIS FILE.

P-1. INFORMATION, THE DISCLOSURE OF WHICH WOULD BE AN UNWARRANTED INVASION OF PERSONAL PRIVACY.

S. PERSONAL IDENTIFYING INFORMATION RELATED TO LAW ENFORCEMENT PERSONNEL AND THEIR FAMILY MEMBERS, THE DISCLOSURE OF WHICH IS ROUTINELY GUARDED FOR SECURITY REASONS.

Exhibit 7

Filing and Security

Primary Case: 209A-DN- F **Case Title:** (U) [redacted] WOMENS CLINIC; P-1

Serial Number: F

Serialized: 07/30/2003

Category: Full Investigation

Initiated: 08/28/2001

Details

Serial #: F **Type:** LHM

Document Title: ANATOMIC GIFT FOUNDATION; HCF - OTH

Approval Date: 07/30/2003

Classification: ~~SH~~

Contents:

Denver, Colorado
July 30, 2003

ANATOMIC GIFT FOUNDATION;
HCF - OTH

On August 28, 2001, the Denver Office of the Federal Bureau of Investigation(FBI) opened an investigation of Anatomic Gift Foundation(AGF), a non-profit organization that provides adult and fetal tissue for applications in medical science, education, and transplantation, after receiving allegations that AGF's fetal tissue business may have been in violation of Title 42, U.S.C., Section 289g, which makes it unlawful to acquire, receive, or transfer human fetal tissue for valuable consideration affecting interstate commerce.

AGF's main office is located at [redacted] AGF was founded in 1994 by [redacted] P-1 [redacted] telephone P-1 AGF currently has operations in Maryland and Arizona. Up until October 1999, AGF also had operations at a location in Aurora, Colorado, within the [redacted] Colorado [redacted] telephone [redacted] is owned by Dr. [redacted]

The allegations against AGF stemmed from a report published by Life Dynamics Incorporated, [redacted] a pro-life organization, which alleged that AGF was engaged in illegal fetal tissue transfers. Life Dynamics had obtained information that AGF sold fetal tissue to researchers, possibly at a substantial profit.

On November 7, 2001, the President of Life Dynamics, Mark Crutcher, was contacted by the FBI and a copy of Life Dynamics' report was requested. Crutcher related that Life Dynamics had investigated allegations that AGF and another organization, Opening Lines, were participating in the illegal sale of fetal tissue. Their investigation lasted 31 months and involved the assistance of an insider who worked at both organizations named Dean Alberty. Based on Life Dynamics' investigation, the ABC program 20/20 televised a report on the matter in March 2000. The issue also came to the attention of Congress, and hearings began on the issue in March 2000.

Exhibit 7

Crutcher felt that the incentive to sell fetal tissue was high because fetal tissue is essential to valuable research by such organizations as pharmaceutical companies, which need fetal tissue to speed up the development of new products. Because such organizations can greatly increase profits by developing new products before competitors, such organizations are willing to pay whatever is necessary to procure fetal tissue.

Crutcher provided the Denver FBI with a copy of the Life Dynamics' report and copies of taped conversations Life Dynamics had made with owners and employees of AGF and Opening Lines during the course of their investigation.

The FBI in Kansas City conducted an investigation of Opening Lines and its owner Miles Jones, but the matter was declined for prosecution in July 2001.

In December 2001, the President of AGF, [redacted] and his brother, P-1 were contacted to see if AGF would supply financial information regarding its fetal tissue business. The [redacted] related that AGF has been defending itself for several years against allegations that it has been selling fetal tissue for profit. Fetal tissue made up only about 10% of AGF's business. The other 90% came from adult tissue donation. AGF discontinued providing fetal tissue to researchers in December 1999, because of harassment from anti-abortionists. AGF continues to be involved in adult tissue donation. The [redacted] maintained that they only recovered their costs when charging researchers for fetal tissue, as allowed by law.

The [redacted] related that AGF had already compiled the financial information the FBI was requesting, because it had been threatened with lawsuits and at least one congressman had wanted the information. [redacted] agreed to provide financial information regarding AGF's fetal tissue business to the FBI.

AGF's employee at the Aurora, Colorado location was P-1, E On December 3, 2001 P-1, E was interviewed regarding P-1, E for AGF. P-1, E

has been working with the [redacted] Women's Clinic to obtain fetal tissue for a researcher at P-1, E named Dr. P-1, E does research on Parkinson's disease and utilizes fetal brain tissue as part of his research. P-1, E was hired to obtain tissue for AGF after AGF's technician at [redacted] left for other employment. Because P-1, E was often at [redacted] anyway getting tissue for Dr. P-1, E AGF hired P-1, E to get tissue for them. P-1, E could work for both Dr. P-1, E and AGF, because Dr. P-1, E was only interested in getting 8-12 week old brain tissue for his research. AGF, on the other hand, was interested in a variety of tissue, including skin, bone, and organs, primarily from fetuses that were over 13 weeks old. P-1, E worked for AGF several years until October 1999 when AGF withdrew from Mayfair.

AGF rented a room at [redacted] that P-1, E used for removing the tissue. [redacted] was paid by both Dr. P-1, E and AGF for the rent of the room. The rent covered the use of the room with a table and refrigerator. The rent also covered electricity and water.

AGF paid P-1, E a salary of $25,000 a year for P-1, E services, with no benefits. P-1, E worked for AGF three or four days a week, depending on the days the clinic was open. P-1, E typically filled orders for 12-15 tissue specimens a week for

Exhibit 7

AGF. Often, several specimens came from one fetus. Because the majority of the patients at the clinic gave consent for the aborted fetuses to be used in research, there was an abundance of tissue P-1, E had many more fetuses than P-1, E needed to fill the orders. All of the excess tissue was discarded because researchers only wanted fresh tissue.

P-1, E did not know how much AGF charged for the specimens. P-1, E only saw the orders P-1, E received from AGF. P-1, E filled the orders and shipped the tissue by Federal Express directly to the researchers. P-1, E then sent a copy of the order E, P-1 shipped back to AGF. AGF had another employee in Kansas City who coordinated between the researchers and P-1, E to make sure the researchers got the tissue they wanted.

P-1, E maintained P-1, E had nothing to do with the abortion procedures. Patients had to sign consent forms in order P-1, E to be able to get the tissue. AGF did not alter the abortion procedures in any way to get tissue.

P-1, E related that AGF got a lot of attention in late 1999. Anti-abortion protesters were harassing the clinic and P-1, E was receiving harassing calls at home. United States Representative Tom Tancredo was involved in support of the anti-abortionists, who were alleging that tissue was being sold at the clinic for profit. In approximately October 1999, AGF pulled out of Colorado. P-1, E stayed home a month because of the harassment. P-1, E then went back to work at the clinic just getting tissue for Dr. P-1, E

P-1, E was aware that AGF has contacted [redacted] a few times since leaving and discussed the possibility of coming back to the clinic. [redacted] does not want AGF to come back because of the pressure and harassment they received when AGF was there. [redacted] has also called P-1, E and asked if P-1, E interested in working for them again.

On January 10, 2002, counsel for [redacted] Fay Clayton, of the law offices of Robinson Curley & Clayton, P.C., 300 South Wacker Drive, Chicago, Illinois 60606, telephone (312)663-3100, provided the financial records requested by the FBI from AGF. The materials were duplicates of records which had been provided to United States Representative Thomas Bliley in early 2000 with regard to the Congressional investigation of fetal tissue procurement. The only difference appears to be that Representative Bliley also received copies of income tax returns, which were not provided to the FBI. The documentation provided by AGF covered primarily the 1998 calender year for AGF's entire fetal tissue business.

A review of the documentation provided by AGF revealed that AGF calculated its price per fetal tissue specimen on a cost-recovery basis. AGF did this by estimating expenditures for a given year and attempting to allocate charges appropriately between the adult and fetal tissue aspects of its work. AGF then determined the number of specimens retrieved from its first trimester and second trimester procedures. They then allocated expenditures between first and second trimester specimens based on the difficulty of retrieval. AGF included both direct and indirect costs associated with the retrieval of the tissue. Such costs included administrative and technical salaries, lab equipment, lab supplies, administrative supplies, rent to clinics, blood screening costs, administrative overhead, and shipping costs. Their expenses for 1998 totaled $201,230. AGF collected 1,611 second trimester specimens and 182 first trimester specimens. The total receipts received by AGF for specimens procured in 1998 was approximately $185,000, based on charges of $90 for second trimester specimens and $220 for first trimester specimens. This resulted in an approximate loss to AGF in 1998 of $16,230.

Exhibit 7

AGF noted that it did not charge different amounts for different types of specimens. A specimen is tissue which has been obtained according to each researcher's protocol. A specimen includes tissue from an organ, skin, or bone. AGF did not charge different amounts for different specimens, because the cost to procure the specimens was approximately the same. AGF did charge a different price depending on whether the specimen was from a first or second trimester fetus. The price for first trimester specimens was higher than second trimester specimens, because they were more difficult and time consuming to obtain and fewer specimens could be obtained per fetus.

AGF did not provide the FBI a breakdown of expenses for years other than 1998, but did provide a breakdown of receipts for the years of 1994-1999. The receipts for AGF's fetal tissue business stayed consistent at approximately $200,000 each year from 1994-1999, except for 1997 where AGF showed receipts from its fetal tissue business of approximately $440,000.

AGF noted that it paid rent to the clinics, in which it procured fetal tissue, in the amount of $100-$600 per month for the use of the clinics' space. AGF also reimbursed clinic staff $10-$12 per hour for performing services on AGF's behalf associated with the procurement of fetal tissue. This included obtaining consent from the patients and drawing blood from patients for tissue testing. AGF estimated that clinic staff provided approximately one hour of service for each specimen procured by AGF. In 1998, AGF paid $11,400 in rent to clinics and $4,130 for clinic staff.

The largest expense for AGF's fetal tissue business in 1998 was for administrative salaries in the amount of $70,000. It is not known how many AGF employees were included in this line item, and the amount of time they were involved in the administration of the fetal tissue business. It is also not known how the administrative salary was allocated between the human tissue and fetal tissue businesses. AGF indicated that administrative duties included supervising and training personnel, assisting researchers with the application and agreement process, assisting researchers in acquiring funding, accounting for accounts payable and receivable, and expanding and improving services.

AGF reported that they paid $40,000 in 1998 in technical salaries, which is consistent with P-1, E statement P-1, E was paid $25,000 a year for performing work at one of AGF's clinics.

The Life Dynamics report regarding AGF focused [redacted] primarily on the [redacted] clinic in Overland Park, Kansas during 1996 and 1997. AGF had a technician on site and was obtaining fetal tissue from the clinic. Life Dynamics learned that Comp Health was being paid $600 by AGF for a site fee. Life Dynamics also estimated that AGF received approximately $19,000 in February 1996 from the sale of fetal tissue procured from Comp Health.

Life Dynamics believed that AGF paid $10 per hour to the clinic for the time the AGF technician was present. Life Dynamics argued that the site fees and hourly fees paid by AGF to clinics amounted to payments for fetal tissue. Life Dynamics believed the hourly payments were for the AGF technician; however, AGF maintains those payments were made to clinics to reimburse for the time spent by clinic staff with the donation process, which involved helping obtain consent and drawing blood.

To determine whether AGF was making a profit on the sale of fetal tissue, Life Dynamics made estimates of AGF's expenses at Comp Health. Life Dynamics estimated administrative

Exhibit 7

and technical salaries for [redacted] to be approximately $3,466.66 a month; site fees to amount to $1,327.17 a month; and miscellaneous expenses to amount to $2,000 a month. This totaled $6,793.83 in expenses for AGF to procure fetal tissue which it sold for approximately $19,000. This formed the basis for Life Dynamics' conclusion that AGF was reaping a substantial profit from the sale of fetal tissue.

There does not seem to be much of a dispute between Life Dynamics and AGF about the prices charged for the sale of the fetal tissue. The major differences in the financial data provided by Life Dynamics and AGF appears to be in the expenses associated with the procurement of fetal tissue. AGF reported its expenses to be much higher than that estimated by Life Dynamics.

Although the data from AGF cannot be precisely compared to Life Dynamics' data because of differences in time, and because AGF's data involved nationwide operations, while Life Dynamics' data focused on just one location, a comparison of the data is useful to show where the two parties disagree.

Life Dynamics estimated miscellaneous costs or overhead to be $2,000 a month. This included employee benefits, equipment, and supplies. To facilitate the comparison of this expense to AGF's data, the expense was calculated as a percentage of receipts by dividing the expense by the total receipts. This expense amounted to only about 10.5% of the estimated receipts of $19,000. This estimate differed significantly from that reported by AGF. Using the same definition of miscellaneous costs, AGF reported miscellaneous costs of $75,700 for 1998 for its entire fetal tissue business. This included all of AGF's costs except payments to clinics and employee salaries. This expense amounted to approximately 40.9% of AGF's reported receipts of $185,000 during the same year.

Life Dynamics estimated administrative and technical salary costs to be $3,466.66 per month. This amounted to approximately 18.2% of the estimated receipts of $19,000. Again, this estimate differed significantly from that reported by AGF. AGF reported administrative and technical salary costs of $110,000 for 1998. This amounted to approximately 59.5% of AGF's receipts of $185,000 during the same year.

Life Dynamics estimated site fees to be $1,327.17 a month. This included rent to the clinic and payments for clinic staff. This amounted to approximately 7.0% of the estimated receipts of $19,000. This figure did not differ significantly from that reported by AGF. AGF reported rent and payments for clinic staff to be $15,530 for 1998. This amounted to approximately 8.4% of AGF's receipts of $185,000 during the same year.

A comparison of the data provided by Life Dynamics and AGF seems to indicate that the largest area of dispute is in the area of miscellaneous expenses and salaries associated with the procurement of fetal tissue. Life Dynamics believed that such expenses were much smaller than that reported by AGF, which resulted in Life Dynamics' conclusion that AGF was making a profit from the sale of fetal tissue.

On March 15, 2002, a summary of the investigation was provided to the United States Attorney's Office, District of Colorado. After reviewing the summary of the investigation, Assistant United States Attorney(AUSA) S who was assigned to the matter, advised that he was planning to decline the matter and no further investigation should be conducted. AUSA S indicated that he would prepare a formal declination letter on Anatomic Gift Foundation. As of this date, no formal declination letter has been provided by AUSA S . This matter

Exhibit 7

is being closed by FBI Denver.

Routing

Drafted by: S

Approved by: S

Exhibit 7

 F

Filing and Security

Primary Case: 209A-DN F

Case Title: (U) [redacted] WOMENS CLINIC; P-1

Serial Number: F

Serialized: 07/30/2003

Category: Full Investigation

Initiated: 08/28/2001

Details

Serial #: F **Type:** EC

Document Title: CASE CLOSING LHM.

Approval Date: 07/30/2003

Classification: NN

Contents:

Precedence: ROUTINE Date: 07/30/2003

To: Criminal Investigative Attn: Health Care Fraud Unit

From: Denver
Squad 10
Contact: SA S F

Approved By: S

Drafted By: S

Case ID #: 209A-DN F (Closed)

Title: ANATOMIC GIFT FOUNDATION;
HCF - OTH

Synopsis: Case closing LHM.

Enclosure(s): Enclosed are the original and three copies of a case closing LHM for FBIHQ.

Details: See enclosed LHM.

LEAD(s):

Set Lead 1: (Info)

CRIMINAL INVESTIGATIVE

AT WASHINGTON, DC

Read and clear.

Routing

Drafted by: S

Approved by: S

Exhibit 8

CMP Analysis
August 25, 2015

Analysis of Center for Medical Progress Videos

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CMP Analysis
August 25, 2015

Executive Summary

At direction of counsel to Planned Parenthood, Fusion GPS analyzed a series of videos recently released by the **Center for Medical Progress (CMP)** purporting to represent undercover sting operations against **Planned Parenthood**. Fusion GPS also commissioned experts to review the videos and conducted preliminary research into the CMP organization and its personnel.

Between July 14th and August 4th, 2015, CMP released a series of videos depicting Planned Parenthood staffers in conversation with CMP operatives posing as employees of a biomedical firm that procures fetal tissue for sale to stem cell researchers. The videos attempt to show that Planned Parenthood profits from the sale of fetal tissue, and, secondarily, that its doctors follow an abortion procedure that violates the so-called "partial birth" abortion ban. A thorough review of these videos in consultation with qualified experts found that they do not present a complete or accurate record of the events they purport to depict.

Each release by CMP contained a short edited video, between eight and fifteen minutes in length, that intercuts clips from the undercover recordings with other content, and a "full footage" video that claims to provide the raw, unedited footage of each interview. A video forensics expert, a television producer, an independent transcription agency, and Fusion GPS staff reviewed this material. While these analysts found no evidence that CMP inserted dialogue not spoken by Planned Parenthood staff, their review did conclude that CMP edited content out of the alleged "full footage" videos, and heavily edited the short videos so as to misrepresent statements made by Planned Parenthood representatives. In addition, the CMP transcript for the "full footage" video shot at Planned Parenthood's Gulf Coast facility in Texas differs substantially from the content of the tape.

At this point, it is impossible to characterize the extent to which CMP's undisclosed edits and cuts distort the meaning of the encounters the videos purport to document. However, the manipulation of the videos does mean they have no evidentiary value in a legal context and cannot be relied upon for any official inquiries unless supplemented by CMP's original material and forensic authentication that this material is supplied in unaltered form. The videos also lack credibility as journalistic products.

Exhibit 8

CMP Video Analysis
August 25, 2015

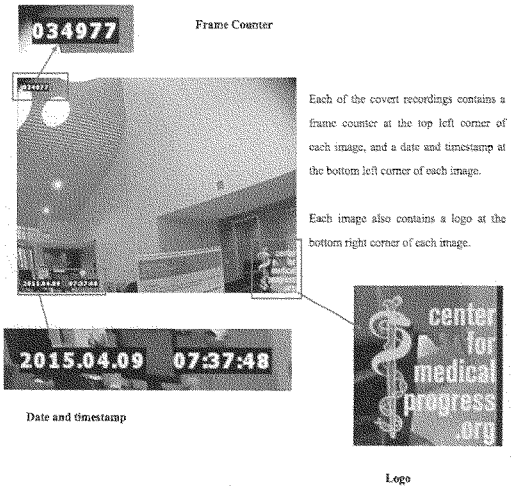
Video Analysis

Full Footage Video Analysis

Fusion GPS analysts reviewed all four of the "full footage" videos released by the Center for Medical Progress, totaling more than 12 hours of tape. This analysis did not reveal widespread evidence of substantive video manipulation, but we did identify cuts, skips, missing tape, and changes in camera angle. A forensic video expert, Grant Fredericks, reviewed segments of tape identified as suspicious during this preliminary review. This professional analysis revealed that the full footage videos contained numerous intentional post-production edits.

All four videos feature a younger man posing as "Robert"[1] and a middle-aged woman posing as "Susan," both of Biomax, a biological sample procurement company specializing in tissue for stem cell research. "Robert" displays detailed technical knowledge of abortion procedure, sample collection, and stem cell research. "Susan" claims to be the CEO of Biomax and appears to be focused on the financial aspects of tissue collection.

All four videos contain a frame counter and date and timestamp. Mr. Fredericks notes that the type of hidden cameras likely used to create these recordings typically allow users to encode the date and time prior to recording. Removal or manipulation of encoded timestamps and frame counters leaves evidence behind in the final video. Mr. Fredericks identifies "loss of significant time and image continuity" attributable to post-production edits. While many of these edits removed likely-irrelevant content from the beginning and end of the interviews, all four videos also contained intentional edits that removed content from the middle of the videos.



[1] In some videos, "Robert" uses the last name "Sarkis."

Exhibit 8

CMP Video Analysis
August 25, 2015

"Intact Fetuses 'Just a Matter of Line Items' for Planend (sic) **Parenthood TX Mega- Center" (hereinafter "Texas")**

This video depicts nearly six hours of conversation between Melissa "Missy" Farrell of Planned Parenthood Gulf Coast and "Robert Sarkis" and "Susan" of Biomax. The video also depicts Planned Parenthood lab facilities and shows tissue collected from aborted fetuses at various gestational stages.

The Texas video is likely the most substantially manipulated of the four full footage videos reviewed in this report. Mr. Fredericks' analysis reveals that "approximately 30 minutes" of the meeting are missing from the video shortly after the eighth minute of recording. The clock superimposed on the video skips from 07:46:47 to 08:15:15 from one frame to the next.

Lighting levels and the Planned Parenthood staffer's ID badge at 08:15:15 match the content in the short video that is missing from the full video, suggesting that the content comes from the missing excerpt. This gap also coincides with approximately 4000 words of dialog in the CMP transcript that does not appear in the video. We discuss the short videos and transcripts in detail below.

Left: Texas "full footage" video at running time 00:08:59:03. Right: Texas "full footage" video at running time 00:08:59:04 (note that running times are continuous and differ from timestamps).

Exhibit 8

About 30 minutes later, the camera's frame counter skips ahead 7,583 frames and the timestamp skips from 08:44:26 to 08:44:39. Mr. Fredericks concludes that "this is an edit caused by human intervention in a post-production environment." Mr. Fredericks finds a similar edit at 12:58:43 by the camera's timestamp, in which the timestamp on the following frame reads 13:50:18. He concludes that this too is a post-production edit resulting in the omission of nearly an hour of recording.

Mr. Fredericks also notes that audio is out of sync at various points within this recording, a common feature in edited video. Many segments of the video contain dialog spoken off- camera, but neither Mr. Fredericks nor Fusion GPS staff identified any evidence of audio manipulation within the video segments provided.

CMP's video editors overlooked identifying information contained within the Texas video. At 13:11:59 on the video's timestamp, CMP operatives can be seen handling a credit card that appears to bear the name "Brianna Allen." At 13:59:36, facial blurring introduced in postproduction to obscure interviewers and other individuals' identities briefly moves off of "Susan's" face.

Planned Parenthood VP Says Fetuses May Come Out Intact, Agrees Payments (hereinafter "Colorado")

Like the Texas video, the Colorado tape depicts "Robert" and "Susan" in conversation with Planned Parenthood staff, and shows footage of a lab facility and the fetal tissue contained therein. Mr. Fredericks identified numerous stops and starts in this tape.

The Colorado video's timestamp skips from 10:27:07 to 11:01:40, and the frame counter skips from 030742 to 041744. This edit, which Mr. Fredericks identifies as the result of human intervention post-production, results in more than 30 minutes of missing video. Similar edits omit two to three minutes of audio and video each at approximately 11:24:49, 11:36:47, and 11:41:44 by the encoded timestamp. Another edit at 12:35:50 omits 10 minutes of audio and video information.

At 11:45:46 on the video's timestamp, Mr. Fredericks identifies an edit that may reflect manual stoppage of the camera during recording. Oversaturation, blurring, and a change in camera angle prior to stoppage indicate the movement of a hand toward the camera lens. These effects also are consistent with the operator pushing a button to stop recording. The next image starts in the middle of a recording "packet" at 12:21:55, indicating removal of material recorded immediately after the operator resumed recording. CMP omitted the video immediately following camera stoppage from its "full footage" tape, which means the video does not constitute the full footage of this encounter.

Planned Parenthood representatives asked Fusion GPS to analyze two segments of dialog in this video that were deemed to be suspicious.

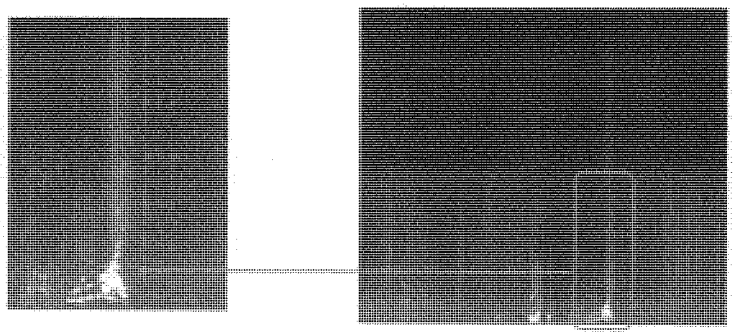
The first segment, approximately an hour and 20 minutes into the video's running time, depicts Planned Parenthood staff off-camera saying a phrase that CMP claims was, "It's a baby." Fusion GPS analysts and independently contracted transcriptionists found this dialog to be unintelligible. Because of the poor quality of the recording, the compression of the file by Youtube, and the lack of access to the original file, it is not possible to enhance the sound sufficiently to determine what is being said.

Exhibit 8

Neither internal nor expert analysis found any artifacts of editing in or around this segment that would suggest the audio was inserted or manipulated using technical tools. Rather, Fusion GPS analysts conclude that this segment simply consists of incomprehensible background chatter picked up by the CMP operative's hidden camera. In our view, CMP created the purported statement, "it's a baby," either through transcription error or intentional fabrication.

Careful review by a number of analysts leads Fusion GPS to conclude that "it's a baby" would be an incongruent statement for the lab tech to make in the context of a lengthy and technical examination of human fetus specimens. In the period prior to this discussion, the CMP operatives and the Planned Parenthood personnel are inspecting a pair of human fetus specimens and engage in a relatively technical discussion of how to identify specific internal organs such as the liver and thymus. Suddenly declaring in the midst of this examination that the subject specimen is "a baby" simply makes no sense.

A second segment of dialog depicts a Planned Parenthood staffer allegedly saying "another boy" approximately two hours and 30 minutes into the video's running time. Again, neither internal nor external analysis found evidence that CMP inserted or manipulated this dialog post hoc. Mr. Fredericks found the audio spectrum to be consistent and continuous before, during, and after this dialog.



Audio spectrum showing a Planned Parenthood representative saying, "It's a boy" approximately two and a half hours into the Colorado tape's running time. This image shows no evidence of audio manipulation.

Although it is unlikely that this dialog was edited in, Fusion GPS finds that the statement lacks context and may have been elicited by CMP's own operatives, who engaged in elaborate efforts to bait Planned Parenthood personnel into using language that could be portrayed as incriminating or otherwise inappropriate.

The analyst says "*another* boy" despite the fact that there is no prior mention of the gender of fetal specimens at any other point in the videos or transcripts. Given that expert analysis found that more than 30 minutes are missing from the Colorado tape prior to this point we deem it likely that CMP deleted initial discussions of fetal gender, most likely by its own personnel.

Exhibit 8

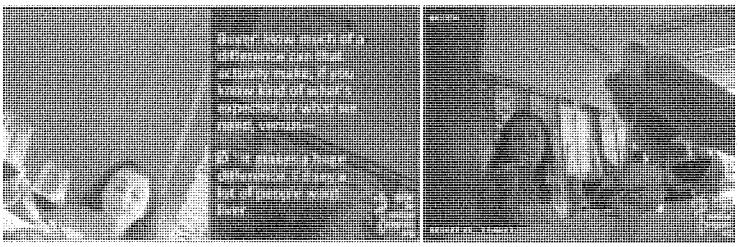
While CMP's undisclosed edits in the earlier portion of the Colorado tape make it impossible to know the broader context of the conversation that led the Planned Parenthood technician to say "another boy," the available tape shows that CMP operatives repeatedly attempted to bait Planned Parenthood staff into discussing the physiology of fetal specimens in lay terms. "Robert" asks, "Was that just the little bits of the skull?" "This is rib cage right here, right?" "This could be neural tissue, could it?" This is part of the pelvis right here, is it not? and many other questions that seem designed to elicit "soundbites" pertaining to fetal viscera. It is thus likely that the removed video contains dialog in which CMP operatives ask about the gender of a specimen.

"Planned Parenthood Uses Partial-Birth Abortions to Sell Baby Parts" (hereinafter "California 2014")

According to encoded timestamps on the CMP video displaying July 25, 2014 (and, in one segment, July 25, 2013), the California 2014 video takes place more than six months prior to the other recordings. This video portrays Deborah Nucatola, Senior Director of Medical Services for PPFA, at a lunch meeting with "Robert" and "Susan."

Mr. Fredericks concludes that "this video has been edited significantly." He identifies a change to the superimposed Center for Medical Progress logo left behind as an artifact of editing system error.

At 14:32:07 on the video's timestamp, the timestamp skips ahead four minutes and the date changes from July 25, 2014 to July 25, 2013. Mr. Fredericks identifies this as a change from footage recorded on one camera to footage recorded on a second device. One minute later, the time stamp jumps ahead by five minutes and the date stamp reverts to 2014, representing a shift back to the original recording device. Visual review of the short and long videos from both California interviews shows clear shifts in perspective from one camera to another.



Left: California 2014 short video at running time 00:03:02. Right: Same dialog in California 2015 "full footage" video (at 00:29:05)

The California 2014 video also contains in-segment edits. The encoded timestamp skips from 4:38:06 to 14:41:08, representing at least three minutes of missing video.

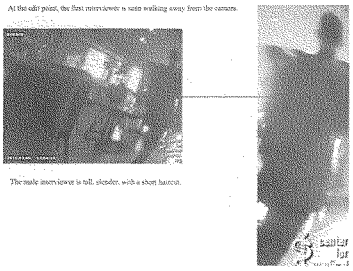
Exhibit 8

It is not possible to estimate the extent to which CMP's undisclosed edits and cuts distort the meaning of the first California video. However, the blatant manipulation of this video renders it useless as "evidence" and means it cannot be relied upon in official inquiries as a credible record of events unless the record is supplemented by CMP's original unedited material.

Second Planned Parenthood Senior Executive Haggles Over Baby Parts Prices (hereinafter "California 2015")

This video, apparently recorded on February 6, 2015, depicts a lunch meeting between "Robert" and "Susan" of Biomax and Planned Parenthood representatives Mary Gatter (President of Medical Directors' Council for PPFA) and Laurel Felczer (Senior Director of Medical Services for Pasadena and San Gabriel Valley).

Like the California 2014 video, this video clearly shows that CMP edited together footage from two different cameras. The video's time stamp jumps backwards from 12:04:53 to 12:04:24 due to what Mr. Fredericks identifies as post-production insertion of tape from a second camera. The second camera used in the California 2015 recording takes longer segments of video, but is otherwise similar to the cameras used in other recordings.



At the point of this edit, the video briefly shows the male interviewer walking away from the camera. The interviewer physically resembles CMP founder David Daledin, though video evidence is insufficient to conclusively determine the interviewer's identity.

Footage of the male interviewer visible in the "California 2014" tape.

Short Video Analysis

Fusion GPS analysts and Mr. Fredericks reviewed CMP's short videos in conjunction with the "full footage" tapes and conclude that the short videos significantly distort and misrepresent the conversations depicted in the full footage videos. Mr. Fredericks notes that the short videos contain "edited conversations where some spoken words are eliminated and some spoken words are added out of context." The short videos of both the California 2014 and California 2015 interviews contain camera angles not visible in the corresponding "full footage" videos. The short video of the Texas interview contains video and audio that do not appear in the Texas "full footage" video.

Exhibit 8

Fusion GPS consulted with an experienced reality and documentary television producer, Scott Goldie, for an expert opinion of the editing techniques used in the short videos. Mr. Goldie identifies the use of ominous music, replays, color manipulation, "scratch" effects, strategic display of frame counters and timestamps, all chosen to create "gotcha" moments.

Mr. Goldie points out that in all four short videos, most of the dialog about compensation comes not from Planned Parenthood representatives but instead from CMP operatives posing as buyers:

[I]t's the "buyer" who is doing all the talking. The "buyer" states: "It's gold out there", "So beneficial", "change the procedure a bit", "financial gain", "I want you to be paid", "compensates", "financially helping you", "financial benefits", "grow the clinic", these are all leading statements voiced by the "buyer". But Farrell simply agreeing to these statements is enough to paint her in a bad light.

This is consistent with Fusion GPS analysts' assessment of the "full footage" videos. In all four interviews, CMP operatives repeatedly bring up compensation, often trying to bait Planned Parenthood representatives into making mercenary statements or naming a higher price for donated tissue. In the California 2015 video, the female interviewer explicitly tells Planned Parenthood representatives that the compensation that they requested for fetal tissue donation is "way too low." In the Colorado video, she tells Planned Parenthood representatives that she wants to pay "top dollar."

The short videos take a great deal of dialog out of context so as to substantively and significantly alter the meaning of the dialog contained in the long videos. For example, Melissa Farrell's statement about "diversifying the revenue stream" for her clinic in the Texas video occurs in the context of a conversation about expanding the services available to patients. In the California 2014 video, Dr. Nucatola's statement that Planned Parenthood wants to donate tissue "in a way that is not perceived as 'This clinic is selling tissue. This clinic is making money off of this'" precedes a discussion of the costs involved in collecting tissue.

Transcript Analysis

Fusion GPS contracted the services of an independent transcription agency, TranscriptionWing[2], to transcribe all four "full footage" videos and the corresponding short videos. This was an ordinary arms-length commercial engagement, and TransciptionWing was not informed of the purpose of the request nor of the ultimate client. Fusion GPS analysts then compared these transcripts to transcripts provided by CMP, and, in the case of significant discrepancies, to the videos themselves. All four transcripts by CMP contain substantive omissions, and the Texas transcript appears to be grossly edited.

The style, errors, and patterns of omission in the CMP transcripts lead Fusion GPS to conclude that CMP most likely transcribed the videos "in-house," rather than contracting transcription to an independent agency. This would also explain the significant discrepancies between the CMP transcript of the Texas footage and what appears on the tape. It appears that CMP transcriptionists reviewed an

[2] http://www.transcriptionwing.com/

Exhibit 8

earlier version of the Texas tape, or possibly that they transcribed recorded "packets" from the raw tape individually before CMP cut the "full-length" video together.

In all four transcripts, CMP omits the names used by its operatives, the company name Biomax, and dialog in which the CMP operatives offer their (presumably fictionalized) back stories. In the California 2014 transcript, CMP's version omits more than 670 words of dialog mostly pertaining to "Susan's" backstory. In the California 2015 video, "Susan" alludes to accidentally calling the male interviewer "David, which is his middle name." In the Colorado video, the male interviewer introduces himself as "David" before correcting himself to say that David is his middle name and that he goes by Robert. These apparent errors provide further evidence to bolster the suspicion that the male interviewer is, in fact, CMP leader David Daleidin. CMP omits all mention of the name "David" in its transcripts.

Many CMP transcripts also alter their operatives' dialog so as to make it seem less like they are baiting Planned Parenthood staff into making unethical statements. For example, in the Colorado transcript, CMP portrays its staff as consistently asking about specimens of a different gestational age than they actually request in the videos.

The Texas video transcript contains the most significant discrepancies. CMP's version of the transcript contains over 4,000 words of dialog that does not appear in the independent transcript or the video.[3] In this dialog, Melissa Farrell allegedly discusses her "a la carte" budget (a phrase she also uses elsewhere in the video) and she and "Robert" engage in a detailed discussion of intact fetuses and the use of medically-induced abortions. Some of this dialog appears to correspond with video used in the short, edited version of the Texas video.

At other points, the CMP transcript of the Texas video appears to omit dialog totaling over 4,000 words.[4] In this segment, apparent in the independent transcript and the video, Farrell asserts that Planned Parenthood will not collect tissue from minors or incarcerated people. Also in this segment, "Susan" asks if Biomax can offer participation bonuses to doctors, and Ferrell responds, "no way." Whereas the content that CMP inserts into its transcript serves to portray Ferrell as flexible regarding Planned Parenthood policies and regulations, the content it omits portrays her as committed to following ethical and legal guidelines.

The numerous errors, discrepancies, and omissions in the CMP transcripts render them useless as "evidence." They also cannot be relied upon in official inquiries as a credible text record of what is said in the videos.

[3] CMP transcript of Texas "full footage: video, pp. 5-15
[4] TranscriptionWing transcript of Texas "full footage" video, pp. 46-56 and pp. 113-115.

Exhibit 9

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

NOV 17 2015

The Honorable Ron Johnson
Chairman
Committee on Homeland Security and Governmental Affairs
United States Senate
Washington, D.C. 20510

Dear Chairman Johnson:

I am writing in further response to your letters regarding research involving fetal tissue and the work of the Department of Health and Human Services (HHS).

The use of fetal tissue in medical research has been an instrumental component of our attempts to understand, treat, and cure a number of conditions and diseases that affect millions of Americans. Scientists have been working with fetal tissue since the 1930s. For example, fetal tissue is an important resource for researchers studying retinal degeneration, pregnancy loss, human development disorders such as Down Syndrome, and early brain development. Fetal tissue has also served as a critical resource for the development of models of human disease, such as HIV/AIDS, which has devastating effects on the human immune system. Importantly, cell lines derived from fetal tissue have also played an essential role in the creation of new vaccines and remain valuable in important efforts such as the pursuit of a vaccine for Ebola.

The Public Health Service Act (42 U.S.C. § 289g-2) prohibits knowingly acquiring, receiving, or otherwise transferring any human fetal tissue for valuable consideration if the transfer affects interstate commerce. Under 42 U.S.C. § 289g-2, the Department of Justice (DOJ) can investigate complaints concerning any person who knowingly acquires, receives, or otherwise transfers any human fetal tissue for valuable consideration if the transfer affects interstate commerce. I understand that DOJ is reviewing all information they have received on this matter, and will determine what steps to take at the appropriate time.

42 U.S.C. § 289g-1 sets forth additional requirements for HHS-conducted or HHS-supported research on the transplantation of human fetal tissue for therapeutic purposes. HHS has not conducted or supported such research since 2007. A list of the research projects on the transplantation of human fetal tissue for therapeutic purposes from 2007 is attached as an addendum to this letter. Additionally, attached are the reports to Congress, from 2008-2014, on HHS-conducted or HHS-supported transplantation research that are required to be submitted annually.

When submitting an application and accepting an award for research involving fetal tissue supported by HHS, the designated representative of the external organization receiving the funding certifies that researchers using these samples are in compliance with applicable legal requirements. In addition, by accepting an award, funding recipients agree that they will follow

Exhibit 9

all applicable legal requirements and the applicable agency's grants policy statement, and must be able to demonstrate their compliance with applicable legal requirements. HHS also requires funding recipients to re-certify when additional funding is awarded that they are in compliance with applicable legal requirements. Your letter asks whether HHS's oversight practices and policies relating to other forms of research differ from its practices and policies relating to fetal tissue research. As a general matter, HHS follows the same policies and procedures for each of its grantees. That said, as mentioned in my previous response, for the small amount of research involving fetal tissue samples that is conducted by researchers at FDA and NIH, researchers obtain tissue from non-profit organizations that have provided assurances to us that they are in compliance with applicable legal requirements. In addition, NIH and FDA have obtained assurances verifying that the research they support is in compliance with applicable legal requirements, including relevant provisions relating to research involving fetal tissue. NIH and FDA have also sent a reminder notice to their intramural research communities that all research must be in compliance with all applicable legal requirements.

The Office for Human Research Protections (OHRP) has jurisdiction under Title 45, Part 46, Code of Federal Regulations (45 CFR 46) with regard to research involving human subjects conducted or supported by HHS or conducted at an institution that has voluntarily agreed to comply with 45 CFR 46 regardless of the source of support for the research. OHRP's role also includes 45 CFR 46, subpart B, which, among other things, regulates research conducted or supported by HHS involving fetal tissue, requiring that such research be conducted in compliance with any applicable federal, state, or local laws and regulations regarding such activities. OHRP's Division of Compliance Oversight evaluates written substantive indications of noncompliance with 45 CFR 46 in connection with research conducted or supported by HHS. OHRP has not, since January 1, 2010, received any substantive indications of noncompliance with 45 CFR 46, subpart B by an HHS- funded or supported research institution in connection with fetal tissue research.[1]

In response to the questions in your letter regarding funding to Planned Parenthood Federation of American and its affiliates ("Planned Parenthood"), as stated in my previous response, HHS provides funding to Planned Parenthood through competitively-awarded grants and contracts. The funds are used to provide critical health services, including annual wellness exams, cancer screenings, contraception, and to further the study of sexually-transmitted diseases. HHS funding to Planned Parenthood does not support research involving fetal tissue. Further, no federal funds can be used to cover abortions except in the case of rape, incest, or when the life of the woman is endangered. This has been federal law, enacted in annual appropriations legislation, since the 1980s.

As stated above, Planned Parenthood receives grant awards through a competitive selection process. For competitive grants or cooperative agreements, unless prohibited by federal statute, the HHS awarding agency must design and execute a merit review process for applications. This process must be described or incorporated by reference in the applicable notice of funding

[1] OHRP has received a request to initiate an investigation regarding the Planned Parenthood videos in question. A copy of that request and OHRP's response is attached. The response notes that OHRP has not been provided with information indicating noncompliance with 45 CFR 46, subpart B by an HHS- funded or supported research institution in connection with these videos.

Exhibit 9

opportunity. Further, like all HHS funding recipients, Planned Parenthood is required to comply with applicable legal requirements. When submitting an application and accepting an award, funding recipients agree that they will follow all applicable legal requirements and the applicable agency's grants policy statement, and must be able to demonstrate their compliance with applicable legal requirements. HHS also requires funding recipients to re-certify when additional funding is awarded that they are in compliance with applicable legal requirements. In addition, grantees, such as Planned Parenthood, that spend over $750,000 in federal funds during their fiscal year (or $500,000 prior to December 26, 2014) are required to obtain an annual audit in compliance with the Single Audit Act and 2 CFR Part 200, subpart F.

I understand that Members of Congress have requested that the HHS Office of Inspector General conduct an audit of the issues raised about Planned Parenthood, fetal tissue transplant research, or fetal tissue research of whatever scope is possible within HHS OIG's jurisdiction. As always, HHS is committed to cooperating with our Inspector General.

Thank you for your interest in the important work of our Department.

Sincerely,

Jim R. Esquea

Jim R. Esquea
Assistant Secretary for Legislation

Enclosures

cc: The Honorable Charles E. Grassley
Chairman
Committee on the Judiciary

The Honorable Joni K. Ernst
United States Senate

The Honorable Thomas R. Carper
Ranking Member
Committee on Homeland Security and Governmental Affairs

The Honorable Patrick Leahy
Ranking Member
Committee on the Judiciary

Exhibit 10

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

The Honorable Charles E. Grassley
Chairman
Committee on the Judiciary
United States Senate
Washington, DC 20515

AUG 14 2015

Dear Chairman Grassley,

Thank you for your recent letter regarding medical research using human fetal tissue. The use of fetal tissue in medical research has been an instrumental component of our attempts to understand, treat, and cure a number of conditions and diseases that affect millions of Americans. Scientists have been working with fetal tissue since the 1930s. For example, fetal tissue is an important resource for researchers studying retinal degeneration, pregnancy loss, human development disorders, and early brain development, with relevance to autism and schizophrenia[1]. Research conducted with fetal tissue continues to be a critical resource for important efforts such as research on degenerative eye disease, human development disorders such as Down syndrome, and infectious diseases, among a host of other diseases.

Within the Department of Health and Human Services (HHS), the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) currently fund or conduct research involving fetal tissue samples. This research constitutes only a tiny fraction of the total research budgets of these institutions.

The majority of this research is conducted by third-party institutions using NIH funding. In FY 2014, research involving fetal tissue samples accounted for less than 0.3 % of NIH's total research budget. Like all HHS funding recipients, NIH employees, grantees, and contractors are required to comply with applicable legal requirements, including relevant provisions relating to research involving fetal tissue. When submitting an application and accepting an award, the designated representative of the organization receiving the funding certifies that researchers using these samples are in compliance with applicable legal requirements such as the Public Health Service Act, 42 U.S.C. § 289g-2, which you reference in your letter, which governs the use of human fetal tissue. In addition, by accepting an award, funding recipients agree that they

[1] In addition, research using cell lines derived from fetal tissue has also played an essential role in the field of vaccine development. The 1954 Nobel Prize in Medicine was awarded for work with fetal cell lines that led to developing a vaccine against polio. Fetal cell lines were also instrumental in the development of vaccines against hepatitis A, rabies, measles, mumps, and rubella and remain valuable in important efforts such as the pursuit of a vaccine for Ebola and new therapeutics for HIV/AIDS.

will follow all applicable legal requirements and the applicable agency's grants policy statement, and must be able to demonstrate their compliance with applicable legal requirements. HHS also requires funding recipients to certify no less than annually that they are in compliance with applicable legal requirements.

NIH has confirmed that third-party institutions receiving NIH funding for research involving fetal tissue samples have confirmed that their activities are in accordance with applicable legal requirements. That assurance includes a specific reference to relevant provisions relating to research involving fetal tissue. As a reminder to all NIH funding recipients, as well as researchers who may apply for funding in the future, NIH has released a guide notice reminding researchers of their obligations to follow applicable legal requirements pertaining to research involving fetal tissue. This guide notice has been published in the NIH Guide to Grants and Contracts, which is the official publication for NIH medical and behavioral research grant policies, guidelines and funding opportunities, and is an effective way to communicate with the entire research community.

In addition, a small amount of research involving fetal tissue samples is conducted by researchers at NIH and FDA. This research involving fetal tissue conducted by NIH researchers accounts for less than 0.01% of its total research budget and is principally related to the study of eye disease, infectious diseases, and human development. The amount of funding involving fetal tissue samples accounts for a tiny fraction of FDA's total research budget and is principally conducted in connection with testing potential new drugs and biologics.

NIH and FDA researchers obtain tissue from non-profit organizations that have provided assurances to us that they are in compliance with applicable legal requirements. In addition, NIH and FDA have obtained assurances verifying that the research they support is in compliance with applicable legal requirements, including relevant provisions relating to research involving fetal tissue. NIH and FDA have also sent a reminder notice to their intramural research communities that all research must be in compliance with all applicable legal requirements.

The Public Health Service Act (42 U.S.C. § 289g-2), prohibits knowingly acquiring, receiving, or otherwise transferring any human fetal tissue for valuable consideration if the transfer affects interstate commerce. Violation of this statute carries criminal penalties that apply to both those who supply and those who acquire human fetal tissue. 42 U.S.C. § 289g-1 sets forth additional requirements for HHS-conducted or HHS-supported research on the transplantation of human fetal tissue for therapeutic purposes. However, HHS has not funded or conducted this specific type of research involving fetal tissue in recent years. Currently, we know of no violation of these laws in connection with the research done at our agencies. Furthermore, as noted above, we have confirmed that HHS researchers working with fetal tissue obtained the tissue from non-profit organizations that provided assurances to us that they are in compliance with all applicable legal requirements.

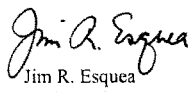
While HHS provides funding to Planned Parenthood Federation of America through competitively-awarded grants and contracts, the funding does not support research involving fetal tissue. Instead, the funds are used to provide critical health services, including annual wellness exams, cancer screenings, contraception, and to further the study of sexually-

Exhibit 10

transmitted diseases. Further, no federal funds can be used to cover abortions or health benefits coverage that includes abortions, except in the case of rape, incest, or when the life of the woman is endangered. This has been federal law, enacted in annual appropriations legislation, since the 1980s.

We hope you find this information helpful. Please let us know if we can be of further assistance. We will also provide this response to Senator Johnson.

Sincerely,



Jim R. Esquea
Assistant Secretary
for Legislation

Exhibit 11

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November 9, 2015

VIA ELECTRONIC MAIL & HAND DELIVERY

The Honorable Charles E. Grassley
Chairman, Committee on the Judiciary
United States Senate
SD-224 Dirksen Senate Office Building
Washington, D.C. 20510-6275

Re: ***Planned Parenthood: Reasonable Payments Associated With Fetal Tissue Donation***

Dear Chairman Grassley:

Please accept this letter in further response to your letter dated October 26, 2015 (the "October 26 letter"), requesting that Planned Parenthood Federation of America ("PPFA") and its affiliates provide documents demonstrating the affiliates' costs associated with fetal tissue donation.[1]

As a threshold matter, it is important to restate what PPFA has already communicated publicly and to your staff. At Planned Parenthood—the nation's leading provider of reproductive health care – facilitating patients' donation of fetal tissue has always been an incidental service offered to patients by a small number of affiliates across the country. Today, only two of 59 affiliates—one in Washington and one in California—facilitate their patients' donation of fetal tissue for medical research. During the last five years, 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. Enclosed please find accountings of payments and costs responsive to the Committee's request that were prepared by the four relevant affiliates.

[1] Federal law defines "human fetal tissue" as "tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth." 42 U.S.C. §§ 289g-1(g), 289g-2(e)(1). That definition does not encompass the donation of tissue from other products of conception, such as placental tissue or decidua, for which certain affiliates have also facilitated patient donations for medical research.

Exhibit 11

The enclosed accountings confirm that the four affiliates complied with federal law governing payments associated with the donation of fetal tissue. The relevant statute expressly permits "reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."[2] As you can see from the cost accountings the affiliates have produced, the reasonable payments each received were less than the allowable costs associated with their fetal tissue donation programs—in some cases, by significant margins.

The affiliates' accountings assign their costs of facilitating fetal tissue donation to four general categories of costs for which it is permissible to receive reasonable payments under federal law. Some or all of these four affiliates have incurred, and recovered, costs associated with coordinating tissue collection and processing; costs associated with obtaining patient consent for donation; costs associated with transportation, preservation, quality control, and storage of tissue; and costs associated with the use of health center facility space by organizations that procure donated tissue.[3] As the statutory language, relevant legislative history, and subsequent government reviews make abundantly clear, recovery of each of these types of reasonable costs is both legally permissible and common practice in the medical research community.[4]

Furthermore, the affiliates' cost accountings are based on a conservative interpretation of the law, as they reflect actual costs incurred. The law provides that a donor of fetal tissue may

---

[2] 42 U.S.C. § 289*g*-2(e)(3).

[3] The history of the federal law governing fetal tissue donation makes plain that clinics are permitted to recover the reasonable costs of obtaining consent from patients prior to donation. *See* Report of the Human Fetal Tissue Transplantation Research Panel 37 (1988) [hereinafter Reagan Panel Report] (affirming that "a tissue retrieval agency may reimburse the abortion clinic for using its space and staff to obtain consent for tissue donations"). Indeed, a review conducted in 2000 by the then-titled U.S. General Accounting Office found that clinics donating fetal tissue are commonly reimbursed for the costs associated with obtaining the necessary consent of patients. *See* U.S. Gen. Accounting Office, GAO-01-65R, Human Fetal Tissue: Acquisition for Federally Funded Biomedical Research (2000) [hereinafter GAO, Human Fetal Tissue]. Similarly, a clinic facilitating the donation of fetal tissue may recover the reasonable costs of allowing a tissue procurer to use facility space. *See* Reagan Panel Report at 11 (explaining that reasonable payments for tissue donation are sometimes intended to cover, among other things, "use of the clinic space by employees of the procurement agency"). And in practice, tissue procurers have regularly and properly reimbursed clinics facilitating tissue donation for the costs of using facility space. *See id.* (explaining that tissue procurement organizations, in practice, pay clinics "a small fee for each fetal tissue retrieved to cover the costs of retrieval, including time of staff and rental of space"); David H. Smith et al., Using Human Fetal Tissue for Transplantation and Research: Selected Issues (1988), *reprinted in* Reagan Panel Report app. at F15 (quoting a tissue procurement organization spokesperson as saying they pay clinics "a rental payment for the use of their equipment and facilities, which may range from $300 to $1,000 per month, depending on the amount of time the technicians are in the clinic").

[4] Consistent with accepted accounting practices, several of these permissible cost categories include allocations for the affiliates' indirect costs that make tissue donations possible for Planned Parenthood patients. The failure to account for indirect costs would yield a cost analysis that did not capture the actual costs associated with facilitating fetal tissue donation. *See* Fed. Accounting Standards Advisory Bd., Handbook of Federal Accounting Standards and Other Pronouncements, at SFFAS 1-46 (as amended June 30, 2014) ("Full assignment of all costs of a period, including general and administrative expenses and all other indirect costs, is an important basis for measuring cost of service.").

Exhibit 11

receive "reasonable payments" associated with general categories of activities relating to fetal tissue donation. The affiliates have applied a conservative approach to this language by reading the word "costs" into the statute, but there may be other, more permissive—and legitimate—interpretations of the law that would yield legally proper payments in higher amounts.

In response to your October 26 letter explaining that "demonstration of [the affiliates'] costs is a key issue of concern for this Committee," the affiliates have each performed a good-faith accounting of their costs associated with facilitating fetal tissue donation, and have demonstrated conclusively that those costs exceeded the payments they received. The October 26 letter separately requested that the affiliates provide cost analyses performed, and related documentation created, at the time their tissue donation programs were initiated, including any independent audit opinions the affiliates may have commissioned in order to comply with PPFA's then-existing guidance on facilitating fetal tissue donation. 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. To state the obvious, the absence of contemporaneous documentation or audits does not implicate compliance with federal or state laws. PPFA's guidance exceeded the requirements of the law. Federal law does *not* require a contemporaneous cost analysis or an independent audit opinion *before* facilitating a patient's donation of fetal tissue for medical research. Indeed, the relevant federal statute does not even refer to documentation requirements. Federal law requires only that payments accepted for donating fetal tissue be "reasonable" and "associated with" several broad categories of tissue procurement activities, and the enclosed accountings confirm that these four affiliates complied with this legal requirement. Moreover, in order to end any unfounded accusations in the future that its affiliates were "profiting" by facilitating their patients' donation of tissue for medical research, PPFA recently announced a policy that affiliates may no longer recover even legally permissible costs.

Over the past several months, partisans have seized on the heavily edited videos recorded by anti-choice extremists to allege that Planned Parenthood affiliates "profited" from facilitating fetal tissue donations for medical research. Putting aside the misleading and unreliable nature of those videos, the allegation is absurd on its face. First of all, Planned Parenthood and its affiliates are all nonprofit organizations, and therefore generate no profits from any revenues they receive to reimburse them for their work providing medical and other services. But even more importantly, the payments these affiliates received for facilitating their patients' fetal tissue donations amounted to a miniscule portion of their overall revenues and budgets:

- 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.

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- 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 PPPSW's total revenue.

In other words, for each of the four affiliates, their total payments were no more than a tiny fraction of one percent of the affiliate's operating revenues. It defies logic—and common sense—to assert that these very modest reimbursements motivated affiliates to facilitate tissue donation out of a desire to "profit" from fetal tissue donation.

Moreover, the payments these affiliates received, which ranged from $35 to $60 for all tissue collected from a single patient, are well within the ranges cited in the public record as reasonable reimbursement amounts. The Human Fetal Tissue Transplantation Research Panel convened by President Ronald Reagan (the "Reagan Panel") in 1988—which recommended restoring federal funding to fetal tissue research—included in the appendices to its report anecdotal evidence of fees charged for fetal tissue procurement, including a letter from a biologics company representing that it paid a tissue procurement organization ("TPO") $50 per tissue donation,[5] and a report from the Poynter Center citing another TPO as paying $300 to $1,000 per month in rent to a clinic that facilitated tissue donation.[6] Similarly, a report issued in 2000 by the U.S. Government Accountability Office ("GAO") described a survey of what NIH-funded researchers paid to procure fetal tissue. GAO reported an average fee of $80 per sample, well above the payment amounts the four Planned Parenthood affiliates received here. And these amounts do not even account for the impact of inflation over the last fifteen years; the $50 payment discussed by the 1988 Reagan Panel would be approximately $100 in 2015 dollars, and the $80 payment referenced by the GAO report in 2000 would be approximately $110 in 2015 dollars.[7] Recent press reports about this issue are consistent with these earlier government reports, with researchers and TPO personnel citing reimbursements of up to $100 per sample as reasonable charges to reimburse costs associated with fetal tissue procurement.[8]

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[5] Letter from H. Fred Voss, Vice President, Research & Dev., Hana Biologics, Inc., to Hon. Arlin M. Adams, Chairman, Human Fetal Tissue Transplantation Research Panel (Sept. 15, 1988), *reprinted in* Reagan Panel Report app. at D266.

[6] Smith, *supra* note 3, at F15.

[7] *See* CPI Inflation Calculator, Bureau of Labor Statistics, http://www.bls.gov/data/inflation_calculator.htm.

[8] *See, e.g.*, Denise Grady & Nicholas St. Fleur, Fetal Tissue From Abortions for Research Is Traded in a Gray Zone, N.Y. Times, July 27, 2015, http://www.nytimes.com/2015/07/28/health/fetal-tissue-from-abortions-for-research-is-traded-in-a-gray-zone.html (stating tissue procurement organizations "pay small fees, usually $100 or less a specimen, to abortion providers" in exchange for procurement services); Dave Levitan, Unspinning the Planned Parenthood Video, FactCheck.org, July 21, 2015, http://www.factcheck.org/2015/07/unspinning-the-planned-parenthood-video/ ("Four experts in the field of human tissue procurement told us the price range discussed in the [Center for Medical Progress] video — $30 to $100 per patient — represents a reasonable fee.").

Exhibit 11

In sum, the payments received by these Planned Parenthood affiliates were associated with their costs of facilitating fetal tissue donation and those payments were consistent with well-documented evidence regarding what is considered "reasonable." That the affiliates have now demonstrated that their costs were more than these payments only underscores what has been clear from the beginning of this inquiry: the very few Planned Parenthood affiliates that received reimbursements for facilitating their patients' fetal tissue donations have not profited, and never sought to profit, from this service.

Finally, your October 26 letter requested that we produce all PPFA and affiliate documents provided to the other three congressional committees investigating PPFA and its affiliates. While these documents are not responsive to the Committee's prior requests, our clients are committed to cooperating with this Committee's inquiry and are therefore producing today more than 24,000 pages of documents that we have produced to the other committees as of this date.

We hope that providing these materials today definitively resolves any concerns the Committee may have had regarding this issue and demonstrates the misleading nature of the allegations that have been leveled against our clients by extremists who are opposed to abortion and other legally protected services that Planned Parenthood provides. Should you have any questions, please contact me at your earliest convenience.

Very truly yours,

K. Lee Blalack II / AMS

K. Lee Blalack II
of O'MELVENY & MYERS LLP

cc: The Honorable Patrick J. Leahy
Ranking Minority Member
Committee on the Judiciary
United States Senate

Jason Foster, Esq.
Chief Investigative Counsel
Committee on the Judiciary
United States Senate

Patrick Davis, Esq.
Investigative Counsel
Committee on the Judiciary
United States Senate

Exhibit 11

[redacted]

[redacted]

David J. Leviss, Esq.
O'Melveny & Myers LLP

Exhibit 12

O'MELVENY & MYERS LLP

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February 26, 2016

VIA ELECTRONIC MAIL

Jason Foster, Esq.
Chief Investigative Counsel, Committee on the Judiciary
United States Senate
SD-224 Dirksen Senate Office Building
Washington, D.C. 20510-6275

Re: ***Planned Parenthood Federation of America***

Dear Jason:

By way of this letter, Planned Parenthood Federation of America ("PPFA") supplements information previously provided in response to this Committee's inquiry. In its November 9, 2015 letter, PPFA stated that "[d]uring the last five years, 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." PPFA has since learned that another affiliate, Planned Parenthood of Wisconsin ("PPWI"), also facilitated fetal tissue donations by a limited number of its patients for research in connection with a study conducted at the University of Wisconsin. We have determined that the donations were facilitated in 2010, and the research was published in 2014. PPWI did not receive any reimbursement for its expenses.

Should you have any questions, please feel free to contact me or Dave.

Sincerely,

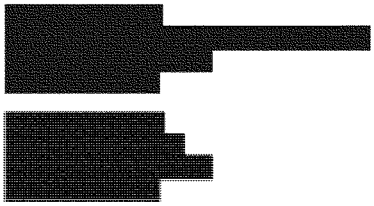
/s/ K. Lee Blalack II

K. Lee Blalack II
of O'MELVENY & MYERS LLP

Exhibit 12

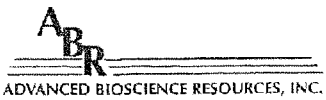
O'MELVENY & MYERS LLP

cc: Patrick Davis, Esq.
Investigative Counsel
Committee on the Judiciary
United States Senate



David J. Leviss, Esq.
O'Melveny & Myers LLP

Exhibit 13



OVERVIEW

ADVANCED BIOSCIENCE RESOURCES is a non-profit corporate foundation established in 1989 under California law to provide biomedical researchers with access to human tissues. ABR was formed exclusively for biomedical, scientific, and educational purposes and is devoted to providing services in connection with the procurement of human organs and tissues for medical and scientific research. ABR specializes in the procurement, preservation and distribution of both human fetal tissues and full term umbilical cord blood for research, and provides a highly individualized, reliable and easily accessible service.

TISSUE COLLECTION AND DISTRIBUTION: The purpose of ABR is to promote cooperative efforts to collect and distribute human tissues and to thereby facilitate research utilizing those tissues. Trained personnel coordinate the retrieval, preservation and delivery of each specimen.

Tissues obtained through ABR are retrieved from routinely performed surgical procedures including first and second trimester induced abortions, and full term deliveries, either natural or caesarian section. Tissues that were once discarded are now available to scientists worldwide through the efforts of ABR. Researchers may specify tissue characteristics, preservation methods, and delivery times.

PRESERVATION METHODS: Each specimen is collected, preserved, and shipped according to the investigator's individual protocol.

QUALITY CONTROL: ABR practices strict quality control procedures and adheres to stringent guidelines for tissue collection and preservation. Consent is obtained in accordance with UAGA and NOTA and AATB guidelines. Tissue specimens are identified, dissected, and transferred to specified medium. A random control number is assigned to each sample to ensure patient identity confidentiality.

To assure proper processing of the tissue, every researcher selects a collection/preservation protocol tailored specifically to his needs. In the collection and distribution of these tissues, every effort is made to exercise the highest standards of medical and laboratory practice. ABR specializes in direct communication with each investigator from the initial application through tissue collection to specimen delivery.

APPLICATION PROCESS: To request human tissue for research, an application for tissue acquisition must be completed and submitted to ABR. The application identifies the medical/scientific institution and principal investigator, and the specific research work intended. The application is reviewed for feasibility and priority, and, if approved, a protocol will be developed to meet the individual research needs.

INVESTIGATOR APPROVAL: ABR will provide tissue to researchers when application information is verified, including information on current research funding and a short summary of their research intent. Investigators must agree to accept responsibility for the potential biohazard of the tissue and to appropriately train laboratory personnel in the proper handling of the tissue. In addition, the researcher must agree to use the tissue solely for research or transplantation research purposes and to acknowledge ABR in any publications resulting from the use of ABR- provided tissue.

SERVICE AND PROCESSING FEES: Participating medical facilities that enable ABR to execute its tissue acquisition and distribution programs may be paid a nominal fee for such services. A minimal processing / preservation / shipment fee is also assessed for services provided to research facilities.

Exhibit 14

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November 23, 2015

Jonathan E. Lopez
(202) 339-8456
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CONFIDENTIAL TREATMENT REQUESTED
VIA ELECTRONIC MAIL

Charles E. Grassley
Chairman
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, D.C. 90510-6275
[redacted]

Dear Chairman Grassley:

Pursuant to Advanced Bioscience Resources, Inc.'s ("ABR") continuing cooperation with the Senate Judiciary Committee's investigation, we respond to your letter dated November 9, 2015, directed to Ms. Linda Tracy, President of ABR.

As you noted, these responses and documents are made in conjunction with ABR's presentation to Committee Staff Members on September 3, 2015 and prior document productions. The documents we are producing will appear in the order they are discussed in this letter and are bates-stamped SJC000057 to SJC000539. Researcher names and institutions have been redacted for safety and potential confidentiality concerns.

1. ABR reimbursed Planned Parenthood Mar Monte (PPMM) and Planned Parenthood Pacific Southwest (PPPSW)[1] 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.

2. We confirm that PPMM provided notice of termination of its relationship with ABR as of June 2010, to be effective as of July 2010, i.e., 30 days after notice was sent.

    a. ABR did not receive invoices from PPMM. Rather, ABR's practice was to send PPMM the accrued reimbursement at the end of each month with a "Statement of Facility Fees" listing the total procurement and associated reimbursement amount. Attached are the "Statements of Facility Fees" sent to PPMM between June 2009

[1] PPPSW was previously named Planned Parenthood San Diego & Riverside Counties.

Exhibit 14

and June 2010.

b. Attached are the "POC Procurement Logs" between June 2009 and June 2010, which list all fetal tissue and maternal blood procured.

c. To the best of Ms. Tracy's recollection, PPMM's director and Ms. Tracy had a telephone call around the time that ABR received the termination notice. There was no specific reason provided for the termination during the phone call and there was no further inquiry or communications.

3. We confirm that ABR had a contractual relationship with PPPSW from 1999 to present.

a. ABR engaged in the same practice with PPPSW as with PPMM with respect to "Statement of Facility Fees," described *infra* at 2a. Attached are the "Statements of Facility Fees" sent to PPPSW between January 2014 and December 2014.

b. After our presentation to you, ABR and the undersigned counsel were informed that Planned Parenthood intended to change its contractual relationships for fetal tissue procurement. On October 13, 2015, [redacted], General Counsel of PPPSW, provided ABR and the undersigned counsel with a letter from [redacted] President of Planned Parenthood Federation of America, to [redacted], Director of the National Institutes of Health, which stated that Planned Parenthood health centers that were donating fetal tissue would continue to do so without receiving any reimbursement for the reasonable expenses. On October 16, 2015, [redacted] sent a letter to Ms. Tracy that PPPSW would no longer accept reimbursement as of October 14, 2015 and requested Ms. Tracy countersign the letter to act as an amendment to the October 1, 2010 agreement between PPPSW and ABR. Attached are the October 13, 2015 and October 16, 2015 letters.

c. Attached are the "POC Procurement Logs" between January 2014 and December 2014, which list all fetal tissue and maternal blood procured.

4. We explained at the September 3, 2015 meeting that we were unclear whether PPPSW executed the January 2012 Addendum as we only had a version executed by Ms. Tracy. However, we confirmed to you that nothing was undertaken under that January 2012 Addendum.

a. As used in the January 2012 Addendum, Regulated Tissue Acquisition is the same process described at 42 U.S.C. sec. 289g-1.

Exhibit 14

ORRICK

Charles E. Grassley
November 23, 2015
Page 3

b. We again confirm that ABR has never performed a Regulated Tissue Acquisition with any Planned Parenthood health center, including PPPSW.

5. 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.

6. 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.

7. ABR does not know whether the videos doctored by the Center for Medical Progress or the statements made by PP employees in those videos are fulsome or accurate. ABR can only comment as to its own practices.

   a. Paragraph 6 of the October 1, 2010 contract between ABR and PPPSW (*see* SJC0000032) provides, in part, "The term of this Agreement shall be for three (3) years, beginning from the date hereof, and terminating three (3) years thereafter, unless either of the parties hereto shall have given the other thirty (30) days' written notice of its intention to terminate this Agreement. .. In default of notice as aforesaid from either party hereto, this Agreement shall continue for further successive terms of one (1) year thereafter . . ."

      The October 1, 2010 contract was scheduled to expire in September 2013. The contract was renewed for successive one (1) year terms.

   b. You have been provided the October 2010 contract which contains the terms applicable to the relationship between ABR and PPPSW until October 2015. *See* SJC0000031-SJC0000033.

8. Your letter requests "invoices ABR sent to its customers." By "customers," we assume you mean researchers. As we explained, ABR assists medical and educational researchers with access to fetal tissue and maternal blood. Attached are the June 2014 statements to researchers.

ABR respectfully requests that all materials and information provided to the Senate Committee on the Judiciary ("Senate Judiciary Committee") during the course of its inquiry, as well as this transmittal letter, (collectively, "ABR materials") be deemed private and confidential business information. The ABR materials included in this and future productions may represent privileged information, confidential private employee information, commercial information, or financial

Exhibit 14

ORRICK

information. ABR's productions do not waive any of those or other privileges that may be available to ABR.

We also request that the ABR materials be kept in a non-public file and that only the Senate Judiciary Committee members and their staff have access to them. Should the Senate Judiciary Committee receive any request for these documents or have the need to disclose them in a hearing or otherwise, we request that the undersigned be notified immediately of the request or disclosure (preferably by telephone), be provided a copy of all written materials pertaining to the request or disclosure, and reasonable opportunity to respond, before any determination that this letter, its enclosures, and/or the information or data contained therein will be produced or disclosed. We further request that we be notified promptly of any determinations with respect to such requests or disclosure and be given ten (10) days' notice before any intended release.

Thank you for your cooperation in this matter. Please contact me if you have any questions about this production or any other issue.

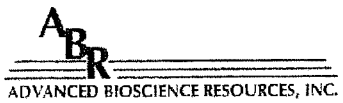
Sincerely,

Jonathan E. Lopez

Enclosures

cc: [redacted]

Exhibit 15



AGREEMENT

This agreement is made as of *"DATE"* between Advanced Bioscience Resources, Inc. ("ABR"), a non-profit foundation organized and existing under the laws of California, and *"FACILITY"*, a professional corporation.

WHEREAS, ABR is an organization devoted to providing services in connection with the procurement of human organs and tissues for medical research; and

WHEREAS, *"FACILITY"* has agreed to provide services to ABR to facilitate the accomplishment of such purpose;

NOW, THEREFORE, in consideration of the premises and mutual covenants contained herein, the parties agree as follows:

1. The term "fetal organ" has the same meaning as the term defined in 42 U.S.C.A. 274 e(c)(1) of the National Organ Transplant Act; that is, the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, organ or any subpart thereof, as derived from a fetus.

2. The term "product of conception" ("POC") means any fetal organ or other fetal or placental material taken from the human uterus during an abortion.

3. *"FACILITY"* will provide, and ABR will pay the reasonable costs for, services and facilities (hereinafter collectively "services") associated with obtaining patients' 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, which includes consent for the acquisition of blood samples for testing pertinent to specified research, and maintaining records of such consents so that verification of consent can be supported.

4. The charge to ABR for the services specified in this Agreement in connection with each POC provided to and used by ABR shall be fifty dollars ($50.00).

5. Any information obtained from *"FACILITY"* patients' charts shall be privileged and the contents of same shall be held so as to preserve the confidentiality of patients. ABR is not entitled to and will not receive information concerning identity of donors except as specified per HIPAA Privacy Rule.

6. ABR warrants that its employees will have current certification for phlebotomy, as well as current OSHA and HIPAA training and certification. ABR warrants that its employees have been verified for employment through appropriate background checks and warrants that no ABR employee working at *"FACILITY"* sites has any record of a criminal conviction. An authorized representative of *"FACILITY"* may conduct audits of ABR employee files at the offices of ABR at [redacted] upon notification and request.

7. The term of this Agreement shall be for one (1) year, beginning from the date hereof, and terminating one (1) year thereafter, unless either of the parties hereto shall have given the other thirty (30) days' written notice of its intention to terminate this Agreement, whereupon same shall terminate thirty (30) days after date of said notice. In default of notice as aforesaid from either party hereto, this Agreement shall continue for further successive terms of one (1) year thereafter and, in default of thirty (30) days' written notice before the end of an annual term either of the parties hereto of its intention not to renew, whereupon this Agreement shall terminate at the end of said term.

[redacted] SJC000040

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Exhibit 15

8. Written notices pursuant to this Agreement shall be sent first class mail, postage prepaid, to:

"FACILITY"

_____

_____

Advanced Bioscience Resources, Inc.

[redacted]

9. The parties do not know how many patients will sign the consent forms in agreement to donate POC's for research, and therefore do not know how many POCs may be supplied thereunder. *"FACILITY"* shall not be obligated to provide any minimum number of POCs; ABR shall not be obligated to take any minimum number of POCs, nor shall ABR be obligated to take all the POCs made available by *"FACILITY"*.

10. The parties hereto hereby mutually agree to defend, protect, and save harmless each other's officers, directors, agents and/or employees or consultants from and against all expenses, liabilities, demand or claims for loss or damage to, property, or personal injury or death suffered as a result of any actions by the parties hereto in the performance of the Agreement and attributable to the fault or negligence of the parties hereto or their respective officers, directors, agents and/or employees or consultants.

11. No modification to this Agreement, nor any waiver of any rights, shall be effective unless agreed in writing by the party to be charged with such waiver or modification, and the waiver of any breach or default shall not constitute a waiver of any other right hereunder or any subsequent breach or default.

12. This Agreement constitutes the entire and exclusive agreement between the parties hereto with respect to its subject matter and merges all other communication and discussion, oral or written.

13. This Agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of law and venue for any dispute arising hereunder shall be in the County of Alameda.

14. The prevailing party in any action to enforce the terms of the Agreement shall be entitled to reimbursement by the other party for all costs (including the reasonable fees of attorneys and other professionals) incurred in connection with such proceeding.

15. This Agreement may be executed in counterparts, each of which will be deemed an original, but both of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed in duplicate by their duly authorized representatives as of the date first above written.

"FACILITY"

By: _____

Advanced Bioscience Resources, Inc.

By: _____
Linda Tracy, RN, President, CTBS

Federal EIN: 94-3110160
California EIN: 370-20518
FDA DHHS FEI: 3005208435

~~CONFIDENTIAL TREATMENT REQUESTED~~

SJC000041

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Exhibit 16

AGREEMENT

This agreement is made as of November 21, 1997, 1997 between Advanced Bioscience Resources, Inc. ("ABR"), a non-profit corporation organized and existing under the laws of California, and Planned Parenthood Mar Monte, a professional corporation.

. ABR warrants that it operates under applicable local, state and federal law as a federally approved non-profit corporation. Additionally, ABR warrants that it operates its tissue procurement and distribution programs in compliance with all local, state and federal laws and regulations governing the procurement and distribution of human tissue.

WHEREAS, ABR is an organization devoted to providing services in connection with the procurement of human organs and tissues for medical research; and

WHEREAS, Planned Parenthood Mar Monte has agreed to provide services to ABR to facilitate the accomplishment of such purpose;

NOW, THEREFORE, in consideration of the premises and mutual covenants contained herein, the parties agree as follows:

1. The term "fetal organ" has the same meaning as the term defined in 42 U.S.C.A. 274 e(c)(1) of the National Organ Transplant Act; that is, the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, organ or any subpart thereof, as derived from a fetus.

2. The term "product of conception" ("POC") means any fetal organ or other fetal or placental material taken from the human uterus during an abortion.

3. Planned Parenthood Mar Monte will provide, and ABR will pay the 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.

4. 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). ABR shall make monthly payments to Planned Parenthood Mar Monte on the 15th of each month for services provided in the prior month.

Exhibit 16

5. Any information obtained from Planned Parenthood Mar Monte patients' charts shall be privileged and the contents of same shall be held so as to preserve the confidentiality of patients. ABR is not entitled to and will not receive information concerning identity of donors except as specified.

6. The term of this Agreement shall be for one (1) year, beginning from the date hereof, and terminating one (1) year thereafter, unless either of the parties hereto shall have given the other thirty (30) days' written notice of its intention to terminate this Agreement, whereupon same shall terminate thirty (30) days after date of said notice. In default of notice as aforesaid from either party hereto, this Agreement shall continue for further successive terms of one (1) year thereafter and, in default of thirty (30) days' written notice before the end of an annual term either of the parties hereto of its intention not to renew, whereupon this Agreement shall terminate at the end of said term.

7. Written notices pursuant to this Agreement shall be sent first class mail, postage prepaid, to:

Planned Parenthood Mar Monte
[redacted]

Advanced Bioscience Resources, Inc.
[redacted]

8. The parties do not know how many patients will sign the consent forms in agreement to donate POC's for research and therapy, and therefore do not know how may POC's will be supplied thereunder. Planned Parenthood Mar Monte shall not be obligated to provided any minimum number of POC's; ABR shall not be obligated to take any minimum number of POCs, nor shall ABR be obligated to take all the POCs made available by Planned Parenthood Mar Monte.

9. The parties hereto hereby mutually agree to defend, protect, and save harmless each other's officers, directors, agents and/or employees or consultants from and against all expenses, liabilities, demand or claims for loss or damage to, property, or personal injury or death suffered as a result of any actions by the parties hereto in the performance of the Agreement and attributable to the fault or negligence of the parties hereto or their respective officers, directors, agents and/or employees or consultants.

10. No modification to this Agreement, nor any waiver of any rights, shall be effective unless agreed in writing by the party to be charged with such waiver or modification, and the waiver of any breach or default shall not constitute a waiver of any other right hereunder or any subsequent breach or default.

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Exhibit 16

11. This Agreement constitutes the entire and exclusive agreement between the parties hereto with respect to its subject matter and merges all other communication and discussion, oral or written.

12. This Agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of law and venue for any dispute arising hereunder shall be in the County of Alameda, California.

13. The prevailing party in any action to enforce the terms of the Agreement shall be entitled to reimbursement by the other party for all costs (including the reasonable fees of attorneys and other professionals) incurred in connection with such proceeding.

14 This Agreement may be executed in counterparts, each of which will be deemed an original, but both of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed in duplicate by their duly authorized representatives as of the date first above written.

Planned Parenthood Mar Monte

By: [redacted]

Print Name

12/11/97

Date

Advanced Bioscience Resources, Inc.

By: Linda Tracy

Linda Tracy, RN, President

12/19/97

Date

Federal EIN: 94-3110160
California EIN: 370-20518

~~CONFIDENTIAL TREATMENT REQUESTED~~

SJC000003

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Exhibit 16

ADVANCED BIOSCIENCE RESOURCES, INC

AGREEMENT

This agreement is made as of November 1, 2007 between Advanced Bioscience Resources, Inc ("ABR"), a non-profit corporation organized and existing under the laws of California, and Planned Parenthood Mar Monte, a professional corporation.

WHEREAS, ABR is an organization devoted to providing services in connection with the procurement of human organs and tissues for medical research; and

WHEREAS, Planned Parenthood Mar Monte has agreed to provide services to ABR to facilitate the accomplishment of such purpose;

NOW, THEREFORE, in consideration of the premises and mutual covenants contained herein, the parties agree as follows:

1. The term "fetal organ" has the same meaning as the term defined in 42 U.S.C.A. 274 e(c)(1) of the National Organ Transplant Act: that is, the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, organ or any subpart thereof, as derived from a fetus.

2. The term "product of conception" ("POC") means any fetal organ or other fetal or placental material taken from the human uterus during an abortion.

3. Planned Parenthood Mar Monte will provide, and ABR will pay the 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.

4. The charge to ABR for the services specified in this Agreement in connection with each POC provided to ABR shall be fifty-five dollars ($55.00)

5. Any information obtained from Planned Parenthood Mar Monte patients' charts shall be privileged and the contents of same shall be held so as to preserve the confidentiality of patients. ABR is not entitled to and will not receive information concerning identity of donors except as specified.

6. The term of this Agreement shall be for one (1) year, beginning from the date hereof, and terminating one (1) year thereafter, unless either of the parties hereto shall have given the other thirty (30) days' written notice of its intention to terminate this Agreement, whereupon same shall terminate thirty (30) days after date of said notice. In default of notice as aforesaid from either party hereto, this Agreement shall continue for further successive terms of one (1) year thereafter and, in default of thirty (30) days' written notice before the end of an annual term either of the parties hereto of its intention not to renew, whereupon this Agreement shall terminate at the end of said term.

7. Written notices pursuant to this Agreement shall be sent first class mail, postage prepaid, to:

Planned Parenthood Mar Monte

[redacted]

Advanced Bioscience Resources, Inc

[redacted]

[redacted] / [redacted]

Exhibit 16

8. The parties do not know how many patients will sign the consent forms in agreement to donate POC's for research and therapy, and therefore do not know how may POC's will be supplied thereunder. Planned Parenthood Mar Monte shall not be obligated to provided any minimum number of POC's; ABR shall not be obligated to take any minimum number of POCs, nor shall ABR be obligated to take all the POCs made available by Planned Parenthood Mar Monte.

9. The parties hereto hereby mutually agree to defend, protect, and save harmless each other's officers, directors, agents and/or employees or consultants from and against all expenses, liabilities, demand or claims for loss or damage to, property, or personal injury or death suffered as a result of any actions by the parties hereto in the performance of the Agreement and attributable to the fault or negligence of the parties hereto or their respective officers, directors, agents and/or employees or consultants.

10. No modification to this Agreement, nor any waiver of any rights, shall be effective unless agreed in writing by the party to be charged with such waiver or modification, and the waiver of any breach or default shall not constitute a waiver of any other right hereunder or any subsequent breach or default.

11. This Agreement constitutes the entire and exclusive agreement between the parties hereto with respect to its subject matter and merges all other communication and discussion, oral or written.

12. This Agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of law and venue for any dispute arising hereunder shall be in the County of Los Angeles.

13. The prevailing party in any action to enforce the terms of the Agreement shall be entitled to reimbursement by the other party for all costs (including the reasonable fees of attorneys and other professionals) incurred in connection with such proceeding.

14. This Agreement may be executed in counterparts, each of which will be deemed an original, but both of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed in duplicate by their duly authorized representatives as of the date first above written.

Planned Parenthood Mar Monte [redacted]

Advanced Bioscience Resources, Inc

By: Linda Tracy
Linda Tracy, RN, President, CTBS

Federal EIN: 94-3110160
California EIN: 370-20518
FDA DHHS FEI: 3005208435

~~CONFIDENTIAL TREATMENT REQUESTED~~

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Exhibit 16

BUSINESS ASSOCIATE AGREEMENT

THIS AGREEMENT is entered into by and between Planned Parenthood Mar Monte, located at [redacted] ("Covered Entity") and Advanced Bioscience Resources, Inc. (ABR), ("Business Associate"). (Individually a "Party" and collectively the "Parties").

WITNESS:

The Privacy Regulation of the Health Insurance Portability and Accountability Act (HIPAA) imposes certain restrictions on the use and disclosure of Protected Health Information ("PHI");

Covered Entity desires to disclose PHI to Business Associate or allow others to disclose PHI to Business Associate on Covered Entity's behalf to perform certain Healthcare Operation activities;

Covered Entity understands that it must enter into this Agreement so that PHI may be disclosed to Business Associate and to allow Business Associate to perform and provide services to Covered Entity.

Therefore, in consideration of good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree to the provisions of this Agreement to comply with the Privacy Regulation and to protect the interests of both Parties:

I. Definitions

The following terms shall have the meaning ascribed to them in this Section. Other capitalized terms shall have the meaning ascribed to them in the context in which they first appear. Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in the Privacy Regulation.

(a) Agreement. "Agreement" refers to this Business Associate Agreement. This Agreement follows and incorporates the Sample Business Associate Contract Provisions found in the Preamble's Appendix to the Final Modification to the Privacy Regulation. *See* 67 Fed. Reg. 53264-66.

(b) Business Associate. "Business Associate," as used in this Agreement, refers to Advanced Bioscience Resources, Inc. (ABR)

(c) Covered Entity. "Covered Entity," as used in this Agreement, refers to Planned Parenthood Mar Monte, [redacted]

(d) Health Care Operations. "Health Care Operations shall have the same meaning as the term "health care operations" in 45 CFR 164.501.

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SJC000006

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Exhibit 16

(e) Individual. "Individual," as used in this Agreement, has the same meaning as the term "individual" in 45CFR 164.501 and includes a person who qualifies as a personal representative in accordance with 45 CFR 164.502.

(f) Privacy Regulation. "Privacy Regulation" means the Standards for Privacy of Individually Identifiable Health Information at 45 CFR Parts 160 and 164.

(g) Protected Health Information (PHI). "Protected Health Information" shall have the same meaning as the term "protected health information" in 45 CFR 164.501 and shall refer to PHI obtained from Covered Entity or obtained by Business Associate on behalf of Covered Entity.

(h) Required By Law. "Required By Law" shall have the same meaning as the term "required by law" in 45 CFR 164.501.

(i) Secretary. "Secretary" shall mean the Secretary of the Department of Health and Human Services or his/her designee.

II. Obligations and Activities of Business Associate

(a) Business Associate agrees to not use or disclose PHI other than as Permitted or required by this Agreement or as Required By Law.

(b) Business Associate agrees to use appropriate safeguards to prevent use or disclosure of PHI other than as provided for by this Agreement.

(c) Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI in violation of the requirements of this Agreement.

(d) Business Associate agrees to report to Covered Entity any use or disclosure of PHI not provided for by this Agreement of which it becomes aware. Business Associate also agrees to report to Covered Entity any security incident that relates to the applicable safeguards described in Section II. (b) above.

(e) Business Associate agrees to ensure that every contractor or agent, to whom Business Associate provides PHI received from Covered Entity or on behalf of Covered Entity, agrees to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to PHI.

(f) Business Associate agrees to provide Covered Entity or, as directed by Covered Entity, an Individual, access to PHI in order to meet the requirements under 45 CFR 164.524, in a time and manner reasonably agreed upon by the Parties.

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SJC000007

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Exhibit 16

(g) Business Associate agrees to make any amendment(s) to PHI that Covered Entity directs or agrees to pursuant to 45 CFR 164.526 at the request of Covered Entity or an Individual, in a time and manner reasonably agreed upon by the Parties.

(h) Business Associate agrees to make its internal practices, books, and records, including policies and procedures, relating to the use and disclosure of PHI received from, or created or received by Business Associate on behalf of Covered Entity, available to the Secretary, in a time and manner reasonably agreed upon or designated by the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the Privacy Regulations.

(i) Business Associate agrees to document disclosures of PHI as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 CFR 164.528.

(j) Business Associate agrees to provide to Covered Entity or an Individual, in a time and manner reasonably negotiated, PHI given to Business Associate, to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 CFR 164.528.

III. **Permitted Uses and Disclosures by Business Associate**

Except as otherwise limited in this Agreement, Business Associate may use or disclose PHI: not applicable 11/15/07 [illegible]

IV. **Specific Use and Disclosure Provisions**

(a) Except as otherwise limited in this Agreement, Business Associate may use PHI for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate.

(b) Except as otherwise limited in this Agreement, Business Associate may disclose PHI for the proper management and administration of Business Associate, provided that such disclosures are Required By Law, or Business Associate obtains reasonable assurances from the person to whom the PHI is disclosed that it will remain confidential and used or further disclosed only as Required By Law or for the purpose for which it was disclosed to the person, and the person notifies Business Associate of any instances of which it is aware that the confidentiality of the PHI has been breached.

(c) Except as otherwise limited in this Agreement, Business Associate may use PHI to provide Data Aggregation services to Covered Entity as permitted by 42 CFR 164.504(e)(2)(i)(B).

~~CONFIDENTIAL TREATMENT REQUESTED~~

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Exhibit 16

(d) Business Associate may use PHI to report violations of law to appropriate Federal and State authorities, consistent with Sec. 164.502(j)(1).

V. Obligations of Covered Entity

(a) Covered Entity shall notify Business Associate of any limitation(s) in its Notice of Privacy Practices, in accordance with 45CFR 164.520, to the extent that such limitation may affect Business Associate's use or disclosure of PHI.

(b) Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by an Individual to use or disclose PHI, to the extent that such changes may affect Business Associate's use or disclosure of PHI.

(c) Covered Entity shall notify Business Associate of any restriction to the use or disclosure of PHI that Covered Entity has agreed to in accordance with 45 CFR 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of PHI.

VI. Permissible Requests By Covered Entity

Covered Entity shall not request Business Associate to use or disclose PHI in any manner that would not be permissible under the Privacy Regulation if done by Covered Entity.

VII. Term and Termination

(a) Term. The Term of this Agreement shall be effective when this Agreement is signed by both parties, and shall terminate when all of the PHI provided by Covered Entity to Business Associate is no longer needed by Business Associate for service described in Section III of Agreement.

(b) Termination for Cause. Upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity shall either:

(1) Provide an opportunity for Business Associate to cure the breach or end the violation and terminate this Agreement if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity;

(2) Immediately terminate this Agreement if Business Associate has breached a material term of this Agreement and cure is not possible; or

(3) If neither termination nor cure is feasible, Covered Entity shall report the violation to the Secretary.

(c)

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Exhibit 16

Effect of Termination.

(1) Except as provided below in paragraph (2) of this section, upon termination of this Agreement, for any reason, Business Associate shall return or destroy all PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the PHI.

(2) In the event that Business Associate determines that returning or destroying the PHI is infeasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. Upon written notification that return or destruction of PHI is infeasible, Business Associate shall extend the protections of this Agreement to such PHI and limit further uses and disclosures of PHI for so long as Business Associate maintains such PHI.

VIII. Miscellaneous

(a) Regulatory References. A reference in this Agreement to a section in the Privacy Regulation means the section as in effect or as amended.

(b) Amendment. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy Regulation.

(c) Survival. The respective rights and obligations of Business Associate under Section VII of this Agreement shall survive the termination of this Agreement.

(d) Interpretation. Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the Privacy Regulation.

ADDENDUM TO PPMM BUSINESS ASSOCIATE AGREEMENT

WHEREAS, the Department of Health and Human Services published a final rule relating to the Security Standards under HIPAA codified at 45 CFR Parts 160 and 164 (Security Rule); and

WHEREAS, the Security Rule requires the Covered Entity to ensure that the Business Associate agrees to certain safeguards and terms relating to the security of

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Exhibit 16

Electronic Protected Health Information. Specifically, the Covered Entity, in accordance with Sec. 164.306, may permit a Business Associate to create, receive, maintain, or transmit EPHI on the Covered Entity's behalf only if the Covered Entity obtains satisfactory assurances, in accordance with Sec. 164.314(a) that the Business Associate appropriately safeguards the information.

Business Associates with a current signed BAA prior to April 20, 2005, have the option of signing a new BAA that has these provisions included or this amendment to the existing BAA.

NOW, **THEREFORE**, in consideration of the mutual covenants and agreements herein contained, the parties agree to the following:

1. The BAA executed by the parties is amended to add the terms and conditions in this Addendum.

2. Terms used, but not otherwise defined, in this Addendum shall have the same meaning as those terms in the Security Rule. These include but are not limited to:

Electronic media has the meaning 45 in CFR § 160.103, which is:

a. Electronic storage media including memory devices in computers (hard drives) and any removable or transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or

b. Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the Internet, extranet, leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and via telephone, are not considered transmissions via electronic media because the information did not exist in electronic form before the transmission.

Electronic Protected Health Information or "EPHI" has the meaning in 45 CFR § 160.103, and is defined as that received from, or created or received on behalf of PPMM.

Security Incident has the meaning in 45 CFR § 164.304, which is the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations.

The Business Associate will:

a. Implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the EPHI that it creates, receives, maintains, or transmits on behalf of the Covered Entity;

b. Ensure that any agent, including a subcontractor, to whom it provides such information agrees to implement reasonable and appropriate safeguards to protect it; and

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Exhibit 16

c. Beginning on April20, 2005, report to the Covered Entity any Security Incident of which it becomes aware, in the following time and manner:

(i) Any actual, successful Security Incident will be reported to the Covered Entity in writing, within five (5) business days of the date on which Business Associate becomes aware of such Security Incident

(ii) Any attempted, unsuccessful Security Incident of which Business Associate becomes aware, will be reported to the Covered Entity in writing, on a reasonable basis, at the written request of the Covered Entity. If the Security Rule is amended to remove the requirement to report unsuccessful attempts at unauthorized access, this subsection (ii) shall no longer apply as of the effective date of the amendment of the Security Rule.

Covered Entity and Business Associate have caused this Business Associate Agreement and the Adendum to the Business Associate Agreement to be signed and delivered by their duly authorized representatives, as of the date set forth below.

Advanced Bioscience Resources, Inc.	PLANNED PARENTHOOD MAR MONTE [redacted]
By: Linda K Tracy	
Print Name: Linda K. Tracy	
Title: President	Title: Vice President of Services
Date: 14 Nov 2007	Date: Nov 20, 2007

October, 2006

~~CONFIDENTIAL TREATMENT REQUESTED~~

SJC0000012

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Exhibit 16

} Parenthood

Planned Parenthood
Mar Monte

Our mission is to ensure that everyone has the knowledge, opportunity and freedom to make every child a wanted child and every family a healthy family.

Plan
Mar Mo

March 4, 20010

Advanced Bioscience Resources, Inc. (ABR)
Linda Tracy
[redacted]

Dear Linda:

In August I wrote to inform you that we anticipated needing to revise our Business Associate Agreement (BAA) in response to the recently established security requirements of the Health Information Technology for Economic and Clinical Health (HITECH) Act. The enclosed BAA reflects these new requirements.

Please review this revised BAA carefully; sign it; and return the signed copy to my attention at Planned Parenthood Mar Monte (PPMM). If you have any questions about the information presented in the BAA, please contact me via email at [redacted] You may also contact me by phone at [redacted]

Thank you for your ongoing collaboration with PPMM.

Sincerely,

[redacted]
PPMM Compliance and Safety Officer

Exhibit 16

PLANNED PARENTHOOD MAR MONTE
BUSINESS ASSOCIATE AGREEMENT

This AGREEMENT is entered into on this 4th day of March 2010, by and between Planned Parenthood Mar Monte, located at [redacted] (herein after "Covered Entity") and **Advanced Bioscience Resources, Inc. (ABR)**, located at [redacted] **(herein after "Business Associate")** (collectively the "Parties").

WITNESSETH:

WHEREAS, the Health Insurance Portability and Accountability Act's ("HIPAA") Privacy Rule imposes certain restrictions on the use and disclosure of Protected Health Information ("PHI") in any format;

WHEREAS, the HIPAA Security Rule imposes certain restrictions on the use and disclosure of Protected Health Information in an electronic format ("ePHI");

WHEREAS, Covered Entity is permitted to make available and/or transfer to Business Associate PHI that is confidential and must be afforded special treatment and protection under the Privacy Rule and Security Rule;

WHEREAS, Business Associate shall provide service(s) to or on behalf of Covered Entity thereby creating a business associate relationship under the Privacy Rule and Security Rule;

WHEREAS, Business Associate agrees that it will use and disclose PHI according to the terms and conditions set forth in this Agreement.

NOW, THEREFORE, Covered Entity and Business Associate agree as follows:

I. **Definitions**

The following terms shall have the meaning ascribed to them in this Section. Other capitalized terms shall have the meaning ascribed to them in other sections of this Agreement. Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in the Privacy Rule, the Security Rule, HIPAA and/or the HITECH Act (as defined below).

(a) Agreement. "Agreement" refers to this Business Associate Agreement between the Parties.

(b) Breach. "Breach" shall mean the acquisition, access, use or disclosure of PHI (as defined herein) in a manner not permitted by the Privacy Rule that compromises the security or privacy of the PHI, subject to the exceptions set forth, in 45 CFR 164.402.

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(c) Business Associate. "Business Associate" shall have the same meaning as the term "Business Associate" in 45 CFR 160.103.

(d) Compliance Date. "Compliance Date" shall mean, in each case, the date by which compliance is required under the referenced provision of HITECH and/or its implementing regulations, as applicable.

(e) Covered Entity. "Covered Entity" shall have the same meaning as the term "Covered Entity" in 45 CFR 160.103.

(f) Designated Record Set. "Designated Record Set" shall have the same meaning as the term "Designated Record Set" in 45 CFR 164.501.

(g) Electronic Media. "Electronic Media" shall have the same meaning as the term "Electronic Media" in 45 CFR 160.103.

(h) Electronic Protected Health Information or e-PHI. "Electronic Protected Health Information" or "ePHI" shall have the same meaning as the term "Electronic protected health information" in 45 CFR 160.103, limited to the information created or received by Business Associate from or on behalf of Covered Entity.

(i) Health Care Operations. "Health Care Operations" shall have the same meaning as the term "health care operations" in 45 CFR 164.501.

(j) HITECH Act. "HITECH Act" shall mean Subtitle D of the Health Information Technology for Economic and Clinical Health Act provisions of the American Recovery and Reinvestment Act of 2009, 42 USC 17921-17954, and any and all references in this Agreement to sections of the HITECH Act shall be deemed to include all associated existing and future implementing regulations, when and as each is effective.

(k) Individual. "Individual" shall have the same meaning as the term "individual" in 45 CFR 160.103 and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g).

(l) Payment. "Payment" shall have the same meaning as the term "payment" in 45 CFR 164.501

(m) Privacy Rule. "Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR Part 160 and Part 164, Subparts A and E.

(n) Protected Health Information or PHI. "Protected Health Information" or "PHI" shall have the same meaning as the term "Protected Health Information" in 45 CFR 160.103, limited to the information created or received by Business Associate from or on behalf of Covered Entity.

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(o) Required By Law. "Required By Law" shall have the same meaning as the term "required by law" in 45 CFR 164.103.

(p) Secretary. "Secretary" shall mean the Secretary of the Department of Health and Human Services or his/her designee.

(q) Security Incident. ""Security Incident" shall have the same meaning as the term "Security incident" in 45 CFR 164.304.

(r) Security Rule. "Security Rule" shall mean the Security Standards, as amended from time to time, at 45 CFR Part 160 and Part 164, Subparts A & C.

(s) Unsecured PHI. "Unsecured PHI" shall mean PHI that is not maintained in the manner set forth in the Guidance Specifying the Technologies and Methodologies that Render Protected Health Information Unusable, Unreadable or Indecipherable to Unauthorized Individuals, published on the Department of Health and Human Services website.

II. Obligations and Activities of Business Associate

(a) Business Associate agrees to not use or disclose PHI other than as necessary to provide the Services to or on behalf of Covered Entity, as permitted or required by this Agreement, and in compliance with each applicable requirement of 45 CFR 164.504(e) or as otherwise Required By Law. Further, Business Associate agrees to not use or disclose PHI in any manner that would not be permissible under the Privacy Rule if done by Covered Entity.

(b) Business Associate agrees to use appropriate safeguards to prevent use or disclosure of PHI other than as provided for by this Agreement. Without limiting the foregoing, Business Associate agrees to implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of any ePHI that Business Associate creates, receives, maintains, or transmits on behalf of Covered Entity; and comply with the Security Rule requirements set forth in 45 CFR 164.308, 164.310, 164.312, and 164.316.

(c) Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI that constitutes a violation of any requirement of this Agreement.

(d) Business Associate agrees to notify Covered Entity without unreasonable delay, and in any event on or before five (5) business days after its discovery of any use or disclosure of PHI not provided for by this Agreement of which it becomes aware, in accordance with 45 CFR 164.504(e)(2(ii)(c); and any Security Incident of which Business Associate becomes aware in accordance with 45 CFR 164.314(a)(2)(i)(c). Business Associate further agrees to train its employees and agents on detection of such incidents and the necessity to make timely reports of such incidents.

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Exhibit 16

(e) Business Associate agrees that without unreasonable delay, and in any event on or before five (5) business days after the discovery by Business Associate, it will notify Covered Entity of any incident that involves an unauthorized acquisition, access, use, or disclosure of PHI, even if Business Associate believes the incident will not rise to the level of a Breach. The notification shall include, to the extent possible, and shall be supplemented on an ongoing basis with: (i) the identification of all individuals whose Unsecured PHI was or is believed to have been involved, (ii) all other information reasonably requested by Covered Entity to enable Covered Entity to perform and document a risk assessment in accordance with 45 CFR Part 164 subpart D with respect to the incident to determine whether a Breach of Unsecured PHI occurred, and (iii) all other information reasonably necessary to provide notice to individuals, the Secretary and/or the media, all in accordance with the security breach notification requirements set forth in 42 USC 17932 and 45 CFR Parts 160 & 164 subparts A, D, & E.

Business Associate further agrees to train its employees and agents on detection of such incidents and the necessity to make timely reports of such incidents. For the purposes of this paragraph, incidents shall be treated as discovered as of the time set forth in 45 CFR 164.410(a). Notwithstanding the foregoing, in Covered Entity's sole discretion and in accordance with its directions, Business Associate shall conduct an investigation of any incident required to be reported under this subsection (e) and shall provide the required notices as set forth in this subsection (e).

(f) Business Associate will ensure that any agent, including a subcontractor, to whom it provides PHI received from, or created or received by Business Associate on behalf of Covered Entity, agrees to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to such information; such restrictions and conditions include but are not limited to requiring the subcontractor or agent to implement reasonable and appropriate safeguards to protect ePHI consistent with the requirements of this Agreement and including, at a minimum, compliance with the requirements or subsection II(b). (g)

(g) Business Associate agrees to provide access to PHI maintained in a Designated Record Set about an Individual, to covered Entity or at the request of Covered Entity, to an Individual, at a time and in a manner reasonably requested by Covered Entity, and all in accordance with the requirements under 45 CFR 164.524.

(h) Notwithstanding subsection (g), in the event that Business Associate in connection with the Services (as defined in section III. Below) uses or maintains an Electronic Health Record of PHI of or about an Individual, then Business Associate shall provide an electronic copy (at the request of Covered Entity, and in the reasonable time and manner requested by Covered Entity) of the PHI, to Covered Entity or, when and as directed by Covered Entity, directly to an Individual or a third party designated by the Individual, all in accordance with 42 USC 17935 (e).

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(i) Business Associate agrees, to the extent PHI in Business Associate's possession constitutes a Designated Record Set, to make available PHI for amendment and incorporate any amendment(s) to PHI that Covered Entity, directly to an Individual or a third party designated by the Individual, all in accordance with 42 USC 17935(e).

(j) Business Associate agrees to make internal practices, books, and records, including policies and procedures, relating to the use and disclosure of PHI received from, or created or received by Business Associate on behalf of Covered Entity available to the Secretary, in a time and manner reasonably agreed upon or designated by the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule.

(k) Business Associate agrees to document such disclosures of PHI and information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 CFR 164.528 and, as of its Compliance Date, in accordance with the requirements for accounting for disclosures made through an Electronic Health record in 42 USC 17935(c).

(l) Business Associate agrees to provide to Covered Entity or an Individual, in the time and manner reasonably requested by Covered Entity, information received or collected by Business Associate, to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 CFR 164.528.

(m) Business Associate agrees to accommodate reasonable requests for confidential communications in accordance with 45 CFR 164.522(b), as directed by Covered Entity.

(n) Business Associate agrees to notify Covered Entity in writing within three (3) days after its receipt directly from an Individual of any request for an accounting of disclosures, access to, or amendment of PHI or for confidential communications as contemplate in subsections (g), (h), (i), (k), (l) and (m).

(o) Business Associate shall take all necessary steps, at the direction of Covered Entity, to comply with requests by Individuals not to send PHI to a Health Plan in accordance with 42 USC 17935(a).

(p) Business Associate agrees to request, use and/or disclose only the minimum amount of PHI necessary to accomplish the purpose of the request, use or disclosure; provided that Business Associate shall comply with 42 USC 17935(b).

(q) Business Associate agrees to not directly or indirectly receive remuneration in exchange for any PHI as prohibited by 42 USC 17935(d) as of its Compliance Date.

(r) Associate agrees to not make or cause to be made any communication about a product or service that is prohibited by 42 USC 17936(a).

[redacted]

SJC0000018

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Exhibit 16

(s) Business Associate agrees to not make or cause to be made any written fundraising communication that is prohibited by 42 USC 17936(b).

III. Permitted Uses and Disclosures by Business Associate

Except as otherwise limited in this Agreement, Business Associate may use or disclose PHI on behalf of, or to provide services to, Covered Entity for the following purposes, if such use or disclosure of PHI would not violate the Privacy Rule if done by Covered Entity or the minimum necessary policies and procedures of Covered Entity:

Except as otherwise limited in this Agreement, Business Associate may use or disclose PHI on behalf of, or to provide services to, Covered Entity for purposes mutually agreed upon by Business Associate and Covered Entity and any further use and disclosure of protected health information is prohibited unless expressly approved by the Covered Entity. (collectively "Services").

IV. Obligations Of Covered Entity

(a) Covered Entity shall notify Business Associate of any limitation(s) in the notice of information practices of any covered entity it obtained PHI from or from Covered Entity's own notice of information privacy practices, in accordance with 45 CFR 164.520, to the extent that such limitation may affect Business Associate's use or disclosure of PHI.

(b) Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by individuals to use or disclose PHI, to the extent that such changes may affect Business Associate's use or disclosure of PHI.

(c) Covered Entity shall notify Business Associate of any restriction to the use or disclosure of PHI that Covered Entity has agreed to in accordance with 45 CFR 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of PHI.

V. Permissible Requests by Covered Entity

Covered Entity shall not request Business Associate to use or disclose PHI in any manner that would not be permissible under the Privacy Rule if done by Covered Entity.

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Exhibit 16

VI. Term and Termination

(a) Termination. The Term of this Agreement shall commence as of the Effective Date, and shall terminate when all of the PHI provided by Covered Entity to Business Associate is no longer needed by Business Associate for service described in Section III of Agreement.

(b) Termination for Cause. Upon either Party's knowledge of a material breach or violation of this Agreement by the other Party, the non-breaching Party shall either:

(1) Provide notice and provide an opportunity for the other Party to cure the breach or end the violation within thirty (30) days after receipt of notice:

(2) Immediately terminate this Agreement if the other Party has breached a material term of this Agreement and cure is not possible or in the absence of a cure reasonably satisfactory to the non-breaching Party; or

(3) If neither termination nor cure is feasible, the non-breaching Party shall report the violation to the Secretary.

(c) Effect of Termination

(1) Except as provided in paragraph (2) of this section, within thirty (30) days after termination or expiration of this Agreement, for any reason, Business Associate shall return or destroy all PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. Destruction of PHI shall be in accordance with Guidance Specifying the Technologies and Methodologies that Render Protected Health Information Unusable, Unreadable or Indecipherable to Unauthorized Individuals, published on the department of Health and Human Services website. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associates. Business Associates shall retain no copies of the PHI.

(2) In the event that Business Associate determines that returning or destroying the PHI is infeasible, Business Associate shall provide to Covered Entity written notification of the conditions that make return or destruction infeasible. If Covered Entity agrees upon written notification that return or destruction of PHI is infeasible, Business Associate may retain the PHI. Business Associate shall extend the protections of this Agreement to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such PHI.

[redacted]
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Exhibit 16

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VII. **Miscellaneous**

(a) Regulatory References. A reference in this Agreement to a section in the Privacy Rule, Security Rule, HIPAA or the HITECH Act means the section as in effect or as amended.

(b) Amendment. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy Rule, the security Rule, HIPAA, or the HITECH Act.

(c) Survival. The respective rights and obligations of Business Associate under Section VI of this Agreement, and Section VII (b), (c) & (d) of this Agreement, shall survive the termination of this Agreement.

(d) Interpretation. Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the Privacy Rule, the Security Rule, HIPAA or the HITECH Act.

(e) Counterparts. This Agreement may be signed in counterpart, and each counterpart shall have the same force and effect as an original and shall constitute an effective, binding agreement on the part of each of the undersigned.

(f) No Agency Relationship. Nothing in this Agreement shall create an agency relationship between Covered Entity and Business Associate under the federal common law of agency or any other body of law.

IN WITNESS WHEREOF, Covered Entity and Business Associate have caused this Agreement to be signed and delivered by their duly authorized representatives, as of the date set forth below.

COVERED ENTITY	**BUSINESS ASSOCIATE**
By: [redacted]	**By:** Linda Tracy
Print Name: [redacted]	**Print Name:** Linda Tracy
Title: Planned Parenthood Mar Monte Compliance & Safety Officer	**Title:** President
Date: March 4, 2010	**Date:** 26 MAR 2010

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Exhibit 16

d Parenthood

Planned Parenthood
Mar Monte

Our mission is to ensure that everyone has the knowledge, opportunity and freedom to make every child a wanted child and every family a healthy family.

Advanced Bioscience Resources, Inc.

June 14, 2010

Dear Ms. Tracy:

This shall serve as 30 days' notice of our intention to terminate our Agreement of November 1, 2007.

Sincerely:

Medical Director
Planned Parenthood Mar Monte

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Exhibit 17

CHARLES E. GRASSLEY, IOWA, CHAIRMAN

ORRIN G. HATCH, UTAH
JEFF SESSIONS, ALABAMA
LINDSEY O. GRAHAM, SOUTH CAROLINA
JOHN CORNYN, TEXAS
MICHAEL S. LEE, UTAH
TED CRUZ, TEXAS
JEFF FLAKE, ARIZONA
DAVID VITTER, LOUISIANA
DAVID A. PERDUE, GEORGIA
THOM TILLIS, NORTH CAROLINA

PATRICK J. LEAHY, VERMONT
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SHELDON WHITEHOUSE, RHODE ISLAND
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CHRISTOPHER A. COONS, DELAWARE
RICHARD BLUMENTHAL, CONNECTICUT

KOLAN L. DAVIS, Chief Counsel and Staff Director
KristINE LUCIUS, Deputy Chief Counsel and Staff Director

United States Senate

COMMITTEE ON THE JUDICIARY

WASHINGTON, DC 20510-6275

July 29, 2015

VIA ELECTRONIC TRANSMISSION

Ms. Linda Tracy
President
Advanced Bioscience Resources, Inc.
[redacted]

Dear Ms. Tracy:

As you are likely aware, a series of videos has recently surfaced in the media involving the acquisition of fetal tissue and Planned Parenthood. In the first video, the Senior Director for Medical Services for the Planned Parenthood Federation of America (PPFA), Deborah Nucatola, discusses at length Planned Parenthood's role in the harvesting and distribution of fetal tissue. In the video, she appears to describe, among other things, the fetal organs available for harvesting, the cost per "specimen," and the coordination with abortion providers to modify their procedures in particular cases to preserve selected organs in order to fill particular orders. Nucatola also explains that the transfer of fetal tissue is largely handled at Planned Parenthood's affiliate level, with the national organization providing some level of coordination. In the second video, the President of PPFA Medical Directors' Council, Mary Gatter, appears to haggle over the price of fetal tissue and to discuss modifying abortion procedures to harvest such fetal tissue.

Advanced Bioscience Resources (ABR) is mentioned in both of those videos. Further, in the third video, Katharine Sheehan, the Medical Director of Planned Parenthood Pacific Southwest, states that her affiliate has had a fetal tissue procurement relationship with ABR for over ten years and had, at the time of the video, just renegotiated the contracts.

Various federal regulations and statutes govern the use of human tissue and organs. For example, it is unlawful under 42 U.S.C. § 274e for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. 42 U.S.C. § 289g-1 further prohibits the use of fetal human tissue for research without the informed consent of the woman having the abortion and prohibits the alteration of abortion methods and procedures solely in order to obtain fetal tissue. Additionally, under 42 U.S.C. § 289g-2, it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce, and 18

Exhibit 17

U.S.C. § 1531 prohibits partial-birth abortions. Accordingly, the Senate Judiciary Committee has initiated an inquiry into the procurement of fetal tissue and related activities described in the videos.

Please provide the Committee with the following by August 12, 2015:

1. All records relating to communications with clinics and other organizations, including ones associated with Planned Parenthood, from which ABR has acquired, currently acquires, or has sought to acquire fetal tissue, relating to such fetal tissue acquisition efforts and activities.

2. All records relating to communications with the Planned Parenthood Federation of America concerning the coordination or facilitation of fetal tissue acquisition from Planned Parenthood affiliates.

3. All contracts that ABR has had since 2005 with any clinic, entity, or individual relating to the procurement, preparation, and transportation of fetal tissue.

4. A detailed accounting of the costs incurred by ABR in procuring, collecting, preparing, storing, and transporting fetal tissue from ABR's suppliers.

5. All contracts that ABR has had since 2005 with its customers relating to ABR's sales of fetal tissue and products derived or developed therefrom.

6. The total amount of revenue generated by ABR from its sales of fetal tissue or products derived or developed therefrom.

7. A detailed accounting of the costs incurred by ABR in preparing, storing, and transporting fetal tissue to ABR's customers.

If you have any questions about this request, please contact Jason Foster of my Committee staff at (202) 224-5225. Thank you for your attention to this important matter.

Sincerely,

Charles E. Grassley
Chairman
Senate Committee on the Judiciary

Exhibit 18

COPY

AGREEMENT

This agreement is made as of June 1, 1999 by Advanced Bioscience Resources, Inc. ("ABR"), a non-profit corporation organized and existing under the laws of California, and Planned Parenthood of San Diego and Riverside Counties, a professional corporation.

WHEREAS, ABR is an organization devoted to providing services in connection with the procurement of human organs and tissues for medical research; and

WHEREAS, Planned Parenthood of San Diego and Riverside Counties may wish to provide services to ABR to facilitate the accomplishment of such purpose;

NOW, THEREFORE, in consideration of the premises and mutual covenants contained herein, the parties agree as follows:

1. The term "fetal organ" has the same meaning as the term defined in 42 U.S.C.A. 274 e(c)(1) of the National Organ Transplant Act; that is, the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, organ or any subpart thereof, as derived from a fetus.

2. The term "product of conception"("POC") means any fetal organ or other fetal or placental material taken from the human uterus during an abortion. Acquisition of the products of conception is provided as a service to the research community. The products of conception are being supplied to ABR with no warranties, expressed or implied, including any warranty of merchantability or fitness for a particular purpose

ABR will take reasonable steps to assure that the products of conception shall be for use in scientific research and that all applicable guidelines set forth by the National Institutes of Health (NIH) or other government agencies regarding the use of the products of conception shall be followed.

Planned Parenthood shall not bear any risk, directly or indirectly, from any handling, preparation, shipment or use of the fetal tissue acquired and distributed by ABR, including, but not exclusive of, any viral or bacterial contaminants.

3. Planned Parenthood of San Diego and Riverside Counties will provide, and ABR will pay the reasonable costs for, services and facilities (hereinafter collectively "services") associated with obtaining consents and with the removal of fetal organs and tissues from POCs, and their processing, preservation, quality control, transportation, and storage; including appropriate space in which employees can accomplish the work of ABR, disposal services for non-used portions of biological waste materials, and for seeking consent for donation of organs and tissues from appropriate donors, and maintaining records of such consents so that verification of consent can be supported. Planned Parenthood of San Diego and Riverside Counties will designate an employee to perform the work required by ABR.

Exhibit 18

4. The fee charged to ABR for the services specified in this Agreement in connection with each POC provided to ABR shall be forty-five dollars ($45.00).

5. Any information obtained from Planned Parenthood of San Diego and Riverside Counties' patients' charts shall be privileged and the contents of same shall be held so as to preserve the confidentiality of patients. ABR is not entitled to and will not receive information concerning identity of donors except as specified.

6. The term of this Agreement shall be for one (1) year, beginning from the date hereof, and terminating one (1) year thereafter, unless either of the parties hereto shall have given the other thirty (30) days' written notice of its intention to terminate this Agreement, whereupon same shall terminate thirty (30) days after date of said notice. In default of notice as aforesaid from either party hereto, this Agreement shall continue for further successive terms of one (1) year thereafter and, in default of thirty (30) days' written notice before the end of an annual term either of the parties hereto of its intention not to renew, whereupon this Agreement shall terminate at the end of said term.

7. Written notices pursuant to this Agreement shall be sent first class mail, postage prepaid, to:

Planned Parenthood of San Diego and Riverside Counties
[redacted]

Advanced Bioscience Resources, Inc.
[redacted]

8. *The parties do not know how many patients will sign the consent forms in* agreement to donate POCs for research, and therefore do not know how many POCs will be supplied thereunder. Planned Parenthood of San Diego and Riverside Counties shall not be obligated to provided any minimum number of POCs; ABR shall not be obligated to take any minimum number of POCs, nor shall ABR be obligated to take all the POCs made available by Planned Parenthood of San Diego and Riverside Counties.

9. The parties hereto hereby mutually agree to defend, protect, and save harmless each other's officers, directors, agents and/or employees or consultants from and against all expenses, liabilities, demands or claims for loss or damage to, property, or personal injury or death suffered as a result of any actions by the parties hereto in the performance of the Agreement and attributable to the fault or negligence of the parties hereto or their respective officers, directors, agents and/or employees or consultants.

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Exhibit 18

10. No modification to this Agreement, nor any waiver of any rights, shall be effective unless agreed in writing by the party to be charged with such waiver or modification, and the waiver of any breach or default shall not constitute a waiver of any other right hereunder or any subsequent breach or default.

11. This Agreement constitutes the entire and exclusive agreement between the parties hereto with respect to its subject matter and merges all other communication and discussion, oral or written.

12. This Agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of law and venue for any dispute arising hereunder shall be in the County of San Diego, California.

13. The prevailing party in any action to enforce the terms of the Agreement shall be entitled to reimbursement by the other party for all costs (including the reasonable fees of attorneys and other professionals) incurred in connection with such proceeding.

14. This Agreement may be executed in counterparts, each of which will be deemed an original, but both of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed in duplicate by their duly authorized representatives as of the date first above written.

Planned Parenthood of San Diego and Riverside Counties

[redacted]

President and CEO

Advanced Bioscience Resources, Inc.

By: Linda Tracy

Linda Tracy, RN, President

Federal E.I.N.: 94-3110160
California E.I.N.: 370-20518

~~CONFIDENTIAL TREATMENT REQUESTED~~

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Exhibit 18

COPY

AGREEMENT

This agreement is made as of June 1, 2005, by Advanced Bioscience Resources, Inc. ("ABR"), a non-profit corporation organized and existing under the laws of California, and Planned Parenthood of San Diego and Riverside Counties ("PPSDRC"), a professional corporation.

WHEREAS, ABR is an organization devoted to providing services in connection with the procurement of human organs and tissues for medical research; and

WHEREAS, PPSDRC may wish to provide services to ABR to facilitate the accomplishment of such purpose;

NOW, THEREFORE, in consideration of the premises and mutual covenants contained herein, the parties agree as follows:

1. The term "fetal organ" has the same meaning as the term defined in 42 U.S.C.A. 274 e(c)(1) of the National Organ Transplant Act; that is, the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, organ or any subpart thereof, as derived from a fetus.

2. The term "product of conception" ("POC") means any fetal organ or other fetal or placental material taken from the human uterus during an abortion. Acquisition of the products of conception is provided as a service to the research community. The products of conception are being supplied to ABR with no warranties, expressed or implied, including any warranty of merchantability or fitness for a particular purpose.

   ABR will take reasonable steps to assure that the products of conception shall be for use in scientific research and that all applicable guidelines set forth by the National Institutes of Health (NIH) or other government agencies regarding the use of the products of conception shall be followed.

   PPSDRC shall not bear any risk, directly or indirectly, from any handling, preparation, shipment or use of the fetal tissue acquired and distributed by ABR, including, but not exclusive of, any viral or bacterial contaminants.

3. PPSDRC will provide, and ABR will pay the reasonable costs for, services and facilities (hereinafter collectively "services") associated with obtaining consents and with the removal of fetal organs and tissues from POCs, and their processing, preservation, quality control, transportation, and storage; including appropriate space in which employees can accomplish the work of ABR, disposal services for non-used portions of biological waste materials, and for seeking consent for donation of organs and tissues from appropriate donors, and maintaining records of such consents so that verification of consent can be supported. ABR will hire an employee to perform the work required by ABR.

CONFIDENTIAL TREATMENT REQUESTED

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Exhibit 18

COPY

4. The fee charged to ABR for the services specified in this Agreement in connection with each POC provided to ABR shall be fifty-five dollars ($55.00).

5. Any information obtained from PPSDRC's patients' charts shall be privileged and the contents of same shall be held so as to preserve the confidentiality of patients. ABR is not entitled to and will not receive information concerning identity of donors except as specified.

6. The term of this Agreement shall be for three (3) years, beginning from the date hereof, and terminating three (3) years thereafter, unless either of the parties hereto shall have given the other thirty (30) days' written notice of its intention to terminate this Agreement, whereupon same shall terminate thirty (30) days after date of said notice. In default of notice as aforesaid from either party hereto, this Agreement shall continue for further successive terms of one (1) year thereafter and, in default, of thirty (30) days' written notice before the end of an annual term either of the parties hereto of its intention not to renew, whereupon this Agreement shall terminate at the end of said term.

7. Written notices pursuant to this Agreement shall be sent first class mail, postage prepaid, to:

Planned Parenthood of San Diego and Riverside Counties
[redacted]

Advanced Bioscience Resources, Inc.
[redacted]

8. The parties do not know how many patients will sign the consent forms in agreement to donate POCs for research, and therefore, do not know how many POCs will be supplied thereunder. PPSDRC shall not be obligated to provide any minimum number of POCs; ABR shall not be obligated to take any minimum number of POCs, nor shall ABR be obligated to take all the POCs made available by PPSDRC.

9. The parties hereto hereby mutually agree to defend, protect, and save harmless each other's officers, directors, agents and/or employees or consultants from and against all expenses, liabilities, demands or claims for loss or damage to, property, or personal injury or death suffered as a result of any actions by the parties hereto in the performance of the Agreement and attributable to the fault or negligence of the parties hereto or their respective officers, directors, agents and/or employees or consultants.

[redacted]

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Exhibit 18

COPY

10. No modification to this Agreement, nor any waiver of any rights, shall be effective unless agreed in writing by the party to be charged with such waiver or modification, and the waiver of any breach or default shall not constitute a waiver of any other right hereunder or any subsequent breach or default.

11. This Agreement constitutes the entire and exclusive agreement between the parties hereto with respect to its subject matter and merges all other communication and discussion, oral or written.

12. This Agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of law and venue for any dispute arising hereunder shall be in the County of San Diego, California or County of Riverside, California.

13. The prevailing party in any action to enforce the terms of the Agreement shall be entitled to reimbursement by the other party for all costs (including the reasonable fees of attorneys and other professionals) incurred in connection with such proceeding.

14. This Agreement may be executed in counterparts, each of which will be deemed an original, but both of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed in duplicate by their duly authorized representatives as of the date first above written.

Planned Parenthood of San Diego and Riverside Counties

By: [redacted]

[redacted] President and CEO

Advanced Bioscience Resources, Inc.

By: Linda Tracy

Linda Tracy, RN, President

Federal E.I.N.: 94-3110180
California E.I.N.: 3709-20518

~~CONFIDENTIAL TREATMENT REQUESTED~~

SJC0000028

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Exhibit 18

9/24/10

Advanced Bioscience
[redacted]

Re: Fetal Tissue Research.
Contract effective 6/1/2005 through 5/31/2010.

Dear Advanced Bioscience

Effective October 4, 2010, we are changing our name. Our new name is:

Planned Parenthood of the Pacific Southwest

Please accept this letter as your official notification of this name change. Attached is a copy of the Certified Amendment to our Articles of Incorporation. All other business information such as address and phone number will remain the same. Should you require other documentation or forms to be completed, please forward them to our office.

Thank you, [redacted]

PPSW Accounting Manager
[redacted]

Attachment: Copy of approved & Amended Articles of Incorporation

PRINTED BY AUTHORITY OF THE CHAIRMAN OF THE SENATE JUDICIARY COMMITTEE

Exhibit 18

A 0706129

ENDORSED - FILED
In the office of the Secretary of State
of the State of California

AUG 23 2010

CERTIFICATE OF AMENDMENT OF
ARTICLES OF INCORPORATION

The undersigned certify that:

1. They are the president and the secretary, respectively, of Planned Parenthood of San Diego and Riverside Counties, a California corporation.

2. Article I of the Articles of Incorporation of this corporation is amended to read as follows:

   The name of this corporation is Planned Parenthood of the Pacific Southwest

3. The foregoing amendment of Articles of Incorporation has been duly approved by the board of directors.

4. The corporation has no members.

We further declare under penalty of perjury under the laws of the State of California that the matters set forth in this certificate are true and correct of our own knowledge.

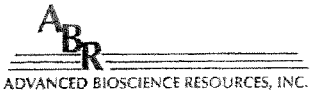
Date: 8/23/10

[redacted]

Chief Executive Officer

[redacted], Secretary

Exhibit 18



AGREEMENT

This agreement is made as of October 1, 2010 between Advanced Bioscience Resources, Inc. ("ABR"), a non-profit corporation organized and existing under the laws of California, and Planned Parenthood of the Pacific Southwest ("PPPSW"), a professional corporation.

WHEREAS, ABR is an organization devoted to providing services in connection with the procurement of human organs and tissues for medical research; and

WHEREAS, PPPS has agreed to provide services to ABR to facilitate the accomplishment of such purpose;

NOW, THEREFORE, in consideration of the premises and mutual covenants contained herein, the parties agree as follows:

1. The term "fetal organ" has the same meaning as the term defined in 42 U.S.C.A. 274 e(c)(1) of the National Organ Transplant Act, that is, the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, organ or any subpart thereof, as derived from a fetus.

2. The term "product of conception" ("POC") means any fetal organ or other fetal or placental material taken from the human uterus during an abortion. Acquisition of the products of conception is provided as a service to the research community. The products of conception are being supplied to ABR with no wasrranties, expressed or implied, including any warranty of merchantability or fitness for a particular purpose.

   ABR will take reasonable steps to assure that the products of conception shall be for use in scientific research and that all applicable guidelines set forth by the National Institutes of Health (NIH) or other governmental agencies regarding the use of the products of conception shall be followed.

   PPPS shall not bear any risk, directly or indirectly, from any handling, preparation, shipment or udr of the fetal tissue acquired and distributed by ABR, including, but not exclusive of, any viarl or bacterial contaminants.

3. PPPS will provide, and ABR will pay the reasonable costs for, services and facilities (hereinafter collectively "services") associated with obtaining consents and with the removal of fetal organs and tissues 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. ABR will hire an employee to perform the work required by ABR.

[redacted] / [redacted]

[redacted]

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Exhibit 18

4. The charge to ABR for the services specified in this Agreement in connection with each POC provided to ABR shall be sixty dollars ($60.00).

5. Any information obtained from PPPSW patients' charts shall be privileged and the contents of same shall be held so as to preserve the confidentiality of patients. ABR is not entitled to and will not receive information concerning identity of donors except as specified.

6. The term of this Agreement shall be for three (3) years, beginning from the date hereof, and terminating three (3) years thereafter, unless either of the parties hereto shall have given the other thirty (30) days' written notice of its intention to terminate this Agreement, whereupon same shall terminate thirty (30) days after date of said notice. In default of notice as aforesaid from either party hereto, this Agreement shall continue for further successive terms of one (1) year thereafter and, in default of thirty (30) days' written notice before the end of an annual term either of the parties hereto of its intention not to renew, whereupon this Agreement shall terminate at the end of said term

7. Written notices pursuant to this Agreement shall be sent first class mail, postage prepaid, to:

Planned Parenthood of the Pacific Southwest
[redacted]

Advanced Bioscience Resources, Inc.
[redacted]

8. The parties do not know how many patients will sign the consent forms in agreement to donate POC's for research and therapy, and therefore do not know how may POC's will be supplied thereunder. PPPS shall not be obligated to provide any minimum number of POC's; ABR shall not be obligated to take any minimum number of POCs, nor shall ABR be obligated to take all the POCs made available by PPPSW.

9. The parties hereto hereby mutually agree to defend, protect, and save harmless each other's officers, directors, agents and/or employees or consultants from and against all expenses, liabilities, demand or claims for loss or damage to, property, or personal injury or death suffered as a result of any actions by the parties hereto in the performance of the Agreement and attributable to the fault or negligence of the parties hereto or their respective officers, directors, agents and/or employees or consultants.

~~CONFIDENTIAL TREATMENT REQUESTED~~

PRINTED BY AUTHORITY OF THE CHAIRMAN OF THE SENATE JUDICIARY COMMITTEE

Exhibit 18

10. No modification to this Agreement, nor any waiver of any rights, shall be effective unless agreed in writing by the party to be charged with such waiver or modification, and the waiver of any breach or default shall not constitute a waiver of any other right hereunder or any subsequent breach or default.

11. This Agreement constitutes the entire and exclusive agreement between the parties hereto with respect to its subject matter and merges all other communication and discussion, oral or written.

12. This Agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of law, and venue for any dispute arising hereunder shall be in the County of San Diego, California or in the County of Riverside, California.

13. The prevailing party in any action to enforce the terms of the Agreement shall be entitled to reimbursement by the other party for all costs (including the reasonable fees of attorneys and other professionals) incurred in connection with such proceeding.

14. This Agreement may be executed in counterparts, each of which will be deemed an original, but both of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed in duplicate by their duly authorized representatives as of the date first above written.

Planned Parenthood of the Pacific Southwest

By: [redacted] 11/1/2016

Sr VP of Patient Services

Advanced Bioscience Resources, Inc.

By: Linda Tracy

Linda Tracy, RN, CTBS
President

Federal EIN: 94-3110160
California EIN: 370-20518
FDA FEI: 3005208435

CONFIDENTIAL TREATMENT REQUESTED

PRINTED BY AUTHORITY OF THE CHAIRMAN OF THE SENATE JUDICIARY COMMITTEE

Exhibit 18

ADVANCED BIOSCIENCE RESOURCES, INC

ADDENDUM to the OCTOBER 2010 AGREEMENT

RE: Regulated Tissue Acquisition (RTA)

This Addendum is made as of January 1, 2012, to the October 2010 Agreement between Advanced Bioscience Resources, Inc. ("ABR"), a non-profit foundation organized and existing under the laws of California, and Planned Parenthood of the Pacific Southwest (PPPSW), a professional corporation.

WHEREAS, ABR is an organization devoted to providing services in connection with the procurement of human organs and tissues for medical research and therapeutic use; and

WHEREAS, PPPSW has agreed to provide services to ABR to facilitate the accomplishment of such purpose,

NOW, THEREFORE, in consideration of the premises and mutual covenants contained herein, PPPSW and ABR agree as follows:

1. ABR's Regulated Tissue Acquisition requires a 2-consecutive-day commitment, hereinafter termed the "RTA component".
   a. ABR Procurement Specialist staff will be present in the designated PPPSW facility the day prior to surgery (Day 1) for the identification, interview and selection of patients as potential candidates for the RTA.
   b. ABR Procurement Specialist CTBS staff will be present in the PPPSW facility the day of surgery (Day 2) for the acquisition of specific tissues from the selected patients and for the coordination of the documentation and distribution of RTA tissues.
   c. More than one RTA component may take place in any given week, potentially utilizing two RTA facilities in one week.
   d. RTA procurement is dependent solely upon ABR-affiliated bio-medical requests
   e. Advance notification to PPPSW of each requested RTA component will occur at least one week prior to the requested RTA component.
2. In addition to Item 3 in the PPPSW / ABR Agreement of October 2010, PPPSW and ABR agree that
   a. PPPSW will provide ABR with the private use of a designated space, hereinafter termed "clean space", within the utilized Planned Parenthood of the Pacific Southwest facility(s). to accomplish the required tasks as set forth in the RTA components.
   b. The assigned "clean space" will be designated for the use of ABR personnel during the RTA components; the assigned "clean space" location will be consistent from week to week; and the assigned "clean space" will be available to ABR up to 8 hours per day during the 2-day RTA component, to allow ABR to accomplish all tasks necessary to the RTA.
3. PPPSW and ABR also agree that:
   a. The charge to ABR for the services specified in this Addendum in connection with each 2-day RTA Component shall be $1000 (one thousand dollars).
   b. If there is no cause for ABR to be present in the PPPSW facility on Day 2 of the RTA component, that is, if there are no qualifying patients on Day 1 of the RTA component, then the charge to ABR for the services of providing the assigned "clean space" shall be $500 (five hundred dollars) only, for Day 1 only.
   c. Payment is due within 45 days from the date service was rendered. Payments for services relating to RTA components will be separate and distinct from the payments for services referenced in the October 2010 PPPSW / ABR Agreement, and will be recorded as "RTA Reimbursement".
4. This Addendum is an addition to the October 2010 Agreement, and does not alter any item in the October 2010 Agreement.
5. This Addendum may be executed in counterparts, each of which will be deemed an original, but both of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have caused this Addendum to be executed in duplicate by their duly authorized representatives as of the date first above written.

Planned Parenthood of the Pacific Southwest	Advanced Bioscience Resources, Inc.
By:_____	By: Linda Tracy
[redacted] SR VP of Patient Services	Linda Tracy, RN, CTBS, President

[redacted]0034

Exhibit 19

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

NOV 17 2015

The Honorable Ron Johnson
Chairman
Committee on Homeland Security and Governmental Affairs
United States Senate
Washington, D.C. 20510

Dear Chairman Johnson:

I am writing in further response to your letters regarding research involving fetal tissue and the work of the Department of Health and Human Services (HHS).

The use of fetal tissue in medical research has been an instrumental component of our attempts to understand, treat, and cure a number of conditions and diseases that affect millions of Americans. Scientists have been working with fetal tissue since the 1930s. For example, fetal tissue is an important resource for researchers studying retinal degeneration, pregnancy loss, human development disorders such as Down Syndrome, and early brain development. Fetal tissue has also served as a critical resource for the development of models of human disease, such as HIV/AIDS, which has devastating effects on the human immune system. Importantly, cell lines derived from fetal tissue have also played an essential role in the creation of new vaccines and remain valuable in important efforts such as the pursuit of a vaccine for Ebola.

The Public Health Service Act (42 U.S.C. § 289g-2) prohibits knowingly acquiring, receiving, or otherwise transferring any human fetal tissue for valuable consideration if the transfer affects interstate commerce. Under 42 U.S.C. § 289g-2, the Department of Justice (DOJ) can investigate complaints concerning any person who knowingly acquires, receives, or otherwise transfers any human fetal tissue for valuable consideration if the transfer affects interstate commerce. I understand that DOJ is reviewing all information they have received on this matter, and will determine what steps to take at the appropriate time.

42 U.S.C. § 289g-1 sets forth additional requirements for HHS-conducted or HHS-supported research on the transplantation of human fetal tissue for therapeutic purposes. HHS has not conducted or supported such research since 2007. A list of the research projects on the transplantation of human fetal tissue for therapeutic purposes from 2007 is attached as an addendum to this letter. Additionally, attached are the reports to Congress, from 2008-2014, on HHS-conducted or HHS-supported transplantation research that are required to be submitted annually.

When submitting an application and accepting an award for research involving fetal tissue supported by HHS, the designated representative of the external organization receiving the funding certifies that researchers using these samples are in compliance with applicable legal requirements. In addition, by accepting an award, funding recipients agree that they will follow

all applicable legal requirements and the applicable agency's grants policy statement, and must be able to demonstrate their compliance with applicable legal requirements. HHS also requires funding recipients to re-certify when additional funding is awarded that they are in compliance with applicable legal requirements. Your letter asks whether HHS's oversight practices and policies relating to other forms of research differ from its practices and policies relating to fetal tissue research. As a general matter, HHS follows the same policies and procedures for each of its grantees. That said, as mentioned in my previous response, for the small amount of research involving fetal tissue samples that is conducted by researchers at FDA and NIH, researchers obtain tissue from non-profit organizations that have provided assurances to us that they are in compliance with applicable legal requirements. In addition, NIH and FDA have obtained assurances verifying that the research they support is in compliance with applicable legal requirements, including relevant provisions relating to research involving fetal tissue. NIH and FDA have also sent a reminder notice to their intramural research communities that all research must be in compliance with all applicable legal requirements.

The Office for Human Research Protections (OHRP) has jurisdiction under Title 45, Part 46, Code of Federal Regulations (45 CFR 46) with regard to research involving human subjects conducted or supported by HHS or conducted at an institution that has voluntarily agreed to comply with 45 CFR 46 regardless of the source of support for the research. OHRP's role also includes 45 CFR 46, subpart B, which, among other things, regulates research conducted or supported by HHS involving fetal tissue, requiring that such research be conducted in compliance with any applicable federal, state, or local laws and regulations regarding such activities. OHRP's Division of Compliance Oversight evaluates written substantive indications of noncompliance with 45 CFR 46 in connection with research conducted or supported by HHS. OHRP has not, since January 1, 2010, received any substantive indications of noncompliance with 45 CFR 46, subpart B by an HHS- funded or supported research institution in connection with fetal tissue research.[1]

In response to the questions in your letter regarding funding to Planned Parenthood Federation of American and its affiliates ("Planned Parenthood"), as stated in my previous response, HHS provides funding to Planned Parenthood through competitively-awarded grants and contracts. The funds are used to provide critical health services, including annual wellness exams, cancer screenings, contraception, and to further the study of sexually-transmitted diseases. HHS funding to Planned Parenthood does not support research involving fetal tissue. Further, no federal funds can be used to cover abortions except in the case of rape, incest, or when the life of the woman is endangered. This has been federal law, enacted in annual appropriations legislation, since the 1980s.

As stated above, Planned Parenthood receives grant awards through a competitive selection process. For competitive grants or cooperative agreements, unless prohibited by federal statute, the HHS awarding agency must design and execute a merit review process for applications. This process must be described or incorporated by reference in the applicable notice of funding

[1] OHRP has received a request to initiate an investigation regarding the Planned Parenthood videos in question. A copy of that request and OHRP's response is attached. The response notes that OHRP has not been provided with information indicating noncompliance with 45 CFR 46, subpart B by an HHS- funded or supported research institution in connection with these videos.

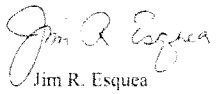
Exhibit 19

opportunity. Further, like all HHS funding recipients, Planned Parenthood is required to comply with applicable legal requirements. When submitting an application and accepting an award, funding recipients agree that they will follow all applicable legal requirements and the applicable agency's grants policy statement, and must be able to demonstrate their compliance with applicable legal requirements. HHS also requires funding recipients to re-certify when additional funding is awarded that they are in compliance with applicable legal requirements. In addition, grantees, such as Planned Parenthood, that spend over $750,000 in federal funds during their fiscal year (or $500,000 prior to December 26, 2014) are required to obtain an annual audit in compliance with the Single Audit Act and 2 CFR Part 200, subpart F.

I understand that Members of Congress have requested that the HHS Office of Inspector General conduct an audit of the issues raised about Planned Parenthood, fetal tissue transplant research, or fetal tissue research of whatever scope is possible within HHS OIG's jurisdiction. As always, HHS is committed to cooperating with our Inspector General.

Thank you for your interest in the important work of our Department.

Sincerely,



Jim R. Esquea
Assistant Secretary for Legislation

Enclosures

cc: The Honorable Charles E. Grassley
Chairman
Committee on the Judiciary

The Honorable Joni K. Ernst
United States Senate

The Honorable Thomas R. Carper
Ranking Member
Committee on Homeland Security and Governmental Affairs

The Honorable Patrick Leahy
Ranking Member
Committee on the Judiciary

Exhibit 20

[redacted]

Planned Parenthood of the Pacific Southwest

October 16, 2015

Jonathan E. Lopez
ORRICK, HERRINGTON & SUTCLIFFE LLP
Orrick Building at Columbia Center
1152 15th Street NW
Washington, DC 20005-1706

Re: Amendment to Contract

Dear Jonathan:

As you know, PPPSW will not be accepting any reimbursements for expenses associated with the fetal tissue donor program between ABR and PPPSW as of Wednesday, October 14, 2015. By signing below, let us deem this to be an Amendment to the October 1, 2010 Agreement, specifically regarding paragraph 4.

Thank you. Please let me know if you have any questions.

Regards,

[redacted]

General Counsel

[redacted]

Advanced Bioscience Resources, Inc.

By: Linda Tracy
Linda Tracy, RN, CTBS
President

19 OCT 2015
Date

~~CONFIDENTIAL TREATMENT REQUESTED~~
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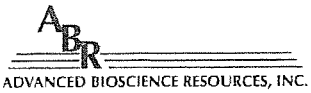
Exhibit 21



PROCUREMENT SPECIALIST / TECHNICIAN

JOB DESCRIPTION

REQUIREMENTS

1. Energetic, self-motivated, ability to work independently, ability to 'multi-task'
2. Skilled, proficient, and certified in phlebotomy
3. Experienced in medical field in general, preferably in women's health care
4. Knowledge of human anatomy
5. Knowledge and application of sterile / aseptic technique
6. Impeccable documentation skills and excellent communication skills
7. Flexibility regarding work availability and ability to work with medical staff
8. Current driver's license in state of residence, have reliable vehicle with current insurance

DUTIES AND RESPONSIBILITIES

PROCUREMENT - Tissue Acquisition and Distribution

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 facility, 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 Fed Ex for shipment to various research facilities
9. Fax completed forms as required to ABR
10. Clean up procurement work area before leaving facility

WAGE AND BENEFITS

1. Employment is probationary for a 30 day period
2. Training period of 4 to 6 weeks, 4 to 6 hours per day, variable Tuesday through Saturday, hourly pay $15.00
3. Mileage reimbursed at current established rate; other expenses reimbursed with submitted receipts
4. 90% medical insurance, 100% dental and vision insurance, life insurance, direct deposit, credit union,
5. Eligible for 401K participation after 1 year of employment

GENERAL

1. Be polite, courteous and professional at all times, maintain flexibility
2. Maintain a respectful relationship with all personnel
3. Attend scheduled ABR staff meetings, and be a company team player

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Exhibit 22

ORRICK, HERRINGTON & SUTCLIFFE LLP
COLUMBIA CENTER
1152 15TH STREET, N.W.
WASHINGTON, D.C. 20005-1706

tel +1-202-339-8400
fax +1-202-339-8500
WWW.ORRICK.COM

February 25, 2016

Jonathan E. Lopez
(202) 339-8456
Jonathan.Lopez@orrick.com

CONFIDENTIAL TREATMENT REQUESTED
VIA ELECTRONIC MAIL

Charles E. Grassley
Chairman
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, D.C. 90510-6275
[redacted]

Dear Chairman Grassley:

Pursuant to Advanced Bioscience Resources, Inc.'s ("ABR") continuing cooperation with the Senate Judiciary Committee's investigation, we respond to your letter dated February 18, 2016, directed to us as ABR's counsel.

Requests 1 and 3: You have requested a description of the space used by ABR at Planned Parenthood Mar Monte ("PPMM") and Planned Parent Pacific Southwest, formerly Planned Parenthood of San Diego and Riverside Counties (collectively, "PPPSW"). The answer is the same for both PPMM and PPPSW. 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.

Requests 2 and 4: You have asked for a description of any ABR materials stored and the method of their storage, if any, at PPMM and PPPSW. ABR instruments, including petri dishes, conical tubes, vacutainers, paperwork, and packing supplies, are stored in a cabinet at each clinic's laboratory. At times, ABR has had a small refrigerator in the laboratory to store solution or media, and has stored packing boxes wherever there is space. Additionally, PP affiliate personnel autoclave ABR instruments daily in PP machines.

ABR respectfully requests that all materials and information provided to the Senate Committee on the Judiciary ("Senate Judiciary Committee") during the course of its inquiry, as well as this transmittal letter, (collectively, "ABR materials") be deemed private and confidential business information. The ABR materials included in this and future productions may represent privileged information, confidential private employee information, commercial information, or financial information. ABR's productions do not waive any of those or other privileges that may be available to ABR.

Exhibit 22

ORRICK

Charles E. Grassley
February 25, 2016
Page 2

We also request that the ABR materials be kept in a non-public file and that only the Senate Judiciary Committee members and their staff have access to them. Should the Senate Judiciary Committee receive any request for these documents or have the need to disclose them in a hearing or otherwise, we request that the undersigned be notified immediately of the request or disclosure (preferably by telephone), be provided a copy of all written materials pertaining to the request or disclosure, and reasonable opportunity to respond, before any determination that this letter, its enclosures, and/or the information or data contained therein will be produced or disclosed. We further request that we be notified promptly of any determinations with respect to such requests or disclosure and be given ten (10) days' notice before any intended release.

Thank you for your cooperation in this matter. Please contact me if you have any questions about this production or any other issue.

Sincerely,

Jonathan E. Lopez

Enclosures

cc: [redacted]

Exhibit 23

TERMS AND CONDITIONS OF SERVICES

1. **Services.**

   1.1 During the term of this agreement, and pursuant to the terms and conditions hereinafter set forth, ABR will use its best efforts to provide services in connection with supplying Facility with the types of human tissues set forth in this application, as approved by ABR, suitable for Facility requirements and in the amounts requested based upon ongoing discussions between Facility and ABR pursuant to the information sent by ABR, in compliance with all applicable federal, state and local laws, rules, regulations, ordinances and guidance.

   1.2 Facility acknowledges and agrees that ABR will provide the following types of services:
   a. Removing tissue. Any fetal tissues provided to 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.
   b. Preserving and processing tissue to a form suitable to the Facility needs.
   c. Seeking informed consent for tissue donations from appropriate individuals at least 18 years of age, obtaining validly executed consent forms only after the donor has decided to terminate her pregnancy, permitting use of such tissue for the purpose required by Facility, and maintaining records of such informed consents in accordance with all applicable federal, state and local laws and regulations and with this agreement.
   d. Obtaining, labeling, storing, and delivering samples of donor or other required serum, and maintaining a system for matching such samples to specific tissue donations.
   e. Preserving tissue viability and cleanliness during removal, processing, preservation, storage and transportation.
   f. Storing tissue and transporting it to Facility in accordance with Section 5.

   1.3 In the event that tissues of the type specified in the application become unavailable to ABR, so that ABR is unable to perform the contemplated services, ABR shall have no obligation to perform such services.

2. **Representations and Warranties.** ABR hereby represents and warrants to Facility that (i) ABR will make no payments to anyone for any tissue transferred in connection with this agreement, and (ii)all tissue (and any related information about the tissue) will be collected and will be disclosed to Facility in compliance with applicable laws and regulations. ABR will not transfer any tissue to Facility if such transfer(for the purposes described in the Title of Research Project under Article V Research Data of the application) would be in violation of any applicable law or regulation or informed consent and (iii) ABR will verify for each tissue delivery that appropriate informed consent for the activities contemplated by Facility was obtained in compliance with applicable laws and regulations for use of such tissue and any associated serum samples, and that adequate records of such informed consent are maintained; provided, however, that the parties hereto acknowledge and agree that such informed consents are extremely confidential in nature and shall not, in any case, be communicated to Facility (although ABR shall make such informed consents available to governmental authorities if requested by such authorities). Such laws and regulations may include 45 CFR Part 46 and (without limitation) the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), in the event related medical information collected after April 15, 2003 contains "Protected Health Information", as that term is defined in HIPAA. Facility hereby represents and warrants to ABR that (i) Facility will neither sell nor transfer for valuable consideration any tissue received through ABR without further manipulation and/or processing to any third party; (ii) Facility will use the tissue only to satisfy its objectives described in the Title of Research Project under Article V Research Data of the application, which are acknowledged and agreed hereto (research and clinical use). (iii) Facility agrees to inform ABR of any changes in clinical or research use of specimens received from ABR, or in any specifications, constraints, etc. in a timely manner, and (iv) Facility understands the bio-hazardous nature of human tissue and agrees to take proper precautionary measures at all times when handling tissue specimen(s).

3. **Term.** The terms of this agreement shall be for one (1) year, beginning from the date hereof, and terminating one (1) year thereafter, unless either of the parties hereto shall have given to the other thirty (30) days written notice of its intention to terminate this agreement, whereupon same shall terminate thirty (30) days after date of said notice. In default of notice as aforesaid from either party hereto, this agreement shall continue for further successive terms of one (1) year thereafter and in default of thirty (30) days written notice before the end of an annual term by either of the parties of its intention not to renew, whereupon this agreement shall terminate at the end of said term.

4. **Payments.** Facility agrees to pay to 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 by ABR. Payments are due net 30 days from the receipt by Facility of ABR's invoice. Fees are subject to change.

5. **Ownership.** Any data, results or intellectual property (collectively, "IP") in or arising out of Facility's use of human tissues provided by ABR hereunder and the human tissues themselves shall be the sole property of Facility (and ABR hereby assigns, and shall assign to Facility any right, title, and interest in such as necessary to accomplish the foregoing). Facility agrees to acknowledge ABR in any publications resulting from the use of ABR provided tissue. Facility agrees to inform ABR of the publication name and the date of the issue in which the results will be published.

6. **Shipment services.**

   6.1 All shipments will be made as soon as possible after request has been received by ABR from Facility.

   6.2 Facility acknowledges that networks of tissue availability are neither permanent nor dependable, but rather they fluctuate. However, ABR shall use its best efforts to transfer the tissue in the amounts requested by Facility.

   6.3 Shipment will be made in the best possible manner so as to preserve the quality of the tissues. It is understood that the fragility of human tissue is such that damage may occur during shipment. ABR will use its best efforts to comply with the handling and shipment protocols provided by Facility.

   6.4 ABR will package the tissue appropriately and, if so requested by Facility, will insure the shipment. Facility agrees to bear all costs associated with insurance and shipment of any tissue.

   6.5 The risk of loss and damage of any tissue shall pass immediately to Facility when the shipment of such tissue is deposited with a carrier for transportation.

7. **Limitation of liability.** Except with respect to liability arising from Section 9 or ABR's breach of Section 2, ABR shall not be responsible or liable under any section of this agreement or under any contract, strict liability or other legal or equitable theory, for the cost of procurement of substitutive services, or any indirect, incidental or consequential damages including, but not limited to, loss of revenues and loss of profits. Except with respect to liability arising from Section 9 or ABR's breach of Section 2, any liability of ABR under any theory whatsoever will be limited exclusively to the provision of equivalent services by ABR or, if unenforceable, to payment of an amount not greater than any amount actually received by ABR from Facility on account of this agreement, except where such liability arises from ABR's negligence or willful misconduct.

8. **No warranties.** It is understood that human tissue is by nature neither permanent nor dependable. Except as expressly set forth in this agreement, ABR makes no representation of any kind, expressed or implied, including any representation with respect to the safety, efficacy or merchantability or the fitness for any purpose with respect to the tissue transferred to Facility in connection with this agreement.

9. **Indemnification.** Facility shall indemnify, defend and hold ABR harmless from and against all claims, causes of actions, suits, damages and costs arising out of, resulting from, or otherwise in respect of, the use of tissue transferred in connection with this agreement, except where such claims are the result of negligence of ABR, its employees, staff or agents or ABR's failure to comply with any governmental requirements, or ABR's failure to adhere to the terms of this agreement. ABR shall indemnify, defend and hold Facility harmless from and against all claims, causes of actions, suits damages and costs to the extent arising out of, resulting from, or otherwise in respect of, the negligence of ABR, its employees, staff or agents, ABR's failure to comply with any governmental requirements, or ABR's failure to adhere to the terms of this agreement. ABR agrees to (i) promptly notify Facility in writing as soon as ABR becomes aware of any claim or action asserted against ABR to which ABR is entitled to indemnification hereunder, and (ii) authorize the Facility the opportunity to control the defense and settlement thereof and otherwise reasonably cooperate with the Facility in such defense or settlement.

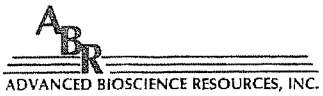
10. **General.** This agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of law. This agreement may not be assigned by either party without the prior written consent of the other.

BY: _____ DATE_____
Linda Tracy, RN, CTBS, President, Advanced Bioscience Resources

BY: _____ DATE_____
Print Name, Title and Facility

Exhibit 24

ADVANCED BIOSCIENCE RESOURCES, INC.



FEES FOR SERVICES SCHEDULE

Effective January 1, 2015

FETAL CADAVEROUS SPECIMEN PROCUREMENT		SERVICE FEE
2nd trimester specimen (13 - 24 weeks)	PER SPECIMEN	$340
1st trimester specimen (8 - 12 weeks)	PER SPECIMEN	$550

BLOOD SPECIMEN PROCUREMENT

Maternal Peripheral	PER SPECIMEN	$260
Adult Peripheral	PER SPECIMEN	$260
Full Term Umbilical Cord	PER SPECIMEN	$550

SPECIAL PROCESSING / PRESERVATION

Case Report Form (CRF) completion	PER CASE	$25
Specimen "cleaning"	PER SPECIMEN	$50
Special requests (evaluated individually)	PER SPECIMEN	$25
Snap freezing (LN2)	PER SPECIMEN	$40
Passive freezing (Dry ice)	PER SHIPMENT	$80
Foreign shipments	PER SHIPMENT	$100
Electronic Fund Transfer (EFT) (Fee varies by bank)	PER INVOICE	$25-$50

The following fees are subject to change, based upon increases imposed from outside labs and courier companies.

INFECTIOUS DISEASE SCREENING (Testing performed on donor blood)

HIV, HBsAg	$95
Additional tests	CALL

DELIVERY (Research facility responsible for delivery fees and fuel surcharges.)
(FedEx billed on research facility's account but reversed to ABR will incur a $15 rebill fee)

Federal Express Domestic Priority Overnight	$120
Federal Express Domestic First Overnight	$150
Federal Express Domestic Saturday Delivery	$170
Foreign and Other Courier Services	CALL
Fuel surcharge (Research facility responsible for additional fuel surcharge)	CALL

Our Terms: Full payment due upon invoice receipt, and within 30 days of the invoice date. Accounts not paid within 30 days of invoice are subject to a 1.5% monthly finance charge.

[redacted] SJC000050

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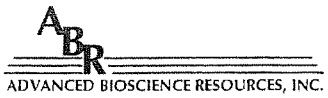
Exhibit 24



FEES FOR SERVICES SCHEDULE

Effective January 1, 2014

FETAL CADAVEROUS SPECIMEN PROCUREMENT		SERVICE FEE
2nd trimester specimen (13 - 24 weeks)	PER SPECIMEN	$325
1st trimester specimen (8 - 12 weeks)	PER SPECIMEN	$525

BLOOD SPECIMEN PROCUREMENT		
Maternal Peripheral	PER SPECIMEN	$250
Adult Peripheral	PER SPECIMEN	$250
Full Term Umbilical Cord	PER SPECIMEN	$535

SPECIAL PROCESSING / PRESERVATION		
Case Report Form (CRF) completion	PER CASE	$25
Specimen "cleaning"	PER SPECIMEN	$50
Special requests (evaluated individually)	PER SPECIMEN	$25
Snap freezing (LN2)	PER SPECIMEN	$40
Passive freezing (Dry ice)	PER SHIPMENT	$80
Foreign shipments	PER SHIPMENT	$100
Electronic Fund Transfer (EFT) (Fee varies by bank)	PER INVOICE	$25-$50

The following fees are subject to change, based upon increases imposed from outside labs and courier companies.

INFECTIOUS DISEASE SCREENING (Testing performed on donor blood)

HIV, HBsAg	$95
Additional tests	CALL

DELIVERY (Research facility responsible for delivery charges.)
(FedEx billed on research facility's account but reversed to ABR will incur a $15 rebill fee)

Federal Express Priority Overnight	$120
Federal Express First Overnight	$150
Federal Express Saturday Delivery	$170
Other courier services	CALL
Fuel surcharge (Research facility responsible for additional fuel surcharge)	CALL

Our Terms: Full payment due upon invoice receipt, and within 30 days of the invoice date. Accounts not paid within 30 days of invoice are subject to a 1.5% monthly finance charge.

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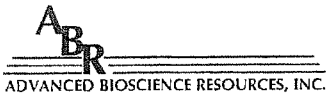
Exhibit 24



FEES FOR SERVICES SCHEDULE

Effective September 1, 2013

FETAL CADAVEROUS PROCUREMENT		SERVICE FEE
2nd trimester D & E (13 - 24 weeks)	PER SPECIMEN	$300
1st trimester aspiration (8 - 12 weeks)	PER SPECIMEN	$515

BLOOD SAMPLE PROCUREMENT		
Maternal Peripheral	PER SPECIMEN	$230
Adult Peripheral	PER SPECIMEN	$230
Full Term Umbilical Cord	PER SPECIMEN	$535

SPECIAL PROCESSING/PRESERVATION		
Case Report Form (CRF) completion	PER CASE	$25
Tissue "cleaning"	PER SPECIMEN	$50
Special requests (evaluated individually)	PER SPECIMEN	$25
Snap freezing (LN2)	PER SPECIMEN	$40
Passive freezing (Dry ice)	PER SHIPMENT	$80
Foreign shipments	PER SHIPMENT	$100
Electronic Fund Transfer (EFT)	PER INVOICE	$25

The following fees are subject to change based upon increases imposed from outside Labs and Courier Companies.

INFECTIOUS DISEASE SCREENING	
HIV, HBsAg	$95
Additional tests	CALL

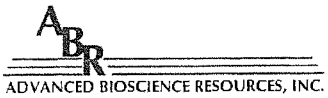
DELIVERY (Applicant responsible for delivery charges.)
(FedEx billed on Researcher's account but reversed to ABR will incur a $15 Rebill Fee)

Federal Express Priority Overnight	$110
Federal Express First Overnight	$140
Federal Express Saturday Delivery	$155
Other courier services	CALL
Fuel Surcharge (Courier charge passed along to Researchers)	CALL

Our Terms: Net Due Upon Receipt

[redacted] SJC000052. [redacted]

Exhibit 24



FEES FOR SERVICES SCHEDULE

Effective January 1, 2013

FETAL CADAVEROUS PROCUREMENT		SERVICE FEE
2nd trimester D & E (13 - 24 weeks)	PER SPECIMEN	$275
1st trimester aspiration (8 - 12 weeks)	PER SPECIMEN	$515

BLOOD SAMPLE PROCUREMENT		
Maternal Peripheral	PER SPECIMEN	$230
Adult Peripheral	PER SPECIMEN	$230
Full Term Umbilical Cord	PER SPECIMEN	$535

SPECIAL PROCESSING/PRESERVATION		
Case Report Form (CRF) completion	PER CASE	$25
Tissue "cleaning"	PER SPECIMEN	$50
Special requests (evaluated individually)	PER SPECIMEN	$25
Snap freezing (LN2)	PER SPECIMEN	$40
Passive freezing (Dry ice)	PER SHIPMENT	$80
Foreign shipments	PER SHIPMENT	$100
Electronic Fund Transfer (EFT)	PER INVOICE	$25

The following fees are subject to change based upon increases imposed from outside Labs and Courier Companies.

INFECTIOUS DISEASE SCREENING	
HIV, HBsAg	$95
Additional tests	CALL

DELIVERY (Applicant responsible for delivery charges.)
(FedEx billed on Researcher's account but reversed to ABR will incur a $15 Rebill Fee)

Federal Express Priority Overnight	$110
Federal Express First Overnight	$140
Federal Express Saturday Delivery	$155
Other courier services	CALL
Fuel Surcharge (Courier charge passed along to Researchers)	CALL

Our Terms: Net Due Upon Receipt

SJC000053

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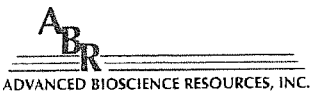
Exhibit 24



FEES FOR SERVICES SCHEDULE

Effective January 1, 2012

FETAL CADAVEROUS PROCUREMENT		SERVICE FEE
2nd trimester D & E (13 - 24 weeks)	PER SPECIMEN	$230
1st trimester aspiration (8 - 12 weeks)	PER SPECIMEN	$450

BLOOD SAMPLE PROCUREMENT		
Maternal Peripheral	PER SPECIMEN	$230
Adult Peripheral	PER SPECIMEN	$230
Full Term Umbilical Cord	PER SPECIMEN	$465

SPECIAL PROCESSING/PRESERVATION		
Case Report Form (CRF) completion	PER CASE	$25
Tissue "cleaning"	PER SPECIMEN	$50
Special requests (evaluated individually)	PER SPECIMEN	$25
Snap freezing (LN2)	PER SPECIMEN	$40
Passive freezing (Dry ice)	PER SHIPMENT	$80
Foreign shipments	PER SHIPMENT	$100
Electronic Fund Transfer (EFT)	PER INVOICE	$25

The following fees are subject to change based upon increases imposed from outside Labs and Courier Companies.

INFECTIOUS DISEASE SCREENING	
HIV, HBsAg	$85
Additional tests	CALL

DELIVERY (Applicant responsible for delivery charges.)
(FedEx billed on Researcher's account but reversed to ABR will incur a $12 Rebill Fee)

Federal Express Priority Overnight	$95
Federal Express First Overnight	$130
Federal Express Saturday Delivery	$115
Other courier services	CALL
Fuel Surcharge (Courier charge passed along to Researchers)	CALL

Our Terms: Net Due Upon Receipt

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Exhibit 24

FEES FOR SERVICES SCHEDULE

Effective January 1, 2011

FETAL CADAVEROUS PROCUREMENT		SERVICE FEE
2nd trimester D & E (13 - 24 weeks)	PER SPECIMEN	$220
1st trimester aspiration (8 - 12 weeks)	PER SPECIMEN	$450
BLOOD SAMPLE PROCUREMENT		
Maternal Peripheral	PER SPECIMEN	$220
Adult Peripheral	PER SPECIMEN	$220
Full Term Umbilical Cord	PER SPECIMEN	$465
SPECIAL PROCESSING/PRESERVATION		
Case Report Form (CRF) completion	PER CASE	$25
Tissue "cleaning"	PER SPECIMEN	$50
Special requests (evaluated individually)	PER SPECIMEN	$25
Snap freezing (LN2)	PER SPECIMEN	$40
Passive freezing (Dry ice)	PER SHIPMENT	$80
Foreign shipments	PER SHIPMENT	$100
Electronic Fund Transfer (EFT)	PER INVOICE	$25

The following fees are subject to change based upon increases imposed from outside Labs and Courier Companies.

INFECTIOUS DISEASE SCREENING	
HIV, HBsAg	$85
Additional tests	CALL

DELIVERY (Applicant responsible for delivery charges.)
(FedEx billed on Researcher's account but reversed to ABR will incur a $10 Rebill Fee)

Federal Express Priority Overnight	$85
Federal Express First Overnight	$115
Federal Express Saturday Delivery	$100
Other courier services	CALL
Fuel Surcharge (Courier charge passed along to Researchers)	CALL

Our Terms: Net Due Upon Receipt

[redacted] / [redacted]

Exhibit 24

ADVANCED BIOSCIENCE RESOURCES, INC

FEES FOR SERVICES SCHEDULE

Effective January 1, 2010

FETAL CADAVEROUS PROCUREMENT		SERVICE FEE
2nd trimester D & E (13 - 24 weeks)	PER SPECIMEN	$200
1st trimester aspiration (8 - 12 weeks)	PER SPECIMEN	$420

BLOOD SAMPLE PROCUREMENT

Maternal Peripheral	PER SPECIMEN	$200
Adult Peripheral	PER SPECIMEN	$200
Full Term Umbilical Cord	PER SPECIMEN	$465

SPECIAL PROCESSING/PRESERVATION

Tissue "cleaning"	PER SPECIMEN	$50
Special requests	PER SPECIMEN	$50
Snap freezing (LN2)	PER SPECIMEN	$40
Passive freezing (Dry ice)	PER SHIPMENT	$80
Foreign requests	PER SHIPMENT	$100
Electronic Fund Transfers	PER INVOICE	$25

The following fees are subject to change based upon increases imposed from outside Labs and Courier Companies.

INFECTIOUS DISEASE SCREENING

HIV, HBsAg	$85
Additional tests	CALL

DELIVERY (Applicant responsible for delivery charges.)
(FedEx billed on Researcher's account but reversed to ABR will incur a $10 Rebill Fee)

Federal Express Priority Overnight	$85
Federal Express First Overnight	$115
Federal Express Saturday Delivery	$100
Other courier services	CALL
Fuel Surcharge (Courier charge passed along to Researchers)	CALL

Our Terms: Net Due Upon Receipt

[redacted] [redacted] [redacted]S3C000056

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Exhibit 25

ADVANCED BIOSCIENCE RESOURCES, INC.

POC PROCUREMENT LOG

DATE	[redacted] JAN 2014	SITE	0004	TECH	[redacted]

POC #	TIME	DONOR ID #	GEST (wks)	FF (mm)	FETAL GENDER	MATERNAL BLOOD ID #	CONSENT
1	0900	[redacted] 201 X	20	31	—	7114 X	VERIFIED YES X
2	1000	[redacted] 202 X	16	20	—	7117 X	VERIFIED YES X
3	1030	[redacted] 203 X	19	29	M	7121 X	VERIFIED YES X
4	1130	[redacted] 204 X	19	29	—	7120 X	VERIFIED YES X
5							VERIFIED YES___
6							VERIFIED YES___
7							VERIFIED YES___
8							VERIFIED YES___
9							VERIFIED YES___
10							VERIFIED YES___
11							VERIFIED YES___
12							VERIFIED YES___
13							VERIFIED YES___
14							VERIFIED YES___
15							VERIFIED YES___
16							VERIFIED YES___

COURIER	TRACKING #	DEST	TIME	PICK UP #
FED EX	[redacted]	[redacted]	1300	1203

[redacted]

Exhibit 26

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6/[redacted]2014	[redacted]	1028746
	TERMS	CUSTOMER #
	Due Upon Receipt	0564

PAID 07/30/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6/[redacted]2014	[redacted]201	7113	20	Brain, 2nd Trimester	[redacted]	325.00
6/[redacted]2014	[redacted]201	7114		HIV/HBsAG/HC		150.00
6/[redacted]2014				Delivery: FedEx-Priority Overnight		120.00
				[redacted]		
					Total	$595.00

Exhibit 27

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6/[redacted]2014	[redacted]	1028739
	TERMS	CUSTOMER #
	Due Upon Receipt	0237

PAID 07/18/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6/[redacted]2014	[redacted]201	7112	20	Eyes (2), 2nd Trimester	[redacted]	650.00
6/[redacted]2014	[redacted]201	7114		HIV/HBsAG/HC		150.00
				Total		$800.00

Exhibit 28

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6/[redacted]2014	[redacted]	1028737
	TERMS	CUSTOMER #
	Due Upon Receipt	0666

PAID 07/18/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6/[redacted]2014	[redacted]201	7110	19	Liver, 2nd Trimester	[redacted]	325.00
6/[redacted]2014	[redacted]201	7114		HIV		50.00
6/[redacted]2014	[redacted]204	7124	19	Liver, 2nd Trimester		325.00
6/[redacted]2014	[redacted]204	7126		HIV		50.00
					Total	**$750.00**

Exhibit 29

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6/[redacted]2014	[redacted]	1028743
	TERMS	CUSTOMER #
	Due Upon Receipt	0446

PAID 07/11/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6/[redacted]2014	[redacted]201	7108	19	Thymus, 2nd Trimester	[redacted]	325.00
6/[redacted]2014	[redacted]201	7109	19	Liver, 2nd Trimester		325.00
6/[redacted]2014	[redacted]201	7114		HIV/HBsAG		95.00
					Total	**$745.00**

Exhibit 30

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6/[redacted]2014	[redacted]	1028744
	TERMS	CUSTOMER #
	Due Upon Receipt	0159

PAID 08/01/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6/[redacted]2014	[redacted]201	7111	20	Lung, 2nd Trimester	[redacted]	325.00
					Total	$325.00

Exhibit 31

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6/[redacted]2014	[redacted]	1028738
	TERMS	CUSTOMER #
	Due Upon Receipt	0620

PAID 06/26/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6/[redacted]2014	[redacted]204	7122	19	Thymus, 2nd Trimester	[redacted]	325.00
6/[redacted]2014	[redacted]204	7123	19	Liver, 2nd Trimester		325.00
6/[redacted]2014				Delivery: FedEx-First Overnight		150.00
				[redacted]		
				Total		$800.00

Exhibit 32

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6/[redacted]2014	[redacted]	1028740
	TERMS	CUSTOMER #
	Due Upon Receipt	0008

PAID 06/25/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6/[redacted]2014	[redacted]203	7120	19	Eyes (2), 2nd Trimester	[redacted]	650.00
6/[redacted]2014	[redacted]203	7121		HIV/HBsAG		95.00
6/[redacted]2014	[redacted]204	7125	19	Eyes (2), 2nd Trimester		650.00
6/[redacted]2014	[redacted]204	7126		HIV/HBsAG		95.00
				[redacted]		
					Total	**$1,490.00**

Exhibit 33

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6/[redacted]2014	[redacted]	1028741
	TERMS	CUSTOMER #
	Due Upon Receipt	0522

PAID 06/25/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6/[redacted]2014	[redacted]203	7117	19	Thymus, 2nd Trimester	[redacted]	325.00
6/[redacted]2014	[redacted]203	7118	19	Liver, 2nd Trimester		325.00
				[redacted]		
					Total	$650.00

Exhibit 34

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6/[redacted]2014	[redacted]	1028742
	TERMS	CUSTOMER #
	Due Upon Receipt	0261

PAID 06/27/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6/[redacted]2014	[redacted]03	7119	19	Kidney (1), 2nd Trimester	[redacted]	325.00
					Total	$325.00

Exhibit 35

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6/[redacted]2014	[redacted]	1028745
	TERMS	CUSTOMER #
	Due Upon Receipt	0596

PAID 06/25/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6/[redacted]2014	[redacted]202	7116	16	Eyes (2), 2nd Trimester	[redacted]	650.00
6/[redacted]2014	[redacted]202	7127		HIV/HC		100.00
				[redacted]		
					Total	$750.00

Exhibit 36

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6/[redacted]2014	[redacted]	1028747
	TERMS	CUSTOMER #
	Due Upon Receipt	0509

PAID 07/18/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6/[redacted]2014	[redacted]202	7115	16	Liver, 2nd Trimester	[redacted]	325.00
6/[redacted]2014	[redacted]903	7145	18	Liver, 2nd Trimester		325.00
6/[redacted]2014	[redacted]904	7149	16	Liver, 2nd Trimester		325.00
6/[redacted]2014				Delivery: FedEx-Priority Overnight		120.00
					Total	**$1,095.00**

Exhibit 37

AGREEMENT

This agreement is made as of October 1, 2010 between Advanced Bioscience Resources, Inc. ("ABR"), a non-profit corporation organized and existing under the laws of California, and Planned Parenthood of the Pacific Southwest ("PPPSW"), a professional corporation.

WHEREAS, ABR is an organization devoted to providing services in connection with the procurement of human organs and tissues for medical research; and

WHEREAS, PPPS has agreed to provide services to ABR to facilitate the accomplishment of such purpose;

NOW, THEREFORE, in consideration of the premises and mutual covenants contained herein, the parties agree as follows:

1. The term "fetal organ" has the same meaning as the term defined in 42 U.S.C.A. 274 e(c)(1) of the National Organ Transplant Act, that is, the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, organ or any subpart thereof, as derived from a fetus.

2. The term "product of conception" ("POC") means any fetal organ or other fetal or placental material taken from the human uterus during an abortion. Acquisition of the products of conception is provided as a service to the research community. The products of conception are being supplied to ABR with no wasrranties, expressed or implied, including any warranty of merchantability or fitness for a particular purpose.

   ABR will take reasonable steps to assure that the products of conception shall be for use in scientific research and that all applicable guidelines set forth by the National Institutes of Health (NIH) or other governmental agencies regarding the use of the products of conception shall be followed.

   PPPSW shall not bear any risk, directly or indirectly, from any handling, preparation, shipment or udr of the fetal tissue acquired and distributed by ABR, including, but not exclusive of, any viarl or bacterial contaminants.

3. PPPSW will provide, and ABR will pay the reasonable costs for, services and facilities (hereinafter collectively "services") associated with obtaining consents and with the removal of fetal organs and tissues 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. ABR will hire an employee to perform the work required by ABR.

Exhibit 37

4. The charge to ABR for the services specified in this Agreement in connection with each POC provided to ABR shall be sixty dollars ($60.00).

5. Any information obtained from PPPSW patients' charts shall be privileged and the contents of same shall be held so as to preserve the confidentiality of patients. ABR is not entitled to and will not receive information concerning identity of donors except as specified.

6. The term of this Agreement shall be for three (3) years, beginning from the date hereof, and terminating three (3) years thereafter, unless either of the parties hereto shall have given the other thirty (30) days' written notice of its intention to terminate this Agreement, whereupon same shall terminate thirty (30) days after date of said notice. In default of notice as aforesaid from either party hereto, this Agreement shall continue for further successive terms of one (1) year thereafter and, in default of thirty (30) days' written notice before the end of an annual term either of the parties hereto of its intention not to renew, whereupon this Agreement shall terminate at the end of said term

7. Written notices pursuant to this Agreement shall be sent first class mail, postage prepaid, to:

Planned Parenthood of the Pacific Southwest
[redacted]

Advanced Bioscience Resources, Inc.
[redacted]

8. The parties do not know how many patients will sign the consent forms in agreement to donate POC's for research and therapy, and therefore do not know how may POC's will be supplied thereunder. PPPS shall not be obligated to provide any minimum number of POC's; ABR shall not be obligated to take any minimum number of POCs, nor shall ABR be obligated to take all the POCs made available by PPPSW.

9. The parties hereto hereby mutually agree to defend, protect, and save harmless each other's officers, directors, agents and/or employees or consultants from and against all expenses, liabilities, demand or claims for loss or damage to, property, or personal injury or death suffered as a result of any actions by the parties hereto in the performance of the Agreement and attributable to the fault or negligence of the parties hereto or their respective officers, directors, agents and/or employees or consultants.

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Exhibit 37

10. No modification to this Agreement, nor any waiver of any rights, shall be effective unless agreed in writing by the party to be charged with such waiver or modification, and the waiver of any breach or default shall not constitute a waiver of any other right hereunder or any subsequent breach or default.

11. This Agreement constitutes the entire and exclusive agreement between the parties hereto with respect to its subject matter and merges all other communication and discussion, oral or written.

12. This Agreement shall be governed by and interpreted under the laws of the State of California, excluding rules of conflicts of law, and venue for any dispute arising hereunder shall be in the County of San Diego, California or in the County of Riverside, California.

13. The prevailing party in any action to enforce the terms of the Agreement shall be entitled to reimbursement by the other party for all costs (including the reasonable fees of attorneys and other professionals) incurred in connection with such proceeding.

14. This Agreement may be executed in counterparts, each of which will be deemed an original, but both of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed in duplicate by their duly authorized representatives as of the date first above written.

Planned Parenthood of the Pacific Southwest

[redacted]

Advanced Bioscience Resources, Inc.

By: Linda Tracy
Linda Tracy, RN, CTBS
President

Federal EIN: 94-3110160
California EIN: 370-20518
FDA FEI: 3005209435

Exhibit 38

ADVANCED BIOSCIENCE RESOURCES, INC.

POC PROCUREMENT LOG

DATE	[redacted] Jun 2014	SITE	10004	TECH	[redacted]

POC #	TIME	DONOR ID #	GEST (wks)	FF (mm)	FETAL GENDER	MATERNAL BLOOD ID #	CONSENT
1	0900	[redacted] 501	20	33	F	—	VERIFIED YES X
2	0945	[redacted] 502	19	29	m	7089	VERIFIED YES X
3	1015	[redacted] 503	17	23	—	—	VERIFIED YES X
4	1030	[redacted] 504	17	23	—	—	VERIFIED YES X
5	1045	[redacted] 505	17	23	—	—	VERIFIED YES X
6	1130	[redacted] 506	20	33	—	7098	VERIFIED YES X
7							VERIFIED YES___
8							VERIFIED YES___
9							VERIFIED YES___
10							VERIFIED YES___
11							VERIFIED YES___
12							VERIFIED YES___
13							VERIFIED YES___
14							VERIFIED YES___
15							VERIFIED YES___
16							VERIFIED YES___

COURIER	TRACKING #	DEST	TIME	PICK UP #
FED EX	[redacted]	[redacted]	1230	522

[redacted] / [redacted]

Exhibit 39

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6[redacted]2014	[redacted]	1028723
	TERMS	CUSTOMER #
	Due Upon Receipt	0564

PAID 07/30/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6[redacted]2014	[redacted]502	5000	19	Brain, 2nd Trimester	[redacted]	325.00
6[redacted]2014	[redacted]502	7089		HIV/HBsAG/HC		150.00
6[redacted]2014				Delivery: FedEx-Priority Overnight		120.00
				[redacted]		
					Total	$595.00

Exhibit 40

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6/[redacted]2014	[redacted]	1028713
	TERMS	CUSTOMER #
	Due Upon Receipt	0613

PAID 09/19/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6/[redacted]2014	[redacted]501	8325	19	Lower Limb (1), 2nd Trimester	[redacted]	325.00
6/[redacted]2014	[redacted]501	8326	19	Lower Limb (1), 2nd Trimester		325.00
6/[redacted]2014	[redacted]			Delivery: FedEx-Priority Overnight		120.00
6/[redacted]2014	[redacted]502	4997	19	Lower Limbs (2), 2nd Trimester		650.00
6/[redacted]2014	[redacted]504	7092	17	Lower Limb (1), 2nd Trimester		325.00
6/[redacted]2014				Delivery: FedEx-Priority Overnight		120.00
				[redacted]		
				Total		**$1,865.00**

Exhibit 41

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6[redacted]2014	[redacted]	1028722
	TERMS	CUSTOMER #
	Due Upon Receipt	0673

PAID 07/25/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6[redacted]2014	[redacted]502	4998	19	Thymus, 2nd Trimester	[redacted]	325.00
6[redacted]2014	[redacted]502	4999	19	Liver, 2nd Trimester		325.00
6[redacted]2014	[redacted]502	7089		HIV/HBsAG		95.00
					Total	**$745.00**

Exhibit 42

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6/[redacted]2014	[redacted]	1028716
	TERMS	CUSTOMER #
	Due Upon Receipt	0620

PAID 06/19/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6/[redacted]2014	[redacted]503	7090	17	Thymus, 2nd Trimester	[redacted]	325.00
6/[redacted]2014	[redacted]503	7091	17	Liver, 2nd Trimester		325.00
6/[redacted]2014				Delivery: FedEx-First Overnight		150.00
6/[redacted]2014				EFT/Wire Transfer Fee		25.00
				[redacted]		
				Total		$825.00

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Exhibit 42

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6/[redacted]2014	[redacted]	1028717
	TERMS	CUSTOMER #
	Due Upon Receipt	0365

PAID 07/30/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6/[redacted]2014	[redacted]506	7096	20	Thymus, 2nd Trimester	[redacted]	325.00
6/[redacted]2014	[redacted]506	7097	20	Liver, 2nd Trimester		325.00
6/[redacted]2014	[redacted]506	7098		HIV/HBsAG/HC		150.00
				[redacted]		
				Total		**$800.00**

Exhibit 42

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6[redacted]2014	[redacted]	1028718
	TERMS	CUSTOMER #
	Due Upon Receipt	0599

PAID 08/01/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6[redacted]2014	[redacted]501	4992	20	Thymus, 2nd Trimester	[redacted]	325.00
6[redacted]2014	[redacted]501	4993	20	Liver, 2nd Trimester		325.00
				[redacted]		
					Total	**$650.00**

Exhibit 42

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6/[redacted]2014	[redacted]	1028719
	TERMS	CUSTOMER #
	Due Upon Receipt	0261

PAID 06/27/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6/[redacted]2014	[redacted]501	4994	20	Kidney (1), 2nd Trimester	[redacted]	325.00
6/[redacted]2014	[redacted]501	4995	20	Brain, 2nd Trimester		325.00
					Total	$650.00

Exhibit 42

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6[redacted]2014	[redacted]	1028720
	TERMS	CUSTOMER #
	Due Upon Receipt	0264

PAID 08/08/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6[redacted]2014	[redacted]504	7093	17	Thymus, 2nd Trimester	[redacted]	325.00
6[redacted]2014	[redacted]504	7094	17	Liver, 2nd Trimester		325.00
				[redacted]		
				Total		$650.00

Exhibit 43

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6/[redacted]2014	[redacted]	1028715
	TERMS	CUSTOMER #
	Due Upon Receipt	0070

PAID

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6/[redacted]/2014	[redacted]505	7095	17	Liver, 2nd Tri-N/C Shipping error	[redacted]	0.00
6/[redacted]/2014				Deliv.: FedEx-Prior.O/N-N/C Misrouted		0.00
					Total	$0.00

Exhibit 44

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6/[redacted]2014	[redacted]	1028755
	TERMS	CUSTOMER #
	Due Upon Receipt	0614

PAID 08/29/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6[redacted]2014	[redacted]401	8341	24	Thymus, 2nd Trimester	[redacted]	325.00
6[redacted]2014	[redacted]401	8342	24	Liver, 2nd Trimester		325.00
					Total	$650.00

Exhibit 44

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6/[redacted]2014	[redacted]	1028756
	TERMS	CUSTOMER #
	Due Upon Receipt	0653

PAID 08/29/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6/[redacted]2014	[redacted]01	8343	24	Liver, 2nd Trimester	[redacted]	325.00
6/[redacted]2014	[redacted]01	8343	24	Spleen, 2nd Tri-N/C for HLA testing		0.00
6/[redacted]2014	[redacted]01	8344		LCMV		185.00
6/[redacted]2014	[redacted]01	8345		HIV/HC		100.00
6/[redacted]2014	[redacted]03	8350	22	Liver, 2nd Trimester		325.00
6/[redacted]2014	[redacted]03	8350	22	Spleen, 2nd Tri-N/C for HLA testing		0.00
6/[redacted]2014	[redacted]03	8351		LCMV		185.00
6/[redacted]2014	[redacted]03	8352		HIV/HC		100.00
6/[redacted]2014				Delivery: FedEx-Priority Overnight		190.00
				[redacted]		
					Total	**$1,410.00**

Exhibit 45

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6[redacted]2014	[redacted]	1028805
	TERMS	CUSTOMER #
	Due Upon Receipt	0376

PAID 08/21/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6[redacted]2014	[redacted]601	8381	17	Brain, 2nd Trimester-Normal	[redacted]	325.00
6[redacted]2014	[redacted]602	8392	21	Brain, 2nd Trimester-Trisomy 21		325.00
6[redacted]2014				Delivery: FedEx-Priority Overnight		120.00
				[redacted]		
				Total		$770.00

Exhibit 46

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6/[redacted]2014	[redacted]	1028808
	TERMS	CUSTOMER #
	Due Upon Receipt	0477

PAID 07/25/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6/[redacted]2014	[redacted]602	8389	21	Liver, 2nd Trimester	[redacted]	325.00
6/[redacted]2014	[redacted]602	8393		HIV/HC		100.00
6/[redacted]2014				Delivery: FedEx-Priority Overnight		120.00
					Total	$545.00

Exhibit 47

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6/[redacted]2014	[redacted]	1028807
	TERMS	CUSTOMER #
	Due Upon Receipt	0237

PAID 08/01/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6/[redacted]2014	[redacted]602	8391	21	Eyes (2), 2nd Trimester	[redacted]	650.00
6/[redacted]2014	[redacted]602	8393		HIV/HBsAG/HC		150.00
					Total	**$800.00**

Exhibit 48

TISSUE ACQUISITION INVOICE

DATE	P.O. #	INVOICE #
6/[redacted]2014	[redacted]	1028806
	TERMS	CUSTOMER #
	Due Upon Receipt	0553

PAID 07/10/2014

BILL TO

[redacted]

PROC. DATE	PATIENT ID	ABR ID	GEST	DESCRIPTION	RESEARCHER	FEE
6/[redacted]2014	[redacted]602	8385	21	Lower Limb (1), 2nd Trimester	[redacted]	325.00
6/[redacted]2014	[redacted]602	8386	21	Thymus, 2nd Trimester		325.00
6/[redacted]2014	[redacted]602	8387	21	Liver, 2nd Trimester		325.00
6/[redacted]2014	[redacted]602	8388	21	Skin, 2nd Trimester		325.00
6/[redacted]2014	[redacted]602	8393		HIV/HBsAG/HC		150.00
6/[redacted]2014				Delivery: FedEx-Priority Overnight		120.00
				[redacted]		
					Total	**$1,570.00**

Exhibit 49

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stem express

StemExpress Statement Regarding Revenue Generated From Fetal Tissue

Founded in 2010, StemExpress is 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. Cells produced by the physicians, scientists, medical technicians and nurses at StemExpress are currently used in research globally aimed at finding cures and treatments for cancer, diabetes, HIV/AIDS, cardiac disease, and other significant medical conditions.

Despite having only 35 employees, StemExpress plays a critical role in helping the global research community as it strives to achieve medical breakthroughs to stamp out global disease and improve quality of life. Our customers in the United States include some of the most prestigious universities and research hospitals, largest pharmaceutical companies, cutting-edge laboratories, and the federal government research agencies. All of the products we provide are offered solely at the request of the nation's and the world's great research institutions.

I. StemExpress's Overall Revenue and Accounting System

StemExpress is currently incorporated as a for-profit company, as it was cheaper and faster to begin business this way five years ago. Today, we operate in a manner that actually is more closely aligned with a not-for-profit organization. Since our founding, all of our net revenue has been reinvested in the company's infrastructure and expansion of our operations. For example, in 2014 we had approximately $450,000 in post-tax net revenue, all of which was reinvested directly into the company.

There are substantial expenses associated with running a business like StemExpress—some exemplar costs include (i) procuring tissue for use in the manufacturing of isolated cells (including salaries and supplies); (ii) running our laboratory and manufacturing isolated cells (including salaries for highly trained staff and extremely expensive equipment); (iii) marketing and sales operations; and (iv) other general and administrative expenses. To provide some perspective on our conservative, mission-driven approach to running StemExpress, the full time CEO, Ms. Cate Dyer, did not receive a salary for the first two years of operation and now receives a modest, below-market, personal salary.

As a small, five-year-old company, StemExpress's modest accounting system does not allow for immediate reporting of revenue or line-item expenses associated with particular types of tissues that are used for cell isolations (*e.g.*, adult tissue v. maternal blood v. fetal tissue). Nevertheless, we have endeavored to respond to the Committee's request for information regarding revenue derived from fetal tissue.

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STEM.JUD00000009

Exhibit 49

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II. Revenue and Costs Associated with Unaltered Fetal Tissue

The majority of StemExpress's business involves isolating and purifying cells derived from donated adult tissue and blood (described in greater detail below). A small portion of our work-flow—approximately 10 percent involves fetal tissue and isolated cells that are manufactured using fetal tissue. It is important to clarify that less than one percent of StemExpress's business in 2014 dealt with unaltered fetal tissue, which has been the source of criticism in the recent attacks against StemExpress and Planned Parenthood. In fact, the central reason that StemExpress continues to offer unaltered fetal tissue to our customers is as an extension of our cell isolation business, as some customers seek both isolated cells manufactured by StemExpress and, on occasion, decide to perform their own cell isolations using unaltered tissue they seek from one company.

As a general matter, StemExpress's limited business in unaltered fetal tissue—which represented less than one percent of the company's revenue in 2014—likely results in a net loss for the company. StemExpress has 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 $1,000 for each procurement. Part of those expenses include the roughly $30,000 paid to two Planned Parenthood clinics for reasonable costs and expenses before StemExpress terminated our relationship with them earlier this month. 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 overhead associated with safely and securely providing these products to our customers.

Some may ask why would we offer any service/product at a loss, and the answer is our mission statement – *StemExpress accelerates the cure and prevention of significant medical conditions at life changing speed.*

III. Manufactured Isolated Cells

The remainder of StemExpress's work with fetal tissue consists of a complex, time-intensive, and expensive cell isolation manufacturing process that takes place in the company's Placerville, California laboratory. We are not alone in the production of isolated cells using fetal tissue (some of our peer competitors in this space include two publicly traded companies with market caps of $6.9 billion and $43 million, respectfully). StemExpress employs a highly educated, extensively trained laboratory staff that includes several university-trained molecular biologists. Our laboratory staff often spends thousands of hours developing and optimizing specific protocols used to manufacture cell isolations. Those protocols may take several shifts in the lab to implement for each batch of isolated cell product that is prepared to meet our customers' requests. Fetal tissues received are unusable for cell isolation processing over forty percent of the time. This low number is exacerbated because as often as a quarter of

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the time, the results of our laboratory staff's efforts produce such low production yields that no salable output is produced due to anticipated complications in the manufacturing process. While StemExpress's cell isolation protocols are highly confidential and proprietary and have taken four years to develop, we are producing a third-party (public) description of cell isolation procedures for developing CD34 stem cells (one of the isolated cell products offered by StemExpress) to provide additional context regarding the complexity of this manufacturing process.

For cell products derived from fetal tissue obtained from Planned Parenthood, StemExpress generated approximately $180,000 in gross (pre-tax) revenue in 2014. However, as you can imagine, there are substantial expenses associated with the manufacturing of isolated cell products, including salaries, expensive laboratory cell isolation equipment, disposables, chemicals, reagents, isolation mediums, other infrastructure expenses and a myriad of additional costs. As noted above, our accounting system does not allow us to generate a cost-based accounting report that assigns specific expenses to each product. By way of reference, our laboratory department and the supporting procurement department incurred over $1.1 million in expenses in 2014.

* * * * *

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STEM.JUD00000011

Exhibit 50

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stem express

StemExpress Second Response to Senate Judiciary Committee September 17 Letter

Request No.	Description
1	**Please provide a list of all the entities from which StemExpress has ever acquired fetal tissue, including each entity's address and point of contact.**

StemExpress has obtained fetal tissue from two Planned Parenthood affiliates, Planned Parenthood Mar Monte ("PPMM") and Planned Parenthood Shasta Pacific ("PPSP"). As you know, StemExpress terminated its relationship with PPMM and PPSP in August 2015. The contact information for PPMM and PPSP is listed below.

- PPMM: [redacted]
- PPSP: [redacted]

StemExpress has also obtained fetal tissue from five independent (non-Planned Parenthood) clinics. StemExpress agrees to identify the states where it has agreements with independent clinics, but will not be providing the names of these clinics to protect their safety and security. To that end, StemExpress has agreements with independent clinics in the following five states:

- Arkansas – one independent clinic
- Arizona – one independent clinic
- California – one independent clinic
- Florida – one independent clinic
- Washington – one independent clinic

Request No.	Description
2	**Please provide copies of all contracts StemExpress has, had, or proposed with suppliers of fetal tissue since the company's creation in 2010, regardless of affiliation with Planned Parenthood, not including the two particular contracts StemExpress has already provided. If StemExpress has acquired fetal tissue from any source without a contract, please list the source entity and the terms of the acquisition.**

See enclosed production of two exemplar agreements between StemExpress and independent clinics, redacted to remove identifying information. The terms of all of StemExpress's agreements with independent clinics are substantially similar to one of these two agreements.

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Exhibit 50

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stem express

~~Confidential Commercial Information~~
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StemExpress Second Response to Senate Judiciary Committee September 17 Letter

Request No.	Description
3	Please provide copies of all monthly invoices StemExpress received from Planned Parenthood Mar Monte from April 2010 to the present.

Please see enclosed production.

Request No.	Description
4	Please provide copies of all monthly invoices StemExpress received from Planned Parenthood Shasta Pacific from May 2012 to the present.

Please see enclosed production.

Request No.	Description
5	Please provide all records relating to communications with Planned Parenthood Mar Monte personnel regarding StemExpress' contract with that affiliate, including communications regarding initial requests to enter into a contract, to convince the affiliate that StemExpress would be a better contractual partner than its competitor, discussions of contractual terms, and any other sales pitches or promotional materials provided.

Please see enclosed production.

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Exhibit 51

STEM-EX, LLC

Services Agreement

This agreement is made as of April 1st, 2010 between Stem-Ex, LLC, a limited liability company, and Planned Parenthood Mar Monte, a professional corporation.

WHEREAS, Stem-Ex is a company devoted to providing services related to the procurement of human organs, tissues, and blood for medical research in order to facilitate medical research utilizing those tissues; and

WHEREAS, Planned Parenthood Mar Monte provides medical services, education programs, and advocacy initiatives in order to improve people's lives;

NOW, THEREFORE, in consideration of the premises and mutual covenants contained in this Agreement, and in order to further their mutual goals, the parties agree as follows:

1. The term "fetal organ" has the same meaning as the term defined in the National Organ Transplant Act (42 U.S.C.A. 274e(c)(1)) and means the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ or any subpart thereof, as from a fetus.

2. The term "product of conception" ("POC") means any fetal organ or other fetal or placental material taken from the human uterus during an abortion.

3. The term "maternal bloods" means blood samples taken from a pregnant woman.

4. Planned Parenthood Mar Monte will provide, and Stem-Ex 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 Stem-Ex 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.

5. 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. Planned Parenthood Mar Monte will invoice Stem-Ex monthly for the number of POC's and number of maternal bloods procured by Stem-Ex. Stem-Ex will pay Planned Parenthood Mar Monte within two weeks of receipt of the invoice.

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STEM.JUD00000001

Exhibit 51

6. Any information obtained from Planned Parenthood Mar Monte patients' charts shall be privileged, and Stem-Ex will treat the information in order to preserve the confidentiality of the patients. Stem-Ex will not receive any information concerning identity of donors except as necessary to obtain patients' consent for use of POCs and maternal bloods.

7. The term of this Agreement shall be for one year, beginning from the date hereof, and terminating one year thereafter. Parties may, at any time, give each other thirty days written notice of the intention to terminate this Agreement, whereupon the Agreement shall terminate thirty days after the receipt of such notice. In the absence of such termination, this Agreement shall continue for further successive terms of one year thereafter.

8. Written notices pursuant to this Agreement shall be sent to the following:

   Attn: Medical Director
   Planned Parenthood Mar Monte
   [redacted]

   Stem-Ex
   [redacted]

9. The parties do not know how many patients will consent to donate POCs or maternal bloods for research, and thus do not know how many POCs or maternal bloods will be obtained pursuant to this Agreement. Planned Parenthood Mar Monte is not obligated to provide any minimum number of POCs or maternal bloods. Stem-Ex is not obligated to take any minimum number of POCs or maternal bloods, nor is Stem-Ex obligated to take all the POCs or maternal bloods made available by Planned Parenthood Mar Monte.

10. The parties mutually agree to defend, protect, and hold harmless each other's officers, directors, agents, employees, and consultants from and against any and all expenses, liabilities, demands or claims for loss or damage to property, or for personal injury or death suffered as a result of any actions by the parties in the performance of the Agreement and attributable to the fault or negligence of the parties or their respective officers, directors, agents, employees, or consultants.

11. No modification to this Agreement, nor any waiver of any rights, shall be effective unless agreed to in writing by the party charged with such waiver or modification. Waiver of any breach or default shall not constitute a waiver of any other right hereunder, or any subsequent breach or default.

12. This Agreement constitutes the entire and exclusive agreement between the parties.

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STEM.JUD00000002

Exhibit 51

13. This Agreement shall be governed by and interpreted under the laws of the State of California, and venue for any dispute arising hereunder shall be in the County of Sacramento.

14. The prevailing party in any action to enforce the terms of the Agreement shall be entitled to reimbursement by the other party for all costs, including the reasonable attorney fees and professional fees, incurred in connection with such proceeding.

15. This Agreement may be executed in counterparts, each of which will be deemed an original, but both of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have executed this agreement by their duly authorized representatives as of the date written above.

Planned Parenthood Mar Monte

By: [redacted]

Title: [redacted]

Stem-Ex, LLC

By: Cathleen Dean

Title: President

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STEM.JUD00000003

Exhibit 51

Services Agreement

This agreement is made as of 5/15/2012 between StemExpress, LLC, a limited liability company, and Planned Parenthood Shasta Pacific, a professional corporation.

WHEREAS, StemExpress is a company devoted to providing services related to the procurement of human organs, tissues, and blood for medical research in order to facilitate medical research utilizing those tissues; and

WHEREAS, Planned Parenthood Shasta Pacific provides medical services, education programs, and advocacy initiatives in order to improve people's lives;

NOW, THEREFORE, in consideration of the promises and mutual covenants contained in this Agreement, and in order to further their mutual goals, the parties agree as follows:

1. The term "fetal organ" has the same meaning as the term defined in the National Organ Transplant Act (42 U.S.C.A. 274e(c)(1)) and means the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ or any subpart thereof, as from a fetus.

2. The term "product of conception" ("POC") means any fetal organ or other fetal or placental material taken from the human uterus during an abortion.

3. The term "maternal bloods" means blood samples taken from a pregnant woman.

4. Planned Parenthood Shasta Pacific 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.

5. 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. Planned Parenthood Shasta Pacific will invoice StemExpress monthly for the number of POC's and number of maternal bloods procured by StemExpress. StemExpress will pay Planned Parenthood Shasta Pacific within thirty days of receipt of the invoice.

[redacted]

Exhibit 51

6. Any information obtained from Planned Parenthood Shasta Pacific patients' charts shall be privileged, and StemExpress will treat the information in order to preserve the confidentiality of the patients. StemExpress will not receive any information concerning identity of donors except as necessary to obtain patients' consent for use of POCs and maternal bloods.

7. The term of this Agreement shall be for one year, beginning from the date hereof, and terminating one year thereafter. Parties may, at any time, give each other thirty days written notice of the intention to terminate this Agreement, whereupon the Agreement shall terminate thirty days after the receipt of such notice. In the absence of such termination, this Agreement shall continue for further successive terms of one year thereafter.

8. Written notices pursuant to this Agreement shall be sent to the following:

Attn: Medical Director
Planned Parenthood Shasta Pacific
[redacted]

StemExpress
[redacted]

9. The parties do not know how many patients will consent to donate POCs or maternal bloods for research, and thus do not know how many POCs or maternal bloods will be obtained pursuant to this Agreement. Planned Parenthood Shasta Pacific is not obligated to provide any minimum number of POCs or maternal bloods. StemExpress is not obligated to take any minimum number of POCs or maternal bloods, nor is StemExpress obligated to take all the POCs or maternal bloods made available by Planned Parenthood Shasta Pacific.

10. The parties mutually agree to defend, protect, and hold harmless each other's officers, directors, agents, employees, and consultants from and against any and all expenses, liabilities, demands or claims for loss or damage to property, or for personal injury or death suffered as a result of any actions by the parties in the

[redacted]

Exhibit 51

performance of the Agreement and attributable to the fault or negligence of the parties or their respective officers, directors, agents, employees, or consultants.

11. No modification to this Agreement, nor any waiver of any rights, shall be effective unless agreed to in writing by the party charged with such waiver or modification. Waiver of any breach or default shall not constitute a waiver of any other right hereunder, or any subsequent breach or default.

12. This Agreement constitutes the entire and exclusive agreement between the parties.

13. This Agreement shall be governed by and interpreted under the laws of the State of California, and venue for any dispute arising hereunder shall be in the County of Sacramento.

14. The prevailing party in any action to enforce the terms of the Agreement shall be entitled to reimbursement by the other party for all costs, including the reasonable attorney fees and professional fees, incurred in connection with such proceeding.

15. This Agreement may be executed in counterparts, each of which will be deemed an original, but both of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have executed this agreement by their duly authorized representatives as of the date written above.

Planned Parenthood Mar[redacted]

By: [redacted] 5/10/12

Tit[redacted]

StemExpress, LLC

By: _____

Title CEO 5/10/12

[redacted]

Exhibit 52

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stemexpress

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StemExpress First Response to Senate Judiciary Committee February 2, 2016 Letter

Request No.	Description
1	**Please provide copies of all invoices StemExpress sent to its customers for August and September of 2012, December 2013, and January 2014.**

Please see the enclosed production reflecting all StemExpress invoices for fetal tissue procured from Planned Parenthood clinics in the above-referenced months.

Request No.	Description
2	**Please provide all procurement logs and researcher procurement forms for collections from Planned Parenthood Mar Monte (PPMM) clinics in August and September of 2012, corresponding to the collections invoiced by PPMM at STEM.JUD00000054-55.**

Please see the enclosed production.

Request No.	Description
3	**Please provide all procurement logs and researcher procurement forms for collections from Planned Parenthood Shasta Pacific (PPSP) clinics corresponding to the collections invoiced by PPSP at STEM.JUD00000112.**

Please see the enclosed production. In reviewing these files, we discovered an accounting error on this PPSP invoice. While the invoice lists 4 Bloods and 32 POCs from [redacted] Health Center, the procurements logs associated with these collections reflect that this should have been 4 POCs and 32 Blood collections. We have notified Planned Parenthood and they are currently reviewing this accounting issue internally. StemExpress' production reflects the procurement documentation for the four POCs from [redacted] Health Center that were actually procured.

Request No.	Description
4	**Please provide all "Procurement Technician Compensation Policies" from 2010 to the present. Is it correct that StemExpress pays or paid its procurement technicians an hourly rate plus a bonus per tissue specimen collected?**

Please see the enclosed production. The compensation terms for StemExpress procurement technicians varied over time and for each individual employee or independent contractor, as reflected in the enclosed documents.

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Exhibit 52

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stemexpress®

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StemExpress First Response to Senate Judiciary Committee February 2, 2016 Letter

Request No.	Description
5	**When working with PPMM and PPSP, did StemExpress typically have its technicians waiting on site at the clinics during abortion procedures to immediately collect fetal tissue acquired from those abortion procedures?**

Yes. Since the majority of StemExpress's work at these clinics consisted of collecting maternal blood, StemExpress personnel were on occasion, but not at all times, located onsite to perform phlebotomies before termination procedures were performed by Planned Parenthood personnel. To the extent that a Planned Parenthood patient provided informed consent, StemExpress personnel were available to procure products of conception (POC).

Request No.	Description
6	**Is it correct that when StemExpress provides its customers with so-called "unaltered fetal tissue," as opposed to "manufactured isolated cells," StemExpress technicians typically package and ship obtained tissue on the day it is collected?**

Yes. Unaltered fetal tissue is packaged and shipped on the same day it is collected to researchers.

Request No.	Description
7	**Is it correct that, pursuant to StemExpress' contracts with PPSM [sic] and PPMM, StemExpress paid PPSM [sic] and PPMM per useable specimen collected, rather than paying a flat fee per aborted fetus, and that, under the right circumstances, multiple useable specimens could be collected from a single aborted fetus?**

No. StemExpress was not invoiced by PPSM and PPMM per specimen. Rather, the PP clinics invoiced StemExpress per products of conception (POC), which includes placental, cord, or fetal tissue, that are procured for use in medical research.

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Exhibit 52

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StemExpress First Response to Senate Judiciary Committee February 2, 2016 Letter

Request No.	Description
8	**Please provide copies of all promotional materials, such as brochures and flyers, StemExpress provided to clinics.**

Please see the enclosed production. For your reference as you review these documents, please note that StemExpress does not have any promotional materials that are specific to fetal tissue as it represents a very small portion of our work with clinics. The overwhelming majority of StemExpress' work with clinics and health centers is related to blood collection (including maternal blood), which was the focus of these marketing materials. As the largest supplier of maternal blood globally, StemExpress supports genetics research around the world through collections from women's clinics, family planning centers, and obstetric physician practices that support full-term pregnancies.

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STEM.JUD00000131

Exhibit 53

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**

Exhibit 54

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stemexpress

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StemExpress First Response to Senate Judiciary Committee February 18, 2016 Letter

Request No.	Description
1	**Please describe the space used by StemExpress at Planned Parenthood Mar Monte (PPMM) clinics in conducting specimen-collection work (e.g, a counter top, several rooms, a wing of the building, etc.).**

The space utilized by StemExpress varied between each PPMM clinic. 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. StemExpress personnel also had access to a separate procedure room or area of the clinic to perform phlebotomy blood draws from donors. StemExpress did not provide any additional compensation to PPMM for the use of the above-reference work spaces.

Request No.	Description
2	**Did StemExpress store materials at PPMM clinics? If so, please describe the materials stored and the means of storage (e.g, two drawers, a freezer shelf, a cupboard, a room, a wing of the building, etc.).**

Yes. StemExpress stored certain materials at PPMM clinics, which varied by clinic. Each of the PPMM clinics provided ongoing storage for many items when StemExpress technicians were not onsite. Some items were stored on a temporary basis, so these items would be there when StemExpress technicians were actively onsite. The types of materials stored included shipping materials, postal boxes, needles, syringes, blood draw tubes, media, medical supplies, and other items necessary to conduct blood draws and POC tissue collection. These materials were stored in cupboards, cabinets, storage shelves, refrigerators, and freezers. StemExpress did not provide any additional compensation to PPMM for the use of the above-reference storage space.

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Exhibit 54

stemexpress

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StemExpress First Response to Senate Judiciary Committee February 2, 2016 Letter

Request No.	Description
3	**Please describe the space used by StemExpress at Planned Parenthood Northern California clinics (formerly Planned Parenthood Shasta Pacific) (PPNC/PPSP) in conducting specimen-collection work.**

The space utilized by StemExpress varied between each PPSP clinic. 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. StemExpress personnel also had access to a separate procedure room or area of the clinic to perform phlebotomy blood draws from donors. StemExpress did not provide any additional compensation to PPSP for the use of the above-reference work spaces.

Request No.	Description
4	**Did StemExpress store materials at PPNC/PPSP clinics? If so, please describe the materials stored and the means of storage.**

Yes. StemExpress stored certain materials at PPSP clinics, which varied by clinic. Each of the PPSP clinics provided ongoing storage for many items when StemExpress technicians were not onsite. Some items were stored on a temporary basis, so these items would be there when StemExpress technicians were actively onsite. The types of materials stored included shipping materials, postal boxes, needles, syringes, blood draw tubes, media, medical supplies, and other items necessary to conduct blood draws and POC tissue collection. These materials were stored in cupboards, cabinets, storage shelves, refrigerators, and freezers. StemExpress did not provide any additional compensation to PPSP for the use of the above-reference storage space.

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STEM.JUD00000133

Exhibit 55

Procurement Technician Compensation Policy
Effective 09/01/2012

Hourly Rate

- Procurement Technicians are compensated at rate of $15 per hour.

Blood Procurement

- All Procurement Technicians are expected to draw at least 15 bloods a week. In addition, blood draws exceeding 15 in a week are reimbursed at an additional $25 for each draw over and above 15.

For example, if a Procurement Technician drew 17 bloods in a week, they would be compensated for an additional 2 blood draws at $25 per draw for a total of $50.

NOTE: IDS Testing samples do not count toward Blood Procurement totals.

Tissue Procurement and IDS Testing

- Tissue Procurement Compensation is based on a per tissue per POC rate. Procurement Technicians are compensated at a rate of $50 for the first tissue procured with any given POC. Any additional tissues procured from the **same** POC are compensated at a rate of $25 per tissue.

For example, if a Procurement Technician procured 2 tissues from the same POC, they would bill $50 for the first tissue and $25 for the second tissue for a total of $75 for that POC.

- IDS Testing for Tissues procured is compensated at $10 per IDS draw. IDS Testing samples do not count toward Blood Procurement totals.

Mileage Reimbursement

- Each StemExpress contractor is assigned a worksite location, which generally is a clinic or the Placerville office/lab. Any mileage driven on behalf of StemExpress exceeding the mileage to and from their resident and their current assigned worksite location will be reimbursed at $.55 per mile based on the Federal Mileage Rate. This rate is subject to change via the federal government and will be changed accordingly.

Exhibit 55

Procurement Technician Compensation Policy
Effective 09/01/2012 (cont.)

Two or More Procurement Technicians working in Unison

- Procurement Technicians often work in unison so procurements are split equality between the technicians.

For example, if two technicians are working together at the same clinic, and two maternal bloods are procured, and both technicians already exceeded their minimum 15 weekly draws, each technician would receive 1 draw toward their additional billing. If one or more of the two technicians have not reached their 15-draw minimum, each draw would count as half a draw for the technician(s) still attempting to meet their weekly minimum.

Exhibit 55

Compensation Policy for Procurement Technicians Effective 08/6/2012

Procurement Technicians (blood and tissue) will receive an hourly rate of $15 for all hours worked. Furthermore, blood draws exceeding 15 a week that fall between 30 to 60cc are reimbursed at $25 for each draw. Please note, at a minimum, all Procurement Technicians are expected to draw at least 15 bloods a week. Any blood draws less than 30cc will not be reimbursed unless specifically requested by researchers, at which time you will be notified. On surgery days, Tissue Procurement Technicians will receive $50 per tissue for Fetal Tissue Procurement regardless of gestation.

Because Procurement Technicians often work in unison, procurements will continue to be split equality between the Technicians. For instance, if two Technicians are working together at the same clinic, and two maternal bloods are procured, and both Technicians already exceeded their minimum 15 weekly draws, each Technician would receive $12.50 per draw. If one or more of the two Technicians have not reached their 15-draw minimum, each draw would count as half a draw for the Technician(s) still attempting to meet their weekly minimum.

Redacted

Exhibit 56

stem express

Researcher Procurement Form

DATE 8/7/12

Delivery Instructions: ○ Billed/Recipient ◉ Billed/StemExpress

Ship To:

Name
C/O
Address
Address 2
City
Country USA

Redacted

Email:
Email 2:
Email 3:
Phone #
Cell Phone
Alt. Phone #

Redacted

FedEx Account StemExpress Acct
Ref#

Tracking # Redacted

Local Delivery: ○ AM ○ PM Deliver By

Procurement Tech 06 Additional Techs Location [redacted]

ID#	TIME	PATIENT#	SPEC#	GEST	SPECIMEN	SEX	COMMENTS
02	1230	[redacted]02	4580	19.3wks	Liver	F	In RPMI
02	1230	[redacted]02	4581	19.3wks	Thymus	F	In RPMI
02	1230	[redacted]02	4582	19.3wks	Torso Skin	F	In RPMI
02	1230	[redacted]02	5720B	---	Maternal Blood Testing	F	HIV, HBSAG

[redacted]

Redacted

Exhibit 57

stem express

Researcher Procurement Form

DATE 8/7/12

Delivery Instructions: ○ Billed/Recipient ◉ Billed/StemExpress

Ship To:

Name

C/O

Address

Address 2

City

Country USA

Redacted

Email:

Email 2:

Email 3:

Phone #

Cell Phone

Alt. Phone #

Redacted

FedEx Account N/A

Tracking #

Ref# Same Day Delivery

Local Delivery: ○ AM ◉ PM Deliver By StemExpress [redacted]

Procurement Tech 06 Additional Techs Location [redacted]

ID#	TIME	PATIENT#	SPEC#	GEST	SPECIMEN	SEX	COMMENTS
02	1230	[redacted]02	4579	19.3wks	Brain	F	In RPMI

[redacted]

Exhibit 58

stem express [redacted]

Invoice

Date	Invoice #
08/10/2012	1710
Terms	**Due Date**
Due on receipt	08/10/2012

Bill To	Ship To
Redacted	Redacted

PAID

Ship Date	Ship Via	Researcher	P.O. No	Shipping
08/07/2012	StemExpress	Redacted	[redacted]	Local Delivery

Description	Qty	Price	Amount Due
08/07/2012			
• Fetal Brain Procurement - ID# 02	1:00	250.00	250.00
• Local Delivery	1:00	195.00	195.00

****NOTE NEW ADDRESS FOR STEMEXPRESS. PLEASE SEND INVOICE PAYMENT TO THE NEW ADDRESS****. Thank you for your business. If you have any questions, contact Redacted at Redacted or by email at [redacted]

Total	$445.00
Payment	$445.00
Balance Due	$0.00

Exhibit 59

stem express [redacted]

Invoice

Date	Invoice #
08/07/2012	1701
Terms	**Due Date**
Due on receipt	08/07/2012

Bill To

Redacted

PAID

Ship Date	Ship Via	Tracking No.	Researcher	Shipping
08/07/2012	FedEx	Redacted	Redacted	StemExpress Acct

Description	Qty	Price	Amount Due
08/07/2012			
• Fetal Liver Procurement - ID# 02	1:00	250.00	250.00
• Fetal Thymus Procurement - ID# 02	1:00	250.00	250.00
• Fetal Torso Skin Procurement - ID# 02	1:00	250.00	250.00
• Infectious Disease Screening: HIV, HBsAg	1:00	75.00	75.00
• Fed Ex Priority Overnight	1:00	85.00	85.00

****NOTE NEW ADDRESS FOR STEMEXPRESS. PLEASE SEND INVOICE PAYMENT TO THE NEW ADDRESS****. Thank you for your business. If you have any questions, contact Redacted at Redacted or by email at Redacted [redacted]

Total	$910.00
Payment	$910.00
Balance Due	$0.00

Exhibit 60

Procurement Technician Compensation Policy
Effective 09/01/2012

Hourly Rate

- Procurement Technicians are compensated at rate of $15 per hour.

Blood Procurement

- All Procurement Technicians are expected to draw at least 15 bloods a week. In addition, blood draws exceeding 15 in a week are reimbursed at an additional $25 for each draw over and above 15.

For example, if a Procurement Technician drew 17 bloods in a week, they would be compensated for an additional 2 blood draws at $25 per draw for a total of $50.

NOTE: IDS Testing samples do not count toward Blood Procurement totals.

Tissue Procurement and IDS Testing

- Tissue Procurement Compensation is based on a per tissue per POC rate. Procurement Technicians are compensated at a rate of $50 for the first tissue procured with any given POC. Any additional tissues procured from the **same** POC are compensated at a rate of $25 per tissue.

For example, if a Procurement Technician procured 2 tissues from the same POC, they would bill $50 for the first tissue and $25 for the second tissue for a total of $75 for that POC.

- IDS Testing for Tissues procured is compensated at $10 per IDS draw. IDS Testing samples do not count toward Blood Procurement totals.

Mileage Reimbursement

- Each StemExpress contractor is assigned a worksite location, which generally is a clinic or the Placerville office/lab. Any mileage driven on behalf of StemExpress exceeding the mileage to and from their resident and their current assigned worksite location will be reimbursed at $.55 per mile based on the Federal Mileage Rate. This rate is subject to change via the federal government and will be changed accordingly.

Exhibit 60

Procurement Technician Compensation Policy
Effective 09/01/2012 (cont.)

Two or More Procurement Technicians working in Unison

- Procurement Technicians often work in unison so procurements are split equality between the technicians.

For example, if two technicians are working together at the same clinic, and two maternal bloods are procured, and both technicians already exceeded their minimum 15 weekly draws, each technician would receive 1 draw toward their additional billing. If one or more of the two technicians have not reached their 15-draw minimum, each draw would count as half a draw for the technician(s) still attempting to meet their weekly minimum.

[redacted]

Exhibit 60

Compensation Policy for Procurement Technicians Effective 08/6/2012

Procurement Technicians (blood and tissue) will receive an hourly rate of $15 for all hours worked. Furthermore, blood draws exceeding 15 a week that fall between 30 to 60cc are reimbursed at $25 for each draw. Please note, at a minimum, all Procurement Technicians are expected to draw at least 15 bloods a week. Any blood draws less than 30cc will not be reimbursed unless specifically requested by researchers, at which time you will be notified. On surgery days, Tissue Procurement Technicians will receive $50 per tissue for Fetal Tissue Procurement regardless of gestation.

Because Procurement Technicians often work in unison, procurements will continue to be split equality between the Technicians. For instance, if two Technicians are working together at the same clinic, and two maternal bloods are procured, and both Technicians already exceeded their minimum 15 weekly draws, each Technician would receive $12.50 per draw. If one or more of the two Technicians have not reached their 15-draw minimum, each draw would count as half a draw for the Technician(s) still attempting to meet their weekly minimum.

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~~CONFIDENTIAL / PROPRIETARY BUSINESS RECORDS~~

Exhibit 61

stem express

[redacted]

SUSTAINING QUALITY OF LIFE THROUGH RESEARCH™

Invoice

Date	Invoice #
01/31/2014	3251
Terms	**Due Date**
Net 30	03/02/2014

Bill To	Ship To
Redacted	Redacted

PAID

Balance Due	Enclosed
$0.00	

Please detach this portion and return with your payment.

Ship Date	Ship Via	Tracking No.	Researcher	P.O. No.	Shipping
01/09/2014	FedEx	Redacted	Redacted	[redacted]	Client Acct

Date	Activity	Quantity	Rate	Amount
01/09/2014	Item #FT0101F: Human Fetal Tissue - Skeletal Muscle POC #05	1	595.00	595.00
01/09/2014	Item #PKG0100: Packaging	1	15.00	15.00

Thank you for your business. If you have any questions, please contact Redacted at Redacted or [redacted]

Please note: Invoices not paid within the designated terms are subject to a late fee equal to 10% of the balance and a 1.5% per month (18% annum) interest fee, compounded monthly.

Total	$610.00
Payment	$610.00
Balance Due	$0.00

Exhibit 62

CunninghamLevy

Cunningham Levy LLP
1250 Connecticut Ave NW, Suite 200
Washington, DC 20036

(202) 261-6564
(202) 261-3508

cunninghamlevy.com

August 14, 2015

***via* Electronic Mail**

Patrick Davis
Jason Foster
Counsels to the U.S. Senate Committee on the Judiciary
[redacted]

Re: Novogenix Laboratories LLC

Dear Patrick and Jason:

On July 31, 2015, on behalf of Novogenix Laboratories LLC ("Novogenix"), I e-mailed to confirm receipt of Senator Grassley's July 30, 2015, letter to Novogenix, and to inform you that Novogenix was preserving documents.

On August 3, 2015, we spoke on the phone and agreed to a rolling response to Senator Grassley's July 30, 2015, letter to Novogenix. We also agreed to clarify some of the requests in the July 30, 2015 letter, and we agreed to engage in future discussions about the scope of some of the letter's other requests, after our firm has reviewed documents. That review is ongoing. We have agreed to talk again on Monday, August 17, 2015, at 1 p.m.

In the meantime, this letter includes information and documentation, in response to some of the requests within the July 30, 2015, letter, as modified and clarified per our August 3, 2015, agreement. On behalf of Novogenix, we reserve the right to supplement our responses. Nothing herein shall constitute an admission by Novogenix or a waiver of its rights or privileges.

1. Novogenix Laboratories LLC was incorporated in February 2010. For the first nine months of the company's existence, it did not perform any services, and it did not gross any revenue; rather, it devoted that time primarily to employee-training. The Executive Director, a Ph.D. in molecular, cell and developmental biology from the University of California, Los Angeles ("UCLA"), led the in-house training. Third-party training from institutions, such as the University of Southern California ("USC"), also occurred in that time and beyond it.

Exhibit 62

CunninghamLevy.

2. We will produce a detailed accounting for FY 2012, FY 2013, FY 2014 and FY 2015 through July 31, 2015. The company's net-revenue history is below:

   In FY 2012, Novogenix's net revenue was **a loss** of $94,249.00.
   In FY 2013, Novogenix's net revenue was **a loss** of $37,056.57.
   In FY 2014, Novogenix's net revenue was **a loss** of $63,041.54.
   For FY 2015 through July 31, 2015, Novogenix's net revenue to date is $481.49.

3. We also have enclosed a sample consent form. (*See* Novo – 000001.)

4. Novogenix has contracted with 102 clients. The purpose of those contracts was only for research. All but three of the clients are labs and academic institutions. The three other clients are biotech and/or pharmaceutical companies. A sample contract is enclosed. (*See* Novo – 00002 – 00008.)

Novogenix continues to work in good faith to cooperate with Senator Grassley's request, and we anticipate the production of additional documents next week.

Sincerely,

Joshua A. Levy /KJW

Joshua A. Levy

Enclosures

Exhibit 63

SPECIMEN DONATION AGREEMENT

This Specimen Donation Agreement (the "Agreement") is effective as of March 1, 2010 (the "Effective Date") by and between Novogenix Laboratories™, LLC ("Novogenix"), a California limited liability company, and Planned Parenthood® Los Angeles, a California nonprofit public benefit corporation [redacted] ("PPLA"). Novogenix and PPLA shall individually be referred to herein as a "Party" and collectively as the "Parties".

1. **Specimens**

   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, attached hereto as **Exhibit A**.

2. **Use of Specimens**

   a. 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, which is attached hereto as **Exhibit B** (and incorporated as terms and conditions of this Agreement), and generally provides that Novogenix will isolate cell types from Specimens and use the sorted cell types to culture organ-specific cell and stem cell lines. Cultured or manipulated cell and stem cells will be cryopreserved and used for future cellular studies (e.g., cell surface marker analysis, gene expression profile, and functional comparison to pluripotent cell-derived cell types), in vitro studies (e.g., differentiation potential of various stem cell types) and animal studies (in vivo functionality of various cell and stem cell types.

   b. Novogenix agrees to conduct cell and stem cell research in compliance with all applicable federal and state laws.

3. **Procedures**

   a. Novogenix will provide PPLA with a sterile container, including storage media, for each Specimen ("Container").

   b. On each PPLA operating surgery day during which the retrieval of Specimens is scheduled, PPLA will: (i) identify patients for potential donation; (ii) obtain informed consent from patients who agree to participate in tissue donation programs; (iii) following pathology analysis of donated specimens, allow Novogenix's designated contact, specified in Section 9(c), below to select material for collection.

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c. To protect the privacy of donors, PPLA will provide to Novogenix only "de-identified" Specimens as defined under the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996's (HIPAA), 45 C.F.R. Parts 160 and 164. Specimens will not include any identifying information about the donor.

d. Novogenix will transport Specimens in accordance with all applicable federal, state and local storage and transfer requirements.

e. Novogenix will store all Specimens in a place not open to the public and will use all reasonable efforts to store Specimens so as to prevent deterioration that would create a health hazard. All waste tissue from each Specimen will be collected by Novogenix's biohazard/medical waste management service provider and incinerated at such provider's designated disposition site. "Waste tissue" in this Agreement means any or all parts of Specimens that Novogenix does not use for research.

f. Novogenix shall notify PPLA within (5) business days of its discovery of any failure (whether material or non-material) by PPLA, or any subcontractor or agent of PPLA, to comply with the terms and conditions of Section 3(b) or (c). The notice, which may be orally communicated to the Chief Medical Officer or his/her designee of PPLA, shall include the circumstances of the failure and the steps taken to remedy the failure and to avoid future reoccurrence of the failure.

4. Payment

a. 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. Novogenix will issue monthly payment to PPLA for any month in which specimens are collected and such payments shall be made within 30 days of the close of the month in which the samples were collected.

5. Confidentiality

Novogenix and PPLA agree to keep confidential and shall not disclose without the prior written consent of the other as otherwise required by law, all confidential information of the other part. "Confidential Information" is (i) any information, documents or materials disclosed by either party to the other during the course of negotiating this Agreement or pursuant to this Agreement; (ii) all information related to this Agreement itself, the terms and conditions of the Agreement, and (iii) information contained in the Donation Consent Forms signed by PPLA clients. Confidential Information shall exclude such information which, (i) is or lawfully becomes generally available to the public, (ii) is lawfully acquired from third parties who have a right to disclose such information; or (iii) by prior mutual written agreement, is released from a confidential status. Prompt written notice of any disclosure required by law shall be provided by the disclosing Party to the other Party.

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Exhibit 63

6. **Ownership**

Once in the possession of Novogenix, all Specimens and any cell lines or stem cell lines derived therefrom by a method of isolation, processing or cellular manipulation shall become the sole property of Novogenix. Neither PPLA nor any PPLA client will have or retain any right, title, interest in or to the Intellectual Property Rights or materials resulting from Novogenix's use of the Specimens. "Intellectual Property Rights" means all intellectual property rights throughout the world, whether existing under intellectual property, unfair competition or trade secret laws, or under statute or at common law or equity, including but not limited to: (i) copyrights, trade secrets, trademarks, trade names, patents, inventions, designs, logos and trade dress, "moral rights," mask works, rights of personality, publicity or privacy, and any other intellectual property and Proprietary rights; (ii) any registration, application or right to apply for any of the right referred to in this clause; and (iii) any and all renewals, reexaminations, extensions and restorations thereof, now or hereafter in force and effect.

7. **Representations and Warranties**

a. Each Party represents and warrants that it is authorized to enter into this Agreement and to perform the services to be performed by it hereunder.

b. PPLA represents and warrants that prior to providing any Specimens to Novogenix, PPLA will obtain any and all necessary clearances, releases, approvals or consents from PPLA's clients in compliance with all applicable federal and state laws and regulations.

c. Novogenix represents and warrants that it will receive and use Specimens for cell and stem cell research in compliance with all applicable federal and state laws and regulations, including without limitation The Uniform Anatomical Gift Act (codified in California as California Health and Safety Code §§ 7150-7156.5), The National Organ Transplantation Act (42 U.S.C § 274e), the HIH Revitalization Act of 1993 (42 U.S.C. §§ 289 g-1 & 289 g-2), California Health and Safety Code §§ 123440 & 123445, and California Health and Safety Code §§ 125300-125320.

d. PPLA does not, and shall not assume any liability for the activities of Novogenix. Novogenix represents and warrants that it maintains and Novogenix covenants that it will maintain comprehensive and general liability insurance and/or other applicable insurance covering the acts and omissions of Novogenix arising in connection with Novogenix's duties herein, with liability limits in the amounts of $1,000,000,000 per occurrence and $3,000,000 annual aggregate. Novogenix shall maintain coverage for claims arising during the term of this Agreement. Novogenix shall provide PPLA with a current certificate evidencing the coverage required by this section. Novogenix shall promptly notify PPLA of any change in the amount or scope of its coverage.

Exhibit 63

e. Novogenix hereby indemnifies, defends and holds harmless PPLA, its agents and representatives, from and against any and all damages, liabilities, loss, costs or expenses (including, without limitation, reasonable attorneys' fees) arising out of or in connection with any breach or alleged breach by Novogenix of any of the warranties, representations or agreements made by Novogenix herein, or any action, inaction omission or errors by Novogenix. PPLA hereby indemnifies, defends and holds harmless Novogenix, its agents and representatives, from and against any and all damages, liabilities, loss, costs or expenses (including, without limitation, reasonable attorneys' fees) arising out of or in connection with any breach or alleged breach by PPLA of any of the warranties, representations or agreements made by the PPLA herein, or any action, inaction omission or errors by PPLA.

The Indemnitee (whether Novogenix or PPLA) shall: (i) provide the Indemnitor reasonable prompt notice in writing of any claim or action and permit the Indemnitor, through counsel reasonably acceptable to the Indemnitee, to answer and defend such claim or action; and (ii) provide the Indemnitor information, assistance and authority, at Indemnitor's expense, to help the Indemnitor to defend such claim or action. The Indemnitor shall not be responsible for any settlement made by the Indemnitee without the Indemnitor's written permission, which permission shall not be unreasonably withheld. The Indemnitee shall have the right to employ separate counsel and participate in the defense of any claim or action. The Indemnitor may not settle any claim or action under this Section on the Indemnitee's behalf without first obtaining the Indemnitee's written permission, which permission will not be unreasonably withheld. The Indemnitor shall reimburse the Indemnitee on demand for any payment made or loss suffered by the Indemnitee regarding an amount subject to the foregoing indemnity, including all reasonably related costs, expenses and attorneys' fees.

f. NOT WITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, THE SPECIMENS ARE BEING SUPPLIED "AS IS", WITH NO WARRANTIES, EXPRESS OR IMPLIED, AND PPLA EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT OF THIRD PARTY PROPRIETARY RIGHTS WITH RESPECT THERETO.

8. **Term and Termination**

Exhibit 63

a. The term of this Agreement shall commence as of the Effective Date (specified on page 1 of this Agreement) and shall continue until terminated pursuant to Section 8(b).

b. Either Party may terminate this Agreement immediately upon written notice at any time with or without cause. Such termination shall be effective upon written notice to such Party or as soon thereafter as is permitted by applicable law. In lieu of termination, PPLA may temporarily suspend the provision of Specimens to Novogenix upon the receipt of notice under Section 9 or any event coming to its attention with respect to a failure of Novogenix to comply with the terms and conditions of this Agreement.

c. Upon termination of this Agreement, neither Party shall have any further obligation hereunder except for (i) obligations occurring prior to the date of termination; and (ii) obligations, promises and covenants contained herein that by their nature expressly extend beyond the term of this Agreement.

9. Notices

a. **General Notices.** Except for Notice of Specimen Delivery under section 9(b), all written notices and statements to be sent to any Party hereunder shall be addressed to the applicable address as may be designated in writing from time to time. All notices shall either be served by personal delivery (with written receipt of delivery), certified or registered mail, return receipt requested, or overnight courier (with written receipt of delivery), all charges paid. Except as otherwise provided herein, such notices hall be deemed given when personally delivered, one (1) day after delivered by overnight courier, or five (5) days after mailing, except that notices of change of address shall be effective only after actual receipt.

b. **Notice of Specimen Delivery.** Telephonic or email notice to Novogenix that a Specimen or Specimens are ready to be collected by Novogenix's designated transportation representative should be made to:

10. Miscellaneous

a. If for any reason a court of competent jurisdiction finds any provision of this Agreement, or portion thereof, to be unenforceable, that provision of the Agreement will be enforced to the maximum extent permissible so as to affect the intent of the Parties, and the remainder of this Agreement will continue in full force and effect. No waiver of any breach of any provision of this Agreement shall constitute a waiver of any prior, concurrent or subsequent breach of the same or any other provisions hereof, and no waiver shall be effective unless made in

writing and signed by an authorized representative of the waiving Party. The Parties and their respective counsel have had an opportunity to review this Agreement which will be interpreted fairly and in accordance with its terms and without any strict construction in favor of or against either Party.

b. This Agreement shall be construed and controlled according to the laws of the State of California applicable to contracts entered into and entirely performed therein. Any dispute arising under, in connection with, or incident to this Agreement or concerning its interpretation will be resolved exclusively in the state or federal courts located in Los Angeles, California, and the Parties irrevocably consent to the exercise of jurisdiction by said courts over them.

c. In the event of any action, suit or proceeding arising from or based upon this Agreement brought by either Party hereto against the other, the prevailing Party shall be entitled to recover from the other its reasonable attorneys' fees in connection therewith in addition to the cost of such action, suit or proceeding.

d. This Agreement may be executed in one or more counterparts and by facsimile, all of which shall be considered one and the same Agreement and each of which shall be deemed an original.

e. Neither Party may assign any of its rights or obligations hereunder without the prior written consent of the other Party. Any attempted assignment in violation of this Section shall be null and void. In addition, Novogenix shall notify PPLA in writing in the event of any acquisition of Novogenix (including an acquisition of stock exceeding 50% of its then outstanding shares) or any merger in which Novogenix is a party.

f. Nothing in this Agreement should be construed as creating an agency, partnership, joint venture, franchise, or employment relationship between the Parties. Neither Party has the authority to make any statements, representation or commitments of any kind, not to take any action binding on the other, except to the extent (if any), provided for in this Agreement.

g. This Agreement, including any exhibits attached hereto which are incorporated by this reference, constitutes the entire agreement between the Parties with respect to its subject matter and merges all prior and contemporaneous communications. It shall not be modified except by a written agreement dated subsequent to the date of this Agreement and signed on behalf of the Parties by their respective authorized representatives.

AUTHORIZED SIGNATURES

Exhibit 63

IN WITNESS WHEREOF, The Parties have entered into this Agreement as of the Effective Date written above.

Novogenix Laboratories™, LLC	**Planned Parenthood ® of Los Angeles**
By (sign): [redacted]	By (sign): [redacted]
Name: [redacted]	Name: [redacted]
Title: President	Title: CEO
Date: 3/29/10	Date: 3/22/10

Exhibit 64

CunninghamLevy.

Cunningham Levy LLP
1250 Connecticut Ave NW, Suite 200
Washington, DC 20036

(202) 261-6564
(202) 261-3508

cunninghamlevy.com

August 24, 2015

***via* Electronic Mail**

Patrick Davis
Jason Foster
Counsels to the U.S. Senate Committee on the Judiciary
[redacted]

Re: Novogenix Laboratories LLC

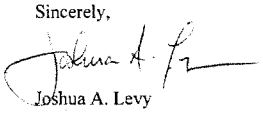
Dear Patrick and Jason:

Through this letter, we are transmitting an additional production, in response to the July 30, 2015, letter that Senator Grassley sent to Novogenix Laboratories LLC ("Novogenix"), as modified per our prior communications. We continue to review documents, cooperate in good faith with the July 30 request, produce documents and information on a rolling basis, and supplement or clarify the production as necessary.

The enclosed presentation of the accounting applies, as you requested and clarified in our phone call of August 17, 2015, to the expenses and revenue related to services rendered with regard to tissue and cells, and not to other business units of Novogenix. Counsel created the presentation for purposes of this production. Any errors are inadvertent, counsel's and not the client's. Should you require further clarification of the presentation, please advise.

Nothing in this letter or production shall be misconstrued as an admission by our client or a waiver of any of our client's rights or privileges.

Sincerely,



Joshua A. Levy

Enclosures

Exhibit 65

Cunningham | Levy | Muse

Cunningham Levy Muse LLP
1250 Connecticut Ave NW, Suite 200
Washington, DC 20036

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F (202) 261-3508

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March 4, 2016

***via* Electronic Mail**

Senator Charles E. Grassley
Chairman
U.S. Senate Committee on the Judiciary
[redacted]

Re: Novogenix Laboratories, LLC

Dear Chairman Grassley:

Through this letter, I am responding on behalf of Novogenix Laboratories LLC ("Novogenix") to your letter of February 18, 2016. Nothing in this letter shall waive any rights or privileges of Novogenix; nor should anything herein be construed as an admission by Novogenix. Novogenix reserves the right to supplement this response.

As discussed last week with your staff, Novogenix stopped doing business in 2015. It is no longer a going concern. Last year, in response to your inquiry, Novogenix produced detailed documentation regarding the company's revenue and expenses, which shows that the company ran losses for four years. It now has come to the end of the line in terms of resources.

1. **According to Novogenix's contract with PPLA, Novogenix paid PPLA $45 per specimen. To clarify, did Novogenix pay a flat fee of $45 per aborted fetus, or did Novogenix pay $45 per individual fetal tissue specimen, such that, under the right circumstances, multiple specimens and payments could be associated with a single aborted fetus?**

   Novogenix paid PPLA $45 for PPLA's costs related to a single PPLA patient. Novogenix would not pay PPLA any additional money related to that PPLA patient.

Exhibit 65

2. **Please provide all procurement logs for the collections corresponding to Novogenix's May 2014 payment of $1980 to PPLA, as documented in the general accounting Novogenix provided the Committee on August 24, 2015.**

   As discussed in our call last week with your staff, upon further review, Novogenix paid PPLA $1890 in May 2014. Also as discussed last week with your staff, the response to this question may satisfy as a response to the first request included in your February 18, 2016, letter. The response is enclosed in the form of a spreadsheet.

3. **When working with PPLA, did Novogenix typically have its technicians waiting on site at the clinics during abortion procedures to immediately collect fetal tissne acquired from those abortion procedures?**

   In a separate area, isolated from the patient, Novogenix employee(s) would wait on site, usually at the clinic's lab.

4. **Please describe the space used by Novogenix at PPLA clinics in conducting specimen-collection work (e.g., a counter top, several rooms, a wing of the building, etc.).**

   At each clinic's lab area, a counter top and the floor space underneath it, as well as access to staff bathrooms, break rooms, kitchen and office space, were allocated to Novogenix.

5. **Did Novogenix store materials at PPLA clinics? If so, please describe the materials stored and the means of storage (e.g., two drawers, a freezer shelf, a cupboard, a room, a wing of the building, etc.)**

   For the most part, Novogenix brought their materials to the clinic. Novogenix employees would use the clinic's gloves, masks, gowns and shoe covers. Depending on the clinic, gloves were stored on the lab's countertop and/or in a wall-dispenser; masks and shoe covers were stored in a cabinet; and gowns were stored in a cabinet located either in the lab or in the hallway.

6. **How were Novogenix technicians operating at PPLA compensated? Did they receive a salary, flat hourly rate, or bonuses per specimen collected?**

   Salary. No bonuses.

Exhibit 65

As discussed last week, we will respond to the remaining questions as soon as possible. We are working with dispatch to complete and submit our response to you.

Sincerely,

Joshua A. Levy / Randy Compton

Exhibit 66

434 West 33rd Street
New York, NY 10001
p: 212.541.7800 · f: 212.245.1845
www.plannedparenthood.org

Planned Parenthood Federation of America

August 27, 2015

The Honorable John A. Boehner
Speaker
U.S. House of Representatives
Washington, DC 20515

The Honorable Mitch McConnell
Majority Leader
U.S. Senate
Washington, DC 20510

The Honorable Nancy Pelosi
Minority Leader
U.S. House of Representatives
Washington, DC 20515

The Honorable Harry Reid
Minority Leader
U.S. Senate
Washington, DC 20510

Dear Speaker Boehner, Leader McConnell, Leader Pelosi, and Leader Reid:

In the last month, Planned Parenthood has been the focus of extensive discussion and scrutiny for our role in fetal tissue research.

Four committees in the Senate and House are currently investigating allegations against Planned Parenthood. The Senate has already held a vote on an effort to strip federal funding from Planned Parenthood, and the House of Representatives may hold a similar vote in September. Several Senators and House members, as well as some Republican Presidential candidates, are advocating shutting down the federal government unless Planned Parenthood is defunded.

We obviously take this matter very seriously. We also agree with Speaker Boehner's view that Congress should get the "facts first" because "the more we learn, the more it will educate our decisions."[1]

I am writing today because we are doing as much as we can to collect the facts and share them with you. We are also cooperating with the House and Senate committees that have requested relevant information from us.

In this letter, I will provide background on the bipartisan 1993 law on fetal tissue research, Planned Parenthood's role in this research, and what we are doing in response to questions that have been raised over the last month. I will also share what we know about anti-abortion extremist David Daleiden and the organizations that spent nearly three years infiltrating our affiliates and trying to entrap our staff into potentially illegal conduct, including the results of a forensic analysis of the doctored videos.

[1] "Boehner Wants 'Facts First' Before Defunding Planned Parenthood," The Hill (July 23, 2015).

Exhibit 66

While I am providing a lot of information in this letter, it is especially important to highlight three points.

First, Planned Parenthood adheres to the highest standards and follows all laws.

Second, Planned Parenthood is proud to have a role in fetal tissue research. Overwhelming bipartisan majorities in both the House and Senate recognized the value of this medical research when Congress passed the NIH Revitalization Act of 1993, and it has led to life-saving discoveries that are helping millions of Americans.

Third, our affiliates' involvement in fetal tissue research is a miniscule part of the work of Planned Parenthood. Despite a deliberate and systematic effort to distort our role, only two of 59 Planned Parenthood affiliates are currently involved with fetal tissue research.

Our affiliates operate health centers, which is where we provide health services to millions of women and men every year. Of the hundreds of health centers that are part of the Planned Parenthood network, just 1% are involved with fetal tissue research.

The attacks on us have the intended purpose of making it appear that fetal tissue research is an enormous focus of Planned Parenthood. But the simple fact is that 99% of our health centers have no involvement in this work. Women who visit our affiliates regularly express a desire to donate tissue from their abortion. But whether because researchers have not requested tissue from the local affiliate or because the local affiliate has chosen not to participate, very few of our health centers offer women this opportunity.

For the few centers that are involved with fetal tissue research, there is absolutely no indication they have deviated from the law or done anything inappropriate. In fact, despite Mr. Daleiden's three-year effort to entrap Planned Parenthood, he failed to succeed in convincing even a single affiliate to enter into a procurement contract with his fake company.

Even though our work involving fetal tissue research is a small part of what Planned Parenthood does, we are committed to continual improvement and meeting the highest medical and ethical standards in all we do, including facilitating tissue donations. I have asked our senior medical leadership to conduct a review of the policies and practices that guide the affiliates that offer tissue donation services and our oversight of these activities. If this review identifies ways we can improve our practices while staying true to our core mission, we will promptly implement them. Furthermore, because the current debate has been marked by considerable confusion over what fetal tissue research is and what rules apply or should apply, I have written to the Director of the National Institutes of Health to suggest that he consider convening an expert panel on fetal tissue research.[2]

[2] Letter from Cecile Richards, President of Planned Parenthood Federation of America, to Francis Collins, Director of the National Institutes of Health (July 29, 2015).

Exhibit 66

Federal Law on Fetal Tissue Research

The federal law on fetal tissue research was shaped by a blue-ribbon panel created in 1988 under the Reagan Administration. Arlin Adams, a retired federal judge opposed to abortion, chaired the panel, which was called the Human Fetal Tissue Transplantation Research Panel. Although the panel's charge – to evaluate the ethics of research involving fetal tissue – was controversial, Judge Adams led the panel to a broad consensus. Its final report stated: "a decisive majority of the panel found that it was acceptable public policy to support transplant research with fetal tissue."[3]

The panel separated the question of the ethics of abortion, about which the panel members had differing views, from the question of the ethics of using fetal tissue from legal elective abortions for medical research. The panel supported fetal tissue research for two primary reasons: (1) "abortion is legal" and "would occur regardless" of the use of fetal tissue in research and (2) "the research in question is intended to achieve significant medical goals."[4] The panel then made a series of recommendations to ensure that any research followed appropriate guidelines.

The panel recommended that "the decision and consent to abort must precede discussion of the possible use of fetal tissue" so that "a woman's abortion decision would be insulated from inducements to abort to provide tissue for transplant research and therapy."[5] The panel recommended prohibiting "payments … associated with the procurement of fetal tissue … except payment for reasonable expenses" so that there would be "no offer of financial incentives or personal gain to encourage abortion or donation of fetal tissue."[6] And the panel recommended that "no abortion should be put off to a later date nor should any abortion be performed by an alternate method entailing greater risk to the pregnant woman in order to supply more useful fetal materials for research."[7]

The panel's work won broad bipartisan support. In 1993, Congress overwhelmingly passed the NIH Health Revitalization Act, which codified the key recommendations of the panel into law. As you know, three of you – Senate Majority Leader McConnell, Senate Minority Leader Reid, and House Minority Leader Pelosi – all voted for the legislation. The final vote was 93 to 4 in the Senate and 290 to 130 in the House.

The law has two main provisions. One section (42 U.S.C. 289g-1) addresses federally funded research on "the transplantation of human fetal tissue for therapeutic purposes." Under this section, the medical researcher must obtain a statement from the attending physician declaring that the consent of the woman for the abortion was obtained prior to the consent for the fetal tissue donation and that there was no alteration of the timing, method, or abortion procedure solely for purposes of obtaining the tissue.

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[3] Report of the Human Fetal Tissue Research Panel, p. 2 (December 1988).
[4] Report of the Human Fetal Tissue Research Panel, pp. 1-2 (December 1988).
[5] Report of the Human Fetal Tissue Research Panel, pp. 2-3 (December 1988).
[6] Report of the Human Fetal Tissue Research Panel, p. 2 (December 1988).
[7] Report of the Human Fetal Tissue Research Panel, p. 14 (December 1988).

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The other provision (42 U.S.C. 289g-2) prohibits the acceptance of any payment for a fetal tissue donation other than "reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."

Under both laws, "human fetal tissue" is defined narrowly to mean "tissue or cells obtained from a dead human embryo or fetus" after an abortion or stillbirth.

Planned Parenthood's Limited Involvement in Fetal Tissue Research

Planned Parenthood is the nation's leading provider of reproductive health care services for women. We are also an important provider of primary and preventive health care for men and young people. Each year, our health centers provide high quality, affordable birth control, lifesaving cancer screenings, testing and treatment for sexually transmitted infections, and other essential care to 2.7 million patients. One in five women in the United States has visited a Planned Parenthood health center at least once in her life.

We are also a trusted provider of education and information on reproductive health. Every year, 1.5 million youth and adults participate in our educational programs. We currently average 6 million visits a month on our web sites where health care information is readily available in English and Spanish.

Planned Parenthood uses an affiliate structure. The national organization, Planned Parenthood Federation of America, establishes policies and accreditation standards for our 59 legally independent affiliates. The affiliates operate nearly 700 health centers across the country, which provide our health care services.

Planned Parenthood distinguishes between two types of services. Core services are those that every affiliate is required to provide. They include birth control, breast exams, pregnancy testing, abortions, identifying and treating sexually transmitted infections, and other essential health services. Optional services are those that affiliates can elect to provide. Offering women the opportunity to donate post-abortion tissue for research is an optional service.

In fact, not only are affiliates not required to be involved with tissue research, very few are. Our doctors report that women regularly ask whether they can donate their tissue for medical research. But the vast majority of our affiliates do not offer this service. In some instances, this may reflect the affiliate's considered decision. In many others, local research institutions simply have not requested tissue donations.

Our few participating affiliates can offer tissue donation services in two ways: through tissue procurement organizations (TPOs) which have been the focus of the recent public debate, or as partners or participants in research studies being conducted by major research programs connected to some of our nation's most prestigious universities, medical schools, and research laboratories.

Today, only one affiliate (in California) is involved with fetal tissue research working through a TPO. That affiliate also has a separate relationship with the University of California.

A second affiliate is involved with fetal tissue research working with the University of Washington. Altogether, the health centers at the affiliates involved with fetal tissue research represent 1% of our centers. Stated the other way, 99% of our health centers do not offer women the opportunity to be involved with fetal tissue research. [8]

When Mr. Daleiden released the first doctored video on July 14, four additional affiliates in California were involved with fetal tissue research. For varying reasons, these affiliates are not doing so presently. One affiliate suspended its program after receiving security threats prompted by Mr. Daleiden's video. Two others had their contracts with a TPO featured in Mr. Daleiden's videos cancelled because of the controversy. The fourth affiliate was working with a research laboratory that had been undergoing renovations and has postponed restarting until the renovations are complete.

At this point, we are aware of no additional affiliates beyond those described above that are involved with fetal tissue research over the last five years.[9] We will continue to make our best efforts to make sure our current understanding is comprehensive.

Compliance with Federal Requirements

As mentioned above, federal law restricts the reimbursement that Planned Parenthood can receive when it facilitates a fetal tissue donation. Our guidance to our affiliates reflects this requirement, stating:

> 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 <u>must</u> be able to demonstrate the reimbursement represents its actual costs.[10]

Our affiliates involved with fetal tissue research comply with this requirement. The California affiliate receives a modest reimbursement of $60 per tissue specimen from the TPO, and the Washington affiliate receives no reimbursement. The four other affiliates whose programs ended after the release of the videos received lesser but comparable amounts. The affiliate working with the research laboratory received no reimbursement. The others received reimbursements from TPOs ranging from $45 to $55 per tissue specimen. In every case, the

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[8] We have one affiliate, located in Oregon, that has a relationship with researchers at the Oregon Health & Sciences University who are studying placental tissue, not fetal tissue. The affiliate provides OHSU with post-abortion tissue from which the researchers extract the placental tissue they are studying. We did not count this affiliate as one that is involved with fetal tissue research because the OHSU researchers are not engaged in fetal tissue research. If we count this affiliate, that does not change the fact that just 1% of our centers are currently involved with this research.

[9] We are aware of four additional affiliates that at some time over the past five years provided donations of post-abortion tissue to support medical research. These include an affiliate in Texas and the affiliate in Colorado that have been included in videos released by Mr. Daleiden. All of these affiliates had arrangements with research universities, not with TPOs, where the research focused on placental or decidual tissue, not fetal tissue.

[10] Planned Parenthood, Programs for Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research (May 2015).

affiliates report that these amounts were intended to recover only their costs, as allowed under the federal law and our guidance.

The other provision of federal law applicable to fetal tissue research has a narrow scope: it applies only to research funded by the Department of Health and Human Services into "the transplantation of human fetal tissue for therapeutic purposes."[11] This month, the Department stated in a letter to Congress that the Department "has not funded or conducted this specific type of research involving fetal tissue in recent years."[12] The federal rules relating to consent and timing and method of abortion when the donated tissue is used for federally funded fetal transplantation research are therefore not applicable to any recent fetal tissue donations in the United States.

While the federal consent, timing, and method requirements apply only to federally funded fetal transplantation research, which no longer occurs, Planned Parenthood has voluntarily included the substance of the federal requirements in our guidance. Specifically, our guidance provides that there be "no substantive alteration in the timing of terminating the pregnancy or of the method used was made for the purpose of obtaining the blood and/or tissue."[13] Moreover, we apply this guidance not only to fetal tissue donations, but to donations of any post-abortion tissue, including placental and decidual tissue. We have taken these steps because we are committed to following the highest medical and ethical standards.

It is important to clarify our guidance on this point. There are only a few methods of abortion: (1) for early abortions, generally, the methods are medication abortion or surgical abortion involving mechanical or manual aspiration and (2) for abortions occurring from approximately 13 weeks gestation, the methods are dilation and extraction (D&E), induction of labor, or in very rare instances hysterotomy. At Planned Parenthood health centers, neither inductions nor hysterotomies are available. A decision about the method to be used is made by the physician in consultation with the woman, taking into account the relevant variables that would bear on that decision.

In performing the selected method, a physician may need to make multiple adjustments to the method as the surgery proceeds. These adjustments are clinical judgments – not a change of method – made by the physician as the abortion proceeds and are always intended to achieve the woman's desired result as safely as possible. The key point, as the 1988 blue-ribbon commission recognized, is that there be no change that would impact the safety or well-being of the patient. The same principle applies in deliveries, where physicians will often make adjustments to facilitate the collection of cord blood if the patient wants to retain or donate this blood. Our understanding, however, is that even adjustments that facilitate fetal tissue donations rarely occur at our few clinics that offer women this service.

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[11] 42 U.S.C. 289g-1.

[12] Letter from Jim Esquea, Assistant Secretary for Legislation at the Department of Health and Human Services, to Senators Joni Ernst and Roy Blunt (August 14, 2015).

[13] Planned Parenthood, Programs for Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research (May 2015).

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What is essential is that in every instance, the physician's focus is on the woman's health because our patients' health is our paramount concern.

The Activities of David Daleiden

Finally, I want to share information with you about the outrageous activities of anti-abortion activist David Daleiden. Mr. Daleiden and his associates have sought to infiltrate Planned Parenthood affiliates and unsuccessfully to entrap Planned Parenthood physicians and staff for nearly three years. It is clear they acted fraudulently and unethically – and perhaps illegally. Yet it is Planned Parenthood, not Mr. Daleiden, that is currently subject to four separate congressional investigations.

Mr. Daleiden's efforts began nearly three years ago with the creation of a fictitious tissue procurement company called Biomax Procurement Services and subsequently a nonprofit called the Center for Medical Progress. According to media reports and analyses by nonprofit organizations, Mr. Daleiden and his associates may have violated many laws, including federal tax laws by misrepresenting the Center for Medical Progress as a biomedicine or bioengineering organization in its application for nonprofit status;[14] California criminal laws that prohibit forgery, fraud, and perjury by creating fake driver licenses or obtaining official licenses fraudulently;[15] California's Invasion of Privacy Act by recording individuals without consent;[16] and California's penal code by making false charitable solicitations.[17] One group says there is also evidence that they may have violated California's law against impersonation and federal and California laws against credit card fraud by stealing the identity of the president of the feminist club at Mr. Daleiden's high school.[18] Indeed, just last week, Mr. Daleiden's attorneys advised a federal district court that he intends to invoke his Fifth Amendment right to refrain from self-incrimination in response to discovery sought by the National Abortion Federation in its lawsuit alleging that Mr. Daleiden and his co-conspirators violated federal and state laws.[19]

We know that the videos Mr. Daleiden has released were deceptively edited to smear Planned Parenthood. They omit exculpatory passages and splice excerpts together to create false impressions. The videos have been denounced as "a total crock,"[20] "distorted … and unfair,"[21] "dishonest,"[22] "grossly misleading and politically irresponsible,"[23] and "swift boating"[24] in editorials across the country.

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[14] "Group Behind Planned Parenthood Sting Video May Have Tricked IRS, Donors," Huffington Post (July 17, 2015).
[15] "The Faces and Fake Names of People Behind Planned Parenthood Attack Videos," RH Reality Check (July 28, 2015).
[16] "Does the Planned Parenthood Video Violate State Recording Laws," MSNBC (July 16, 2015).
[17] Letter from Brad Woodhouse, President of American Democracy Legal Fund, to Kamala Harris, California Attorney General (July 21, 2015).
[18] "The Faces and Fake Names of People Behind Planned Parenthood Attack Videos," RH Reality Check (July 28, 2015).
[19] Civil Minutes, National Abortion Federation v. Center for Medical Progress (case no. 15-cv-03522-WHO) (August 21, 2015) (available online at http://prochoice.org/wp-content/uploads/2015-08-21-78-Civil-Minutes.pdf).
[20] "Undercover Sting of Planned Parenthood is Off Base, As Usual," Los Angeles Times (July 16, 2015).
[21] "Stop the Vendetta Against Planned Parenthood," Washington Post (July 31, 2015).
[22] "The Campaign of Deception Against Planned Parenthood," New York Times (July 22, 2015).

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Our analysis of the videos released by Mr. Daledien documents numerous instances where the videos have been heavily edited to change the meaning of what Planned Parenthood staff said and deceive the public. The first five short videos he released have at least 47 splices where content is edited out but the conversation appears seamless. Critical context is omitted, including Planned Parenthood staff members repeatedly saying that there is no "profit" from tissue donation and should not be, that tissue donation programs must follow the law, and that substantial changes to medical procedures would not occur. Quotes are attributed to Planned Parenthood staff members with no audio evidence that the quote was actually made at the time it appears in the video. Among these is one discredited, provocative quote that the Washington Post used in an editorial and about which it later issued a correction.

The first video received the most attention. We know from the longer version of the video that Dr. Deborah Nucatola at least ten times explained that Planned Parenthood affiliates do not profit from fetal tissue donation, making statements such as: "affiliates are not looking to make money by doing this. They're looking to serve their patients and just make it not impact their bottom line." Yet none of the highly relevant and exculpatory passages were included in the edited video excerpt that Mr. Daleiden initially released to national media.

The other videos are similarly distorted. Dr. Savita Ginde of our Colorado affiliate repeatedly told the Biomax representative that legal counsel would have to review any contract with Biomax. These references were consistently deleted from the video excerpt Mr. Daleiden released. Indeed, legal counsel did in fact review the proposed Biomax contract and objected to its terms because they did not comply with federal law.

Because of these significant distortions and omissions, we contracted with a research firm which engaged the services of a video forensics expert, a television producer, and an independent transcription agency. These experts concluded that the videos – even the alleged "full footage" videos – do not present a complete or accurate record of the events they purport to depict.[25] Their review revealed that Mr. Daleiden edited content out of the alleged "full footage" videos, heavily edited the short videos so as to misrepresent statements made by Planned Parenthood representatives, and produced transcripts with substantive omissions or edits.

Forensic video analysis revealed that each of the four "full footage" videos contained intentional edits that removed content from the middle of the videos, including approximately 30 minutes of missing footage from the recordings featuring staff at our Colorado and Texas affiliates. Analysis of the transcripts released by Mr. Daleiden revealed that one transcript includes over 4,000 words that do not appear in the video or the independent transcript.

With respect to the short videos, the forensic review confirmed dozens of misleading edits, cuts, and splices designed to alter the meaning of the underlying dialogue.

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[23] "Videos About Planned Parenthood are Grossly Misleading," San Jose Mercury News (July 27, 2015).
[24] "The Truth About Planned Parenthood," Michigan Public Radio (July 28, 2015).
[25] Fusion GPS CMP Analysis (August 25, 2015).

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This review ultimately concluded that the manipulation of the videos and the transcripts means they have no evidentiary value in a legal context and cannot be relied upon for any official inquiries unless supplemented by the original video in unaltered form. I have enclosed the report of the forensic analysis with this letter.

While the edited videos are replete with distortions and selective editing, it is what is missing from the videos that is most important: any credible evidence that Planned Parenthood has done anything wrong. All of Mr. Daleiden's efforts to entrap our affiliates into potentially illegal contracts failed. In fact, there is no evidence in any of the videos that our affiliates have ever received anything more than reimbursement for their reasonable costs, as the law permits.

Fifteen years ago, a congressional committee launched a similar investigation into allegations that Planned Parenthood centers sold fetal tissue. Like the current investigations, this investigation was prompted by video from a hidden camera and statements from an anti-abortion extremist claiming to have witnessed large-scale violations of federal law. At the congressional hearing, questioning revealed multiple contradictions in the testimony of the star witness. When the witness recanted his most inflammatory claims, a Republican committee member stated, "I found there to be so many inconsistencies in your testimony … your credibility, as far as this member is concerned, is shot."[26] Roll Call reported in an article entitled "Fetal Tissue Hearing Thrown into Chaos" that the members were "left pointing fingers over who was to blame for [the] botched hearing ... after the panel's star witness left with his credibility in tatters."[27]

Already five states – South Dakota, Georgia, Indiana, Massachusetts, and Pennsylvania – have conducted investigations and cleared Planned Parenthood of any wrongdoing.[28] We are confident that as additional states complete their investigations and as the congressional committees carry out their oversight activities, the facts will once again fully vindicate Planned Parenthood and indict those who are seeking to distort the facts and smear our reputation.

Conclusion

I respectfully ask that you put yourselves in our place. Imagine if a group of individuals tried for several years to secretly film your offices, obtaining fraudulent identification to gain access to restricted areas, creating a fictitious company to deceive your staff, and misleading the IRS in an application for nonprofit status. Imagine if they released selectively edited videos of excerpted and manipulated conversations involving your staff aimed at creating the worst impression possible. And imagine if they edited the videos so context was lost, exculpatory statements were omitted, and statements were stitched together out of sequence to create a fraudulent impression.

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[26] Hearing before the Subcommittee on Health and Environment, Committee on Commerce, U.S. House of Representatives, "Fetal Tissue: Is it Being Sold In Violation of Federal Law?" 106th Congress (March 9, 2000).
[27] "Fetal Tissue Hearing Thrown into Chaos," Roll Call (March 13, 2000).
[28] "Indiana Clears Planned Parenthood of Wrongdoing After Videos," Associated Press (July 30, 2015); "Health Department: No Evidence of Fetal Tissue Sale in State," KDLT News (August. 12, 2015); "Planned Parenthood 'fully compliant with law, Healy says,'" The Boston Globe (July 29, 2015);); "Georgia Abortion Clinics Follow Law on Fetal Remains, State Says," Atlanta Journal Constitution (August. 12, 2015); "PA Inquiry Clears Planned Parenthood," Philadelphia Inquirer (August. 22, 2015).

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That's exactly what has happened to Planned Parenthood. And in our case, four congressional committees have launched investigations into our conduct – and none are investigating the person behind this fraud.

We are also facing votes to defund our entire organization even though 99% of our health centers do not participate in tissue donations and all of them comply with all laws and provide essential health services to women and men.

While our involvement with fetal tissue research is a small component of Planned Parenthood, it offers the potential of life-saving research. Earlier this month, the Department of Health and Human Services wrote Congress that "fetal tissue continues to be a critical resource for important efforts such as research on degenerative eye disease, human development disorders such as Down syndrome, and infectious diseases, among a host of other diseases."[29] We stand behind our affiliates that contribute to these efforts to discover medical breakthroughs.

As I wrote to NIH Director Collins, if changes to the nation's fetal tissue laws are to be considered, they should be guided by the deliberations of a new blue ribbon panel. The sensationalistic atmosphere the doctored videos seek to create is exactly the opposite of the reasoned and deliberate process President Reagan set in motion with the Human Fetal Tissue Transplantation Research Panel. The videos mislead rather than inform the public debate.

I hope this letter will help put us on a different path by clarifying the facts and demonstrating our commitment to providing the highest level of compassionate care to the millions of women and men we serve.

Sincerely,

Cecile Richards

Cecile Richards
President
Planned Parenthood Federation of America

CC:
The Honorable Charles E. Grassley, Chairman
Senate Judiciary Committee

The Honorable Patrick J. Leahy, Ranking Member
Senate Judiciary Committee

[29] Letter from Jim Esquea, Assistant Secretary for Legislation at the Department of Health and Human Services, to Senators Joni Ernst and Roy Blunt (August 14, 2015).

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The Honorable Robert W. Goodlatte, Chairman
House Judiciary Committee

The Honorable John Conyers Jr., Ranking Member
House Judiciary Committee

The Honorable Fred Upton, Chairman
House Energy and Commerce Committee

The Honorable Frank Pallone, Jr., Ranking Member
House Energy and Commerce Committee

The Honorable Tim Murphy, Chairman
Subcommittee on Oversight and Investigations

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations

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VIA ELECTRONIC MAIL & HAND DELIVERY

The Honorable Charles E. Grassley
Chairman, Committee on the Judiciary
United States Senate
SD-224 Dirksen Senate Office Building
Washington, D.C. 20510-6275

Re: ***Planned Parenthood: Reasonable Payments Associated With Fetal Tissue Donation***

Dear Chairman Grassley:

Please accept this letter in further response to your letter dated October 26, 2015 (the "October 26 letter"), requesting that Planned Parenthood Federation of America ("PPFA") and its affiliates provide documents demonstrating the affiliates' costs associated with fetal tissue donation.[1]

As a threshold matter, it is important to restate what PPFA has already communicated publicly and to your staff. At Planned Parenthood—the nation's leading provider of reproductive health care—facilitating patients' donation of fetal tissue has always been an incidental service offered to patients by a small number of affiliates across the country. Today, only two of 59 affiliates—one in Washington and one in California—facilitate their patients' donation of fetal tissue for medical research. During the last five years, 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. Enclosed please find accountings of payments and costs responsive to the Committee's request that were prepared by the four relevant affiliates.

[1] Federal law defines "human fetal tissue" as "tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth." 42 U.S.C. §§ 289g-1(g), 289g-2(e)(1). That definition does not encompass the donation of tissue from other products of conception, such as placental tissue or decidua, for which certain affiliates have also facilitated patient donations for medical research.

The enclosed accountings confirm that the four affiliates complied with federal law governing payments associated with the donation of fetal tissue. The relevant statute expressly permits "reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."[2] As you can see from the cost accountings the affiliates have produced, the reasonable payments each received were less than the allowable costs associated with their fetal tissue donation programs—in some cases, by significant margins.

The affiliates' accountings assign their costs of facilitating fetal tissue donation to four general categories of costs for which it is permissible to receive reasonable payments under federal law. Some or all of these four affiliates have incurred, and recovered, costs associated with coordinating tissue collection and processing; costs associated with obtaining patient consent for donation; costs associated with transportation, preservation, quality control, and storage of tissue; and costs associated with the use of health center facility space by organizations that procure donated tissue.[3] As the statutory language, relevant legislative history, and subsequent government reviews make abundantly clear, recovery of each of these types of reasonable costs is both legally permissible and common practice in the medical research community.[4]

Furthermore, the affiliates' cost accountings are based on a conservative interpretation of the law, as they reflect actual costs incurred. The law provides that a donor of fetal tissue may

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[2] 42 U.S.C. § 289g-2(e)(3).

[3] The history of the federal law governing fetal tissue donation makes plain that clinics are permitted to recover the reasonable costs of obtaining consent from patients prior to donation. *See* Report of the Human Fetal Tissue Transplantation Research Panel 37 (1988) [hereinafter Reagan Panel Report] (affirming that "a tissue retrieval agency may reimburse the abortion clinic for using its space and staff to obtain consent for tissue donations"). Indeed, a review conducted in 2000 by the then-titled U.S. General Accounting Office found that clinics donating fetal tissue are commonly reimbursed for the costs associated with obtaining the necessary consent of patients. *See* U.S. Gen. Accounting Office, GAO-01-65R, Human Fetal Tissue: Acquisition for Federally Funded Biomedical Research (2000) [hereinafter GAO, Human Fetal Tissue]. Similarly, a clinic facilitating the donation of fetal tissue may recover the reasonable costs of allowing a tissue procurer to use facility space. *See* Reagan Panel Report at 11 (explaining that reasonable payments for tissue donation are sometimes intended to cover, among other things, "use of the clinic space by employees of the procurement agency"). And in practice, tissue procurers have regularly and properly reimbursed clinics facilitating tissue donation for the costs of using facility space. *See id.* (explaining that tissue procurement organizations, in practice, pay clinics "a small fee for each fetal tissue retrieved to cover the costs of retrieval, including time of staff and rental of space"); David H. Smith et al., Using Human Fetal Tissue for Transplantation and Research: Selected Issues (1988), *reprinted in* Reagan Panel Report app. at F15 (quoting a tissue procurement organization spokesperson as saying they pay clinics "a rental payment for the use of their equipment and facilities, which may range from $300 to $1,000 per month, depending on the amount of time the technicians are in the clinic").

[4] Consistent with accepted accounting practices, several of these permissible cost categories include allocations for the affiliates' indirect costs that make tissue donations possible for Planned Parenthood patients. The failure to account for indirect costs would yield a cost analysis that did not capture the actual costs associated with facilitating fetal tissue donation. *See* Fed. Accounting Standards Advisory Bd., Handbook of Federal Accounting Standards and Other Pronouncements, at SFFAS 1-46 (as amended June 30, 2014) ("Full assignment of all costs of a period, including general and administrative expenses and all other indirect costs, is an important basis for measuring cost of service.").

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receive "reasonable payments" associated with general categories of activities relating to fetal tissue donation. The affiliates have applied a conservative approach to this language by reading the word "costs" into the statute, but there may be other, more permissive—and legitimate—interpretations of the law that would yield legally proper payments in higher amounts.

In response to your October 26 letter explaining that "demonstration of [the affiliates'] costs is a key issue of concern for this Committee," the affiliates have each performed a good-faith accounting of their costs associated with facilitating fetal tissue donation, and have demonstrated conclusively that those costs exceeded the payments they received. The October 26 letter separately requested that the affiliates provide cost analyses performed, and related documentation created, at the time their tissue donation programs were initiated, including any independent audit opinions the affiliates may have commissioned in order to comply with PPFA's then-existing guidance on facilitating fetal tissue donation. 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. To state the obvious, the absence of contemporaneous documentation or audits does not implicate compliance with federal or state laws. PPFA's guidance exceeded the requirements of the law. Federal law does *not* require a contemporaneous cost analysis or an independent audit opinion *before* facilitating a patient's donation of fetal tissue for medical research. Indeed, the relevant federal statute does not even refer to documentation requirements. Federal law requires only that payments accepted for donating fetal tissue be "reasonable" and "associated with" several broad categories of tissue procurement activities, and the enclosed accountings confirm that these four affiliates complied with this legal requirement. Moreover, in order to end any unfounded accusations in the future that its affiliates were "profiting" by facilitating their patients' donation of tissue for medical research, PPFA recently announced a policy that affiliates may no longer recover even legally permissible costs.

Over the past several months, partisans have seized on the heavily edited videos recorded by anti-choice extremists to allege that Planned Parenthood affiliates "profited" from facilitating fetal tissue donations for medical research. Putting aside the misleading and unreliable nature of those videos, the allegation is absurd on its face. First of all, Planned Parenthood and its affiliates are all nonprofit organizations, and therefore generate no profits from any revenues they receive to reimburse them for their work providing medical and other services. But even more importantly, the payments these affiliates received for facilitating their patients' fetal tissue donations amounted to a miniscule portion of their overall revenues and budgets:

- 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 PPPSW's total revenue.

In other words, for each of the four affiliates, their total payments were no more than a tiny fraction of one percent of the affiliate's operating revenues. It defies logic—and common sense—to assert that these very modest reimbursements motivated affiliates to facilitate tissue donation out of a desire to "profit" from fetal tissue donation.

Moreover, the payments these affiliates received, which ranged from $35 to $60 for all tissue collected from a single patient, are well within the ranges cited in the public record as reasonable reimbursement amounts. The Human Fetal Tissue Transplantation Research Panel convened by President Ronald Reagan (the "Reagan Panel") in 1988—which recommended restoring federal funding to fetal tissue research—included in the appendices to its report anecdotal evidence of fees charged for fetal tissue procurement, including a letter from a biologics company representing that it paid a tissue procurement organization ("TPO") $50 per tissue donation,[5] and a report from the Poynter Center citing another TPO as paying $300 to $1,000 per month in rent to a clinic that facilitated tissue donation.[6] Similarly, a report issued in 2000 by the U.S. Government Accountability Office ("GAO") described a survey of what NIH-funded researchers paid to procure fetal tissue. GAO reported an average fee of $80 per sample, well above the payment amounts the four Planned Parenthood affiliates received here. And these amounts do not even account for the impact of inflation over the last fifteen years; the $50 payment discussed by the 1988 Reagan Panel would be approximately $100 in 2015 dollars, and the $80 payment referenced by the GAO report in 2000 would be approximately $110 in 2015 dollars.[7] Recent press reports about this issue are consistent with these earlier government reports, with researchers and TPO personnel citing reimbursements of up to $100 per sample as reasonable charges to reimburse costs associated with fetal tissue procurement.[8]

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[5] Letter from H. Fred Voss, Vice President, Research & Dev., Hana Biologics, Inc., to Hon. Arlin M. Adams, Chairman, Human Fetal Tissue Transplantation Research Panel (Sept. 15, 1988), *reprinted in* Reagan Panel Report app. at D266.

[6] Smith, *supra* note 3, at F15.

[7] *See* CPI Inflation Calculator, Bureau of Labor Statistics, http://www.bls.gov/data/inflation_calculator.htm.

[8] *See, e.g.*, Denise Grady & Nicholas St. Fleur, Fetal Tissue From Abortions for Research Is Traded in a Gray Zone, N.Y. Times, July 27, 2015, http://www.nytimes.com/2015/07/28/health/fetal-tissue-from-abortions-for-research-is-traded-in-a-gray-zone.html (stating tissue procurement organizations "pay small fees, usually $100 or less a specimen, to abortion providers" in exchange for procurement services); Dave Levitan, Unspinning the Planned Parenthood Video, FactCheck.org, July 21, 2015, http://www.factcheck.org/2015/07/unspinning-the-planned-parenthood-video (''Four experts in the field of human tissue procurement told us the price range discussed in the [Center for Medical Progress] video — $30 to $100 per patient — represents a reasonable fee.").

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In sum, the payments received by these Planned Parenthood affiliates were associated with their costs of facilitating fetal tissue donation and those payments were consistent with well-documented evidence regarding what is considered "reasonable." That the affiliates have now demonstrated that their costs were more than these payments only underscores what has been clear from the beginning of this inquiry: the very few Planned Parenthood affiliates that received reimbursements for facilitating their patients' fetal tissue donations have not profited, and never sought to profit, from this service.

Finally, your October 26 letter requested that we produce all PPFA and affiliate documents provided to the other three congressional committees investigating PPFA and its affiliates. While these documents are not responsive to the Committee's prior requests, our clients are committed to cooperating with this Committee's inquiry and are therefore producing today more than 24,000 pages of documents that we have produced to the other committees as of this date.

We hope that providing these materials today definitively resolves any concerns the Committee may have had regarding this issue and demonstrates the misleading nature of the allegations that have been leveled against our clients by extremists who are opposed to abortion and other legally protected services that Planned Parenthood provides. Should you have any questions, please contact me at your earliest convenience.

Very truly yours,

K. Lee Blalack II / Ams

K. Lee Blalack II
of O'MELVENY & MYERS LLP

cc: The Honorable Patrick J. Leahy
Ranking Minority Member
Committee on the Judiciary
United States Senate

Jason Foster, Esq.
Chief Investigative Counsel
Committee on the Judiciary
United States Senate

Patrick Davis, Esq.
Investigative Counsel
Committee on the Judiciary
United States Senate

Exhibit 67

[redacted]

[redacted]

David J. Leviss, Esq.
O'Melveny & Myers LLP

Exhibit 68

CHARLES E. GRASSLEY, IOWA, CHAIRMAN

ORRIN G. HATCH, UTAH
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RICHARD BLUMENTHAL, CONNECTICUT

United States Senate
COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510-6275

July 15, 2015

VIA ELECTRONIC TRANSMISSION

Ms. Cecile Richards
President
Planned Parenthood Federation of America
434 West 33rd Street
New York, NY 10001

Dear Ms. Richards:

As you are aware, federal funding accounts for about 40% of Planned Parenthood's annual revenue, and in fiscal year 2014, Planned Parenthood and its affiliates had assets of approximately $1.3 billion, according to its most recent annual report. Recently, a video has surfaced in the media in which Planned Parenthood's Senior Director for Medical Services, Deborah Nucatola, discusses at length Planned Parenthood's role in the harvesting of fetal tissue. In the video, she describes, among other things, the fetal organs available for harvesting, the cost per "specimen," and the coordination with abortion providers to modify their procedures in particular cases to preserve particular organs in order to fill particular orders. Additionally, Nucatola allegedly stated that she encourages local affiliates to determine which fetal organs are in most demand and described how abortion providers allegedly alter the method of abortion to keep the desired organs intact.

As you know, 42 U.S.C. § 274e prohibits buying or selling human body parts and 42 U.S.C. § 289g-1 prohibits the use of fetal human tissue for research without the informed consent of the woman having the abortion and prohibits the alteration of abortion methods and procedures solely in order to obtain fetal tissue. Additionally, 42 U.S.C. § 289g-2 prohibits the commercial trafficking of body parts from an aborted fetus, and 18 U.S.C. § 1531 prohibits partial-birth abortions. Accordingly, the Senate Judiciary Committee is initiating an inquiry into Planned Parenthood's role in the procurement of fetal tissue and related activities described in the video.

Please provide the Committee with the following by July 29, 2015:

1. All records relating to Planned Parenthood's provision of fetal tissue as well as all records relating to Planned Parenthood's facilitation or coordination of such provision of fetal tissue by any of its affiliates, including:

Exhibit 68

a. All presentations, notes, and policies, including manuals on medical practice, as well as descriptions, communications or other records relating to these services.
b. All records relating to Deborah Nucatola and the collection or provision of fetal tissue, including any related presentations, meetings, notes, emails, or other correspondence with abortion providers or with those seeking to acquire fetal organs or tissue.
c. Copies of all instructions, guidance, or communications to abortion providers related to modifying abortion procedures in order to collect particular fetal organs intact.
d. Copies of all physician certifications pursuant to 42 U.S.C. 289g-1(b)(2) in relation to any provision of fetal tissue facilitated or coordinated by Deborah Nucatola.

2. Copies of any and all contracts that each Planned Parenthood affiliate has with companies that procure fetal organs, and the names and contact information of all abortion providers and clinic managers in each Planned Parenthood affiliate.

3. Copies of the memoranda, standard operating procedures, and any other interpretations of the federal Partial Birth Abortion prohibition that are used to instruct abortion providers and clinic managers of all Planned Parenthood affiliates.

4. Copies of the types of consent forms used to obtain consent for such use of fetal tissue from women having abortions.

5. The total amount of revenue generated by Planned Parenthood's provision of fetal tissue.

6. A detailed accounting of the costs incurred by Planned Parenthood's provision of fetal tissue.

If you have any questions about this request, please contact Jason Foster of my Committee staff at (202) 224-5225. Thank you for your attention to this important matter.

Sincerely,

Charles E. Grassley
Chairman
Senate Committee on the Judiciary

Exhibit 69

CHARLES E. GRASSLEY, IOWA, CHAIRMAN
ORRIN G. HATCH, UTAH
JEFF SESSIONS, ALABAMA
LINDSEY O. GRAHAM, SOUTH CAROLINA
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AL FRANKEN, MINNESOTA
CHRISTOPHER A. COONS, DELAWARE
RICHARD BLUMENTHAL, CONNECTICUT
Kolan L. Davis, Chief Counsel and Staff Director
Kathleen L. Kraus, Democratic Chief Counsel and Staff Director

United States Senate
COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510-6275

July 23, 2015

VIA ELECTRONIC TRANSMISSION

[redacted]
CEO
Planned Parenthood of Los Angeles
[redacted]

Dear [redacted]:

As you are likely aware, last week a video surfaced in the media in which the Senior Director for Medical Services for the Planned Parenthood Federation of America (PPFA), Deborah Nucatola, discusses at length Planned Parenthood's role in the harvesting and distribution of fetal tissue. In that video, she appears to describe, among other things, the fetal organs available for harvesting, the cost per "specimen," and the coordination with abortion providers to modify their procedures in particular cases to preserve selected organs in order to fill particular orders. Nucatola also explains that the transfer of fetal tissue is largely handled at Planned Parenthood's affiliate level, with the national organization providing some level of coordination. This week, a second video was released, in which the President of PPFA Medical Directors' Council, Mary Gatter, appears to haggle over the price of fetal tissue and to discuss modifying abortion procedures to harvest such fetal tissue.

Various federal regulations and statutes govern the use of human tissue and organs. For example, it is unlawful under 42 U.S.C. § 274e for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. 42 U.S.C. § 289g-1 further prohibits the use of fetal human tissue for research without the informed consent of the woman having the abortion and prohibits the alteration of abortion methods and procedures solely in order to obtain fetal tissue. Additionally, under 42 U.S.C. § 289g-2, it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce, and 18 U.S.C. § 1531 prohibits partial-birth abortions. Accordingly, the Senate Judiciary Committee is initiating an inquiry into the procurement of fetal tissue and related activities described in the video.

Please provide the Committee with the following by August 6, 2015:

Exhibit 69

1. All records relating to Planned Parenthood of Los Angeles's provision of fetal tissue as well as all records relating to the Planned Parenthood Federation of America's facilitation or coordination of such provision of fetal tissue, including:
   a. All presentations, notes, and policies, including manuals on medical practice, as well as descriptions, communications or other records relating to these services.
   b. All records relating to Deborah Nucatola and the collection or provision of fetal tissue, including any related presentations, meetings, notes, emails, or other correspondence with abortion providers or with those seeking to acquire fetal organs or tissue.
   c. All records relating to Mary Gatter and the collection or provision of fetal tissue, including any related presentations, meetings, notes, emails, or other correspondence with abortion providers or with those seeking to acquire fetal organs or tissue.
   d. Copies of all instructions, guidance, or communications to abortion providers related to modifying abortion procedures in order to collect particular fetal organs intact.
   e. Copies of all physician certifications pursuant to 42 U.S.C. 289g-1(b)(2) in relation to any provision of fetal tissue by Planned Parenthood of Los Angeles.

2. All communications, and all records relating to communications, with companies or organizations that acquire or facilitate the acquisition of fetal tissue relating to such efforts and activities, including copies of any and all contracts that Planned Parenthood of Los Angeles currently has or previously had with companies or organizations that procure fetal tissue.

3. Copies of the memoranda, standard operating procedures, and any other interpretations of the federal Partial Birth Abortion prohibition that are used to instruct Planned Parenthood of Los Angeles's abortion providers and clinic managers.

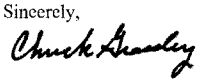
4. Copies of the types of consent forms used to obtain consent for such use of fetal tissue from women having abortions.

5. The total amount of revenue generated by Planned Parenthood of Los Angeles's provision of fetal tissue.

6. A detailed accounting of the costs incurred by Planned Parenthood of Los Angeles's provision of fetal tissue, including a specific breakdown of costs associated with tissue collection, preparation, storage, and transportation.

If you have any questions about this request, please contact Jason Foster of my Committee staff at (202) 224-5225. Thank you for your attention to this important matter.

Sincerely,



Charles E. Grassley
Chairman
Senate Committee on the Judiciary

Exhibit 70

MEMORANDUM

TO: AFFILIATE CHIEF EXECUTIVES
AFFILIATE MEDICAL DIRECTORS
PATIENT SERVICE DIRECTORS

FROM: [redacted], Senior Director, Public Policy Litigation and Law
[redacted], Acting Vice President for Medical Affairs
[redacted], Vice President For Medical Services

RE: Federal Regulations for Aborted Pregnancy Tissue Donation Programs

DATE: April 4, 2001

Among the enclosed standards is a new standard for "Aborted Pregnancy Tissue Donation Programs. This Memorandum is to supplement the standard by advising affiliates of the federal law relating to payment for participation in such programs, and to provide affiliates with two alternative approaches to assuring compliance with these laws.

A. An Overview of the Federal Law

Fetal tissue donation programs are governed by two federal laws, the National Organ Transplant Act (42 U.S.C. 274e) (NOTA) and the NIH Revitalization Act of 1993 (42 U.S.C. 289g-1 and 2) (NIHRA). These laws, particularly NIHRA, govern many aspects of fetal tissue donation programs, and the attached Standard addresses all of these issues that affect medical practice and clinical functions.

These laws also forbid the payment or receipt of valuable consideration for fetal tissue. However, they permit "reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage" of fetal tissue. In addition, NOTA permits reasonable payments for the "removal" of fetal tissue when the research is supported by federal funds. (These laws do not affect a provider's ability to charge its normal and customary fee for the abortion.)

Exhibit 70

B. Assuring Compliance With Federal Law

Affiliates can choose one of two methods to comply with these laws.

1. One method would be to recover *no costs* associated with any aspect of participation in a fetal tissue donation program. This would mean that all staff time, clinic space, supplies, etc., would be donated by the affiliate, and the affiliate would receive no payments or in-kind services from the entity to whom the tissue is being donated.

2. The second method would be to employ an independent auditor to conduct a credible and good-faith analysis of the actual costs incurred *by the affiliate* in the transportation, implantation, processing, preservation, quality control, or storage of the fetal tissue and, if the research is supported by federal funds, for the removal of the fetal tissue. Under this method, affiliates must maintain careful records of actual tissue donations and of payments received from the researcher or the tissue-gathering entity. Affiliates must be able to demonstrate that the payments do not exceed the actual costs of the actual tissue donations.

Sometimes tissue-gathering entities offer to pay rent for space occupied by one of their employees who would be on-site at a clinic on a regular basis. If an affiliate determines to enter into such an arrangement, then the independent auditor would also conduct a credible and good-faith computation of the actual cost of the space occupied by the tissue-gathering entity employee, in order to determine the amount of rent to be paid by that entity.

PPFA accreditation reviews will confirm, in the same way as for any other Medical Standard, that one of these two methods has been employed by any affiliate that chooses to participate in an aborted pregnancy tissue donation program.

C. Compliance With State Laws

We remind affiliates that, in addition to the federal laws outlined above, there are laws in many states governing fetal tissue donation programs. Affiliates must take great care to assure compliance with those laws as well.

If you have questions about the federal statutes, feel free to call [redacted] at: [redacted].

Exhibit 71

ABORTED PREGNANCY TISSUE DONATION PROGRAMS

I. General Information

A. Introduction

Aborted -pregnancy tissue donation and research are humanitarian undertakings that hold the potential to cure disease, save lives, and ameliorate suffering. Affiliate participation in a donation program is entirely voluntary.

Affiliates that choose to participate in such programs **must** recognize that there are federal, and frequently state, laws that govern these activities, as well as ethical considerations. Great care **must** be taken to assure that these programs are above reproach in all of these respects.

B. Provision of Services

1. Affiliates initiating an abortal tissue donation program **must** request approval for a new service (see Manual of Standards and Guidelines Section, 1-C-1).

   Note: the Medical Division does not need to review and approve specific affiliate protocols provided they are in compliance with all applicable PPFA Medical Standards & Guidelines.

2. If the affiliate is a partner in a specific research study or project that includes the provision of donated abortal tissue, and which involves the participation and consent of the patient as a research subject, this research project must be registered in the Medical Division as research and must meet all the documentation requirements of Category 2 research (See Section I-E-1)

3. Monitoring of affiliate abortal tissue donation programs will take place as part of the affiliate recertification process.

4. Affiliate protocols **must** include provisions to ensure compliance with federal, state and local laws, if any, regarding:

   a. Minors' consent and participation in aborted pregnancy tissue donation;

   b. Documentation;

   c. Retention of records; and

   d. Storage and transfer of aborted pregnancy tissue.

II. Counseling and Informed Consent

The following **must** be in any protocol and **must** be stated in mandatory language:

A. The option of donating abortal tissue **must** ***not*** be offered to a patient until

1. After she has decided to have an abortion and,

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Exhibit 71

2. She has completed the process of signing an informed voluntary consent to the abortion.

B. If the patient is interested in donating aborted pregnancy tissue, she **must** provide a separate informed and voluntary consent and sign the Consent for the Donation of Aborted Pregnancy Tissue for Medical Research, Education, or Treatment" form (See Section VII-D-2). The counseling process **must** include, and the consent form reflect that:

1. The donation is made without any restriction regarding who might receive the donated tissue or for what purpose it might be used.

2. There is no financial remuneration or consideration provided to the patient for her consent to donate tissue.

C. If, in addition to donating abortal tissue, the patient is participating in a research project involving the donated abortal tissue, any consent form required by the IRB-approved protocol must be signed *in addition to the* PPFA Consent for the Donation of Aborted Pregnancy Tissue for Medical Research, Education, or Treatment.

D. The timing, method or procedure of abortion cannot and will not be substantively altered for the purpose of obtaining the tissue

NOTE: The wording in the consent for donation of abortal tissue for research has been adopted from the 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.

III. Documentation:

For preservation of the anonymity of abortal tissue donation, documentation may be kept in a file separate from the patient's medical record. A system must exist in the affiliate whereby the documentation of abortal tissue donation can be retrieved and cross-referenced with the patient's medical record. The documentation must be kept on file for in accordance with state laws governing the retention of medical records.

There must be documentation of the following.

A. Patient signed all applicable consents, including, at a minimum, the PPFA Consent for the Donation of Aborted Pregnancy Tissue for Medical Research, Education, or Treatment form (See Section VII-D-2).

B. Notation signed by the clinician performing the abortion that :

1. Abortal tissue was donated;

2. Consent for the abortion was obtained prior to requesting or obtaining consent for the tissue donation;

3. No substantive alteration in the timing or method used to terminate the pregnancy was made for the purpose of obtaining the tissue.

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Exhibit 72

ABORTED PREGNANCY TISSUE DONATION PROGRAMS

I. General Information

Aborted pregnancy tissue donation and research are humanitarian undertakings that hold the potential to cure disease, save lives, and ameliorate suffering. Affiliate participation in donation programs is entirely voluntary.

Affiliates that choose to participate in such programs **must** recognize that there are federal, and frequently, state laws that govern these activities, as well as ethical considerations. Great care **must** be taken to assure that these programs are above reproach in all respects.

Provision of Services

1. Affiliates initiating an aborted tissue donation program **must** request approval for a new service (See Section I-C-1, Approval of Affiliate Clinical Services.)
   Note: the Medical Affairs Division does not need to review and approve specific affiliate protocols if they are in compliance with all applicable *PPFA Medical Standards & Guidelines.*
2. If the affiliate is a partner in a specific research study or project that includes the provision of donated aborted tissue and also involves the participation and consent of the client as a research subject, this research project **must** be registered in the Medical Affairs Division as research and **must** meet all the documentation requirements of Category-2 research (See Section I-E-1, Affiliate Research)
3. Affiliate aborted tissue donation programs will be monitored as part of the affiliate recertification process.
4. Affiliate protocols **must** include provisions to ensure compliance with any federal, state, and local laws regarding
   - minors' consent and participation in aborted pregnancy tissue donation
   - documentation
   - retention of records
   - storage and transfer of aborted pregnancy tissue

II. Counseling and Informed Consent

The following **must** be in any protocol and **must** be stated in mandatory language

1. The option of donating aborted tissue **must** not be offered to a client until
   - after she has decided to have an abortion
   - she has completed the process of signing an informed voluntary consent to the abortion
2. If the client is interested in donating aborted pregnancy tissue, she **must** provide a separate informed and voluntary consent and sign the Consent for the Donation of Aborted Pregnancy Tissue for Medical Research, Education, or Treatment, Section VII-E-2. The counseling process **must** instruct, and the consent form reflect, that
   - The donation is made without any restriction regarding who might receive the donated tissue or for what purpose it might be used.
   - There is no financial remuneration or consideration provided to the client for her consent to donate tissue.
3. If, in addition to donating aborted tissue, the client is participating in a research project involving the donated aborted tissue, any consent form required by the IRB-approved

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Exhibit 72

protocol **must** be signed in addition to the PPFA Consent for the Donation of Aborted Pregnancy Tissue for Medical Research, Education, or Treatment, Section VII-E-2.

4. The timing, method, or procedure of abortion **must not** be substantively altered for the purpose of obtaining the tissue

Note: 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.

III. Documentation

To preserve the anonymity of the donor, documentation may be kept in a file separate from the client's medical record. A system **must** be maintained in the affiliate from which documentation of aborted tissue donation can be retrieved and cross-referenced with the client's medical record. The documentation **must** be kept on file in accordance with state laws governing the retention of medical records.

Documentation **must** include

1. All applicable consents signed by the client, including, at a minimum, the PPFA Consent for the Donation of Aborted Pregnancy Tissue for Medical Research, Education, or Treatment form, Section VII-E-2.
2. Notation signed by the clinician performing the abortion that
   - Aborted tissue was donated.
   - Consent for the abortion was obtained prior to requesting or obtaining consent for the tissue donation.
   - No substantive alteration in the timing of terminating the pregnancy or of the method used was made for the purpose of obtaining the tissue.

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Exhibit 73

Aborted Tissue Programs

January 5, 2011

Notes from call with [redacted]

Clinical Services sought background/historical information from [redacted] and [redacted] about aborted tissue programs. In 2001 a memo was sent to affiliates that outlined the laws on aborted tissue donation programs and the requirement to maintain scrupulous accounting information to be able to prove that payments received cover administrative costs only.

We recently learned that some affiliates:

1. Are including blood samples along with the aborted tissue
2. Made alterations to the PPFA CIIC
3. Are receiving payments to cover administrative costs associated with the program

It was determined that including a blood sample is acceptable. [redacted] approved the alterations in the CIIC language.

Follow-up steps:

1. Original memo from 2001 will be reviewed by [redacted] when [redacted] returns to the office next week and resent to affiliates that are currently participating in aborted tissue programs.
2. [redacted] and or others will call affiliates that need additional guidance.
3. In the future, [redacted] will review aborted tissue CIICs altered by affiliates
4. [redacted] will share the memo with accreditation.
5. [redacted] and [redacted] will discuss with accreditation at next CS/AED meeting.

Exhibit 74

From: ClinicalServices
Subject: Aborted Pregnancy Tissue Donation Programs
Date: Wednesday, January 26, 2011 11:19:11 AM
Attachments: Aborted Tissue Programs MEMO 040401.doc

To: Affiliate CEOs, Medical Directors, Patient Services Directors

Cc: Affiliate Services Division

From: [redacted] Senior Director, Clinical Services

[redacted] Director, Clinical Services

Date: January 26, 2011

Re: Aborted Pregnancy Tissue Donation Programs

Recently we have been in communication with several affiliates about the Client Information for Informed Consent (CIIC) — Donation of Aborted Pregnancy Tissue for Medical Research, Education, or Treatment used in their aborted pregnancy tissue donation programs (Section VII-E-1). We want to remind everyone that changes to the CIIC require approval from Clinical Services. Requests should be sent through Affiliate 411.

We would also like to take this opportunity to remind affiliates about the federal law relating to payment for participation in such programs. The attached memo was sent almost exactly 10 years ago (yikes!). Given the time that has elapsed and that there has likely been staff turnover, we thought it would be helpful to resend it to assure continuing compliance with the statutes.

If you have any questions related to the law please contact [redacted] at [redacted]

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Exhibit 74

MEMORANDUM

TO: AFFILIATE CHIEF EXECUTIVES
AFFILIATE MEDICAL DIRECTORS
PATIENT SERVICE DIRECTORS

FROM: [redacted] Senior Director, Public Policy Litigation and Law
[redacted] Acting Vice President for Medical Affairs
[redacted] Vice President For Medical Services

RE: Federal Regulations for Aborted Pregnancy Tissue Donation Programs

DATE: April 4, 2001

Among the enclosed standards is a new standard for "Aborted Pregnancy Tissue Donation Programs. This Memorandum is to supplement the standard by advising affiliates of the federal law relating to payment for participation in such programs, and to provide affiliates with two alternative approaches to assuring compliance with these laws.

A. An Overview of the Federal Law

Fetal tissue donation programs are governed by two federal laws, the National Organ Transplant Act (42 U.S.C. 274e) (NOTA) and the NIH Revitalization Act of 1993 (42 U.S.C. 289g-1 and 2) (NIHRA). These laws, particularly NIHRA, govern many aspects of fetal tissue donation programs, and the attached Standard addresses all of these issues that affect medical practice and clinical functions.

These laws also forbid the payment or receipt of valuable consideration for fetal tissue. However, they permit "reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage" of fetal tissue. In addition, NOTA permits reasonable payments for the "removal" of fetal tissue when the research is supported by federal funds. (These laws do not affect a provider's ability to charge its normal and customary fee for the abortion.)

Exhibit 74

B. Assuring Compliance With Federal Law

Affiliates can choose one of two methods to comply with these laws.

1. One method would be to recover *no costs* associated with any aspect of participation in a fetal tissue donation program. This would mean that all staff time, clinic space, supplies, etc., would be donated by the affiliate, and the affiliate would receive no payments or in-kind services from the entity to whom the tissue is being donated.

2. The second method would be to employ an independent auditor to conduct a credible and good-faith analysis of the actual costs incurred *by the affiliate* in the transportation, implantation, processing, preservation, quality control, or storage of the fetal tissue and, if the research is supported by federal funds, for the removal of the fetal tissue. Under this method, affiliates must maintain careful records of actual tissue donations and of payments received from the researcher or the tissue-gathering entity. Affiliates must be able to demonstrate that the payments do not exceed the actual costs of the actual tissue donations.

Sometimes tissue-gathering entities offer to pay rent for space occupied by one of their employees who would be on-site at a clinic on a regular basis. If an affiliate determines to enter into such an arrangement, then the independent auditor would also conduct a credible and good-faith computation of the actual cost of the space occupied by the tissue-gathering entity employee, in order to determine the amount of rent to be paid by that entity.

PPFA accreditation reviews will confirm, in the same way as for any other Medical Standard, that one of these two methods has been employed by any affiliate that chooses to participate in an aborted pregnancy tissue donation program.

C. Compliance With State Laws

We remind affiliates that, in addition to the federal laws outlined above, there are laws in many states governing fetal tissue donation programs. Affiliates must take great care to assure compliance with those laws as well.

If you have questions about the federal statutes, feel free to call [redacted] at: [redacted].

Exhibit 75

PROGRAMS FOR DONATION OF BLOOD AND/OR ABORTED PREGNANCY TISSUE FOR MEDICAL, RESEARCH, EDUCATION, OR TREATMENT

I. General Information

Aborted pregnancy tissue donation and research are humanitarian undertakings that hold the potential to cure disease, save lives, and ameliorate suffering. Affiliate participation in donation programs is entirely voluntary.

State/ local laws

Affiliates that choose to participate in such programs **must** recognize that there are federal, and frequently, state laws that govern these activities, as well as ethical considerations. Great care **must** be taken to assure that these programs are above reproach in all respects.

Provision of Services

1. Affiliate **must** submit a written request to initiate an aborted tissue and/or blood donation program to PPFA for review and approval. Submit request to Affiliate 411 Request Form. (See Section I-A-1 Clinical Program Structure for requirements.)

1-Text was deleted

2. If the affiliate is a partner in a specific research study or project that includes the provision of donated aborted tissue and/or blood and also involves the participation and consent of the client as a research subject, this research project **must** be registered with the PPFA Research Department and **must** meet all the documentation requirements. (See Section I-D-1 Research). The required registration form can be accessed at Affiliate Study Submission Site.

AED Review

2-Text was deleted

3. Affiliate protocols **must** include provisions to ensure compliance with any federal, state, and local laws regarding
   - minors' consent and participation in aborted pregnancy tissue donation
   - documentation
   - retention of records
   - storage and transfer of aborted pregnancy tissue

Required Protocols

State/ local laws

4. The timing, method, or procedure of abortion **must** not be substantively altered for the purpose of obtaining the tissue and/or blood.

II. Client Education and Informed Consent

The following **must** be in any protocol and **must** be stated in mandatory language:

1. The option of donating aborted tissue **must** not be offered to a client until
   - after she has decided to have an abortion
   - she has completed the process of signing an informed voluntary consent to the abortion
2. If the client is interested in donating blood and/or aborted pregnancy tissue, she **must** provide a separate informed and voluntary consent and sign the [PPFA] Consent for the Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research, Education, or Treatment (Section VII-E-2). The informed consent process **must** instruct, and the consent form reflect, that

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Exhibit 75

- The donation is made without any restriction regarding who might receive the donated tissue or for what purpose it might be used.
- There is no financial remuneration or consideration provided to the client for her consent to donate tissue.

3. The wording in the consent for donation of blood and/or abortal tissue for research has been adopted from federal statute. The affiliate **must** seek approval from PPFA Medical Services to alter the consent form language other than to add the affiliate name, address, and phone number or other demographic information. Submit request to Affiliate 411 Request Form.
4. If, in addition to donating blood and/or aborted tissue, the client is participating in a research project involving the donated blood and/or aborted tissue, any consent form required by the IRB-approved protocol **must** be signed in addition to the [PPFA] Consent for the Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research, Education, or Treatment (Section VII-E-2).

3-Text was deleted

4-Text was deleted

III. Documentation

5-Text was deleted

State/ local laws

To preserve the anonymity of the donor, documentation may be kept separate from the client's medical record. A system **must** be maintained in the affiliate from which documentation of aborted tissue donation can be retrieved and cross-referenced with the client's medical record. The documentation **must** be kept on file in accordance with state laws governing the retention of medical records.

Documentation **must** include

1. all applicable consents signed by the client, including, at a minimum, the [PPFA] Consent for the Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research, Education, or Treatment form (Section VII-E-2).
2. notation signed by the clinician performing the abortion that
   - Blood and/or aborted tissue was donated.
   - Consent for the abortion was obtained prior to requesting or obtaining consent for the blood and/or tissue donation.
   - No substantive alteration in the timing of terminating the pregnancy or of the method used was made for the purpose of obtaining the blood and/or tissue.

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Exhibit 76

PROGRAMS FOR DONATION OF BLOOD AND/OR ABORTED PREGNANCY TISSUE FOR MEDICAL RESEARCH, EDUCATION, OR TREATMENT

I. General Information

Aborted pregnancy tissue donation and research are humanitarian undertakings that hold the potential to cure disease, save lives, and ameliorate suffering. Affiliate participation in donation programs is entirely voluntary.

Affiliates that choose to participate in such programs **must** recognize that there are federal, and frequently, state laws that govern these activities, as well as ethical considerations. Great care **must** be taken to assure that these programs are above reproach in all respects.

Provision of Services

1. Affiliate **must** submit a written request to initiate an aborted tissue and/or blood donation program to PPFA for review and approval. Submit request to Affiliate 411 Request Form. (See Section I-A-1 Clinical Program Structure for requirements.)
2. If the affiliate is a partner in a specific research study or project that includes the provision of donated aborted tissue and/or blood and also involves the participation and consent of the client as a research subject, this research project **must** be registered with the PPFA Research Department and **must** meet all the documentation requirements. (See Section I-D-1 Research). The required registration form can be accessed at Affiliate Study Submission Site.
3. Affiliate protocols **must** include provisions to ensure compliance with any federal, state, and local laws regarding
   - minors' consent and participation in aborted pregnancy tissue donation
   - documentation
   - retention of records
   - storage and transfer of aborted pregnancy tissue
4. The timing, method, or procedure of abortion **must** not be substantively altered for the purpose of obtaining the tissue and/or blood.

II. Client Education and Informed Consent

The following **must** be in any protocol and **must** be stated in mandatory language:

1. The option of donating aborted tissue **must** not be offered to a client until
   - after she has decided to have an abortion
   - she has completed the process of signing an informed voluntary consent to the abortion
2. If the client is interested in donating blood and/or aborted pregnancy tissue, she **must** provide a separate informed and voluntary consent and sign the [PPFA] Consent for the Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research, Education, or Treatment (Section VII-E-2). The informed consent process **must** instruct, and the consent form reflect, that

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Exhibit 76

- The donation is made without any restriction regarding who might receive the donated tissue or for what purpose it might be used.
- There is no financial remuneration or consideration provided to the client for her consent to donate tissue.

3. The wording in the consent for donation of blood and/or abortal tissue for research has been adopted from federal statute. The affiliate **must** seek approval from PPFA Medical Services to alter the consent form language other than to add the affiliate name, address, and phone number or other demographic information. Submit request to Affiliate 411 Request Form.
4. If, in addition to donating blood and/or aborted tissue, the client is participating in a research project involving the donated blood and/or aborted tissue, any consent form required by the IRB-approved protocol **must** be signed in addition to the [PPFA] Consent for the Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research, Education, or Treatment (Section VII-E-2).

III. Documentation

To preserve the anonymity of the donor, documentation may be kept separate from the client's medical record. A system **must** be maintained in the affiliate from which documentation of aborted tissue donation can be retrieved and cross-referenced with the client's medical record. The documentation **must** be kept on file in accordance with state laws governing the retention of medical records.

Documentation **must** include

1. all applicable consents signed by the client, including, at a minimum, the [PPFA] Consent for the Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research, Education, or Treatment form (Section VII-E-2).
2. notation signed by the clinician performing the abortion that
   - Blood and/or aborted tissue was donated.
   - Consent for the abortion was obtained prior to requesting or obtaining consent for the blood and/or tissue donation.
   - No substantive alteration in the timing of terminating the pregnancy or of the method used was made for the purpose of obtaining the blood and/or tissue.

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Exhibit 77

[redacted]

PPFA Guidance for Participation in Fetal Tissue Donation Programs

[redacted]
To: [redacted]
Bcc: [redacted]

Tue, May 5, 2015 at 3:23 PM

To: Affiliate CEOS, Affiliate COOs, and Affiliate Patient Services Directors,
From: [redacted] Director & Counsel, Health Center Regulatory Strategy, CAPS; [redacted] National Director, CAPS
Date: May 5, 2015
Re: PPFA Guidance for Participation in Fetal Tissue Donation Programs

Dear Colleagues,

Aborted pregnancy tissue donation and research are humanitarian undertakings that hold the potential to cure disease, save lives, and ameliorate suffering. Affiliate participation in donation programs is entirely voluntary.

Affiliates that choose to participate in such programs must recognize that there are federal, and frequently, state laws that govern these activities, as well as ethical considerations. Great care must be taken to assure that these programs are above reproach in all respects.

We would like to direct your attention to updated PPFA guidance on aborted pregnancy tissue donation programs. This guidance includes information on:

- Federal restrictions on participation in such programs, including important guidance on financial reimbursement and patient information/consent;
- Affiliate responsibilities when participating in such programs, including responsibilities to PPFA when participating in related research studies; and
- Additional information on where to obtain additional legal or other guidance from PPFA.

Previously, this PPFA guidance was housed in the PPFA Medical Standards and Guidelines. This information will now live on the CAPS Intranet site.

Affiliates considering or currently participating in an aborted pregnancy tissue donation program should contact [redacted] at [redacted] for more information about the updated PPFA guidance.

Best regards,

[redacted]

Exhibit 77

[redacted] Director and Counsel, Health Center Regulatory Strategy, CAPS
[redacted] National Director, CAPS

[redacted]

Director and Counsel, Health Center Regulatory Strategy, CAPS
Planned Parenthood Federation of America
[redacted]

"Admitted to practice only in the state of New York."

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Learn more about how CAPS can provide support to your affiliate here.

[redacted]

Exhibit 78

Programs for Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research
May 2015

PROGRAMS FOR DONATION OF BLOOD AND/OR ABORTED PREGNANCY TISSUE FOR MEDICAL RESEARCH

Aborted pregnancy tissue donation and research are humanitarian undertakings that hold the potential to cure disease, save lives, and ameliorate suffering. Affiliate participation in donation programs is entirely voluntary.

Affiliates that choose to participate in such programs must recognize that there are federal, and frequently, state laws that govern these activities, as well as ethical considerations. Great care must be taken to assure that these programs are above reproach in all respects.

FEDERAL LAW (42 U.S.C. 274e.; 42 U.S.C. 289g) – in force as of May 2015

A. 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 document and demonstrate actual costs.

B. Federal law establishes additional requirements applicable whenever the research involving fetal tissue is conducted or supported by the federal government. PPFA recommends that these requirements be adhered to without regard to whether the tissue donation program is federally supported or not. These requirements are:

   1. That the client's consent to donate not be sought until after she has decided to have an abortion and has signed the consent form for the abortion.
   2. That the client acknowledge that the blood or tissue is being donated as a gift and that she will not be paid.
   3. That the client acknowledge that she has not been told and that she has no control over who will get the donated blood and/or tissue or what it will be used for.
   4. That there be no changes to how or when the abortion is done in order to obtain the blood or tissue.

PPFA recommends that the client sign a consent, separate from her informed consent to the abortion, in which she acknowledges the above. The "Consent for the Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research" has been provided as a sample. See the third page of this document.

AFFILIATE RESPONSIBILITIES

A. Affiliate must have protocols that ensure compliance with the federal requirements described above as well as any state or local laws regarding:

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Exhibit 78

Programs for Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research
May 2015

1. Minors' consent and participation in aborted pregnancy tissue donation
2. Documentation
3. Retention of records
4. Storage and transfer of aborted pregnancy tissue.

B. It must be documented that no substantive alteration in the timing of terminating the pregnancy or of the method used was made for the purpose of obtaining the blood and/or tissue.

C. Documentation may be kept separate from the client's medical record. There must be a system in place that enables the cross-referencing of documentation of aborted tissue donation with the client's medical record.

D. If the affiliate is a partner in a specific research study or project that includes the provision of donated aborted tissue and/or blood and also involves the participation and consent of the client as a research subject, this research project **must** be registered with the PPFA Research Department and **must** meet all the documentation requirements.

ADDITIDNAL GUIDANCE

A. For questions about federal law or about your state or local laws, if any, consult a local attorney and CAPS at [redacted]

B. For more information about research and the research registration form, consult the Research Manual or contact the Research Department at [redacted]

C. For any other questions about programs for donation of blood and/or aborted pregnancy tissue, contact CAPS at [redacted]

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Exhibit 79

CHARLES E. GRASSLEY, IOWA, CHAIRMAN

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KristINE J. LUCIUS, *Democratic Chief Counsel and Staff Director*

United States Senate

COMMITTEE ON THE JUDICIARY

WASHINGTON, DC 20510-6275

October 2, 2015

VIA ELECTRONIC TRANSMISSION

K. Lee Blalack, II, Esq.
O'Melveny & Myers LLP
1625 Eye Street, NW
Washington, DC 20006-4001

counsel for

Planned Parenthood Federation of America (PPFA) & all Planned Parenthood Affiliates

Dear Mr. Blalack:

On July 15 and July 23, 2015, I wrote to PPFA and all of the Planned Parenthood affiliates, respectively, regarding their roles in the acquisition and transfer of human fetal tissue. Although your clients' subsequent document productions have partially addressed some of the issues I raised nearly three months ago, these documents are not fully responsive to any of my requests. In fact, some issues I raised have not been addressed at all. Accordingly, I am writing to insist that your clients provide an adequate response to my questions concerning the costs they incur in their fetal tissue programs.

As you know, under 42 U.S.C. § 289g-2, it is illegal for anyone to transfer human fetal tissue for valuable consideration, although that law does allow "reasonable payments" for the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue. In my letters, I asked Planned Parenthood to explain, among other things, the total amount of revenue generated by Planned Parenthood's provision of fetal tissue, as well as to provide a detailed accounting of the costs incurred by Planned Parenthood's provision of fetal tissue. Since then, PPFA and its affiliates have produced well over 1,000 pages of documents to the Committee relating to their fetal tissue programs, but not a single document provides any accounting of any actual costs incurred by Planned Parenthood.

Exhibit 79

According to the documents Planned Parenthood has provided, the affiliates were instructed to keep detailed records of these costs. The 2001 PPFA memorandum you provided us, titled "Federal Regulations for Aborted Pregnancy Tissue Donation Programs," had specific instructions to the affiliates for complying with fetal tissue laws on payments, including determining and documenting costs.[1] As stated in that memorandum, the affiliates could either:

1) accept no payments at all for 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[.]"[2]

If the affiliates did choose the second option, the memorandum states they "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."[3] Once again, although PPFA and Planned Parenthood affiliates have produced well over 1,000 pages of documents related to their fetal tissue programs, we have not received any evidence of records of any independent auditors determining the actuals costs for the Planned Parenthood affiliates who received payments for fetal tissue programs.

The 2001 memorandum also states: "PPFA accreditation reviews will confirm . . . that one of these two ways has been employed by any affiliate that chooses to participate in aborted pregnancy tissue donation programs."[4] Similarly, as noted in the 2004 version of Planned Parenthood's Manual of Medical Standards and Guidance, 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."[5] However, the Committee has not received any documents with any evidence to show PPFA monitoring its affiliates through the recertification process to ensure that the affiliates had independent auditors analyze their costs or to confirm that PPFA affiliates were only accepting payments as set by such auditors.

Moreover, in addressing affiliate fetal tissue programs, the May 2015 PPFA Manual states:

> If an affiliate chooses to accept reimbursement for allowable expenses, it must be able to demonstrate the reimbursement represents its actual

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[1] PPFA-SEN_JUD-000540-41.
[2] *Id.*
[3] *Id.*
[4] *Id.*
[5] PPFA-SEN_JUD-000523.

Exhibit 79

costs. PPFA recommends that an affiliate consult with CAPS about steps to take to documents and demonstrate actual costs.[6]

In short, the documents your clients have provided seem to state that the affiliates should have substantial documentation of their actual fetal tissue program costs. Despite the fact that I asked for a detailed accounting of such costs in my letters, and although Planned Parenthood has had well over two months to provide documents related to its affiliates' fetal tissue programs, it has so far failed to produce any evidence of the actual costs affiliates incurred in their fetal tissue programs.

Accordingly, please provide the following by October 9, 2015:

1) Copies of all reports by independent auditors establishing the costs incurred by Planned Parenthood affiliates in fetal tissue programs. If any affiliate that accepted payments in connection with its fetal tissue program did not utilize an independent auditor to establish its reimbursement costs, please explain why.

2) Copies of all records relating to PPFA's accreditation reviews of affiliates' fetal tissue programs, including any records relating to PPFA's confirmation that the affiliates had either accepted no payments or only accepted payments for costs determined by an independent auditor. If PPFA did not conduct such recertification reviews, or if the reviews did not include an evaluation of the affiliates' auditor reports and payment compliance, please explain why.

3) Copies of all other records relating to the documentation and demonstration of the actual costs of affiliates' fetal tissue programs. If there is no such documentation, please explain why.

If you have any questions about this request, please contact Patrick Davis of my Committee staff at (202) 224-5225. Thank you for your attention to this important matter.

Sincerely,

Charles E. Grassley
Chairman
Senate Committee on the Judiciary

cc: The Honorable Patrick Leahy
Ranking Member

[6] PPFA-SEN_JUD000055-56.

Exhibit 80

Planned Parenthood: Shasta-Diablo, Inc. DBA Planned Parenthood Northern California (FY 2015)[1]

Costs Associated with Coordinating Tissue Collection and Processing		
Staff Time[2] Supervising / Coordinating with Stem Express Representative		
Vice President of Medical Services	$	359.32
Center Director	$	168.86
Abortion Services Coordinator	$	397.62
Operations Costs[3]	$	154.89
General Administrative & Medical Overhead[4]	$	194.52
Subtotal	**$**	**1,275.21**

Costs Associated with Obtaining Patient Consent for Donation		
Staff Time Verifying and Signing Consent Forms		
Medical Director	$	87.35
Staff Time Scanning Consent Forms		
Flow Coordinator	$	12.74
Operations Costs	$	21.02
General Administrative & Medical Overhead	$	21.80
Subtotal	**$**	**142.91**

Costs Associated with Transportation, Preservation, Quality Control, and Storage		
Staff Time Coordinating Courier Service for Stem Express Representative		
Flow Coordinator	$	12.74
Staff Time Screening Donated Tissue		
Medical Director	$	16.91
Staff Time Invoicing Stem Express Reimbursement and Coordinating Program		
Medical Services Manager	$	301.95
Supplies / Equipment		
Autoclave Sterilization Indicator Tape	$	0.78
Chemical Sterilization Indicator Strip	$	1.22

[1] This analysis reflects costs and reimbursements for the Concord health center only. The Walnut Creek health center also made five donations, one of which resulted in no reimbursement and has been written off as non-collectible, totaling $220.00 in reimbursements. Costs and reimbursements from the Walnut Creek center have been excluded from this analysis due to their small size.
[2] Staff costs are calculated by multiplying the employee's wage and benefits by the amount of time spent on tasks associated with the fetal tissue donation program.
[3] Operations Costs represent additional direct costs allowed per 2 C.F.R. § 200, including telephone usage, postage, office supplies, and other direct costs.
[4] General Administrative & Medical Overhead represents the portion of costs for overall function and management associated with maintaining the tissue donation program, exclusive of the costs directly allocated.

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Exhibit 80

Tubing for Sterile Instrument Transportation	$	4.72
Operations Costs	$	36.42
General Administrative & Medical Overhead	$	67.45
Subtotal	**$**	**442.19**
Costs Associated with Use of Facility Space		
Use of Space by Stem Express Representatives		
Dedicated Work Areas[5]	$	166.89
Storage Areas[6]	$	125.76
General Administrative & Medical Overhead	$	52.68
Subtotal	**$**	**345.33**
TOTAL COSTS	**$**	**2,205.64**
Reimbursements		
Reimbursement		
$55.00 Service Fee for 25 Donations[7]	$	1,375.00
TOTAL REIMBURSEMENTS	**$**	**1,375.00**
NET GAIN/LOSS	**$**	**(830.64)**
PERCENT GAIN/LOSS		**(60.41%)**

[5] Represents the portion of facilities costs used by Stem Express representatives on days present, including the costs of utilities, taxes, depreciation, and repairs & maintenance.
[6] Represents the portion of facilities costs used by Stem Express representatives for storage of materials and supplies.
[7] The Concord health center made a total of 31 donations, six of which resulted in no reimbursements and have since been written off as non-collectible.

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Exhibit 81

Planned Parenthood of the Pacific Southwest (FY 2015)

Costs Associated with Coordinating Tissue Collection and Processing		
Staff Time[1] Communicating with ABR Representative Prior to Collection		
Front Desk	$	154.56
Center Manager	$	534.49
Flow Coordinator	$	325.62
Medical Assistant	$	112.28
Staff Time Supervising / Coordinating with ABR Representative		
Center Manager	$	3,008.40
Flow Coordinator	$	4,808.84
Medical Assistant	$	1,017.52
Supplies / Equipment		
Chucks	$	23.42
Disposable Gloves	$	95.82
Ziploc Bags	$	21.54
General Administrative & Medical Overhead[2]	$	2,501.38
Subtotal	$	**12,603.87**
Costs Associated with Obtaining Patient Consent for Donation		
Staff Time Discussing Program with Patients, Obtaining Consent or Declination		
Medical Assistant	$	5,789.94
Staff Time Preparing Consent Forms, Whiteboard, and Anonymized Consent List		
Front Desk	$	907.44
Medical Assistant	$	1,651.51
Manager	$	585.48
Flow Coordinator	$	825.21
Staff Time Sending Consent Forms to Administrative Office		
Front Desk	$	131.00
Supplies / Equipment		
Photocopies	$	184.00
General Administrative & Medical Overhead	$	2,494.47
Subtotal	$	**12,569.05**
Costs Associated with Transportation, Preservation, Quality Control, and Storage		
Extra Tissue Examination Time[3]		
Medical Assistant	$	1,194.97

[1] Staff costs are calculated by multiplying the employee's wage and benefits by the amount of time spent on tasks associated with the fetal tissue donation program.
[2] General Administrative & Medical Overhead represents the portion of costs for overall function and management associated with maintaining the tissue donation program, exclusive of the costs directly allocated.
[3] These figures represent additional time required to examine products of conception because the tissue was either not washed or washed in cold water, as required for donation.

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[redacted]
[redacted]
PPPSW-SEN_JUD-000129

Exhibit 81

Flow Coordinator	$	52.80
Staff Time Transferring Tissue to ABR Representative		
Medical Assistant	$	235.52
Flow Coordinator	$	195.04
Staff Time Managing Deliveries, Moving Boxes, and Discarding Documents for ABR Representative		
Center Manager	$	447.12
Medical Assistant	$	253.00
Front Desk	$	220.80
Staff Time Coordinating Courier Service for ABR Representative		
Front Desk	$	1,015.68
Medical Assistant	$	9.75
Center Manager	$	149.04
Staff Time Invoicing ABR Reimbursement		
Center Manager	$	35.64
Staff Time Installing Shelf for ABR Representative		
Maintenance	$	25.92
Supplies / Equipment		
Shelf for ABR Representative	$	279.21
General Administrative & Medical Overhead	$	1,018.75
Subtotal	**$**	**5,133.24**
Costs Associated with Use of Facility Space		
Use of Space by ABR Representatives		
Dedicated Work Areas[4]	$	124.60
Storage Areas	$	1,588.51
Shared Common Areas[5]	$	4,157.91
General Administrative & Medical Overhead	$	1,453.66
Subtotal	**$**	**7,324.68**
TOTAL COSTS	**$**	**37,630.84**
Reimbursements		
Reimbursement		
$60.00 Service Fee for 316 Donations	$	18,960.00
TOTAL REIMBURSEMENTS	**$**	**18,960.00**
NET GAIN/LOSS	**$**	**(18,670.84)**
PERCENT GAIN/LOSS		**(98.47%)**

[4] Represents the portion of facilities costs used by ABR representative on days present, including the costs of utilities, taxes, depreciation, and repairs & maintenance.
[5] Represents the portion of common-area space utilized by ABR representative on days present.

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Exhibit 82

Planned Parenthood of Los Angeles (FY 2015)

Costs Associated with Coordinating Tissue Collection and Processing		
Staff Time[1] Preparing Surgical List and Internal Coordination		
Front Desk	$	59.28
Registered Nurse	$	141.96
Staff Time Coordinating with Novogenix Representative		
Center Manager	$	390.00
Front Desk	$	79.04
Medical Assistant	$	265.20
Staff Time Attending Morning Meetings' Discussion of Donation Program		
Center Manager	$	93.60
Clinician	$	532.48
Front Desk	$	76.96
Licensed Vocational Nurse	$	97.76
Medical Assistant	$	332.80
Registered Nurse	$	567.84
Surgical Technician	$	91.52
Staff Time Managing and Overseeing Tissue Donation Program		
Medical Director	$	1,476.90
Vice President of Patient Services	$	660.00
Supplies / Equipment		
Disposable Gloves	$	129.28
Disposable Masks	$	22.88
Laundry	$	62.40
Shoe Covers	$	37.44
Underpads	$	80.08
Management & General Overhead[2]	$	638.76
Subtotal	**$**	**5,836.18**

Costs Associated with Obtaining Patient Consent for Donation		
Staff Time Discussing Program with Patients, Obtaining Consent or Declination		
Clinician	$	4,333.56
Medical Assistant	$	1,835.36
Registered Nurse	$	1,061.97
Staff Time Preparing, Processing, and Photocopying Consent Forms		
Front Desk	$	492.11
Registered Nurse	$	189.28
Supplies / Equipment		
Photocopies	$	4.87

[1] Staff costs are calculated by multiplying the employee's wage and benefits by the amount of time spent on tasks associated with the fetal tissue donation program.
[2] Management & General Overhead represents the portion of costs for overall function and management associated with maintaining the tissue donation program, exclusive of the costs directly allocated.

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Exhibit 82

Printing	$	218.40
Slipsheets	$	10.74
Management & General Overhead	$	1,001.18
Subtotal	**$**	**9,147.47**
Costs Associated with Transportation, Preservation, Quality Control, and Storage		
Staff Time Transferring Tissue to Novogenix Representative		
Surgical Technician	$	158.90
Staff Time Disposing of Unused Tissue		
Surgical Technician	$	158.90
Staff Time Coordinating with Novogenix Representative		
Surgical Technician	$	246.48
Staff Time Invoicing Novogenix Reimbursement		
Administrative Assistant for Patient Services	$	84.42
Staff Time Revising Electronic Health Records		
Nurse Informatics	$	57.30
Management & General Overhead	$	86.77
Subtotal	**$**	**792.77**
Costs Associated with Use of Facility Space		
Use of Space by Novogenix Representatives		
Dedicated Work Areas[3]	$	282.51
Shared Common Areas[4]	$	642.97
Management & General Overhead	$	113.74
Subtotal	**$**	**1,039.22**
TOTAL COSTS	**$**	**16,815.65**
Reimbursements		
Reimbursement		
$45.00 Service Fee for 350 Donations	$	15,750.00
TOTAL REIMBURSEMENTS	**$**	**15,750.00**
NET GAIN/LOSS	**$**	**(1,065.65)**
PERCENT GAIN/LOSS		**(6.77%)**

[3] Represents the portion of facilities costs for space dedicated for the Novogenix representative on days present, including the costs of utilities, taxes, depreciation, and repairs & maintenance.
[4] Represents the portion of common-area space utilized by Novogenix representative on days present.

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Exhibit 83

Planned Parenthood Mar Monte (FY 2015)

Costs Associated with Coordinating Tissue Collection and Processing		
Staff Time[1] Coordinating and Managing Patient Flow		
Health Services Specialist	$	831.14
Abortion Coordinator	$	5,017.20
Staff Time Supervising / Coordinating with Stem Express Representative		
Center Manager	$	579.62
Chief Medical Officer	$	347.78
Supplies / Equipment		
Disposable Gloves	$	104.55
Flush Solutions	$	90.34
Gauze	$	5.89
Band-Aids	$	4.32
Operations Costs[2]	$	853.42
General Administrative & Medical Overhead[3]	$	1,880.22
Subtotal	**$**	**9,714.48**
Costs Associated with Obtaining Patient Consent for Donation		
Staff Time Interpreting Consent Forms		
Health Services Specialist	$	1,170.44
Staff Time Verifying and Signing Consent Forms		
Clinician	$	1,813.33
Staff Time Scanning Consent Forms		
Check-Out Specialist	$	183.85
Supplies / Equipment		
Photocopies	$	130.98
Operations Costs	$	378.92
General Administrative & Medical Overhead	$	882.60
Subtotal	**$**	**4,560.12**
Costs Associated with Transportation, Preservation, Quality Control, and Storage		
Staff Time Cleaning Stem Express Equipment		
Health Services Specialist	$	260.61
Staff Time Invoicing Stem Express Reimbursement		
Assistant Lab Manager	$	704.33
Accountant	$	237.43

[1] Staff costs are calculated by multiplying the employee's wage and benefits by the amount of time spent on tasks associated with the fetal tissue donation program.
[2] Operations Costs represent additional direct costs allowed per 2 C.F.R. § 200, including telephone usage, postage, office supplies, and other direct costs.
[3] General Administrative & Medical Overhead represents the portion of costs for overall function and management associated with maintaining the tissue donation program, exclusive of the costs directly allocated.

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Exhibit 83

Supplies / Equipment		
Shipping Labels	$	8.79
Operations Costs	$	142.62
General Administrative & Medical Overhead	$	324.91
Subtotal	**$**	**1,678.69**
Costs Associated with Use of Facility Space		
Use of Space by Stem Express Representatives		
Dedicated Work Areas[4]	$	4,286.55
Storage Areas[5]	$	1,005.47
Subtotal	**$**	**5,292.02**
TOTAL COSTS	**$**	**21,245.32**
Reimbursements		
Reimbursement		
$55.00 Service Fee for 176 Donations	$	9,680.00
$35.00 Service Fee for 265 Donations	$	9,275.00
TOTAL REIMBURSEMENTS	**$**	**18,955.00**
NET GAIN/LOSS	**$**	**(2,209.32)**
PERCENT GAIN/LOSS		**(12.08%)**

[4] Represents the portion of facilities costs used by Stem Express representatives on days present, including the costs of utilities, taxes, depreciation, and repairs & maintenance.
[5] Represents the portion of facilities costs used by Stem Express representatives for storage of materials and supplies.

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Exhibit 84

CHARLES E. GRASSLEY, IOWA, CHAIRMAN

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Kolan L. Davis, Chief Counsel and Staff Director
Kristine Lucius, Democratic Chief Counsel and Staff Director

United States Senate

COMMITTEE ON THE JUDICIARY

WASHINGTON, DC 20510-6275

February 22, 2016

The Honorable Sylvia Matthews Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Burwell:

On August 14, 2015, HHS Assistant Secretary for Legislation Jim Esquea sent nearly identical letters in response to separate inquiries from Chairmen Johnson and Grassley and Senators Ernst and Blunt regarding the fetal tissue harvesting practices of the Planned Parenthood Federation of America (Planned Parenthood), an HHS grant recipient. Mr. Esquea's response letter not only failed to fully respond to the questions raised in our inquiries, but it also raised additional concerns about the adequacy of the Department's general oversight of HHS grant recipients that engage in activities involving fetal tissue.

In reaction to Mr. Esquea's inadequate response, Chairman Johnson, Senator Ernst, and I wrote to you on September 28, 2015, with a number of specific factual questions about HHS's role in these issues. Unfortunately, the response we received from Mr. Esquea on November 17, 2015, entirely failed to address some of the questions in our letter. In particular, our September 28, 2015, letter raised the following issues:

2. Under 42 U.S.C. § 289g-l(b)(2), in connection with any research HHS funds or conducts on the transplantation of human fetal tissue for therapeutic purposes, the physician who performs the abortion from which the fetal tissue was acquired is required to make a signed, written statement declaring, among other things, that consent for the abortion was acquired prior to requesting or obtaining consent for the donation of the fetal tissue, that no alteration of the timing, method, or procedures used to terminate the pregnancy was made solely for obtaining the tissue, and that the abortion was performed in accordance with applicable State law. Under subsection (c), the individual with primary responsibility for conducting such research also must make a signed, written statement to declare a number of things. Moreover, under subsection (d), agency heads or other entities conducting fetal tissue research must make these required certification documents

Exhibit 84

available for audit by the HHS Secretary. **Has an HHS Secretary ever exercised his or her authority under this 1993 statute to conduct audits?** If not, please explain. If yes:

a. How many audits of agency heads or entities conducting fetal tissue research have been conducted to date? (In responding please list number of audits conducted in each year from 1993 to the present, and detail the target as well as scope of each such audit.)
b. Did any such audit(s) disclose that a violation of applicable laws and regulations had occurred, contrary to the recipient's certification? Please explain.
c. Did any such audit(s) disclose material omissions or deficiencies in certification statements, repeat violations of 42 U.S.C. § 289g-1 (or regulations promulgated under that statute), or violations of other statutes or regulations? If so, please describe all such omissions, deficiencies, and violations, as well as any punitive or remedial measures taken by the Secretary in response.

These are straight-forward factual questions that HHS should be able to easily answer—has HHS ever conducted any audits, and if so, describe them and their results—yet HHS has failed to do so. Accordingly, please answer these questions by March 7, 2016.

If you have any questions about this request, please contact Patrick Davis of the Judiciary Committee staff at (202) 224-5225. Thank you again for your assistance in this matter.

Sincerely,

Charles E. Grassley
Chairman
Senate Committee on the Judiciary

cc: The Honorable Patrick Leahy
Ranking Member
Senate Committee on the Judiciary

Exhibit 85

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

The Honorable Charles E. Grassley
Chairman
Committee on the Judiciary
United States Senate
Washington, DC 20510

FEB 29 2016

Dear Chairman Grassley:

Thank you for your February 22, 2016, letter regarding medical research using human fetal tissue. You asked whether a Secretary of the Department of Health and Human Services (HHS) has exercised his or her authority under 42 U.S.C. § 289g-1 to conduct audits regarding research conducted or supported by HHS on the transplantation of human fetal tissue for therapeutic purposes. As we have stated in our previous letters on this topic, HHS has not conducted or supported related research since 2007, and accordingly has not conducted any such audits since then. Before that time, we are not aware of an HHS Secretary exercising his or her authority under 42 U.S.C. § 289g-1 to conduct an audit of such research on the transplantation of fetal tissue for therapeutic purposes.

We hope you find this information helpful. Thank you for your interest in the important work of our Department.

Sincerely,

Jim R. Esquea

Jim R. Esquea
Assistant Secretary for Legislation

cc: The Honorable Patrick Leahy
Ranking Member

Report and
Recommendations

Research on the Fetus

The National Commission
for the Protection of
Human Subjects
of Biomedical and
Behavioral Research

Report and
Recommendations

Research on the Fetus

The National Commission
for the Protection of
Human Subjects
of Biomedical and
Behavioral Research

1975

U.S. Department of Health, Education, and Welfare
DHEW Publication No. (OS) 76-127

Appendix I

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

Westwood Building, Room 125
5333 Westbard Avenue
Bethesda, Maryland 20016

July 25, 1975

Honorable Caspar W. Weinberger
Secretary of Health, Education, and Welfare
Washington, D.C. 20201

Dear Mr. Secretary:

On behalf of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and pursuant to Section 202(b) of the National Research Act (Public Law 93-348), I am pleased to submit to you the Commission's Report and Recommendations: Research on the Fetus. An appendix volume, containing materials reviewed by the Commission in its deliberations, accompanies the report.

Sincerely yours,

Kenneth John Ryan, M.D.
Chairman

Appendix I

NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

COMMISSIONERS

Kenneth John Ryan, M.D., Chairman
Chief of Staff
Boston Hospital for Women

Joseph V. Brady, Ph.D.
Professor of Behavioral Biology
Johns Hopkins University

Robert E. Cooke, M.D.
Vice Chancellor for Health Sciences
University of Wisconsin

Dorothy I. Height
President
National Council of Negro Women, Inc.

Albert R. Jonsen, Ph.D.
Adjunct Associate Professor of Bioethics
University of California at San Francisco

Patricia King, J.D.
Associate Professor of Law
Georgetown University Law Center

Karen Lebacqz, Ph.D.
Assistant Professor of Christian Ethics
Pacific School of Religion

David W. Louisell, J.D.
Professor of Law
University of California at Berkeley

Donald W. Seldin, M.D.
Professor and Chairman, Department
Internal Medicine
University of Texas at Dallas

Eliot Stellar, Ph.D.
Provost of the University and
Professor of Physiological Psychology
University of Pennsylvania

Robert H. Turtle, LL.B.
Attorney
VomBaur, Coburn, Simmons & Turtle
Washington, D.C.

Appendix I

The Commission wishes to thank the members of its staff for the valuable assistance provided in the study of research on the fetus and the preparation of this report.

COMMISSION STAFF

Charles U. Lowe, M.D.
Executive Director

Michael S. Yesley, J.D.
Staff Director

Professional Staff

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Edward Dixon, J.D.
Bradford Gray, Ph.D.
Miriam Kelty, Ph.D.
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Support Staff

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Lisa J.Gray
Marie D. Madigan
Erma L. Pender
Susan F. Shreiber

Assistance was also provided by Charles McCarthy, William Dommel and Anthony Buividas.

PREFACE

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established by Title II of the National Research Act (Public Law 93-348) to study the ethical principles underlying biomedical and behavioral research on human subjects and to make recommendations to the Secretary, DHEW, and to Congress for the protection of these subjects. This report was prepared in response to a section of the Act that required the Commission to "conduct an investigation and study of the nature and extent of research involving living fetuses, the purposes for which such research has been undertaken, and alternative means for achieving such purposes" (Section 202(b)).

This volume, Report and Recommendations: Research on the Fetus, contains the Commission's Recommendations, the underlying Deliberations and Conclusions, a dissenting statement and an additional statement by Commission members, and summaries of materials presented to the Commission. An appendix volume contains the complete texts of reports and papers prepared for the Commission on the ethical, legal and medical aspects of research on the fetus and other material reviewed by the Commission in its deliberations.

Appendix I

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Appendix I

I.

THE MANDATE

The National Research Act (P.L. 93-348) established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and gave the Commission a mandate to investigate and study research involving the living fetus, and to recommend whether and under what circumstances such research should be conducted or supported by the Department of Health, Education, and Welfare. A deadline of four months after the members of the Commission took office was imposed for the Commission to conduct its study and make recommendations to the Secretary, DHEW. The priority assigned by Congress to research involving the fetus indicates the concern that unconscionable acts involving the fetus may have been performed in the name of scientific inquiry, with only proxy consent on behalf of the fetus.

The members of the Commission determined at the outset to undertake a careful study of the nature and extent of research on the fetus, the range of views on the ethical acceptability of such research, and the legal issues involved, prior to formulating their recommendations. To this end, the Commission has accumulated an extensive body of information, held public hearings, questioned a panel of distinguished ethicists, and conducted lengthy deliberations. In the course of these activities, the Commission has given close scrutiny to many important questions that surround research on the fetus, for example: What are the purposes of research on the fetus? What procedures have been employed in such research? Are there alternatives to such research? Can appropriate consent to such research be obtained by proxy? Under what conditions may research be done on a fetus that is to be aborted, or a nonviable delivered fetus? What review of proposed research should be required?

In the remainder of Section I, the background and activities of the Commission are summarized, and the definitions used in this report are set forth. Reports, papers and testimony that were prepared for or presented to the Commission are summarized in Sections II to VII of this report. The Commission's own

statement of its deliberations and conclusions appears in Section VIII, and the recommendations themselves are set forth in Section IX, together with a statement by a member of the Commission dissenting in part from the recommendations. Separate views of members of the Commission are set forth in Section X.

The Appendix to the report contains the entire text of the papers and reports that were prepared under contract to the Commission, and certain other materials that were reviewed by the Commission during its deliberations.

Legislative Background. The National Research Act contains two provisions regarding research on the fetus: (1) the mandate to the Commission to conduct studies and make recommendations to the Secretary, DHEW, (section 202(b)), and (2) a prohibition, in effect until the Commission has made recommendations, on "research [conducted or supported by DHEW] in the United States or abroad on a living human fetus, before or after the induced abortion of such fetus, unless such research is done for the purpose of assuring the survival of such fetus" (section 213). These two provisions were drafted by a conference committee that resolved the differences between the acts originally passed in 1973 by the House of Representatives and Senate, respectively.

The original House act contained a prohibition against the conduct or support by DHEW of research that would violate any ethical standard adopted by the National Institutes of Health or the National Institute of Mental Health. This provision was perceived as a prohibition of research on the living fetus, as a result of policy then in force at NIH. In addition, both the House and Senate acts contained floor amendments explicitly prohibiting the conduct or support of research on the fetus by DHEW. The House amendment, adopted by a vote of 354 to 9, proscribed research on a fetus that is outside the uterus and has a beating heart, while the Senate prohibition applied to research in connection with an abortion. Among other differences between the acts, the House prohibitions were permanent, while the Senate prohibition was temporary. The conference committee adopted the Senate approach, imposing a moratorium until this Commission made recommendations. The moratorium adopted by the conference committee applies to research conducted on a fetus before or after an induced abortion of the fetus (except to assure the survival of the fetus); the mandate for the Commission's study and recommendations applies more generally to research involving the living fetus.

Appendix I

The Commission has reviewed the committee reports (Nos. 93-244, 93-381, and 93-1148) and the record of the floor debate that led to the passage of the National Research Act (Congressional Record, daily eds. May 31, 1973; September 11, 1973; June 27 and 28, 1974). Other legislative materials that have been reviewed include the Hearings on Biomedical Research Ethics and the Protection of Human Subjects, before the House Subcommittee on Public Health and Environment (September 27 and 28, 1973), and the Hearing on Fetal Research before the Senate Subcommittee on Health (July 19, 1974).

It is clear from the legislative history that the National Research Act, as passed by both Houses and signed into law by President Nixon on July 12, 1974, reflects an acknowledgement by the majority of legislators that the issues surrounding research on the fetus require much study and deliberation before policies are established regarding support by the Secretary, DHEW. That assignment was given to the Commission, and this report describes how the assignment was carried out and the conclusions that were reached.

Existing Codes and Other Relevant Material. To assist its deliberations, the Commission referred to the following pre-existing codes and other materials relating to human experimentation:

1. The Nuremberg Code (1946-1949).
2. The Declaration of Helsinki (revised, 1964).
3. The Use of Fetuses and Fetal Material for Research, Report of the Advisory Group, chaired by Sir John Peel (London, 1972).
4. Protection of Human Subjects: Policies and Procedures, draft document of the Department of Health, Education, and Welfare (38 Federal Register No. 221, Part II, November 16, 1973).
5. Protection of Human Subjects: Proposed Policy, Department of Health, Education, and Welfare (39 Federal Register No. 165, Part III, August 23, 1974).

(The above documents are included in the Appendix to this report.)

Meetings of the Commission. Secretary Weinberger administered the oath of office to the members of the Commission on December 3, 1974, thereby fixing the deadline for this report. Section 202(b) of the National Research Act requires that recommendations of the Commission with respect to research on the living fetus be transmitted to the Secretary "not later than the expiration of the 4-month period beginning on the first day of the first month that follows the date on which all members of the Commission have taken office." This 4-month period expired April 30, 1975.

The Commission conducted seven meetings devoted primarily to the topic of research on the fetus. These meetings were well attended by the public. One day of the February meeting was devoted to a public hearing of the views of persons interested in research on the fetus; oral testimony was given by 23 witnesses, some representing research, religious or other organizations and some appearing as concerned citizens to express their viewpoints (see Section VI for summaries of the views presented). At the March meeting, three public officials testified about the involvement of their respective agencies or offices in research on the fetus (see Section VI), and the members of the Commission held a roundtable discussion with several ethicists who had prepared papers covering a wide spectrum of secular opinion and religious persuasion (see Section V for summaries of these papers).

Studies and Investigations. The Commission contracted for a number of studies and investigations. These included a study, undertaken primarily through the review of the literature, of the nature, extent and purposes of research on the fetus, conducted under contract with Yale University (see Section II); an historical study of the role of research involving living fetuses in certain advances in medical science and practice, conducted under contract with Battelle-Columbus Laboratories (see Section III); and a study utilizing available data to establish guidelines for determining fetal viability and death, conducted under contract with Columbia University (see Section VII).

In addition to these studies, papers outlining their views on research on the fetus were prepared by the following ethicists and philosophers: Sissela Bok of Harvard University; Joseph Fletcher of the Institute of Religion and Human Development; Marc Lappé of the Hastings Institute of Society, Ethics, and the

Life Sciences; Richard McCormick and LeRoy Walters of the Kennedy Institute for the Study of Human Reproduction and Bioethics; Paul Ramsey of Princeton University; Seymour Siegel of the Jewish Theological Seminary and Richard Wasserstrom of the University of California at Los Angeles (see Section V). Stephen Toulmin, of the University of Chicago, prepared an analysis of the ethical views that were presented to the Commission, identifying areas of consensus as well as divergence. Leon Kass, of Georgetown University, prepared a philosophical paper on the determination of fetal viability and death (see Section VII). Papers on the legal issues of research on the fetus were prepared by Alexander M. Capron of the University of Pennsylvania Law School, and John P. Wilson of Boston University Law School (*see* Section IV).

(All of the above studies, investigations and papers appear in the Appendix.)

Definitions. For the purposes of this report, the Commission has used the following definitions which, in some instances, differ from medical, legal or common usage. These definitions have been adopted in the interest of clarity and to conform to the language used in the legislative mandate.

"Fetus" refers to the human from the time of implantation until a determination is made following delivery that it is viable or possibly viable. If it is viable or possibly viable, it is thereupon designated an infant. (Hereafter, the term "fetus" will refer to a living fetus unless otherwise specified.)

"Viable infant" refers to an infant likely to survive to the point of sustaining life independently, given the support of available medical technology. This judgment is made by a physician.

"Possibly viable infant" means the fetus *ex utero* which has not yet been determined to be viable or nonviable. This is a decision to be made by a physician. Operationally, the physician may consider that an infant with a gestational age of 20 to 24 weeks (five to six lunar months; four and one-half to five and one-half calendar months) and a weight between 500 to 600 grams may fall into this indeterminate category. These indices depend upon present technology and should be reviewed periodically.

Appendix I

"Nonviable fetus" refers to the fetus *ex utero* which, although it is living, cannot possibly survive to the point of sustaining life independently, given the support of available medical technology. Although it may be presumed that a fetus is nonviable at a gestational age less than 20 weeks (five lunar months; four and one-half calendar months) and weight less than 500 grams, a specific determination as to viability must be made by a physician in each instance. The Commission is not aware of any well-documented instances of survival of infants of less than 24 weeks (six lunar months; five and one-half calendar months) gestational age and weighing less than 600 grams; it has chosen lower indices to provide a margin of safety. These indices depend upon present technology and should be reviewed periodically.

"Dead fetus" *ex utero* refers to a fetus ex utero which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, or pulsation of umbilical cord (if still attached). Generally, some organs, tissues and cells (referred to collectively as fetal tissue) remain alive for varying periods of time after the total organism is dead.

"Fetal material" refers to the placenta, amniotic fluid, fetal membranes and the umbilical cord.

"Research" refers to the systematic collection of data or observations in accordance with a designed protocol.

"Therapeutic research" refers to research designed to improve the health condition of the research subject by prophylactic, diagnostic or treatment methods that depart from standard medical practice but hold out a reasonable expectation of success.

"Nontherapeutic research" refers to research not designed to improve the health condition of the research subject by prophylactic, diagnostic or treatment methods.

II.

THE NATURE AND EXTENT OF RESEARCH INVOLVING THE FETUS AND THE PURPOSES FOR WHICH SUCH RESEARCH HAS BEEN UNDERTAKEN

An extensive review of the scientific literature, focusing on a period covering the last ten years, formed the basis for the Commission's investigation of the nature, extent and purposes of research on the fetus. The review was conducted under contract with Yale University, Maurice J. Mahoney, M.D., Principal Investigator. The investigation included an all-language review of published research, utilizing the MEDLARS computer indexing and search system of the National Library of Medicine, a review of selected bibliographies and abstracts, a survey of departments of pediatrics and obstetrics at medical schools in the United States and Canada to identify current research on the fetus, and a review of NIH grant applications and contracts since 1972 involving research on the fetus. In addition, the Food and Drug Administration provided information on fetal research conducted in fulfillment of its regulations.

For the purpose of summarizing the review, research involving the fetus has been considered in four general categories.

1. Assessment of Fetal Growth and Development *In Utero*. Over 600 publications dealing with investigations of fetal development and physiology were identified. In general, the purpose of these investigations was to obtain information on normal developmental processes, as a basis for detecting and understanding abnormal processes and ultimately treating the fetal patient. To this end, numerous experimental approaches were employed.

Studies of normal fetal growth relied primarily on anatomic studies of the dead fetus. Studies of fetal physiology involved both the fetus *in utero* and organs and tissues removed from the dead fetus. In some instances, this research required administration of a substance to the mother prior to an abortion or delivery by caesarean section, followed by analysis to detect the presence of the substance or its metabolic effects in blood from the umbilical cord or in tissues from the dead fetus. Information on the normal volume of amniotic fluid

at various stages of pregnancy was obtained by injecting a substance into the fluid and assessing the degree of dilution of that substance; these studies were performed before abortion, during management of disease states (Rh disease), and in normal term pregnancies. Similarly, numerous chemicals were measured in amniotic fluid to establish normal data.

Research also focused on the development of fetal behavior *in utero*. Fetal breathing movements were detected by ultrasound as early as 13 weeks after the conception. Fetal hearing was documented by demonstrating changes in fetal heart rate or EEG in response to sound transmitted through the mother's abdomen. Vision was inferred from changes in fetal heart rate in response to light shined transabdominally. Increased rates of fetal swallowing after injection of saccharin into amniotic fluid suggested the presence of fetal taste capability. Observation of the fetus outside the uterus indicated response to touch at 7 weeks and the presence of swallowing movements at 12 weeks of gestation.

2. Diagnosis of Fetal Disease or Abnormality. Well over 1000 papers have been published in the last 10 years dealing with intrauterine diagnosis of fetal disease or abnormality. Much of this research involved amniocentesis, a procedure in which a needle is inserted through the mother's abdomen into the uterus and amniotic fluid is removed for analysis. Amniocentesis originally came into extensive use for monitoring the status of the fetus affected by Rh disease in the third trimester of pregnancy. Research related to treating Rh disease indicated that the yellow color of the amniotic fluid correlated with the severity of anemia in the fetus. This color index was later used as an indication of the need for intrauterine transfusion, a procedure subsequently developed to treat severely affected infants.

The knowledge that amniocentesis was safe in the third trimester of pregnancy, coupled with the demonstration that cells shed from the skin of the fetus into the amniotic fluid could be grown in tissue culture, led to application of amniocentesis to detection of genetic disease *in* the second trimester. The research conducted in developing this procedure focused first on demonstrating in fetal cells from amniotic fluid the normal values for enzymes known to be defective in genetic disease. This research was conducted largely on amniotic fluid samples withdrawn as a routine part of the procedure of inducing abortion.

Once it had been demonstrated that the enzyme was expressed in fetal cells and normal values were known, application to diagnosis of the abnormal condition in the fetus at risk was undertaken. The reported research documents a steady progression in development and application of amniocentesis, so that potentially over 60 inborn errors of metabolism (such as Tay-Sachs disease) and virtually all chromosome abnormalities (such as Down's syndrome), as well as the lack of these defects in the fetus at risk, can be diagnosed *in utero,* at a time when the mother can elect therapeutic abortion of an affected fetus.

Research directed at prenatal diagnosis of disease currently focuses on three main objectives. The first involves attempts to extend diagnostic capability to additional diseases, such as cystic fibrosis of the pancreas, which cannot now be detected by amniocentesis. A second approach attempts to detect fetal cells in the maternal circulation and separate these from maternal cells for chemical analysis, thus avoiding any risks and difficulties encountered during amniocentesis. The third direction is the development of fetoscopy, a process by which an instrument is inserted into the uterus and a sample of fetal blood is obtained from the placenta under direct visualization. The blood sample is analyzed to diagnose disorders such as sickle cell disease or thalassemia which cannot be detected by amniocentesis. The time needed for laboratory analysis following fetoscopy is markedly shorter than the four to six weeks required to obtain tissue culture results in amniocentesis. Fetoscopy also permits visual examination of the fetus for external physical defects.

Because of the unknown but theoretically significant risks that remained following animal studies, fetoscopy was developed selectively in women undergoing elective abortion. The first clinical applications have been reported in recent months: three fetuses at risk for beta-thalassemia, whose mothers were seeking abortion to avoid the possibility of having an affected child, were diagnosed as free of disease following fetoscopy. All three have been born and are normal.

Research has also been directed at the identification of physical defects in the developing fetus. The most handicapping defects are those of the neural tube (anencephaly or meningomyelocele). Initial research efforts were devoted to developing X-ray techniques to view the fetus for these defects by injection of radiopaque substances into amniotic fluid (amniography or fetography). These studies primarily involved women having a family history of neural tube defects

and whose fetuses were consequently at increased risk. More recently, elevated levels of alpha-fetoprotein in amniotic fluid (or maternal blood) were found to be associated with neural tube defects, and may serve as a screening test for these disorders. Ultrasound has come into use to determine internal and external structural detail of the developing fetus and thereby to detect anencephaly, meningomyelocele, and even congenital heart disease.

Amniocentesis also opened another area of fetal research: the assessment of fetal lung maturity. Studies of normal amniotic fluid in the last trimester of pregnancy provided an indication that increased concentrations of lecithin relative to sphingomyelin reflect maturation of the fetal lung; infants with mature lungs did not develop respiratory distress. This predictive test (the L/S ratio) was applied when women went into premature labor, or when induced delivery was indicated due to Rh disease or maternal diabetes, to assess the risk that the delivered infant would develop respiratory distress. When the lungs were immature, delivery could be delayed, depending on the relative risks of intrauterine versus extrauterine life. In the last three years, attempts to induce fetal lung maturation by administration of corticosteroids to the mother have added a new dimension to this clinical situation. Following animal studies indicating that this procedure was safe and effective, human studies were undertaken intending to benefit the fetus involved. Results reported to date suggest that the procedure is successful, but studies of possible long-term side effects of this intrauterine therapy are continuing.

Assessment of fetal well-being is another goal of fetal research. Ultrasound has been used to assess fetal size and gestational age, and to monitor fetal respiratory movements, certain types of which have been found to indicate fetal distress. Studies of hormones, metabolic products and chemicals in amniotic fluid (and in maternal blood and urine) identified numerous substances associated with either abnormalities of fetal growth or with fetal distress. In the last decade, monitoring the fetal heart rate and sampling fetal scalp blood during labor developed from research techniques to clinical application for indication of fetal distress.

3. Fetal Pharmacology and Therapy. Over 400 publications in the last 10 years involving fetal pharmacology were identified in the literature search;

less than 20 percent of these included research on the living fetus. Of the latter studies, the majority were coincidental studies conducted as an adjunct to clinically accepted procedures. For example, the largest category encompassed studies of transplacental drug movement or effects on the fetus of analgesic or anesthetic agents given to the mother during labor and delivery.

The research techniques employed in investigations of this type included antepartum transfusion of the fetus with blood containing drugs, and administration of drugs or agents to the mother for therapeutic or research reasons. The ensuing studies involved assessment of effects on the fetal electrocardiogram, determination of fetal movements or structures by ultrasound, amniotic fluid sampling, scalp or umbilical cord blood sampling, and studying placental passage and fetal distribution patterns in tissues of the dead fetus. The studies were conducted either prior to abortion or in normal pregnancies, usually at the time of delivery.

In general, studies to determine the effects of a drug on the fetus were retrospective, involved the fetus incidentally or after death, or involved the infant, child or adult. Thus, all studies of the influence of oral contraceptives or other drugs on multiple births or congenital abnormalities were retrospective. study of the effects on the fetus of drugs administered to treat maternal illness during pregnancy (including anticonvulsants, antibiotics, hormones and psychopharmacologic agents) in which the fetus was an incidental participant, were also largely retrospective. Studies of effects on the fetus and newborn infant of analgesic and anesthetic agents given at delivery also involved the fetus incidentally, but were conducted prospectively. Recently attempts were made to focus prospective pharmacologic studies of antibiotics intentionally, rather than incidentally, on the fetus. Different antibiotics were administered to pregnant women before abortion to compare quantitative movement of these agents across the placenta, as well as absolute levels achieved in fetal tissues. The results served as a guideline for drug selection to treat intrauterine infections, particularly syphilis. Studies conducted on the dead fetus after abortion showed the clear superiority of one drug over the other.

In addition to assessing effects of drugs on the fetus and measuring placental transfer of drugs, fetal pharmacologic research included attempts to

modify drug structures so that they will or will not cross the placenta to affect the fetus. Such research also included study of the effects of certain drugs (such as phenobarbital or corticosteroids) in inducing enzyme activity *in* the fetus (to prevent hyperbilirubinemia or speed fetal lung maturation and prevent respiratory distress syndrome).

Effects on the fetus of live attenuated virus vaccines administered to the mother were also examined. Preliminary testing of rubella vaccine in monkeys indicated that the vaccine virus did not cross the placenta. In contrast, studies on women requesting therapeutic abortion showed clearly that the vaccine virus did indeed cross the placenta and infect the fetus, indicating the danger of administering the vaccine during pregnancy. Similarly, a study conducted with mumps vaccine virus showed that the virus infected the placenta, but not the fetus.

Attempts at fetal therapy *in utero, in* addition to blood transfusion for Rh disease and corticosteroid administration to speed fetal lung maturity, were conducted recently as an adjunct to amniocentesis. Examples of this type of fetal therapy include the administration of hydrocortisone to the fetus *in utero* to treat the adrenogenital syndrome, maternal dietary therapy for fetal galactosemia, and administration to the mother of large doses of vitamin B_{12} to treat fetal methylmalonic acidemia.

4. Research Involving the Nonviable Fetus. The quantity of research on the nonviable fetus *ex utero* has been small; much of such research included the nonviable fetus only at the extreme end of the spectrum of studies of premature infants. Such studies included measurements of amino acid levels in plasma of infants with intrauterine malnutrition, administration of bromide to measure total body water in low birth weight infants, and the study of hemoglobin in blood from the umbilical cord as an indicator of fetal maturity. The purpose of this research was to gain information that could be of benefit to other fetuses and infants.

Research was also conducted involving the nonviable fetus during abortion by hysterotomy but before the fetus and placenta were physically removed from the uterus. A study conducted in the United States reported the feasibility of delivering a portion of the umbilical cord from the uterus and using it as a site

for drug administration and blood sampling. Another study, this one undertaken in Finland, employed the technique to infuse noradrenaline via the umbilical vein; study of metabolites subsequently obtained demonstrated the functional maturity of the fetal sympathetic nervous system. Several studies in Sweden used similar techniques: radiolabeled chemicals were administered to the fetus via the umbilical vessels, and metabolites were then studied in the umbilical vein and, following completion of the abortion, in the fetus. In another Finnish study, arginine and insulin were injected into blood vessels of eight fetuses (450-600 grams) with the placenta attached to the uterus, and blood samples were taken from the umbilical cord to assess fetal endocrine regulation of glucose metabolism. These studies were conducted solely to gain information on fetal metabolism for the benefit of other fetuses and infants.

The nonviable fetus was the subject of research to develop a life-support system ("artificial placenta") for sustaining very small premature infants, as well as to obtain data on normal fetal physiology. Some of this life-support system research was conducted only with larger infants (viable by weight criteria) who had failed on respirators and were tried on experimental systems as an ultimate therapeutic effort to achieve survival. Of the published studies with clearly nonviable fetuses, one was conducted in the United States. Published in 1963, this research involved 15 fetuses, obtained following therapeutic abortion at 9-24 weeks gestational age. The fetuses were immersed in salt solution containing oxygen at extremely high pressure, in an attempt to provide oxygen for the fetus through the skin. The longest survival was 22 hours. In an earlier study in Scandinavia, seven fetuses weighing 200-375 grams, from both spontaneous and induced abortions, were perfused with oxygenated blood through the umbilical vessels. Longest survival was 12 hours. A third study, conducted in England, utilized a similar method and included eight fetuses obtained following hysterotomy abortion and weighing 300-980 grams. Longest survival was 5 hours. No other studies of this type involving nonviable fetuses were found in the literature review.

Studies of fetal physiology conducted on the delivered fetus utilized several experimental approaches. In a study conducted in Sweden, the intact fetal-placental unit obtained by hysterotomy abortion was removed and utilized for perfusion studies. A study performed in England involved cannulating the

carotid and umbilical arteries of the aborted fetus and measuring fetal glucose levels in response to administration of growth hormone. Four fetuses from hysterotomy abortions at 16-20 weeks gestation were perfused via the umbilical vessels in a study in Scotland which demonstrated that the fetus could synthesize estriol independent of the placenta. A similar study by the same investigators involving six fetuses demonstrated that the 16-20 week fetus could synthesize testosterone from progesterone. To learn whether the human fetal brain could metabolize ketone bodies as an alternative to glucose, brain metabolism was isolated in eight human fetuses (12-17 weeks gestation) after hysterotomy abortion by perfusing the head separated from the rest of the body. This study, conducted in Finland, demonstrated that the human fetus, like previously studied animal fetuses, could modify metabolic processes to utilize ketone bodies.

These studies of the nonviable fetus represent the total number reported in the world scientific literature, as well as could be ascertained from review of the most comprehensive bibliographic search ever undertaken of research involving the human fetus. The total number of citations involving fetal research was well in excess of 3000; the reports of research on the nonviable fetus that were found numbered less than 20. Certainly some reports of such research may have been missed even by this thorough review, but it is safe to conclude that the amount of research conducted on the nonviable fetus has been extremely limited. Of the principal investigators conducting this type of research, three were from the United States; two of these investigators conducted their research abroad. The only research conducted in the United States on the nonviable fetus *ex utero* was the study involving attempts to develop an artificial life-support system. The literature survey disclosed no reports of research conducted in the United States on the nonviable fetus intended solely to obtain information on normal physiologic function.

In summary, research involving the fetus includes a broad spectrum of studies of the fetus both inside and outside the uterus. The research may be as innocuous as observation, or involve mild manipulation such as weighing or measuring, or more extensive manipulation such as altering the environment, administering a drug or agent, or noninvasive monitoring. Diagnostic studies may involve sampling amniotic fluid, urine, blood, or spinal fluid, or performing

biopsies. The most extensive or invasive procedures include perfusion studies and other attempts to maintain function.

The extent of research on the fetus is reflected by the more than 3000 citations included in the literature review of such research. Most involved the fetus *in utero;* less than 20 articles involved the nonviable fetus.

The purposes for which research on the fetus has been undertaken include obtaining knowledge of normal fetal growth and development as a basis for understanding the abnormal; diagnosing fetal disease or abnormality; studying fetal pharmacology and the effects of chemical and other agents on the fetus, in order to develop fetal therapy; and developing techniques to save the lives of ever smaller premature infants.

Appendix I

III.

ALTERNATIVE MEANS FOR ACHIEVING THE PURPOSES FOR WHICH RESEARCH INVOLVING LIVING FETUSES HAS BEEN UNDERTAKEN

In the development of new medical procedures or drugs to be employed in the treatment of humans, research is usually initiated with animal models, which are used until probable effectiveness and low degree of risk are determined. Ultimately, it becomes necessary to conduct the research on humans, since initial human applications are experimental regardless of the amount of preceding animal research. In some instances, pertinent animal models may not exist or may have certain limitations, so that studies on humans begin at a relatively early stage. In all instances, however, the question may be asked whether studies on humans began at an appropriate time, or whether the information that was required could have been obtained using alternative research means, i.e., studies on animal models.

The broad nature of the survey of the nature and extent of research on the fetus (Section II) did not permit detailed evaluation of alternative means. Therefore, the Commission contracted with Battelle-Columbus Laboratories to conduct a more intensive analysis of this issue in connection with four advances in which research on the fetus played a part. The Battelle report to the Commission traces the historical development of (1) rubella vaccine, (2) the use of amniocentesis for prenatal diagnosis of genetic defects, (3) the diagnosis and treatment, as well as prevention, of Rh isoimmunization disease, and (4) the management of respiratory distress syndrome. The study identifies pertinent animal research that was conducted and attempts to assess whether the human research was necessary and appropriate, or whether animal models could have been substituted. Finally, the study evaluates the likelihood that the advance would have been achieved if all research on the fetus, both therapeutic and nontherapeutic, had been prohibited. In preparing the report and analysis, extensive bibliographies on each topic, prepared by staff of the National Library of Medicine, were utilized. In addition, a number of scientists whose research had been of greatest importance to the advances were interviewed.

Appendix I

1. In the case of congenital rubella syndrome, descriptions of the condition (which comprises congenital heart disease, cataracts, deafness and mental retardation) and its etiology (maternal rubella infection during pregnancy) were drawn from research on the living child and material from dead fetuses. Attenuation of the rubella virus for vaccine purposes was accomplished in tissue culture using nonhuman cells. Vaccine trials were conducted on adults and children. The vaccine was found safe and effective, and it was licensed in 1969, 28 years after the congenital rubella syndrome was first described.

No research on the living human fetus was required to develop the vaccine. A question remained, however, as to the safety of administering the vaccine during pregnancy or to women in the child-bearing years. Should a pregnant woman, without immunity to rubella, be vaccinated to prevent the risk to the fetus that would ensue if she contracted natural rubella? Some experimental animal models for the rubella condition had been developed, the rhesus monkey being the closest one to the human. Accordingly, pregnant monkeys were inoculated with either rubella virus or the vaccine virus. Subsequent study showed that five of six monkey fetuses whose mothers received slightly attenuated rubella virus were infected, but none of the six monkey fetuses whose mothers received vaccine virus was infected. Thus, the animal model suggested that the vaccine virus did not cross the placenta and was safe to administer during pregnancy, although other vaccine viruses were known to cross the human placenta.

Human studies were then undertaken. Because of the potential risk to the fetus, women requesting therapeutic abortion were employed as subjects. These volunteers received the vaccine and underwent the abortion 11 to 30 days later. Examination of tissues from the dead aborted fetuses showed that, in contrast to the results in monkeys, the vaccine virus did cross the human placenta and infect the fetus. On the basis of this research involving the fetus in anticipation of abortion, as well as subsequent reports of damage to the fetus following accidental rubella vaccination during pregnancy, administration of rubella vaccine to pregnant women or women who might become pregnant within 60 days of vaccination is proscribed.

Two alternatives to the planned testing of rubella vaccine on pregnant women in anticipation of abortion can be considered. First, more extensive animal testing of the vaccine could have been conducted. The usefulness of such a

procedure, however, would be questionable. Based on prior experience with the inconsistencies of placental passage of any agent, the human situation would remain unknown after any amount of animal testing. Testing in the human is still required even after negative results in animal models, with the same safeguards as if no animal testing had been conducted.

The second alternative would be to wait for the accidental vaccination of pregnant women and observe the outcome. This in fact occurred in several instances after the planned testing. The women involved, who had wanted pregnancies, elected instead to terminate their pregnancies by abortion due to the risk to the fetus, and studies of tissue from the dead fetuses confirmed that they had been infected by the virus. Thus, the effect in humans could have been learned in this instance by retrospective research. At issue here in the selection of alternatives is the question whether it is preferable to proceed by design with women planning abortions, or to work retrospectively with women who desire pregnancy but were accidentally vaccinated.

2. The use of amniocentesis (removal of amniotic fluid via a needle inserted into the uterus through the mother's abdomen) as a clinical procedure dates from 1882, when it was introduced as a treatment for polyhydramnios (excess accumulation of amniotic fluid). There is no evidence that animal studies were conducted prior to that time, and comparatively little research has been done on amniocentesis as a procedure apart from its applications. The Battelle study of amniocentesis thus involved evaluation of the uses to which the procedure has been put, as well as alternative means for developing the procedure. Amniocentesis has found application in three main areas of research: prenatal diagnosis of genetic disease, diagnosis of Rh disease, and assessment of fetal maturity related to respiratory distress syndrome. Its use in the latter two areas will be discussed in parts 3 and 4 of this section.

Two lines of research provided impetus for prenatal diagnosis of genetic disease: development of the technology for tissue culture and identification of the sex chromatin as an indicator of sex in single cells. In 1955 it was shown that fetal sex could be predicted from the sex chromatin pattern of amniotic fluid cells. Application of this technique to prenatal detection of sex-linked disorders was first reported in 1960. Rapid progress in tissue culture research

led to success in culturing fetal amniotic fluid cells in 1966, intrauterine diagnosis of a chromosome abnormality in 1967, and the first intrauterine diagnosis of metabolic disorders using cultured amniotic fluid cells in the following year. Research in this area steadily expanded as chromosomal and metabolic disorders were added to the list of conditions diagnosable *in utero*. At present, virtually any chromosomal anomaly and potentially over 60 metabolic disorders can be detected prenatally by amniocentesis. The possibility of diagnosis and selective abortion of abnormal fetuses has enabled the birth of normal children to families that otherwise would not have risked pregnancy, and has permitted families to avoid the impact of the birth of a defective or doomed child.

All research to detect genetic defects involved the living human fetus. Much of it utilized amniotic fluid obtained in the normal course of abortion, in order to ascertain normal values. Such research was obviously nonbeneficial for the fetuses involved. Only research conducted on women at risk for having a fetus with the disorder in question could be considered beneficial, in that many of these women desired an abortion unless it could be shown that the fetus would be normal.

An alternative means to develop the procedure of amniocentesis would have been to conduct more extensive animal research. Animal models have numerous limitations with regard to amniocentesis, however, including shape of the pelvis, size and shape of the uterus, number of fetuses present (which confounds cell analysis), and the marked irritability of the uterus in many species such that even slight manipulation induces abortion, fetal resorption or congenital malformations. Recently some animals have been found in which amniocentesis can be performed, but even in these it is difficult in midpregnancy, when it must be done for effective intrauterine diagnosis of genetic defects.

While animal models might have been utilized more extensively in developing the technique of amniocentesis, there is no alternative to human experimentation for the purpose of developing the diagnostic tests for genetic metabolic disorders used with amniocentesis. The conditions are unique to the human species. Only by study of cells in amniotic fluid from pregnant humans, both normal and those at risk for genetic disease in the fetus, was it possible to assess whether the genetic defect was expressed in these cells, and to determine the normal and

abnormal values for the responsible enzymes in the cells as the basis for prenatal diagnosis. This research utilized only amniotic fluid and the fetal cells in it, and thus was not invasive of the fetus. In the early stages of developing the technique, however, the possible risks to the fetus were greater than those for many invasive procedures.

3. The history of Rh isoimmunization disease encompasses the description of the disorder, determination of its cause, initiation of successful treatment, and development of effective prevention, all within four decades. Characterization of this disorder, which combines hemolytic anemia, jaundice, and intrauterine death or (if delivered) severe brain damage, was accomplished in the 1930's from study of autopsy material and newborn infants. Research on blood groups, utilizing both human and animal material, led in 1941 to the demonstration from studies of mothers and newborns that Rh sensitization in an Rh negative mother to an Rh positive fetus produced hemolytic anemia in the fetus. In 1945, treatment of affected newborn infants by exchange transfusion was initiated and mortality began to decline.

Use of amniocentesis was introduced in 1956 to obtain amniotic fluid which provided an indicator of how severely the fetus was affected and, late in pregnancy, whether labor should be induced to enable treatment of the fetus outside the uterus. In 1963, treatment of the severely affected fetus by intrauterine blood transfusion was initiated, resulting in a 60 percent reduction of the stillbirth rate for affected infants. Ongoing studies of the etiology of the disease, using pregnant women, provided indications that sensitization of the mother usually occurred at the time of delivery of her first Rh positive infant, when a large volume of fetal Rh positive cells entered the mother's circulation. As the result of research conducted largely with prisoners, a vaccine was developed to prevent this sensitization. Trials of the vaccine, administered to women after delivery, began in 1964. Results indicated virtually complete effectiveness, and the vaccine (RhoGam) became commercially available in 1968.

Research on the fetus played no part in developing the RhoGam vaccine, but such research was essential in demonstrating the basic cause of the disease and in developing methods for prenatal diagnosis and treatment. All significant research on the fetus related to Rh disease was conducted on mothers and fetuses

at risk for the disease, and can be categorized as beneficial research. The size of the benefits achieved may be appreciated by reviewing statistics related to the disorder. Approximately 12 percent of couples in the United States are at risk for having an affected infant. Nearly 25,000 infants could be affected yearly. Since initiation of exchange transfusion, neonatal mortality of affected infants has dropped to about 2.5 percent. Intrauterine transfusion has reduced the annual number of stillbirths due to the disease from 10,000 to less than half that number. The entire amount of money used to support Rh disease research from 1930 through the successful development of the vaccine in 1966 is the equivalent of the present cost to society for lifetime care of six children irreparably brain damaged by the disease.

Limited animal models were available for study of Rh disease and were utilized in some instances. Intrauterine transfusion, for example, was first conducted on animals. Extensive research has been conducted to develop an animal model of the actual disease, but the hamadryas baboon is the only species that has been found in which the disease is sufficiently similar to the condition in man for the animal to serve as a useful model. The limitations of animal models and the urgency of developing a treatment for fetuses otherwise likely to die led physician researchers to attempt experimental therapy with favorable risk/benefit ratio in human subjects. In these instances, the risk of not doing the research was approximately 50 percent intrauterine death; in the face of such odds, even such a hazardous experimental therapeutic procedure as intrauterine transfusion was considered acceptable.

4. Respiratory distress syndrome (RDS) is a major cause of infant mortality. In the United States approximately 40,000 cases occur annually; 95 percent of these cases are premature infants, and overall mortality is in excess of 25 percent. Study of the development of advances related to this condition revealed a picture of frequent interaction of animal model and clinical studies involving the living human fetus in the third trimester. In addition, advances in therapy were achieved from research involving affected premature infants.

The key experimental work elucidating the basic cause of the condition involved study of the lungs of deceased infants who died of RDS or other causes. This research indicated that lungs of infants with RDS lacked a chemical

(surfactant) which acted to keep open the smallest air passages in the lung; surfactant was present in the lungs of unaffected infants. Subsequent studies, again relying primarily on autopsy material, delineated the biochemistry of surfactant, and it was suggested that amniotic fluid might provide an indicator of the presence of surfactant. Studies were then conducted of amniotic fluid obtained at various stages in the last trimester of pregnancy, solely to learn the normal values of the phospholipid components of surfactant; this research was nonbeneficial for the fetuses involved. Results indicated that a marked increase in the content of lecithin relative to sphingomyelin in amniotic fluid correlated with the appearance of surfactant in the fetal lung, and indicated that the lungs were mature enough that the fetus, if delivered, would probably not develop RDS. The report of these studies in 1971 strongly influenced obstetric management of premature labor and diabetic pregnancy, by providing an index of the time when delivery could proceed with minimum risk of RDS.

Another line of research quickly had an impact on RDS management. Animal studies in the 1950's showed that steroids were capable of inducing enzyme activity in the fetus. Studies involving the pregnant woman and the living fetus in 1961 demonstrated that cortisone crossed the human placenta. Animal studies in the late 1960's and early 1970's indicated that corticosteroids could induce enzymes and thereby increase surfactant in fetal lungs. In the species studied (lambs, rabbits and rats) the steroids did not cross the placenta and had to be administered directly to the fetus. Based on the previous demonstration that steroids crossed the human placenta, and later clinical studies of mothers receiving steroid therapy during pregnancy that had not suggested any ill effects on the fetus, clinical trials were initiated in pregnant women at risk of having infants affected by RDS. The results obtained to date indicate that corticosteroids are highly effective in preventing RDS, without undesirable side effects. Although the treatment remains experimental, it holds promise for markedly reducing the incidence of RDS.

The interplay between animal and human studies was essential in achieving the advances in clinical management and prevention of RDS. Relevant animal models were used when available, and although no extensive search for an animal model was evident before the human steroid trials, the research appeared to be a logical and carefully planned step undertaken to provide therapy for a condition of high risk to the fetuses treated.

Appendix I

The following conclusions are drawn from the Battelle study:

A. Animal models were utilized extensively, but adequate and appropriate models were not always available when they were needed. In some instances little or no-animal research preceded human studies. In other instances intensive searches for animal models were undertaken (as in Rh disease), but investigators appear to have been reluctant to postpone therapeutic research until an animal model was found.

B. Investigators generally proceeded to clinical trials characterized by very high ratios of benefit to risk.

C. A total ban on all research on the fetus, or postponement of such research until more appropriate and exact animal models were sought and studied, would probably have significantly delayed or halted indefinitely the progress in three of the four areas that were analyzed. Only development of the rubella vaccine could have progressed unimpeded.

A more limited ban would have had less effect, depending on the nature and scope of the prohibitions imposed. For example, a ban only on nontherapeutic research on the fetus would not have affected research on Rh disease, but would have sharply curtailed research with amniocentesis, due to the resulting inability to determine normal values for abnormal enzymes in metabolic disorders. The research which developed L/S ratios, used in RDS diagnosis, might have been possible making use of fluid obtained during caesarean sections or in Rh disease studies. A selective ban on research before or after induced abortion would clearly have permitted the L/S ratio research for RDS diagnosis, but could still have severely curtailed development of amniocentesis for prenatal diagnosis by making ascertainment of normal values extremely difficult. A ban on invasive research on the fetus would have permitted development of amniocentesis, although the risks to the fetus from this noninvasive procedure were potentially greater than those from many invasive procedures.

IV.

LEGAL ISSUES

Papers on the legal issues involved in research on the fetus were prepared for the commission by Professor Alexander M. Capron, University of Pennsylvania Law School, and Assistant Dean John P. Wilson, Boston University School of Law. Both papers are structured, at least in part, according to categories of research, that is, whether the research is therapeutic or nontherapeutic, whether the fetal subject is viable, nonviable or dead, and whether it is inside or outside the uterus. The interests of the fetus at different stages of development are balanced against the interests of other parties, and the protection of fetal interests is addressed in discussion of appropriate consent requirements. A summary of both papers follows.

The Dead Fetus. The Uniform Anatomical Gift Act (UAGA), which has been adopted in all fifty states and the District of Columbia, permits research on the dead fetus and the products of conception, provided consent has been given by either parent and the other parent has not objected. Professor Capron states that the UAGA should be read in the context of common law requirements on consent; thus, the authorization should be "informed" and "voluntary." In the latter regard, consent should not unnecessarily be sought immediately before or after an abortion. Dean Wilson suggests that it is wise to require the consent of both parents.

Aside from the UAGA, Professor Capron points out that the statutes of five states presently impose varying degrees of restriction on research on the dead fetus (Massachusetts, South Dakota, Illinois, Indiana, and Ohio); all of these restrictions apply only to the products of induced and not spontaneous abortions. Other laws that might affect research on the dead fetus are the grave robbing statutes, which would apply only when the consent required by the UAGA has not been obtained. As a matter of medical practice, however, maternal consent is not generally sought for postabortion examinations. (Both authors note and discuss a pending Massachusetts case.)

Professor Capron states that the various state laws on death certification provide little guidance on the question of defining death with respect to the fetus. Such laws do, however, introduce another complication by recognizing different categories requiring certification. (Other reports prepared for the Commission suggest medical criteria for determining fetal death; see Section VII of this report.)

The Viable Infant. Research on the viable infant is discussed at length by Professor Capron. He states that therapeutic research on a viable infant, whether or not there has been an induced abortion, is generally sanctioned under criminal and civil law. The law is presently unsettled with respect to nontherapeutic research, and, as a practical matter, the exercise of caution in introducing any risk is indicated. The recently enacted fetal research statutes have probably not altered the common law with respect to research on the viable infant after induced abortion, i.e., therapeutic research may be conducted. In the absence of a special statute, the protection afforded the viable infant attaches only after it is in fact *ex utero*.

Although the interests of the viable infant do not depend on the manner in which it came to be alive *ex utero*, Professor Capron points out that this might be relevant to the issue of appropriate consent to involvement of the infant in research. The question is whether the decision to abort should disqualify the parents (or at least the mother) from exercising further control after the infant is alive *ex utero*. The argument for disqualification has an obvious rationale in conflict of interest, but it faces at least three problems: (1) Since the Supreme Court has declared in Roe v. Wade that women have a constitutional right to abortion, basing maternal disqualification on the exercise of that right may be an unconstitutional penalty. (2) Since the abortion itself is legal, the fetus is not thereby deprived of any rights which the parents were obliged to protect. (3) The decision to abort does not necessarily cast the woman as being irrevocably opposed to the rights of the fetus, since the mother's decision was based on the erroneous assumption that there would be no live issue from the pregnancy. Professor Capron suggests that rather than presumptive disqualification in all cases, judicial proceedings may be an appropriate forum for balancing the rights of all concerned, and that it would be preferable to presume that

parents retain control over a viable infant. Certain states, however, have written into their abortion statutes some form of parental forfeiture of rights (Louisiana, Missouri, Montana, Kentucky, Indiana, South Dakota).

Dean Wilson suggests that, at least with respect to therapeutic research, the power of consent should not be removed from a mother and father because they are minors. Also, he expresses the belief that only therapeutic research should be conducted on the viable infant.

The Fetus *In Utero*. Although the fetus does not achieve the interests of a full person until live birth, it is not entirely without protection while still *in utero*. Professor Capron points out that the criminal law in various states, with expansions under civil law, recognizes interests of the fetus *in utero* in two ways of possible relevance to research. First, there are some recent statutes seeking to safeguard the fetus *in utero* against life-threatening intentional injury, and some older statutes that depart from the common law by prohibiting "feticide." It is unlikely that the older statutes would apply to research on the fetus, since the element of intent to do harm would be missing. All of these statutes must, of course, be examined in the light of Roe v. Wade.

Second, interests of the fetus *in utero* are recognized in the criminal law by protecting the fetus against injuries which cause its death or impairment after it is born alive. The effect of such protection is to put pressure on those involved to assure that the abortion is "effective." Thus, Professor Capron suggests, the law may be recognizing, not fetal interests, but the interests of human beings, after birth, not to suffer because of culpable acts of other persons.

In some jurisdictions, Professor Capron finds that the civil law recognizes a broader fetal interest in protection against harm *in utero*. The courts in at least 21 states have recognized a cause of action for injuries to a viable fetus that lead to its stillbirth. Once the fetus is viable, Professor Capron states, the decision in Roe v. Wade does not appear to be an absolute bar to holding that the fetus and its parents have an interest in its potentiality for life.

If the fetus is in fact born alive, the protection under civil law is even broader, with no importance being attached to the question whether the injury

that causes impairment or subsequent death occurred before or after viability. (Professor Capron expresses his disagreement with the argument that subsequent live birth is not a necessary element in court decisions regarding the vesting of property interests.)

Finally, if the fetus is both injured and dies before it is viable, recovery for its wrongful death has not been allowed under civil law.

Dean Wilson expresses the opinion that there should be no difference in the rights accorded to the fetus *in* utero before or after viability, and only therapeutic research or nontherapeutic research that imposes no risk should be permitted in both cases. He would apply the same conditions to research in anticipation of abortion. As grounds for protecting the fetus *in utero* before viability, he suggests that research on such a fetus might have a brutalizing effect on society as a whole.

With respect to the question of consent to research on the fetus *in utero*, Professor Capron holds that if the fetus is viable, it is in approximately the same position as a viable infant, i.e., consent by the parents to therapeutic research would be appropriate, but nontherapeutic research that introduces genuine risk should not be undertaken at all. If the fetus is not yet viable, Professor Capron discerns two difficult consent issues: (1) Should there be a separate consent, in addition to that of the mother, when the research is directed at the fetus? A possible answer is that the mother's right of decision to destroy the fetus, recognized by Roe v. Wade, includes a right to permit the fetus to be used in research that is less harmful than total destruction and is done for legitimate scientific reasons. (2) Can the consent of the mother to participate in (nontherapeutic) research directed at the fetus be tied to an agreement to abort? Without such an agreement, parties such as the father and state welfare officials may have grounds to insist that their interests in the potential child be protected. On the other hand, an agreement to abort would probably be unenforceable.

Professor Capron sees no clear answer to the question of appropriate consent to research on the fetus *in utero* before viability. He suggests a partial solution along the lines of the Massachusetts fetal research statute, which provides that research may take place when the fetus is not the subject of a planned

abortion and that a statement, signed by the woman, that she is not planning an abortion supplies conclusive evidence on the point. Such an arrangement would not be immune from attack in light of the Roe v. Wade decision, but it would raise fewer questions, Professor Capron states, if it were a condition of government funding.

In accordance with his views concerning permissible research on the fetus *in utero,* Dean Wilson expresses the belief that the woman should be permitted to consent only to therapeutic research and nontherapeutic research that imposes no risk.

The Nonviable Fetus *Ex Utero*. Professor Capron notes that the law generally does not distinguish between viability and nonviability after birth. Full protection as a person is given, notwithstanding that immaturity may preclude the nonviable fetus from having an independent existence. Professor Capron suggests that legislative consideration of the concept of viability as currently understood might lead to distinctions being made on that basis.

With respect to consent, Professor Capron states that the same rules would apply for therapeutic research on the viable fetus as for such research on the viable infant. For nontherapeutic research on the nonviable fetus, he suggests that judicial review might be appropriate.

Appendix I

V.

ETHICAL ISSUES

Eight ethicists and philosophers prepared for the Commission papers outlining their views on research on the fetus. Summaries of each of these papers follows:

Sissela Bok, Ph.D.

Dr. Bok identifies two lines of argument opposed to research on the fetus: (1) the fetus is a person and, consequently, research without its consent and not for its benefit is an assault upon its humanity; and (2) research on the fetus will lead society to condone research on other categories of the defenseless. Dr. Bok answers these arguments and concludes that, in order to seek knowledge not otherwise obtainable, research should be permitted at early gestational stages, provided careful safeguards are utilized.

The first argument is countered by a presentation and discussion of four reasons for protecting humans from harm: (1) the victim's anguish, suffering and deprivation of continued experience of life; (2) the brutalization of the agent; (3) the grief of those who care about the victim; and (4) the establishment of a pattern that ultimately will harm all of society. Dr. Bok contends that none of these reasons apply in the early stages of gestational life.

The second argument against research on the fetus advances the last reason for protecting humans from harm as crucial even with respect to research in the first weeks of gestational life. Dr. Bok asserts that no data have been developed to support the applicability of the fourth reason to research on the fetus, and that, in any case, safeguards can be developed to prevent the alleged sequential abuses.

Since the fetus is not a person, consent on its behalf is unnecessary. However, maternal consent should be obtained, even for research following abortion, in deference to the woman's sensitivities.

Dr. Bok concludes that since the means are defensible and the end is desirable, research on the fetus should be permitted during the first 18 weeks of gestational age and when the fetus is under 300 grams in weight. These limits provide a margin of safety to prevent accidental experimentation on a viable fetus. Only therapeutic research on a fetus older than 18 weeks or more than 300 grams in weight should be permitted.

Dr. Bok would permit research on a fetus scheduled for abortion, provided the mother consents and the research is properly reviewed. She would not prohibit experimentation which keeps a nonviable fetus alive for a period of time or which hastens its death.

Joseph Fletcher, D.D.

"Rightness and wrongness are judged according to results, not according to asolute prohibitions or requirements." This statement provides a key to understanding the position taken by Dr. Fletcher regarding the ethics of research on the fetus. The result which justifies such research is the safety of people, especially children, from genetic and congenital disorders, uterine infections and a host of other maladies.

Dr. Fletcher states that the core question is whether the fetus is a person. He contends that although the fetus is a potential person, it does not become an actual person, ethically and legally, until it is born alive and lives entirely outside the mother's body with an independent cardiovascular system. Until the fetus becomes an "actual person" it is an "object," a nonpersonal organism which has value only insofar as it is wanted by its progenitors. It is not entitled to protection as a human subject whether viable or not until it becomes a live-born baby.

Dr. Fletcher states that the following categories of research on the fetus may be justified, depending upon the clinical situation and the design: (1) use of a dead fetus *ex utero* with or without maternal consent; (2) use of a live fetus *ex utero,* nonviable or viable, if survival is not wanted and there is maternal consent; (3) use of a live fetus *in utero* if survival is not wanted and there is maternal consent; and (4) use of a live fetus *in utero,* even if survival is intended, if there is no substantial risk to the fetus and if there is maternal and paternal-spouse consent.

Finally, Dr. Fletcher concludes that regulations by the Executive Branch and legislation by Congress (even though temporary) restricting research on the fetus are unethical if the ethics they are based upon are not fully and frankly disclosed.

Marc Lappé, Ph.D.

Dr. Lappé's essay is developed from a "natural law" perspective. It defends five principles pertaining to research on the fetus and makes five policy recommendations to the Commission.

(1) The wanted fetus has a right to protection *in utero*. This principle is based on its unique vulnerability to environmental insult which might interfere with the fulfillment of its genetic potential.

(2) Principle (1) is not altered by societal acceptance of abortion. The Supreme Court has allowed a woman to decide that a fetus will no longer receive her protection; it does not follow that others in society are similarly authorized. Further, living fetuses *ex utero* have claims on our duties to afford them protection from experimentation by virtue of our basic medical tenets to preserve life. The Supreme Court offered no guidance on how to treat the fetus once out of the womb.

(3) The conditions under which society respects the fetus' right to protection are compromised by the decision and actions taken in the course of an abortion. Moral concern for the fetus dictates a choice of procedures which subject the woman to minimal morbidity risks while expeditiously expelling the fetus and rendering it incapable of survival.

(4) The costs of research on the fetus should be balanced by resultant goods. Society should make efforts to endow the abortion process with values it would not otherwise have had. Abortion-related research is therefore justified if and only if it is intended to aid other fetuses.

(5) The definition of fetal death and the application of the definition must be made independently from any possible future use of the fetus in experimentation.

Dr. Lappé notes that the problem of consent gives us most difficulty in that even if the fetus were accorded full rights of personhood, it would not do to delegate the parent as proxy since (in the case of abortion) the parent cannot be said to have the interests of the fetus at heart. He offers no solution to the problem, however, except to observe that were the fetus regarded as worthy of all the rights of personhood, we would not sanction nontherapeutic research at all.

Dr. Lappé recommends that the Commission (1) affirm its commitment to protect fetuses *in utero;* (2) provide a statement of concern for abortion-related abuse or neglect, including maternal exposure to harmful agents and insensitive or unethical choice of abortifacients; (3) limit research on the fetus *in utero* which is to be a subject of abortion to cases where no risk to the fetus is involved and the purpose of the research is to aid fetuses as a class; (4) restrict basic nonviable fetal research intended to benefit society generally to dead fetuses; and (5) require that fetal death be ascertained by criteria which separate the purposes of experimentation from the choice of abortion method and from the methodology used to ascertain that death has occurred.

Richard A. McCormick, S.J.

Dr. McCormick defends a moral position concerning research on the fetus and distinguishes it from an acceptable public policy concerning such research. Public policy is to be determined, not only by morality, but by feasibility as well. The feasibility test is particularly difficult in a society characterized by moral pluralism and cultural pragmatism.

Dr. McCormick holds that parents may give proxy or vicarious consent for a child to participate in nontherapeutic experimentation where there is "no discernible risk or undue discomfort." Proxy consent is morally legitimate insofar as it is a reasonable construction of what the child ought to choose if it were able. This position is rooted in the premise that all humans, including children, have an obligation in social justice to contribute to the benefit of the human community. The same obligation can be extended to the fetus. Research on the fetus is morally permissible if maternal proxy consent is obtained, abortion is not contemplated, the risk or discomfort to the fetus is not discernible, and the results of the experiment cannot be obtained in any other way. Because

Dr. McCormick judges most abortions to be immoral, experimental procedures prior to, during, and after abortion (except in the rare instances of legitimate abortion) are morally objectionable because they cooperate with and profit from an immoral system. While Dr. McCormick regards such cooperation as morally objectionable, he believes that his moral position cannot be fully adopted as public policy, since it cannot pass the feasibility test in a society which allows large-scale abortions.

Dr. McCormick recommends that the measure of proxy consent regarded as valid for subjects of research who are children is suitable to determine acceptable research on the fetus. He makes the following policy proposals which acknowledge both the moral pluralism and the cultural pragmatism characteristic of American society: (1) the research must be necessary; (2) the researcher bears the onus of showing the necessity; (3) there must be no discernible risk for the fetus or the mother or, if the fetus is dying, there must be no added pain or discomfort; (4) the researcher bears the onus of showing that there is no discernible risk; (5) these policy demands must be secured by adequate review and prior approval of all research on the fetus.

Paul Ramsey, Ph.D.

Dr. Ramsey seeks to distinguish between fetal life and fetal viability. Life, he suggests, should be defined for the fetus according to the presence or absence of vital signs which define life and death in other individuals. Viability should not be confused with life, for a fetus may be living yet nonviable. This new human research subject, one which is neither dead nor viable, is the subject of Dr. Ramsey's essay. He is not willing to say it may be entered into research protocols, but he does say that care should be taken not to enter a viable infant by mistake. To this end he recommends that viability be defined for research purposes on the safe side of possibly viable birth weight, crown-rump length or gestational age. He makes the following proposals to the Commission:

(1) The Peel Report prohibits procedures carried out with the deliberate intent of ascertaining the harm they might do to the fetus. Such a prohibition should be included in the American policy as well. "Do not harm"

encompasses "intend no harm." This principle embraces the intention of the physician and not merely "codes of action."

(2) The subjective rule (Peel) must be supplemented by an objective limitation of risks by categorically prohibiting research in anticipation of abortion if that research entails known or uncertain risks.

(3) Respect for the dignity of human life must not be compromised whatever the age, circumstances, or expectation of life of the individual. The recent Supreme Court decision on abortion did not nullify the obligation to protect the developing fetus from harm, even if that harm is less than abortion.

(4) Vital functions of an individual abortus should not be artificially maintained except where the purpose of the activity is to develop new methods for enabling that abortus to survive to the point of viability.

(5) Ethical standards applicable to research on the fetus are the same as would be subscribed to in proposed research on the unconscious, on the dying (in the case of spontaneous abortion), on the (perhaps justly) condemned (in cases of induced abortion), or in experimentation with children.

For the most part, this means that the use of these subjects in nontherapeutic research is an abuse, for one ought not to "presume" or "construe" consent for acts of charity. Dr. Ramsey agrees with Dr. McCormick that "one stops and should stop precisely at the point where 'construed' consent does indeed involve self-sacrifice or works of mercy. The dividing line is reached when experiments involve discernible risk, undue discomfort, or inconvenience."

Seymour Siegel, D.H.L.

Dr. Siegel makes the following points:

(1) A bias for life is the foundation of the Judeo-Christian world view and it undergirds medical research. It may be affirmed outside the Judeo-Christian tradition. The bias for life requires individuals to strive to sustain life where it exists, not to terminate or harm life, and in cases of doubt to be on the side of life. A present individual takes precedence over a possible future individual. The bias for life is to be exercised whatever the status of the life before us and whatever the life expectation may be.

(2) The indeterminancy of the future requires that utmost caution should be employed in all decisions relating to research on the fetus, since neither the medical nor the social effects of such research can be predicted with certainty.

(3) The fetus is not the same as an infant since it has no independent life system and is tied to the mother.

(4) A fetus has real but limited rights, derived from its potential human life. The fetus' right to life is mitigated when the fetus threatens someone else's life; however, unless such a threat is present, the fetus' potential humanity requires that we protect and revere its life.

(5) The fetus *in utero* may be the subject of research that (a) helps the mother, (b) is harmless to the fetus, or (c) is designed to help the fetus. Dr. Siegel endorses the Peel Commission dictum that no procedures may be carried out to see what harm they might do the fetus.

(6) The fetus *ex utero* has more rights than the fetus *in utero*. Prolongation or early termination of the nonviable fetus should be prohibited.

(7) Criteria for death of the fetus should be the same as for other individuals.

(8) Consent of the mother or guardian is ordinarily sufficient, but parental consent, when an abortion is contemplated, is dubious. For such cases, consent should be supplemented by a special board. There must be strict separation of attending physician and researcher.

(9) Proposed guidelines: (a) fetal research should be limited to cases which present no harm or offer assistance to the life system of the subjects; (b) no procedures should be permitted which are likely to harm the fetus--before, during, or after abortion; (c) a fetus *ex utero* and alive should not be subject to research unless it is intended to enhance the life of that fetus or unless the research involves no risk to the subject; and (d) criteria for determining death of the fetus should be the same as for other human individuals.

Appendix I

LeRoy Walters, Ph.D.

Dr. Walters surveys various ways of categorizing research on the fetus: (1) according to the condition of the fetus, (2) according to the chronological age of the fetus, and (3) according to the formal object of the research.

He concludes that research on the fetus is not one but many things, and he focuses on nontherapeutic research on the fetus because it seems to raise serious public policy questions, and on research before, during and after induced abortion since that is a primary concern of the Commission's authorizing legislation. Four possible positions can be developed with respect to such research. Dr. Walters defends the position that nontherapeutic research on the fetus should be permitted only to the extent that such research is permitted on children or on fetuses which will be carried to term.

The essay endorses McCormick's thesis that parents may properly consent to a child's participation in nontherapeutic research which the child should be willing to take part in if the child were able to consent. This position is extended to cover the prenatal period as well. Because of difficulties associated with consent in cases where an abortion decision has been made, nontherapeutic research procedures should be permissible in the case of fetuses before or after abortion to the extent that they are permissible in the case of fetuses which will be brought to term. This position supposes that there is substantial continuity between previable and viable fetal life and postnatal life.

Although public policy making includes an ethical component, it also includes other factors, such as continuity with generally accepted societal principles, accommodation of a variety of belief systems and interests, and clearly understandable formulation. Three public policy propositions are recommended, all of which are based upon a policy of equality of treatment for all categories of human subjects: (1) nontherapeutic research on children should be permitted, if such research involves no risk or only minimal risk to subjects; (2) nontherapeutic research on fetuses which will be carried to term should be permitted, if such research involves no risk or minimal risk to the subjects; (3) nontherapeutic research procedures which are permitted in the case of fetuses which will be carried to term should also be permitted in the case of (a) live fetuses which will be aborted and (b) live fetuses which have been aborted.

Richard Wasserstrom, Ph.D.

Dr. Wasserstrom identifies four views concerning the status of the human fetus. He endorses the view that the fetus is in a unique moral category, closest to that of a newborn infant. The fetus has great value because of its potential to become a fully developed human being. It follows that abortion is morally worrisome because it involves destruction of an entity that possesses the potential to be and to produce things of the highest value. It also follows that if abortion has already taken place and the fetus is nonviable, then research in no way affects the fetus' ability to realize any of its potential.

Dr. Wasserstrom states that the resolution of the problem of consent for research on the fetus depends entirely on how one views the status of the fetus. That is, if one views the fetus as tissue, then consent on behalf of the fetus is meaningless. If one views the fetus as a child, then proxy consent is necessary. Dr. Wasserstrom believes, however, that even if the fetus is considered to be only tissue, consent should be obtained from the parents out of respect for their sensitivities.

Because abortion is a morally worrisome act, the decision to have an abortion should be kept easily revocable until the time of its performance. For this reason, Dr. Wasserstrom recommends that no research on the fetus *in utero* should be permitted if it involves a substantial risk of injury to the fetus.

Dr. Wasserstrom concludes that research on the nonviable fetus *ex utero* is permissible provided that: (1) the mother (if unmarried) or both parents consent before the abortion; (2) a review body has determined that the research may yield important information not otherwise obtainable; (3) the medical counselors of the pregnant woman have in no way been affiliated with the experimentation; and (4) the fetus is not possibly viable.

(An analysis of the papers summarized above was prepared for the Commission by Stephen Toulmin, Ph.D. This analysis is set forth in its entirety in the Appendix.)

Appendix I

VI.

VIEWS PRESENTED AT PUBLIC HEARINGS

Public hearings were held by the commission to provide interested persons with an opportunity to present their views on research on the fetus. Testimony was given by scientists, physicians, representatives of various organizations, concerned private citizens, lawyers and public officials. They presented a broad range of views that received careful consideration at the hearings and in the subsequent deliberations of the Commission. Brief summaries of the presentations follow.

1. C. D. Christian, M.D. (American College of Obstetricians and Gynecologists). Dr. Christian presented to the Commission a set of guidelines for the conduct of research on the pregnant woman and fetus, as prepared by the Committee on Bioethics of the College. The guidelines include recommendations that animal models be fully explored before human research is initiated, that clinical management of the patient should not be altered by research objectives, that research which would knowingly harm the fetus is not appropriate even in anticipation of abortion, that a fetus of doubtful viability should be treated as a viable infant, and that prolonging or shortening the life of the nonviable fetus only for research purposes is not appropriate.

2. Robert G. Marshall (Special Assistant for Congressional Affairs, U.S. Coalition for Life). Mr. Marshall opposed any research that is not directed at preserving the life or restoring the health of the immediate patient. In addition, he suggested adoption of the Golden Rule as a criterion for experimentation; a prohibition on the participation of the medically needy as subjects of research, except in circumstances of immediate danger to life; and a requirement that prospective participants be required to write out their understanding of the purpose of an experiment prior to being accepted as subjects. (During questioning, Mr. Marshall said that he would not object to observational procedures including, for example, fetoscopy.)

3. Thomas K. Oliver, Jr., M.D. (Association of American Medical Colleges). Dr. Oliver cited improvement in statistics of infant mortality and morbidity, which may be attributed directly to research on the fetus and newborn infant. He described the research leading to improved care of Rh disease and respiratory distress syndrome, which could have been conducted only on the human fetus and newborn, as specific examples of advances resulting from research on the fetus. He urged the creation of an Ethical Advisory Board to review those research proposals which raise ethical questions, rather than the imposition of guidelines that would not be responsive to changing circumstances.

4. Judith Mears (Reproductive Freedom Project, American Civil Liberties Union). Ms. Mears urged that the Commission not draft protections for the fetus that would undermine the Supreme Court's rulings in Doe v. Bolton and Roe v. Wade regarding a woman's rights with respect to abortion. In addition, she urged the support of research to improve the safety of abortion procedures. (Ms. Mears agreed, during questioning, that the Roe and Doe decisions do not speak to the issue of experimentation and would not, therefore, render regulation of such research unconstitutional so long as a woman's access to abortion and other health services is not abridged.)

5. David G. Nathan, M.D. (Professor of Pediatrics, Harvard Medical School). Dr. Nathan focused his discussion on fetoscopy. He described this experimental technique for obtaining a sample of fetal blood to enable prenatal detection of disorders such as sickle cell disease and thalassemia, the reasons for conducting initial trials in women about to undergo abortion, and the evolution of the technique to the point where it has had successful clinical application. Dr. Nathan stressed the importance of studies that can be conducted simultaneously with the abortion procedure and consequently avoid any possibility of a change of mind about abortion after the research has begun.

6. Audrey McMahon (mother of two developmentally disabled children). Ms. McMahon stressed the need for research into the causes and treatment of developmental disabilities, and urged that such research not be curtailed.

7. Robert Greenberg, M.D. (Society for Pediatric Research and the American Pediatric Society). Dr. Greenberg presented statistics on the high rates of infant mortality and abnormal fetal development as indicators that the current health status of the fetus is poor. Dr. Greenberg stated that genuine concern for the fetus requires marked improvement of the health care available to the developing human during intrauterine life. Such improvements in health care require acquisition of further understanding through increased research.

8. Sumner Yaffe, M.D. (American Academy of Pediatrics). Dr. Yaffe cited numerous advances in fetal therapeutics resulting from research on the fetus and emphasized the acute need for more extensive research in fetal clinical pharmacology. He presented the Academy's code of ethics for research involving the fetus and fetal material. The code states that research intended to benefit the mother or fetus *in utero* may be conducted with informed consent; that research on the viable delivered fetus (premature infant) may be carried out as long as nothing is done that is inconsistent with treatment necessary to promote the life of the infant; and that research on the nonviable fetus before or after abortion should be permitted, providing appropriate animal studies have been completed, parental consent is obtained, the researchers have no part in deciding timing or procedures for terminating the pregnancy or in determining viability, the research has been approved by an Institutional Review Board which is satisfied that the information cannot be obtained in any other way, experiments are not done in the delivery room, there is no monetary exchange for fetal material, and full records are kept.

9. Lois Schiffer (Women's Equity Action League, Women's Legal Defense Fund, Human Rights for Women). Ms. Schiffer cautioned against developing a policy that would abrogate constitutionally protected interests, such as the preeminence of a pregnant woman's right to health care. She underscored the need for continuing research in order to provide pregnant women with optimum medical advice and treatment (including improved abortion techniques). She suggested, additionally, that a requirement of paternal or spousal consent in conjunction with research on the fetus would contravene the holdings in the Roe and Doe decisions and that such consent serves no legitimate purpose if no child will be born.

Finally, she urged the adequate representation of women on ethical review committees that will be applying policy to specific cases.

10. Kay Jacobs Katz (National Capital Tay-Sachs Foundation). Ms. Katz described the illness and death of her daughter, a victim of Tay-Sachs disease, and emphasized that only because of the availability of prenatal diagnosis did she have the courage to risk a further pregnancy that has resulted in the birth of a normal child. She urged the commission not to restrict research that might develop procedures for prenatal diagnosis of other genetic diseases, nor to curtail research that might lead to the development of effective therapy for inborn errors of metabolism.

11. Arthur M. Silverstein, Ph.D. (American Society for Experimental Pathology). Dr. Silverstein pointed out the limitations of animals as models for the human fetus in experimentation. He cited the numerous uses of cells and tissues from the dead fetus in biomedical science, and urged that scientists not be deprived of the opportunity to study such tissues. He urged continued availability of fresh fetal materials for study and for use in transplantation. He concluded by asking the Commission to recognize that society owes to the developing fetus an acknowledgement of its special problems and a determination to attempt to solve these problems and do medical justice to the fetus through research.

12. Msgr. James T. McHugh (U.S. Catholic Conference). Msgr. McHugh stated that the fetus is a human being from the earliest stages of development, and that the ethical norms governing research on the fetus derive from those governing research on all human subjects, especially infants and children. Pre-abortion research is inconsistent with human dignity and is therefore unacceptable. Consent by the mother to such research is a mockery, he said, inasmuch as she has already decided to extinguish the life of the fetus; further, such research would eliminate any possibility of a mother's change of mind concerning abortion.

He urged Federal regulations of research on the fetus to permit only projects involving, for example, amniocentesis, fetoscopy, tissue culture, or procedures that would entail no risk to the fetus, and to limit those to circumstances in which their application would serve the purpose of protecting maternal health

and assuring safe delivery of the fetus. He urged that animal models be used to the extent possible, even if this would be more expensive and demanding. He stated that the Government should permit research on the fetus only for the purpose of enhancing the survival or well-being of the fetus involved, and only if it can be conducted in a manner that will respect the rights and dignity of the fetus.

13. Jo Anne Brasel, M.D. (Endocrine Society). Dr. Brasel cited examples of contributions of fetal endocrinologic research to fetal welfare and survival. Continuation of research on the fetus was urged to permit study of such problems as hormonal deficiency states and care of the fetus of the diabetic mother. She expressed the full support of the Society for efforts to see that ethical considerations are met in the conduct of human research, but asserted that the welfare of future mothers and infants would not be served by wholesale interdiction of research.

14. Nancy Raymond, R.N. (Public Relations Director, Maryland Action for Human Life). Ms. Raymond urged that the fetus be treated with fairness and dignity, whether or not an abortion is anticipated or has been conducted. She advocated a prohibition of research on the fetus, but would make the following exceptions from such a prohibition: remedial procedures; procedures to study the fetus within the womb, if they do not substantially jeopardize the fetus and it is not a candidate for planned abortion; diagnostic procedures that do not substantially jeopardize the fetus, even if it is a candidate for planned abortion; and diagnostic procedures that are judged to be in the best interest of the particular fetus and will provide the mother with information about her fetus, even if an abortion is contemplated. She suggested that a panel of medical and nonmedical persons be created to advise scientists on the acceptability of research on the fetus.

15. Sean O'Reilly, M.D. (Professor of Neurology at George Washington University). Dr. O'Reilly's testimony (read in his absence) urged protection of the fetus from experimentation without its informed consent. He stated that the fetus obviously cannot give consent, and that parents can consent only to

therapeutic research on the fetus. He argued that parents forfeit any right to consent to any other research on the fetus once they have elected to abort it.

16. Chris Mooney (President, Pregnancy Aid Centers, Inc.) Ms. Mooney viewed abortion as the worst solution to the problem of unwanted pregnancy, preferring to improve methods and availability of counseling and contraception. She expressed the fear that research on the fetus before and after abortion will further entrench our dependence on this pseudo-solution, by persuading women to abort in order to contribute to the cause of science. If science becomes dependent on abortion for research subjects, scientists and society will be even less inclined to develop viable alternatives to abortion. She urged that no money be offered for the use of an aborted fetus in research. (During questioning, Ms. Mooney said she has no knowledge of cases in which research did, in fact, operate as an inducement to abortion, and agreed that regulations could be devised to avoid that possibility.)

17. Walter L. Herrmann, M.D. (Society for Gynecologic Investigation). Dr. Herrmann pointed out that the interrelation of mother and fetus *in* utero requires that they both be considered in research involving either of them. He observed that the attitude of confidence rather than fear of the modern woman contemplating pregnancy is due to improved pregnancy care resulting from maternal and fetal research. Many unanswered questions remain, however, which demand continuation of such research. He urged that, in developing regulations for research on the fetus, the abortion issue be kept separate and emphasis be placed On the pregnant women as the subject to be protected, so as not to infringe upon her rights or deprive her of the benefits of scientific discovery.

18. Mary O'Donnell (Nursing student; member, National Youth Pro-Life Coalition). Ms. O'Donnell argued that fetal life is human life deserving of our respect and protection. She would permit diagnostic procedures when undertaken to promote well-being or survival, and all life-preserving procedures. She would find drug research in anticipation of abortion unacceptable because it deprives a woman of the opportunity to change her mind and violates basic moral values.

19. Leroy A. Jackson, M.D. (Obstetrician in private practice, Washington, D.C.). Dr. Jackson cited procedures derived from research on the fetus that have improved his ability as a physician to provide medical care to his patients. He focused his testimony on the need to assure that consent from the mother for research on the fetus is truly informed consent, and that minorities and other groups do not bear a disproportionate share of the research burden. To these ends, he urged that research review committees contain members racially representative of and capable of communicating adequately with individuals on whom the research is conducted, that consent form wording be reviewed in detail, and that non-Government research agencies follow Government guidelines.

20. Karen Mulhauser (National Abortion Rights Action League). Ms. Mulhauser urged that the Commission recommend no limitations on research on the nonviable fetus *in utero*, provided informed consent is received from the pregnant woman. She also opposed any limitation of research to develop improved and safer abortion techniques.

21. Ernest L. Hopkins, M.D. (Professor of Obstetrics and Gynecology, Howard University). Dr. Hopkins cited statistics indicating that black infants and mothers have markedly higher morbidity and mortality in childbirth and the first year of life than do whites, and thus have a significant stake in research directed toward pregnancy and infancy. It is essential that research be conducted, he stated, as well as mandatory that the rights of the subject be protected. He advised the Commission that a mother often arrives at a decision to terminate pregnancy because she cannot support her present family. These are honorable women with wisdom, he said. They are very emotionally involved with the pregnancy, but they know the birth of a baby would be catastrophic. They decide, reluctantly, to have an abortion because they see no alternative.

22. J. V. Klavins, Ph.D. (Professor of Pathology, State University of New York at Stony Brook). Dr. Klavins suggested that research on the fetus could be conducted with consent of the mother (and father when available). Since abortion is legal, he argued, research that causes no harm or suffering to the fetus-to-be-aborted is certainly acceptable. He stated that research on the human

fetus is no more likely to be dehumanizing than artificial insemination has been, that "do no harm" be used as the guiding principle in research on the fetus, and that society not be allowed to interfere with the parents' right to make decisions concerning the best interest of their offspring.

23. Myron Winick, M.D. (American Institute of Nutrition and the American Society for Clinical Nutrition). Dr. Winick reviewed nutrition problems relevant to the fetus and cited research needed to approach solutions to such problems. For example, knowledge is needed of the way the human fetus gets and uses essential nutrients *in utero*. Acquisition of this knowledge may require nonbeneficial research, he stated. The aim of the research, he pointed out, is to improve fetal growth and the quality of life, and, when a malnourished fetus is identified, to assist the fetus, not to terminate the pregnancy.

24. Aubrey Milunsky, M.D. (Assistant Professor of Pediatrics, Harvard Medical School). Dr. Milunsky presented written testimony focusing on prenatal diagnosis of genetic disease by amniocentesis. He pointed out that research on the fetus was essential to developing amniocentesis, which is now an accepted clinical procedure. The research aspects of prenatal diagnosis now involve extending diagnostic possibilities to other diseases and developing methods of prenatal treatment of an affected fetus as an alternative to abortion. He argued that to halt such research now would prohibit extending to other populations (such as those affected by sickle cell disease) the option of prenatal diagnosis, and also would prohibit the possible development of treatments for the diagnosed diseases.

25. Louis Hellman, M.D. (Deputy Assistant Secretary for Population Affairs, DHEW). Dr. Hellman reviewed the activities of his office in supporting research and providing services in family planning, noting that the objectives directly affected the health of mothers and infants. Enabling women to have fewer children implies that those born should have optimum chances for survival and good health. Thus, the Office of Population Affairs has an interest in all aspects of maternal and fetal research directed at reducing mortality and morbidity. In the conduct of such research, Dr. Hellman stated, obtaining properly

informed consent and review of the research by a committee of peers do not constitute significant barriers. He advocated conducting such reviews locally rather than in Washington. He expressed a personal distaste for nonbeneficial research on the aborted fetus, for which an outright prohibition might be considered, but cautioned that such a course would be unlikely to stop the search for new knowledge, perhaps in another country or in another generation. He concluded that knowledge cannot be sequestered nor the course of its attainment blocked, and he suggested that the wiser direction would be adequate regulation of research on the fetus rather than outright prohibition.

26. Norman Kretchmer, M.D. (Director, National Institute of Child Health and Human Development, National Institutes of Health). Dr. Kretchmer summarized the policies and procedures presently in effect at NIH for the protection of human subjects studied in research activities. Proposals involving extramural research (which is conducted at institutions other than NIH) undergo a three-stage process of review, including: (1) review by the institution proposing the research, (2) review by scientific peers acting as consultants to NIH, and (3) review by the National Advisory Councils of the Institutes supporting the projects.

The first stage is performed by an Institutional Review Board (IRE), a panel consisting of members with diverse backgrounds and drawn from various disciplines. It is the responsibility of the IRE to review the proposal for scientific merit, community acceptability, the balance of risks and benefits, and any other factors that might bear upon the protection of the rights and welfare of the subjects.

The second stage of review is conducted by scientific peers, to evaluate the soundness of the research design, the relevant professional experience of the investigator, adequacy of facilities, scientific importance of the research, and the like. In addition, the reviewing body may consider the investigator's evaluation of risks and benefits, as well as any procedures suggested to protect the subjects against possible risks.

The final stage of review is conducted by a National Advisory Council, a panel composed of two-thirds scientists and one-third nonscientists. Their responsibility is to recommend policy for the Institute and to advise the

Director, NIH (or, in some cases, the Secretary, DHEW) concerning funding of research proposals, giving consideration to the protection of the rights of human subjects, among other things.

Research conducted within NIH (intramural research) undergoes review by the branch chief and clinical director of the Institute conducting the research. It may also be subject to review and approval by the Clinical Research Committee and the Medical Board of the Clinical Center. The Medical Board includes in its membership clinicians, scientists and laymen. All studies involving normal volunteers must be submitted to the Medical Board. Studies which involve potential benefits to patients who have been admitted to the Clinical Center generally are reviewed by clinical associates, attending physicians and the chief of the branch involved. When such studies represent a significant deviation from accepted practice or are associated with unusual hazards, however, they must be reviewed by the Clinical Research Committee.

For fiscal year 1974, NIH has identified about one hundred projects (with a total support of $3.5 million) which involved research on the fetus. These included monitoring of labor, fetal response to growth promoting substances, development of a "fetal risk index," and others. Under the ban imposed by P.L. 93-348, research on the living human fetus, before or after induced abortion, is not supported by NIH unless such research is done with the intention of assisting the survival of the fetus.

27. John Jennings, M.D. (Associate Commissioner, Food and Drug Administration).* Dr. Jennings testified that FDA has legislative authority to ensure that research submitted to the agency by industry to show the safety and effectiveness of a drug is conducted under conditions that will protect subjects. In this regard, FDA believes it should act in accord, insofar as feasible, with DHEW guidelines for protection of human subjects in research conducted or supported by the Department.

*Dr. Jennings was accompanied by Dr. Frances Kelsey, Dr. Carl Leventhal and Mr. William Vodra.

Most drugs currently marketed bear a warning on that label that they have not been tested for safety in pregnant women. Nevertheless, Dr. Jennings stated, such drugs, with potentially harmful effects on the fetus, are being used by pregnant women and by women of childbearing age, in spite of the label disclaimers. Therefore, the American Academy of Pediatrics has recommended to FDA that all marketed drugs be evaluated regarding their potential for producing adverse effects in the fetus.

Dr. Jennings expressed confidence that although difficult ethical problems are raised by research on the fetus, the Commission would be able to develop flexible guidelines that would safeguard both consumers and subjects.

In response to questions, representatives from FDA explained that no marketing of a drug is permitted until tests on animal teratology and reproduction have been completed. These tests include: (1) studies of normal and reproductive performance from the beginning of pregnancy through delivery, following administration of the drug to both males and females, (2) studies of teratology, following administration of the drug during pregnancy at the time of organ development, and (3) tests following administration of the drug from the end of pregnancy through lactation. FDA requests additional studies in primates if first studies indicate a need for further investigation.

Appendix I

VII.

FETAL VIABILITY AND DEATH

The definitions of fetal viability and death present important issues in the conduct of research on the fetus. Accordingly, the Commission contracted for two studies in this area: the first, a medical study to define fetal viability and death based on present capabilities of medical technology; the second, an analysis of ethical and philosophical as well as scientific considerations in defining fetal viability and death.

The first study was conducted under contract with Columbia University, Richard Behrman, M.D., Principal Investigator. It included (1) a survey of the changes over the last 10 years in survival rates of premature infants and the advances in technology that have contributed to improved survival; (2) an assessment of the present state of medical technology designed to sustain premature infants; and (3) based on the foregoing, a recommendation for guidelines for use by physicians in determining whether a fetus, delivered spontaneously or by induced abortion, is viable, nonviable or dead. Consultation with representatives of professional societies in pediatrics and obstetrics, surveys of selected newborn intensive care units in the United States and Canada, statistical surveys and literature reviews were employed in carrying out this charge.

Assessment of changes in survival of premature infants relied primarily on data from New York City and from geographically dispersed infant intensive care units, as no national or international data broken down by weight group under 2500 grams were available. New York data showed a 4.5 percent increase in survival rate (26 percent reduction in mortality) of all infants under 2500 grams for the period covering the years 1962 to 1971. The improvement was primarily in the lower weight groups: 68 percent increase in survival rate under 1000 grams, 20 percent increase from 1001 to 1500 grams, and 6 percent from 1501 to 2000 grams. Infants cared for in intensive care units showed an even greater improvement in survival.

Appendix I

Many innovations in caring for the fetus *in utero* and the delivered premature infant were introduced in the last decade. The large number of these innovations, and their introduction at different times in different centers, generally made it impossible to establish a direct correlation between a given technologic innovation and a change in infant survival. One exception, where such a correlation may be made, is the effect on survival of monitoring fetal heart rate and acid-base balance during labor. At Los Angeles County USC Medical Center, monitoring was introduced as a routine procedure for high risk obstetrical patients in 1970; low risk patients were unmonitored. Between 1970 and 1973, the intrapartum death rate of infants weighing more than 1500 grams decreased 64 percent, and the fetal death rate became lower for the monitored high risk women than in the unmonitored low risk women. Comparable results were obtained in New York City at Columbia Presbyterian Medical Center, where over 90 percent of the monitoring was done on high risk ward patients, primarily black, poor or Spanish-speaking; the low risk private patients were unmonitored. Following introduction of monitoring, the high risk monitored patients had 10 percent fewer fetal deaths, 14 percent fewer perinatal deaths, and 37 percent fewer intrapartum fetal deaths than the unmonitored low risk private patients.

Overall improvement in premature survival may be traced more generally to the gradual adoption of other innovations. For example, the improved rates during the years 1967 through 1969 may be related to advances first introduced during the years 1964 through 1966, which included amniocentesis for intrauterine diagnosis of infants severely affected with erythroblastosis; fetal transfusion *in utero;* reorganization of premature nurseries into intensive care centers; extensive monitoring of gases and other substances in blood, and of vital signs, with more aggressive attention to correction of abnormal values; hand ventilation with ambu bags; regulation of the thermal environment; and greater density of nursing personnel. Increases in survival in the period 1970 to 1973 may be correlated with a constellation of advances in the years 1968 through 1970. These included extensive study of amniotic fluid in managing high risk pregnancies; fetal heart rate and uterine pressure monitoring during labor; improved infant transport systems and referral to intensive care units; major advances in design and techniques for use of infant respirators; total intravenous alimentation;

and use of phototherapy for jaundice. Numerous other innovations have been introduced, but these are the major advances that have come into widespread use.

Impact of these changes on survival is reflected in data from University College Hospital in London, where survival rate of infants 1001 to 1500 grams was a steady 45 to 50 percent during the 1950's and early 1960's. During the period 1966 to 1970, the survival rate increased to 70 percent. Equally significant is an indication of decreased morbidity. During the 1950's and 1960's, the handicap rate for infants weighing less than 1500 grams at birth ranged from 33 percent to 60 percent. A recent study evaluating the outcome of such infants born from 1966 to 1970 indicated that 90.5 percent had no detectable handicap.

Despite these advances in the technology of caring for premature infants, there remain limits beyond which the best care cannot result in survival. To ascertain the present limits, surveys were conducted of vital statistics of the United States (including individual states) and Quebec, the medical literature, and 27 major centers with obstetric services and special intensive care units for premature infants. These centers represent the optimal care that present medical technology can provide. Despite differences in data base from various sources, two facts emerged clearly: probability of survival of infants weighing less than 750 grams was extremely small, and no cases were found from any documentable source of any infant surviving with a birth weight below 600 grams at a gestational age of 24 weeks or less. Some rare cases were documented of infants surviving with birth weights below 600 grams, but in each instance, the gestational age exceeded 24 weeks, and the cases thus represented more mature infants who for various reasons were small-for-dates. Other rare cases were documented of infants born before 25 weeks gestational age who survived, but in each instance birth weight exceeded 600 grams. Thus, on an empirical basis the current limits of viability are clear: there is no unambiguous documentation that an infant born weighing less than 601 grams at a gestational age of 24 weeks or less has ever survived.

The concept of viability implies a prediction as to whether a delivered fetus is capable of survival. A prematurely delivered fetus is viable when a minimal number of independently sustained, basic, integrative physiologic functions are present. The sum of these functions must support the inference that

the fetus is able to increase in tissue mass (growth) and increase the number, complexity and coordination of basic physiologic functions (development) as a self-sustaining organism. This development must be independent of any connection with the mother and supported only by generally accepted medical treatments. If these coordinated functions are not present, the fetus is nonviable. This may be the case even though some signs of life are apparent.

The following functions, taken together, constitute the minimal number of basic integrative physiologic functions to support an inference of viability: (1) Perfusion of tissues with adequate oxygen and prevention of increasing accumulation of carbon dioxide and/or lactic and other organic acids. This function consists of the following components:

(a) inflation of the lungs with oxygen,

(b) transfer of oxygen across the alveolar membranes into the circulation and elimination of carbon dioxide from the circulation into the expired gas, and

(c) Cardiac contractions of sufficient strength and regularity to distribute oxygenated blood to tissues and organs throughout the body, and to eliminate organic acids from those tissues and organs.

(2) Neurologic regulation of the components of the cardio-respiratory perfusion function, of the capacity to ingest nutrients, and of spontaneous and reflex muscle movements.

These functions in the prematurely delivered fetus cannot at present be assessed separately in a consistent, reliable and exact manner. The absence of the sum of these functions, however, can be assessed indirectly in a reasonable and reliable manner by measurement of weight and an estimation of gestational age. Thus, organisms of less than 601 grams at delivery and gestational age of 24 weeks or less are at present nonviable; signs of life such as a beating heart, spontaneous respiratory movement, pulsation of the umbilical cord and spontaneous movement of voluntary muscles are not adequate in themselves to be used to determine the existence of basic integrative functions.

A weight of 601 grams or more and gestational age over 24 weeks may indicate that the minimal basic functions necessary for independent growth and

development are present. Such a prematurely delivered fetus may be considered at least possibly viable. At these weights and gestational ages, a sign of life such as a beating heart, spontaneous respiratory movement, pulsation of the umbilical cord or spontaneous movement of voluntary muscles indicates possible viability.

Prediction of extrauterine viability of the fetus while it is still *in utero* takes on an additional dimension of complexity. The fetus *in utero,* in the absence of clear signs that death has occurred, is always at least potentially viable as long as it remains in the uterus. However, it cannot be weighed, size assessments based on uterine size are inaccurate, and estimates of gestational age based on menstrual history are often inexact. The best medical technology can provide at present is an index of gestational age based on measurement of head size, using ultrasound. In the best hands, this technique is accurate within ±1 week at 20-26 weeks. Relating gestational age to fetal weight, and taking into account the range of error and normal variation, an estimated gestational age of 22 weeks or less by ultrasound would virtually eliminate the possibility of fetal weight above 600 grams and actual gestational age greater than 24 weeks. Such an estimate would permit the prediction that if such a fetus were outside the uterus, it would be nonviable.

Employing present technology, therefore, research on the fetus *in utero,* undertaken before an abortion to occur not later than 22 weeks gestational age as estimated by ultrasound, would not impact on a fetus with a chance for survival after the abortion. Any reduction of the 22 week limit would provide an additional safeguard.

Whatever the boundaries are for viability, there is always a chance that a viable infant may be born after a prediction of nonviability by gestational age. When this occurs, the premature infant clearly must be cared for in accord with accepted medical practice. Further, these criteria for viability are based on current technology, which is subject to change. Accordingly, the criteria should be reviewed periodically.

Death of the delivered fetus is judged to have occurred when there is a cessation of the minimal basic integrative physiologic functions which, considered together, may result in self-sustained extrauterine growth and development. The

absence of all of the following signs indicates the cessation of these minimal basic integrative physiologic functions:

(1) heart beat,
(2) spontaneous respiratory movements,
(3) spontaneous movement of voluntary muscles, and
(4) pulsation of the umbilical cord.

Approaching the same issues of fetal viability and death from the viewpoint of a physician-scientist and philosopher, Dr. Leon Kass, in an essay prepared for the Commission, came to conclusions similar to those reached by Dr. Behrman on criteria for determining death and defining fetal viability (though Dr. Kass was more conservative on the latter). In clarifying the terminology, Dr. Kass distinguished between the terms "viable" and "nonviable" (which refer to states of a living fetus) and "alive" and "dead" (which refer to mutually exclusive conditions of the organism independent of its stage of development). The terms "viable" and "nonviable" are predictive of future outcome, which is dependent on the fetal stage of development and relation to the environment. Thus, the determination of viability is influenced by whether the fetus is inside or outside the uterus, and by the technology available for sustaining life. A fetus that is alive inside the uterus is always at least potentially viable; the same fetus outside the uterus may be viable or nonviable.

As criteria for determining death, Dr. Kass suggested that a fetus be considered dead if, based on ordinary procedures of medical practice, it has experienced an irreversible cessation of spontaneous circulatory and respiratory functions and an irreversible cessation of spontaneous central nervous functions. These criteria are evidenced on examination of the fetus by absence of the following:

(1) spontaneous muscular movement,
(2) response to external stimuli,
(3) elicitable reflexes,
(4) spontaneous respiration, and
(5) spontaneous heart function manifested by heartbeat and pulse.

These criteria differ from those suggested by Dr. Behrman only by the addition of (2) and (3). Dr. Kass advised that the presence of anyone of these functions is a sign that the fetus is alive (again in agreement with Dr. Behrman), and he further suggested that use of the EEG is unnecessary in making the diagnosis of death. Finally, he recommended that the fetus in utero be considered alive until proved dead, and that the fetus being aborted be presumed alive until examination reveals it to be dead.

A viable fetus was defined by Dr. Kass as one that has reached the stage of development at which it is able to sustain itself outside the mother's body. In suggesting criteria for fetal viability based on present technology, Dr. Kass supported use of essentially the same physiologic criteria as suggested by Dr. Behrman, but would not rely upon weight or gestational age to indicate the presence of these integrated functions in the delivered fetus. He suggested that the delivered fetus should be considered viable in the presence of all five of the functions listed above (the absence of which is definitive of death). Of these, respiratory activity is the *sine qua non* of viability. Following delivery of the fetus, adequate time should be allowed to assess the presence of life and determine viability before research involving the fetus can be considered. This evaluation should be made by the delivering obstetrician, and then only if he is not himself likely to be engaged in subsequent research involving the fetus.

It is more difficult to determine whether the fetus *in utero* would be viable, if delivered, and, due to the possibility of error, Dr. Kass advised caution. He suggested that viability of the fetus *in utero* be evaluated according to gestational age. The fetus *in utero* is potentially viable before 20 weeks gestational age, but nonviable if removed from the uterus. It should be considered viable after the age of 28 weeks. Accurate evaluation of the viability of a fetus *in utero* between 20 and 28 weeks gestational age is not possible; such a fetus should be presumed viable if a heartbeat is audible using a stethoscope. The fetus which is to be aborted before the heartbeat is audible should be regarded as potentially viable until the abortion procedure is actually in progress, after which it may be considered nonviable.

VIII.

DELIBERATIONS AND CONCLUSIONS

The charge to the Commission is to investigate and study research involving the living fetus and to make recommendations to the Secretary, DHEW, on "policies defining the circumstances (if any) under which such research may be conducted or supported." The Commission has attempted to fulfill that duty by conducting investigations into research on the fetus and by providing a public forum for the presentation and analysis of views on this subject. It must be recognized that the Commission was placed under severe limitations of time by its Congressional mandate. As a result, these considerations on research involving fetuses have necessarily been developed prior to the Commission's larger task of studying the nature of research, the basic ethical principles which should guide it, the problem of informed consent and the review process.

After the Commission identified the information that was required for adequate consideration of the charge, a compendium of pertinent scientific literature and medical experience was prepared by consultants and contractors. In addition, a broad range of views was presented in letters, reports and testimony by theologians, philosophers, physicians, scientists, lawyers, public officials and private citizens. The Commission then undertook critical analysis of the studies and presentations, and conducted public deliberations on the issues involved. Finally, the Commission formulated its Recommendations.

This section of the Commission's report summarizes the reasoning and conclusions that emerged during the deliberations. Section IX of the report sets forth the Commission's Recommendations to the Secretary, DHEW. These Recommendations arise from and are consistent with the Deliberations and Conclusions of the Commission. The Recommendations should be considered only within the context of the Deliberations that precede them.

A. Preface to Deliberations and Conclusions. Throughout the deliberations of the Commission, the belief has been affirmed that the fetus as a human subject

is deserving of care and respect. Although the Commission has not addressed directly the issues of the personhood and the civil status of the fetus, the members of the Commission are convinced that moral concern should extend to all who share human genetic heritage, and that the fetus, regardless of life prospects, should be treated respectfully and with dignity.

The members of the Commission are also convinced that medical research has resulted in significant improvements in the care of the unborn threatened by death or disease, and they recognize that further progress is anticipated. Within the broad category of medical research, however, public concern has been expressed with regard to the nature and necessity of research on the human fetus. The evidence presented to the Commission was based upon a comprehensive search of the world's literature and a review of more than 3000 communications in scientific periodicals. The preponderance of all research involved experimental procedures designed to benefit directly a fetus threatened by premature delivery, disease or death, or to elucidate normal processes or development. Some research constituted an element in the health care of pregnant women. Other research involved only observation or the use of noninvasive procedures bearing little or no risk. A final class of investigation (falling outside the present mandate of the Commission) has made use of tissues of the dead fetus, in accordance with accepted standards for treatment of the human cadaver. The Commission finds that, to the best of its knowledge, these types of research have not contravened accepted ethical standards.

Nonetheless, the Commission notes that there have been instances of abuse in the area of fetal research. Moreover, differences of opinion exist as to whether desired results could have been attained without the use of the human fetus in non therapeutic research.

Concern has also been expressed that the poor and minority groups may bear an inequitable burden as research subjects. The Commission believes that those groups which are most vulnerable to inequitable treatment should receive special protection.

The Commission concludes that some information which is in the public interest and which provides significant advances in health care can be attained only through the use of the human fetus as a research subject. The Recommendations

which follow express the Commission's belief that, while the exigencies of research and the moral imperatives of fair and respectful treatment may appear to be mutually limiting, they are not incompatible.

B. Ethical Principles and Requirements Governing Research on Human Subjects with Special Reference to the Fetus and the Pregnant Woman. The Commission has a mandate to develop the ethical principles underlying the conduct of all research involving human subjects. Until it can adequately fulfill this charge, its statement of principles is necessarily limited. In the interim, it proposes the following as basic ethical principles for use of human subjects in general, and research involving the fetus and the pregnant woman in particular.

Scientific inquiry is a distinctly human endeavor. So, too, is the protection of individual integrity. Freedom of inquiry and the social benefits derived therefrom, as well as protection of the individual are valued highly and are to be encouraged. For the most part, they are compatible pursuits. When occasionally they appear to be in conflict, efforts must be made through public deliberation to effect a resolution.

In effecting this resolution, the integrity of the individual is preeminent. It is therefore the duty of the Commission to specify the boundaries that respect for the fetus must impose upon freedom of scientific inquiry. The Commission has considered the principles proposed by ethicists in relation to the exigencies of scientific inquiry, the requirements and present limitations of medical practice, and legal commentary. Among the general principles for research on human subjects judged to be valid and binding are: (1) to avoid harm whenever possible, or at least to minimize harm; (2) to provide for fair treatment by avoiding discrimination between classes or among members of the same class; and (3) to respect the integrity of human subjects by requiring informed consent. An additional principle pertinent to the issue at hand is to respect the human character of the fetus.

To this end, the Commission concludes that in order to be considered ethically acceptable, research involving the fetus should be determined by adequate review to meet certain general requirements:

(1) Appropriate prior investigations using animal models and non-pregnant humans must have been completed.

(2) The knowledge to be gained must be important and obtainable by no reasonable alternative means.

(3) Risks and benefits to both the mother and the fetus must have been fully evaluated and described.

(4) Informed consent must be sought and granted under proper conditions.

(5) Subjects must be selected so that risks and benefits will not fall inequitably among economic, racial, ethnic and social classes.

These requirements apply to all research on the human fetus. In the application of these principles, however, the Commission found it helpful to consider the following distinctions: (1) therapeutic and nontherapeutic research; (2) research directed toward the pregnant woman and that directed toward the fetus; (3) research involving the fetus-going-to-term and the fetus-to-be-aborted; (4) research occurring before, during or after an abortion procedure; and (5) research which involves the nonviable fetus *ex utero* and that which involves the possibly viable infant. The first two distinctions encompass the entire period of the pregnancy through delivery; the latter three refer to different portions of the developmental continuum.

The Commission observes that the fetus is sometimes an unintended subject of research when a woman participating in an investigation is incorrectly presumed not to be pregnant. Care should be taken to minimize this possibility.

C. Application to Research Involving the Fetus. The application of the general principles enumerated above to the use of the human fetus as a research subject presents problems because the fetus cannot be a willing participant in experimentation. As with children, the comatose and other subjects unable to consent, difficult questions arise regarding the balance of risk and benefit and the validity of proxy consent.

In particular, some would question whether subjects unable to consent should ever be subjected to risk in scientific research. However, there is general agreement that where the benefits as well as the risks of research accrue to the subject, proxy consent may be presumed adequate to protect the subject's interests. The more difficult case is that where the subject must bear risks without direct benefit.

Appendix I

The Commission has not yet studied the issues surrounding informed consent and the validity of proxy consent for nontherapeutic research (including the difficult issue of consent by a pregnant minor). These problems will be explored under the broader mandate of the Commission. In the interim, the Commission has taken various perspectives into consideration in its deliberations about the use of the fetus as a subject in different research settings. The Deliberations and Conclusions of the Commission regarding the application of general principles to the use of the fetus as a human subject in scientific research are as follows:

1. In therapeutic research directed toward the fetus, the fetal subject is selected on the basis of its health condition, benefits and risks accrue to that fetus, and proxy consent is directed toward that subject's own welfare. Hence, with adequate review to assess scientific merit, prior research, the balance of risks and benefits, and the sufficiency of the consent process, such research conforms with all relevant principles and is both ethically acceptable and laudable. In view of the necessary involvement of the woman in such research, her consent is considered mandatory; in view of the father's possible ongoing responsibility, his objection is considered sufficient to veto.

2. Therapeutic research directed toward the pregnant woman may expose the fetus to risk for the benefit of another subject and thus is at first glance more problematic. Recognizing the woman's priority regarding her own health care, however, the Commission concludes that such research is ethically acceptable provided that the woman has been fully informed of the possible impact on the fetus and that other general requirements have been met. Protection for the fetus is further provided by requiring that research put the fetus at minimum risk consistent with the provision of health care for the woman. Moreover, therapeutic research directed toward the pregnant woman frequently benefits the fetus, though it need not necessarily do so. In view of the woman's right to privacy regarding her own health care, the Commission concludes that the informed consent of the woman is both necessary and sufficient.

In general, the Commission concludes that therapeutic research directed toward the health condition of either the fetus or the pregnant woman is, in principle, ethical. Such research benefits not only the individual woman or

fetus but also women and fetuses as a class, and should therefore be encouraged actively.

The Commission, in making recommendations on therapeutic and nontherapeutic research directed toward the pregnant woman, (Recommendations (2) and (3)), in no way intends to preclude research on improving abortion techniques otherwise permitted by law and government regulation.

3. Nontherapeutic research directed toward the fetus *in utero* or toward the pregnant woman poses difficult problems because the fetus may be exposed to risk for the benefit of others.

Here, the Commission concludes that where no additional risks are imposed on the fetus (e.g., where fluid withdrawn during the course of treatment is used additionally for nontherapeutic research), or where risks are so minimal as to be negligible, proxy consent by the parent(s) is sufficient to provide protection. (Hence, the consent of the woman is sufficient provided the father does not object.) The Commission recognizes that the term "minimal" involves a value judgment and acknowledges that medical opinion will differ regarding what constitutes "minimal risk." Determination of acceptable minimal risk is a function of the review process.

When the risks cannot be fully assessed, or are more than minimal, the situation is more problematic. The Commission affirms as a general principle that manifest risks imposed upon nonconsenting subjects cannot be tolerated. Therefore, the Commission concludes that only minimal risk can be accepted as permissible for nonconsenting subjects in nontherapeutic research.

The Commission affirms that the woman's decision for abortion does not, in itself, change the status of the fetus for purposes of protection. Thus, the same principles apply whether or not abortion is contemplated; in both cases, only minimal risk is acceptable.

Differences of opinion have arisen in the Commission, however, regarding the interpretation of risk to the fetus-to-be-aborted and thus whether some experiments that would not be permissible on a fetus-going-to-term might be permissible on a fetus-to-be-aborted. Some members hold that no procedures should be applied to a fetus-to-be-aborted that would not be applied to a

fetus-going-to-term. Indeed, it was also suggested that any research involving fetuses-to-be-aborted must also involve fetuses-going-to-term. Others argue that, while a woman's decision for abortion does not change the status of the fetus per se, it does make a significant difference in one respect--namely, in the risk of harm to the fetus. For example, the injection of a drug which crosses the placenta may not injure the fetus which is aborted within two weeks of injection, where it might injure the fetus two months after injection. There is always, of course, the possibility that a woman might change her mind about the abortion. Even taking this into account, however, some members argue that risks to the fetus-to-be-aborted may be considered "minimal" in research which would entail more than minimal risk for a fetus-going-to-term.

There is basic agreement among Commission members as to the validity of the equality principle. There is disagreement as to its application to individual fetuses and classes of fetuses. Anticipating that differences of interpretation will arise over the application of the basic principles of equality and the determination of "minimal risk," the Commission recommends review at the national level. The Commission believes that such review would provide the appropriate forum for determination of the scientific and public merit of such research. In addition, such review would facilitate public discussion of the sensitive issues surrounding the use of vulnerable nonconsenting subjects in research.

The question of consent is a complicated one in this area of research. The Commission holds that procedures that are part of the research design should be fully disclosed and clearly distinguished from those which are dictated by the health care needs of the pregnant woman or her fetus. Questions have been raised regarding the validity of parental proxy consent where the parent(s) have made a decision for abortion. The Commission recognizes that unresolved problems both of law and of fact surround this question. It is the considered opinion, however, that women who have decided to abort should not be presumed to abandon thereby all interest in and concern for the fetus. In view of the close relationship between the woman and the fetus, therefore, and the necessary involvement of the woman in the research process, the woman's consent is considered necessary. The Commission is divided on the question of whether her consent alone is sufficient. Assignment of an advocate for the fetus was proposed

as an additional safeguard; this issue will be thoroughly explored in connection with the Commission's review of the consent process. Most of the Commissioners agree that in view of the father's possible responsibility for the child, should it be brought to term, the objection of the father should be sufficient to veto. Several Commissioners, however, hold that for nontherapeutic research directed toward the pregnant woman, the woman's consent alone should be sufficient and the father should have no veto.

4. Research on the fetus during the abortion procedure or on the nonviable fetus *ex utero* raises sensitive problems because such a fetus must be considered a dying subject. By definition, therefore, the research is nontherapeutic in that the benefits will not accrue to the subject. Moreover, the question of consent is complicated because of the special vulnerability of the dying subject.

The Commission considers that the status of the fetus as dying alters the situation in two ways. First, the question of risk becomes less relevant, since the dying fetus cannot be "harmed" in the sense of "injured for life." Once the abortion procedure has begun, or after it is completed, there is no chance of a change of mind on the woman's part which will result in a living, injured subject. Second, however, while questions of risk become less relevant, considerations of respect for the dignity of the fetus continue to be of paramount importance, and require that the fetus be treated with the respect due to dying subjects. While dying subjects may not be "harmed" in the sense of "injured for life," issues of violation of integrity are nonetheless central. The Commission concludes, therefore, that out of respect for the dying subjects, no nontherapeutic interventions are permissible which would alter the duration of life of the nonviable fetus *ex utero*.

Additional protection is provided by requiring that no significant changes are made in the abortion procedure strictly for purposes of research. The Commission was divided on the question of whether a woman has a right to accept modifications in the timing or method of the abortion procedure in the interest of research, and whether the investigator could ethically request her to do so. Some Commission members desired that neither the research nor the investigator in any way influence the abortion procedure; others felt that modifications in

timing or method of abortion were acceptable provided no new elements of risk were introduced. Still others held that even if modifications increased the risk, they would be acceptable provided the woman had been fully informed of all risks, and provided such modifications did not postpone the abortion beyond the twentieth week of gestational age (five lunar months, four and one-half calendar months). Despite this division of opinion, the Recommendation of the Commission on this matter is that the design and conduct of a nontherapeutic research protocol should not determine the recommendations by a physician regarding the advisability, timing or method of abortion. No members of the Commission desired less stringent measures.

Furthermore, it is possible that, due to mistaken estimation of gestational age, an abortion may issue in a possibly viable infant. If there is any danger that this might happen, research which would entail more than minimal risk would be absolutely prohibited. In order to avoid that possibility the Commission recommends that, should research during abortion be approved by national review, it be always on condition that estimated gestational age be below 20 weeks. There is, of course, a moral and legal obligation to attempt to save the life of a possibly viable infant.

Finally, the Commission has been made aware that certain research, particularly that involving the living nonviable fetus, has disturbed the moral sensitivity of many persons. While it believes that its Recommendations would preclude objectionable research by adherence to strict review processes, problems of interpretation or application of the Commission's Recommendations may still arise. In that event, the Commission proposes ethical review at a national level in which informed public disclosure and assessment of the problems, the type of proposed research and the scientific and public importance of the expected results can take place.

D. Review Procedures. The Commission will conduct comprehensive studies of existing review mechanisms in connection with its broad mandate to develop guidelines and make recommendations concerning ethical issues involved in research on human subjects. Until the Commission has completed these studies, it can offer only tentative conclusions and recommendations regarding review mechanisms.

In the interim, the Commission finds that existing review procedures required by statute (P.L. 93-348) and DHEW regulations (45 CFR 46) suffice for all therapeutic research involving the pregnant woman and the fetus, and for all nontherapeutic research which imposes minimal or no risk and which would be acceptable for conduct on a fetus *in utero* to be carried to term or on an infant. Guidelines to be employed under the existing review procedures include: (1) importance of the knowledge to be gained; (2) completion of appropriate studies on animal models and nonpregnant humans and existence of no reasonable alternative; (3) full evaluation and disclosure of the risks and benefits that are involved; and (4) supervision of the conditions under which consent is sought and granted, and of the information that is disclosed during that process.

The case is different, however, for nontherapeutic research directed toward a pregnant woman or a fetus if it involves more than minimal risk or would not be acceptable for application to an infant. Questions may arise concerning the definition of risk or the assessment of scientific and public importance of the research. In such cases, the Commission considers current review procedures insufficient. It recommends these categories be reviewed by a national review body to determine whether the proposed research could be conducted within the spirit of the Commission's recommendations. It would interpret these recommendations and apply them to the proposed research, and in addition, assess the scientific and public value of the anticipated results of the investigation.

The national review panel should be composed of individuals having diverse backgrounds, experience and interests, and be so constituted as to be able to deal with the legal, ethical, and medical issues involved in research on the human fetus. In addition to the professions of law, medicine, and the research sciences, there should be adequate representation of women, members of minority groups, and individuals conversant with the various ethical persuasions of the general community.

Inasmuch as even such a panel cannot always judge public attitudes, panel meetings should be open to the public, and, in addition, public participation through written and oral submissions should be sought.

E. Compensation. The Commission expressed a strong conviction that considerable attention be given to the issue of provision of compensation to those who may be injured as a consequence of their participation as research subjects.

Concerns regarding the use of inducements for participation in research are only partially met by the Commission's Recommendation (14) on the prohibition of the procurement of an abortion for research purposes. Compensation not only for injury from research but for participation in research as a normal volunteer or in a therapeutic situation will be part of later Commission deliberations.

F. Research Conducted Outside the United States. The Commission has considered the advisability of modifying its standards for research which is supported by the Secretary, DHEW, and is conducted outside the United States. It has concluded that its recommendations should apply as a single minimal standard, but that research should also comply with any more stringent limitations imposed by statutes or standards of the country in which the research will be conducted.

G. The Moratorium on Fetal Research. The Commission notes that the restrictions on fetal research (imposed by Section 213 of P.L. 93-348) have been construed broadly throughout the research community, with the result that ethically acceptable research, which might yield important biomedical information, has been halted. For this reason, it is considered in the public interest that the moratorium be lifted immediately, that the Secretary take special care thereafter that the Commission's concerns for the protection of the fetus as a research subject are met, and appropriate regulations based upon the Commission's recommendations be implemented within a year from the date of submission of this report to the Secretary, DHEW. Until final regulations are published, the existing review panels at the agency and institutional levels should utilize the Deliberations and Recommendations of the Commission in evaluating the acceptability of all grant and contract proposals submitted for funding.

H. Synthesis. The Commission concludes that certain prior conditions apply broadly to all research involving the fetus, if ethical considerations are to be met. These requirements include evidence of pertinent investigations in animal models and nonpregnant humans, lack of alternative means to obtain the information, careful assessment of the risks and benefits of the research, and procedures to ensure that informed consent has been sought and granted under proper conditions. Determinations as to whether these essential requirements have been met may be made under existing review procedures, pending study by the Commission of the entire review process.

In the judgment of the Commission, therapeutic research directed toward the health care of the pregnant woman or the fetus raises little concern, provided it meets the essential requirements for research involving the fetus, and is conducted under appropriate medical and legal safeguards.

For the most part, nontherapeutic research involving the fetus to be carried to term or the fetus before, during or after abortion is acceptable so long as it imposes minimal or no risk to the fetus and, when abortion is involved, imposes no change in the timing or procedure for terminating pregnancy which would add any significant risk. When a research protocol or procedure presents special problems of interpretation or application of these guidelines, it should be subject to national ethical review; and it should be approved only if the knowledge to be gained is of medical importance, can be obtained in no other way, and the research proposal does not offend community sensibilities.

IX.

RECOMMENDATIONS

1. Therapeutic research directed toward the fetus may be conducted or supported, and should be encouraged, by the Secretary, DHEW, provided such research (a) conforms to appropriate medical standards, (b) has received the informed consent of the mother, the father not dissenting, and (c) has been approved by existing review procedures with adequate provision for the monitoring of the consent process. (Adopted unanimously.)

2. Therapeutic research directed toward the pregnant woman may be conducted or supported, and should be encouraged, by the Secretary, DHEW, provided such research (a) has been evaluated for possible impact on the fetus, (b) will place the fetus at risk to the minimum extent consistent with meeting the health needs of the pregnant woman, (c) has been approved by existing review procedures with adequate provision for the monitoring of the consent process, and (d) the pregnant woman has given her informed consent. (Adopted unanimously.)

3. Nontherapeutic research directed toward the pregnant woman may be conducted or supported by the Secretary, DHEW, provided such research (a) has been evaluated for possible impact on the fetus, (b) will impose minimal or no risk to the well-being of the fetus, (c) has been approved by existing review procedures with adequate provision for the monitoring of the consent process, (d) special care has been taken to assure that the woman has been fully informed regarding possible impact on the fetus, and (e) the woman has given informed consent. (Adopted unanimously.)

It is further provided that nontherapeutic research directed at the pregnant woman may be conducted or supported (f) only if the father has not objected, both where abortion is not at issue (adopted by a vote of 8 to 1) and where an abortion is anticipated (adopted by a vote of 5 to 4).

4. Nontherapeutic research directed toward the fetus *in utero* (other than research in anticipation of, or during, abortion) may be conducted or supported by the Secretary, DHEW, provided (a) the purpose of such research is the development of important biomedical knowledge that cannot be obtained by alternative means, (b) investigation on pertinent animal models and nonpregnant humans has preceded such research, (c) minimal or no risk to the well-being of the fetus will be imposed by the research, (d) the research has been approved by existing review procedures with adequate provision for the monitoring of the consent process, (e) the informed consent of the mother has been obtained, and (f) the father has not objected to the research. (Adopted unanimously.)

5. Nontherapeutic research directed toward the fetus in anticipation of abortion may be conducted or supported by the Secretary, DHEW, provided such research is carried out within the guideline for all other nontherapeutic research directed toward the fetus *in utero*. Such research presenting special problems related to the interpretation or application of these guidelines may be conducted or supported by the Secretary, DHEW, provided such research has been approved. by a national ethical review body. (Adopted by a vote of 8 to 1.)

6. Nontherapeutic research directed toward the fetus during the abortion procedure and nontherapeutic research directed toward the nonviable fetus *ex utero* maybe conducted or supported by the Secretary, DHEW, provided (a) the purpose of such research is the development of important biomedical knowledge that cannot be obtained by alternative means, (b) investigation on pertinent animal models and nonpregnant humans (when appropriate) has preceded such research, (c) the research has been approved by existing review procedures with adequate provision for the monitoring of the consent process, (d) the informed consent of the mother has been obtained, and (e) the father has not objected to the research; and provided further that (f) the fetus is less than 20 weeks gestational age, (g) no significant procedural changes are introduced into the abortion procedure in the interest of research alone, and (h) no intrusion into the fetus is made which alters the duration of life. Such research presenting special problems related to the interpretation or application of these guidelines may be conducted or supported by the Secretary, DHEW, provided such research has been approved by a national ethical review body. (Adopted by a vote of 8 to 1.)

7. Nontherapeutic research directed toward the possibly viable infant may be conducted or supported by the Secretary, DHEW, provided (a) the purpose of such research is the development of important biomedical knowledge that cannot be obtained by alternative means, (b) investigation on pertinent animal models and nonpregnant humans (when appropriate) has preceded such research, (c) no additional risk to the well-being of the infant will be imposed by the research, (d) the research has been approved by existing review procedures with adequate provision for the monitoring of the consent process, and (e) informed consent of either parent has been given and neither parent has objected. (Adopted unanimously.)

8. Review Procedures. Until the Commission makes its recommendations regarding review and consent procedures, the review procedures mentioned above are to be those presently required by the Department of Health, Education, and Welfare. In addition, provision for monitoring the consent process shall be required in order to ensure adequacy of the consent process and to prevent unfair discrimination in the selection of research subjects, for all categories of research mentioned above. A national ethical review, as required in Recommendations (5) and (6), shall be carried out by an appropriate body designated by the Secretary, DHEW, until the establishment of the National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research. In order to facilitate public understanding and the presentation of public attitudes toward special problems reviewed by the national review body, appropriate provision should be made for public attendance and public participation in the national review process. (Adopted unanimously, one abstention.)

9. Research on the Dead Fetus and Fetal Tissue. The Commission recommends that use of the dead fetus, fetal tissue and fetal material for research purposes be permitted, consistent with local law, the Uniform Anatomical Gift Act and commonly held convictions about respect for the dead. (Adopted unanimously, one abstention.)

10. The design and conduct of a nontherapeutic research protocol should not determine recommendations by a physician regarding the advisability, timing or method of abortion. (Adopted by a vote of 6 to 2.)

11. Decisions made by a personal physician concerning the health care of a pregnant woman or fetus should not be compromised for research purposes, and when a physician of record is involved in a prospective research protocol, independent medical judgment on these issues is required. In such cases, review panels should assure that procedures for such independent medical judgment are adequate, and all conflict of interest or appearance thereof between appropriate health care and research objectives should be avoided. (Adopted unanimously.)

12. The Commission recommends that research on abortion techniques continue as permitted by law and government regulation. (Adopted by a vote of 6 to 2.)

13. The Commission recommends that attention be drawn to Section 214(d) of the National Research Act (P.L. 93-348) which provides that:

> "No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part by the Secretary of Health, Education, and Welfare if his performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions."
>
> (Adopted unanimously.)

14. No inducements, monetary or otherwise, should be offered to procure an abortion for research purposes. (Adopted unanimously.)

15. Research which is supported by the Secretary, DHEW, to be conducted outside the United States should at the minimum comply in full with the standards and procedures recommended herein. (Adopted unanimously.)

16. The moratorium which is currently in effect should be lifted immediately, allowing research to proceed under current regulations but with the application of the Commission's Recommendations to the review process. All the foregoing Recommendations of the Commission should be implemented as soon as the Secretary, DHEW, is able to promulgate regulations based upon these Recommendations and the public response to them. (Adopted by a vote of 9 to 1.)

DISSENTING STATEMENT OF
COMMISSIONER DAVID W. LOUISELL

I am compelled to disagree with the Commission's Recommendations (and the reasoning and definitions on which they are based) insofar as they succumb to the error of sacrificing the interests of innocent human life to a postulated social need. I fear this is the inevitable result of Recommendations (5) and (6). These would permit nontherapeutic research on the fetus in anticipation of abortion and during the abortion procedure, and on a living infant after abortion when the infant is considered nonviable, even though such research is precluded by recognized norms governing human research in general. Although the Commission uses adroit language to minimize the appearance of violating standard norms, no facile verbal formula can avoid the reality that under these Recommendations the fetus and nonviable infant will be subjected to nontherapeutic research from which other humans are protected.

I disagree with regret, not only because of the Commission's zealous efforts but also because there is significant good in its Report especially its showing that much of the research in this area is therapeutic for the individuals involved, both born and unborn, and hence of unquestioned morality when based on prudent medical judgment. The Report also makes clear that some research, even though non therapeutic, is merely observational or otherwise without significant risk to the subject, and therefore is within standard human research norms and as unexceptional morally as it is useful scientifically.

But the good in much of the Report cannot blind me to its departure from our society's most basic moral commitment: the essential equality of all human beings. For me the lessons of history are too poignant, and those of this century too fresh, to ignore another violation of human integrity and autonomy by subjecting unconsenting human beings, whether or not viable, to harmful research even for laudable scientific purposes.

Admittedly, the Supreme Court's rationale in its abortion decisions of 1973--Roe v. Wade and Doe v. Bolton, 310 U.S. 113, 179--has given this Commission an all but impossible task. For many see in that rationale a total negation of fetal rights, absolutely so for the first two trimesters and substantially

so for the third. The confusion is understandable, rooted as it is in the Court's invocation of the specially constructed legal fiction of "potential" human life, its acceptance of the notion that human life must be "meaningful" in order to be deserving of legal protection, and its resuscitation of the concept of partial human personhood, which had been thought dead in American society since the demise of the Dredd Scott decision. Little wonder that intelligent people are asking: how can one who has no right to life itself have the lesser right of precluding experimentation on his or her person?

It seems to me that there are at least two compelling answers to the notion that Roe and Doe have placed fetal experimentation, and experimentation on nonviable infants, altogether outside the established protections for human experimentation. First, while we must abide the Court's mandate in a particular case on the issues actually decided even though the decision is wrong and in fact only an exercise of "raw judicial power" (White, J., dissenting in Roe and Doe), this does not mean we should extend an erroneous rationale to other situations. To the contrary, while seeking to have the wrong corrected by the Court itself, or by the public, the citizen should resist its extension to other contexts. As Abraham Lincoln, discussing the Dredd Scott decision, put it:

> "(T)he candid citizen must confess that if the policy of the government upon vital questions affecting the whole people, is to be irrevocably fixed by decisions of the Supreme Court, the instant that they are made, in ordinary litigation between parties in personal actions, the people will have ceased to be their own rulers, having, to that extent, practically resigned their government, into the hands of that eminent tribunal." (4 Basler, The Collected Works of Abraham Lincoln 262, 268 (1963).)

Thus even if the Court had intended by its Roe and Doe rationale to exclude the unborn, and newly born nonviable infants, from all legal protection including that against harmful experimentation, I can see no legal principle which would justify, let alone require, passive submission to such a breach of our moral tradition and commitment.

Secondly, the Court in Roe and Doe did not have before it, and presumably did not intend to pass upon and did not in fact pass upon, the question of experimentation on the fetus or born infant. Certainly that question was not

directly involved in those cases. Granting the fullest intendment to those decisions possibly arguable, it seems to me that the woman's new-found constitutional right of privacy is fulfilled upon having the fetus aborted. If an infant survives the abortion, there is hardly an additional right of privacy to then have him or her killed or harmed in any way, including harm by experimentation impermissible under standard norms. At least Roe and Doe should not be assumed to recognize such a right. And while the Court's unfortunate language respecting "potential" and "meaningful" life is thought by some to imply a total abandonment of *in utero* life for all legal purposes, at least for the first two trimesters, such a conclusion would so starkly confront our social, legal, and moral traditions that I think we should not assume it. To the contrary we should assume that the language was limited by the abortion context in which used and was not intended to effect a departure from the limits on human experimentation universally recognized at least in principle.

A shorthand way, developed during the Commission's deliberations, of stating the principle that would adhere to recognized human experimentation norms and that should be recommended in place of Recommendation (5) is: No research should be permitted on a fetus-to-be-aborted that would not be permitted on one to go to term. This principle is essential if all of the unborn are to have the protection of recognized limits on human experimentation. Any lesser protection violates the autonomy and integrity of the fetus, and even a decision to have an abortion cannot justify ignoring this fact. There is not only the practical problem of a possible change of mind by the pregnant woman. For me, the chief vice of Recommendation (5) is that it permits an escape hatch from human experimentation principles merely by decision of a national ethical review body. No principled basis for an exception has been, nor in my judgment can be, formulated. The argument that the fetus-to-be-aborted "will die anyway" proves too much. All of us "will die anyway." A woman's decision to have an abortion, however protected by Roe and Doe in the interests of her privacy or freedom of her own body, does not change the nature or quality of fetal life.

Recommendation (6) concerns what is now called the "nonviable fetus *ex utero*" but which up to now has been known by the law, and I think by society generally, as an infant, however premature. This Recommendation is unacceptable to me because, on approval of a national review body, it makes certain infants

up to five months gestational age potential research material, provided the mother who has of course consented to the abortion, also consents to the experimentation and the father has not objected. In my judgment all infants, however premature or inevitable their death, are within the norms governing human experimentation generally. We do not subject the aged dying to unconsented experimentation, nor should we the youthful dying.

Both Recommendations (5) and (6) have the additional vice of giving the researcher a vested interest in the actual effectuation of a particular abortion, and society a vested interest in permissive abortion in general.

I would, therefore, turn aside any approval, even in science's name, that would by euphemism or other verbal device, subject any unconsenting human being, born or unborn, to harmful research, even that intended to be good for society. Scientific purposes might be served by nontherapeutic research on retarded children, or brain dissection of the old who have ceased to lead "meaningful" lives, but such research is not proposed--at least not yet. As George Bernard Shaw put it in The Doctor's Dilemma: "No man is allowed to put his mother in the stove because he desires to know how long an adult woman will survive the temperature of 500 degrees Fahrenheit, no matter how important or interesting that particular addition to the store of human knowledge may be." Is it the mere youth of the fetus that is thought to foreclose the full protection of established human experimentation norms? Such reasoning would imply that a child is less deserving of protection than an adult. But reason, our tradition, and the U.N. Declaration of Human Rights all speak to the contrary, emphasizing the need of special protection for the young.

Even if I were to approach my task as a Commissioner from a utilitarian viewpoint only, I would have to say that on the record here I am not convinced that an adequate showing has been made of the necessity for nontherapeutic fetal experimentation in the scientific or social interest. The Commission's reliance is on the Battelle Report and its reliance is misplaced. The relevant Congressional mandate was to conduct an investigation and study of the alternative means for achieving the purposes of fetal research (P.L. 93-348, July 12, 1974, Sec. 202(b); National Research Act).

As Commissioner Robert E. Cooke, M.D., who is sophisticated in research procedures, pointed out in his Critique of the Battelle Report: "The only true objective approach beyond question, since scientists make [the analysis of the necessity for nontherapeutic fetal research], is to collect information and analyze past research accomplishments with the intention of disproving, not proving the hypothesis that research utilizing the living human fetus nonbeneficially is necessary." The Battelle Report seems to me not in accord with the Congressional intention in that it proceeds from a viewpoint opposite to that quoted, and is really an effort to prove the indispensability of nontherapeutic research. In any event, if that is its purpose, it fails to achieve it, for most of what it claims to have been necessary could be justified as therapeutic research or at least as noninvasive of the fetus (e.g., probably amniocentesis). In view of haste with which this statement must be prepared if it is to accompany the Commission's report, rather than enlarge upon these views now I refer both to the Cooke Critique and the Battelle Report itself both of which I am informed will be a part of or appended to the Commission's Report.

An emotional plea was made at the Commission's hearings not to acknowledge limitations on experimentation that would inhibit the court-granted permissive abortion. However, until its last meeting, I think the Commission for the most part admirably resisted the temptation to distort its purpose by pro-abortion advocacy. But at the last meeting, without prior preparation or discussion, it adopted Recommendation (12) promotive of research on abortion techniques. This I feel is not germane to our task, is imprudent and certainly was not adequately considered.

Finally, I do not think that the Commission should urge lifting the moratorium on fetal research as stated in Recommendation (16). To the extent that duration of the moratorium is controlled by Section 213 of the National Research Aot, the subject is beyond our control and we ought not assume authority that is not ours. This is matter not for us and not, ultimately, for any administrative official, but for Congress. If the American people as a democratic society really intend to withdraw from the fetus and nonviable infant the protection of the established principles governing human experimentation, that action I feel should come from the Congress of the United States, in the absence of a practical way to have a national vote, Assuming that any representative voice is adequate

to bespeak so basic and drastic a change in the public philosophy of the United States, it could only be the voice of Congress. Of course there is no reason why the Secretary of DHEW cannot immediately make clear that no researcher need stand in fear of therapeutic research.

As noted at the outset, the Commission's work has achieved some good results in reducing the possibilities of manifest abuses and thereby according a measure of protection to humans at risk by reason of research. That it has not been more successful is in my judgment not due so much to the Commission's failings as to the harsh and pervasive reality that American society is itself at risk--the risk of losing its dedication "to the proposition that all men are created equal." We may have to learn once again that when the bell tolls for the lost rights of any human being, even the politically weakest, it tolls for all.

David W. Louisell
Elizabeth Josselyn Boalt Professor of Law
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Appendix I

STATEMENT OF COMMISSIONER KAREN LEBACQZ,
WITH THE CONCURRENCE OF COMMISSIONER ALBERT R. JONSEN
ON THE FIRST ITEM

The following comments include some points of dissent from the Recommendations of the commission. For the most part, however, these comments are intended as elaborations on the Report rather than dissent from it.

1. At several points, the Commission established as a criterion for permissible research an acceptable level of risk--e.g., "no risk" or "minimal risk." I support the Commission's Recommendations regarding such criteria, but I wish to make several interpretative comments.

First, I think it should be stressed that in the first trials on human subjects or on a new class of human subjects, the risks are almost always unknown. The Commission heard compelling evidence that differences in physiology and pharmacology between human and other mammalian fetuses are such that even with substantial trials in animal models it is often not possible to assess the risks for the first trials with human fetuses. For example, evidence from animal trials in the testing of thalidomide provided grounds for an estimation of low risk to human subjects; the initial trials in the human fetus resulted in massive teratogenic effects.

I would therefore urge review boards to exercise caution in the interpretation of "risk" and to avoid the temptation to consider the risks "minimal" when in fact they cannot be fully assessed.

Second, I think it important to emphasize the evaluative nature of judgments of risk. The term "risk" means chance of harm. Interpretation of risk involves both an assessment of statistical chance of injury and an assessment of the nature of the injury. Value judgments about what constitutes a "harm" and what percentage chance of harm is acceptable are both involved in the determination of acceptable risk. A small chance of great harm may be considered unacceptable where a greater chance of a smaller harm would be acceptable. For example, it is commonly accepted that a 1-2 percent chance of having a child with Down's syndrome is a "high" risk, where the same chance of minor infection from

amniocentesis would be considered a "low" risk. Opinions will differ both about what constitutes "harm" or injury and also about what chance of a particular harm is acceptable.

For all these reasons, the interpretation of risk and the designation of acceptable "minimal risk" merit considerable attention by the scientific community and the lay public. The provision of national review in problematic instances should engender serious deliberation on these critical issues.

Third, the establishment of criteria for "no risk" or "minimal risk" is obviously related to the interpretation of "harm." In general, the Commission has discussed "harm" in terms of two indices: (1) injury or diminished faculty, and (2) pain. A third commonly accepted definition of "harm" is "offense against right or morality"; this meaning of harm has been subsumed under the rubric of violation of dignity or integrity of the fetus, and thus is separated out of the Commission's deliberations on acceptable levels of risk. In establishing acceptable levels of risk, therefore, the Commission has been concerned with injury and pain to the fetus.

Several ethicists argued cogently before the Commission that the ability to experience pain is morally relevant to decisions regarding research. Indeed, the argument was advanced that the ability to experience pain is a more appropriate consideration than is viability for purposes of establishing the limits of intervention into fetal life.

However, scientific opinion is divided on the question of whether the fetus can experience pain--and on the appropriate indices on which to measure the experience of pain. Several experts argue that the fetus does not feel pain.

I believe that the Commission has implicitly accepted this view in making Recommendation (6) regarding research on the fetus during the abortion procedure and on the nonviable fetus *ex utero*. Should this view not be correct, and should the fetus indeed be able to experience pain before the twentieth week of gestation, I would modify Recommendation (6) in two ways:

First, the Recommendation as it now stands does not specify an acceptable level of risk. The reason for this omission is essentially as follows: in a dying subject prior to viability, "diminution of faculties" does not appear to

be a meaningful index of harm since this index refers largely to future life expectations. Therefore, the critical meaning of "harm" for such a subject lies in the possibility of experiencing pain. If the fetus does not feel pain it cannot be "harmed" in this sense, and thus there is no risk of harm for such a fetus. It is for this reason that the Commission has not specified an acceptable level of "risk" for fetuses in this category, although it has been careful to protect the dignity of the fetus.

Clearly, however, if the fetus does indeed feel pain, then it can be "harmed" by the above definition of harm. If so, then I would argue that an acceptable level of risk should be established at the same level as that considered acceptable for fetuses *in utero*--namely, "no risk" or "minimal risk."

Second, the Commission has concluded that out of respect for the dying subject, no interventions are permissible which would alter the duration of life of the subject--i.e., by shortening or lengthening the dying process (item 6h). I find the prohibition against shortening the life of the dying fetus to be acceptable provided the fetus does not feel pain. If the fetus does feel pain, however, then its dying may be painful and respect for the dying subject may require that its pain be minimized even if its life-span is shortened in so doing.

2. The commission has stated that its provisions regarding therapeutic and nontherapeutic research directed toward the pregnant woman are not intended to limit research on improving abortion techniques. I support this stand and wish to clarify the reasons for my support.

In supporting this statement, I neither condone nor encourage widespread abortion. However, I do believe that some abortions are both legally and morally justifiable. It is therefore consonant with the principle of minimizing harm to develop techniques of abortion that are least harmful. Indeed, under the present climate of legal freedom to abort and widespread practice of abortion, adherence to the principle of not-harming may impose an obligation on us to research abortion technology in order to minimize harm. This obligation arises not only out of consideration of the health and well-being of the woman but also from a concern for possible pain or discomfort of the fetus during the abortion procedure.

3. Evidence presented to the Commission indicates that there is a strong emphasis in the law on avoiding possible injury to a child to be born. This evidence, coupled with the uncertainty of risks in a new class of human subjects, suggests that considerable importance ought to be attached to the question of compensation for injury incurred during research.

The Commission will study this question in depth at a later time, and therefore has not made any recommendations on compensation at this time. As a matter of personal opinion, I would like to note that I am reluctant to allow any research on the living human fetus unless provision has been made for adequate compensation of subjects injured during research.

4. The Commission's Recommendation on research during the abortion procedure and on the nonviable fetus ex *utero* prevents prolongation of the dying process for purposes of research. This prohibition may appear to have the effect of preventing research on the development of an artificial placenta.

It is my understanding that such an effect does not necessarily follow. Steps toward the development of an artificial placenta are prohibited only through nontherapeutic research; innovative therapy or therapeutic research on the possibly viable infant is not only condoned but encouraged. Thus the development of an artificial placenta may proceed, but under more restricted circumstances in which it is limited to therapeutic research or to nontherapeutic research which does not alter the duration of life. I do not believe that it was the intention of the Commission to curtail all research toward the development of an artificial placenta, nor do I believe that such will be the effect of the Commission's Recommendations.

Were the Recommendations to have such an effect, however, I would dissent. Indeed, I would argue that a prematurely delivered fetus that is unable to survive, given the support of available medical technology, would have an interest in the development of an artificial placenta that would allow others like it to survive. Thus it would not be contrary to the interests of that fetus for it to be subjected to nontherapeutic research in the development of an artificial placenta.

In making such an argument, I invoke a principle that I call the "principle of proximity": namely, that research is ethically more acceptable the more closely it approximates what the considered interests of the subject would reasonably be. For example, Hans Jonas has argued that dying subjects should not be used in nontherapeutic research, even when they have consented, unless the research deals directly with the cause from which they are dying; that is, it is presumed that a dying subject has an interest in his/her own disease which legitimates research on that disease where research in general would not be legitimate.

Such a principle is, of course, open to wide interpretation. But I think it not unreasonable to suggest that the dying fetus would have an interest in the cause of its dying or in the development of technology which would allow others like it to survive. On such a principle, one might argue that it is more ethically acceptable to use dying fetuses with Tay-Sachs disease as subjects in nontherapeutic research on Tay-Sachs disease than in nontherapeutic research on general fetal pharmacology. Similarly, one might argue that it is ethically acceptable to use nonviable fetuses *ex utero* as subjects in nontherapeutic research on the development of an artificial placenta. The development of a full rationale for such a position would require an analysis along the lines suggested by McCormick and Toulmin, and I cannot attempt that here. At this point I simply wish to suggest that I believe it is possible to argue for both therapeutic and nontherapeutic research directed toward the development of an artificial placenta.

5. Finally, members of the Commission disagreed about changes in the timing or method of abortion in relation to research. Recommendation (10) states clearly that the recommendations of a physician regarding timing and method of abortion should not be determined by the design or conduct of nontherapeutic research. I am in full agreement with this Recommendation.

The provision in Recommendation (6) (item g), however, is more ambiguous. I would argue that changes in timing or method of abortion are ethically acceptable provided that they are freely chosen by the woman and that she has been fully informed of all possible risks from such changes. I base this argument on the right of any patient to be informed about alternative courses of treatment and

to choose between them. It seems to me that the pregnant woman, as a patient, may choose the timing and method of abortion, provided that she has been fully informed of the following: 1) the relation of alternative methods of abortion to possible research on the fetus; 2) risks to herself and to possible future children of alternative possible methods of abortion; and 3) procedures which would be introduced into the abortion as part of the research design which would not be medically indicated.

Some members of the Commission have argued that a woman might choose such changes provided that they entail no additional risk. While I appreciate the concern to protect the woman's health and well-being, such a restriction seems to me a violation of her right to freedom of choice as a patient. Thus I would allow a woman to choose to delay her abortion until the second trimester for purposes of research, provided that she has been fully informed of all risks in so doing. One restriction seems imperative to me, however: in no case, should she be allowed to delay the abortion beyond the twentieth week of gestation for research purposes. This position is reflected in the Deliberations and Conclusions of the Commission's Report.

Report of the Advisory Committee
to the Director, National Institutes of Health

Human Fetal Tissue Transplantation Research

December 14, 1988
Bethesda, Maryland

REPORT OF THE ADVISORY COMMITTEE TO THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH

Human Fetal Tissue Transplantation Research

December 14, 1988

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- Statement of Dr. Kenneth J. Ryan C3
- Statement of Dr. LeRoy Walters C5
- Statement of Dr. James F. Childress C7
- Statement of Dr. Jane L. Delgado (provided in writing only) C9

- Statement of Mr. James Bopp, Jr., Esq. C11
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Appendix II

SUMMARY OF THE 58TH MEETING OF THE
ADVISORY COMMITTEE TO THE DIRECTOR, NIH

DECEMBER 14, 1988

HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH

EXECUTIVE SUMMARY

The Advisory Committee to the Director, National Institutes of Health (NIH), joined by representatives of the National Advisory Councils of the NIH Institutes, met on December 14 to review the Report of the Human Fetal Tissue Transplantation Research Panel. The Panel was constituted as an *ad hoc* consultants group to the Advisory Committee to the Director, NIH, and charged with reviewing the ethical, legal, and scientific issues surrounding the use of human fetal tissue derived from induced abortions in transplantation research. During its review, the Committee heard presentations by nine members of the Panel, including its Chairman, with an additional statement entered into the record without the Panel member being present. The Panel presentations summarized many of the considerations leading to the report and elaborated on some of the reasons for individual Panel member concurrence or dissent. After the Panel presentations, the Committee members and Council representatives discussed the report, inviting comments and further clarification from the Panel members present. Three unanimous recommendations emerged from the deliberations of the Advisory Committee and the Council representatives: (1) to accept the report and recommendations of the Human Fetal Tissue Transplantation Research Panel; (2) to recommend that the Assistant Secretary for Health lift the moratorium on Federal funding of human fetal tissue transplantation research utilizing tissue from induced abortions; and (3) to accept current laws and regulations governing human fetal tissue research with the development of additional policy guidance as appropriate, to be prepared by NIH staff, to implement the recommendations of the Human Fetal Tissue Transplantation Research Panel.

INTRODUCTION

In October 1987, the NIH submitted a request to the Assistant Secretary for Health for the approval of an experimental implant of human fetal cells derived from induced abortion tissue aspirates into the brain of a Parkinson's patient. The protocol was proposed by intramural investigators in the National Institute of Neurological and Communicative Disorders and Stroke. Although this research procedure did not require the approval of the Department of Health and Human Services, the Director, NIH, elected to advise the Assistant Secretary for Health of this proposed research project because of the broad scientific and ethical implications surrounding this area of research.

On March 22, 1988, the Assistant Secretary for Health responded by requesting that the NIH "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." At the same time, he outlined a series of 10 questions related to this research issue to guide the panel of consultants in their deliberations. Concurrently, the Assistant Secretary for Health withheld his approval of the proposed experiment and future experiments, pending the outcome of the meeting of a panel of consultants called for the specific purpose of reviewing the legal, scientific, and ethical issues surrounding the human fetal tissue transplantation research issue.

The Human Fetal Tissue Transplantation Research Panel, which was convened as an *ad hoc* group of consultants to the Advisory Committee to the Director, NIH, met three times: September 14-16, October 20-21, and December 5, 1988. The first two days, the Panel heard public testimony from over 50 experts in the fields of science, law, and ethics, including representatives from diverse organizations. After the public testimony, the Panel met for the remainder of the time deliberating among themselves on the questions posed by the Assistant Secretary for Health, drafting responses to the questions, and developing supporting considerations to explain the Panel's rationale in arriving at the responses to the questions posed. All of the meetings of the Panel were open to the public and were well attended by interested individuals and the media.

The Advisory Committee to the Director, NIH, met on December 14 to consider the report of the Human Fetal Tissue Transplantation Research Panel and to provide the Director, NIH, with the Committee's recommendations relative to the content and recommendations contained in the report.

SUMMARY OF PRESENTATIONS BY INDIVIDUAL HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH PANEL MEMBERS

Individual members of the Human Fetal Tissue Transplantation Research Panel had been invited by the Director, NIH, to address the Advisory Committee at its meeting on December 14 to provide the Committee further insight into the deliberations of the Panel. Nine of the ten members of the Panel present at the meeting, including the Chairman, made brief statements that further clarified their work on the Panel or explained their vote on the 10 questions the Panel was asked to address in developing its report. An additional statement by a Panel member was entered into the record without the member being present.

The individual Panel presentations confirmed the wide diversity of convictions, interpretations, and points of view that were reflected in the Panel report. On the question of using human fetal tissue derived from elective abortions for transplantation, the individual Panel presentations described three general positions. One position held that abortion is legal; consequently, the use of the tissue derived from such abortions for research is an acceptable, and even desirable research activity, and is consistent with sound ethical and moral principles. The second position maintained that induced abortion is immoral and that Federal funding of research using tissue from such abortions would institutionalize an immoral activity. As a middle point between these two views was the position that regardless of how serious, or even morally tragic, a decision for an abortion and the action following that decision might be, abortion is presently legal, and the issues

surrounding the abortion are entirely separable from the issues surrounding the use of the tissue in research, provided that appropriate protections are established to guide the research. Each of these three positions was given further support in the invited arguments and presentations by the individual Panel members.

One Panel member noted that the scientific community has long been concerned about the use of fetal tissue in transplantation research, and previous commissions, such as the 1975 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, have dealt with this issue. However, the underlying "tension" in dealing with this issue revolves not around the science of this type of research, but the manner in which human fetal tissue is obtained--that is, by induced abortions. It is the tremendous polarization of attitudes on abortion that makes public debate on this issue very difficult. It was emphasized that the work of the Human Fetal Tissue Transplantation Research Panel was an excellent illustration of the benefits of such panels and commissions because a forum is created in which rational debate on complex issues is encouraged and fostered.

Another Panel member elected to concentrate on two issues--the morality of using human fetal tissue derived from an abortion and the importance of gaining maternal consent in the donation process. This Panel member's conclusion was that society should not reject using human fetal tissue for transplantation research because the tissue is derived from an induced abortion, since the use of such tissue does not imply complicity in the decision or the act of abortion. On the issue of maternal donation of fetal tissue, the Panel member underscored that it was imperative to protect the right of the pregnant woman to donate her fetal tissue since the abortion request did not negate her rights as a donor of her own tissue.

Two Panel members expressed unequivocal opposition to abortion and characterized the use of human fetal tissue for research as complicity in the act of abortion. They stressed that sanctioning the use of human fetal tissue in transplantation research would serve as a further inducement to pregnant women to abort, because a possible societal good could now be inferred from the use of aborted tissue. Additionally, if therapy using fetal tissue transplantation techniques proves beneficial in treating certain diseases, there may conceivably be an increased demand for fetal tissue that does not keep pace with the supply. This then would represent a further inducement to abort and would result in an increased number of abortions nationally.

Another Panel member pointed out that public policy needs to be based on a moral framework that recognizes the plurality of our society, that is, differences in values, beliefs, and lifestyles, and not on individual moral interpretations. Furthermore, for many moral problems there may exist more than one correct solution, and in developing public policy, open debate of the issues and building consensus is the best approach to take.

Yet another Panel member concluded that the NIH needs to take the lead in this area of research to assure that safeguards and protections are put in place to guide the research efforts of scientists. It was further pointed out

that, despite the moratorium, at least two institutions have recently engaged in privately funded transplantation research using human fetal tissue.

One of the Panel members advanced the argument that it could be considered immoral and unethical for the fetal tissue from induced abortions to be discarded if there is the potential for its positive therapeutic use. Furthermore, using human fetal tissue does not signify approval of abortion, and the Panel member drew the analogy to organ transplantation from homicide and accident victims. Use of organs donated from such sources does not mean that society approves of homicide or encourages accidents.

Finally, one of the Panel members pointed out that while the Panel did not break new ground, it did update the ethical, legal, and scientific discussions on this issue. The report of the Panel was also consistent with the international consensus on human fetal tissue transplantation research developed in eight countries, including the National Health and Medical Research Council of Australia, the British Medical Association, the French National Ethics Consultative Committee for Life and Health, and the Parliamentary Assembly of the Council of Europe. In concluding his statement, this Panel member suggested that the deliberations of the Panel underscored the need for a standing Ethics Board at the Department of Health and Human Services to allow for a recurrent review of fast-changing ethical and scientific issues.

A copy of the full text of each Panel member presentation is located in the Appendix to this report.

DELIBERATIONS OF THE MEMBERS OF THE ADVISORY COMMITTEE AND THE COUNCIL REPRESENTATIVES

In the course of its deliberations, the Advisory Committee recognized that abortion is a moral issue for many in our society, but noted that the Panel was directed to provide advice on what is the appropriate public policy in a single area--the use of post-mortem fetal tissue derived from elective abortions in transplantation research. The Advisory Committee members and the Council representatives quickly concluded that the Panel's report was clearly an impressive and skillfully crafted document, and that given the divisiveness underlying our society on the issues related to the topic under consideration, the report represented a remarkable consensus and praised the Panel for its extensive and thoughtful work. The Committee further concluded that the consensus of the Panel reflected the consensus of the country itself, where widely divergent views are held about the morality of elective abortions and about the use of fetal materials derived from such abortions for the purposes of research.

The Committee then discussed three possible actions it could take relative to the report: (1) accept or reject the report; (2) modify the report; or, (3) write its own report on this issue. After some discussion involving recommending minor word changes in the Panel report, the Committee agreed that it would not reach a different or better consensus in writing another, independent report on this issue. The Advisory Committee then voted

unanimously (19 yea) to accept the report and recommendations of the Human Fetal Tissue Transplantation Research Panel as written.

After its vote to accept the Panel report, the Committee turned its attention to the temporary moratorium on federally funded transplantation research using human fetal tissue from induced abortions issued on March 22, 1988, by the Assistant Secretary for Health. Several Committee members and Council representatives voiced the opinion that they had not read anything in the Panel report or heard any arguments earlier in the day to justify continuing the temporary moratorium. However, several other members requested a clarification on the protections and guidelines currently in place relative to this area of research and also asked what amendments or changes to existing Federal regulations would be necessary to accommodate some of the concerns expressed by the Panel in its report.

In clarifying this issue, NIH staff pointed out that the operative Federal guidelines relative to the transplantation research issue are found in 45 CFR 46. It was further emphasized that these regulations already contain most of the recommendations made by the Panel relative to issues of timing, method, and procedures used to terminate the pregnancy, right of donation, and protection from inducements. These provisions were designed to legally separate the researcher and the individuals who perform the abortion from any relationship to or decisions about termination of pregnancy. It was also suggested by NIH staff, and confirmed by the Director, NIH, that if it was the intention of the Advisory Committee, appropriate NIH staff would make a point-by-point comparison of 45 CFR 46 with the recommendations of the Panel and draft additional policy guidelines if needed. The Advisory Committee urged the NIH not to draft new regulations incorporating the Panel recommendations because the state of the science is changing rapidly and because of the lengthy departmental procedures involved in promulgating regulations that might delay the research process by several years. Furthermore, developing precise policy guidelines would be an effective approach, as they would have the force of regulations and could be developed and implemented within the research community within 2 to 4 months. This latter point was underscored by several Advisory Committee members and Council representatives, with the proviso that any policy guidelines developed presently need to be reviewed and updated as appropriate to keep pace with changes in the science.

It also was pointed out that once the policy guidelines were developed and implemented by institutions and investigators receiving Federal funds for research, compliance with the policy guidelines would be a condition for the receipt of such funds. Several Committee members observed that the existence of strong Federal guidelines usually influences the private sector to follow established Federal procedures in conducting its own research. However, in the absence of Federal direction in this area of research, researchers could continue to obtain human fetal material from induced abortions for their research efforts, but it would be procured without Federal funding or the oversight recommended by the Panel. In addition, the material and the donor would not necessarily have the protections provided in the Federal regulations and policy guidelines.

In these discussions, the Committee briefly reviewed the scientific justification for proceeding with research in this area, including the scientific evidence that intrafamilial transplantation should be prohibited on the basis of current knowledge. It was pointed out that in some disease areas, such as Parkinson's disease and juvenile diabetes, the results of animal studies provide justification for conducting human studies. The Committee was informed that in these disease conditions, first trimester fetal tissue is optimal for transplantation. One Council representative noted that recently the American Association of Neurological Surgeons had formally adopted the position that evidence now exists from animal research that justifies clinical studies on patients with Parkinson's disease. In other disease states such as Alzheimer's disease, Huntington's disease, spinal cord injury, and neuroendocrine deficiencies, experts recommend further animal studies.

The Advisory Committee concluded this portion of its deliberations by voting unanimously (19 yea) to recommend that the Assistant Secretary for Health lift the moratorium on Federal funding of human fetal tissue transplantation research utilizing tissue derived from induced abortions.

There followed a brief discussion among the Committee members and the Council representatives on a variety of issues, including concerns about screening tissue to be used in research to assure that it is disease free; providing selective demographic data to researchers and tissue recipients about tissue donors; insulating a woman's consent to abort from her consent to donate tissue; preventing monetary or other gains for the donation; requiring that procurement agencies not profit from such transactions; reaffirming that the paramount concern in obtaining fetal tissue should continue to be the health of the pregnant woman; and emphasizing that the properties of fetal tissue, such as the optimum gestational age for use in research, should not be a factor in deciding the timing or the procedure of an abortion.

The Committee also raised questions about the details of the Uniform Anatomical Gift Act (UAGA), the Hyde Amendment, and the National Organ Transplant Act as they pertain to this area of research and engaged the Panel members in further discussion. In their responses, Panel members to a great extent reemphasized their earlier views and comments. The Committee was satisfied that if any problems exist, they could be specifically identified and resolved during the drafting of additional policy guidelines.

Finally, the Advisory Committee members and Council representatives voted unanimously for a third time (19 yea) to accept current laws and regulations governing human fetal tissue research with the development of additional policy guidance as appropriate, to be prepared by NIH staff, to implement the recommendations of the Human Fetal Tissue Transplantation Research Panel.

SUMMARY AND RECOMMENDATIONS

The Advisory Committee to the Director, NIH, together with representatives of the National Advisory Councils of the NIH Institutes, met on December 14 to review the Report of the Human Fetal Tissue Transplantation Research Panel. The Advisory Committee heard individual presentations from 9 of the 10 members of the Panel present at the meeting, with an additional

statement entered into the record by a Panel member not present. The Advisory Committee members and Council representatives recognized that abortion is a moral issue for many in our society, but noted that the Panel was directed to provide advice on what is the appropriate public policy in a single area--the use of post-mortem fetal tissue derived from induced abortions in transplantation research. The Advisory Committee members and the Council representatives concluded that the Panel's report represented a remarkable consensus on the issues and praised the Panel for its thoughtful report.

After an extensive review and discussion of the Panel report, the Committee unanimously voted three recommendations:

- to accept the report and recommendations of the Human Fetal Tissue Transplantation Research Panel as written;
- to recommend that the Assistant Secretary for Health lift the moratorium on Federal funding of human fetal tissue transplantation research utilizing tissue from induced abortions; and
- to accept current laws and regulations governing human fetal tissue research with the development of additional policy guidance as appropriate, to be prepared by NIH staff, to implement the recommendations of the Human Fetal Tissue Transplantation Research Panel.

Agenda

Appendix II

AGENDA

58th Meeting of the Advisory Committee
to the Director, NIH

December 14-15, 1988

Building 31, Conference Room 10
National Institutes of Health
Bethesda, Maryland

HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH

December 14, 1988

MORNING SESSION

9:00 Introduction . . . . . Dr. Wyngaarden

9:15 Status Report on Activities Resulting from June 27-28, 1988 Advisory Committee to the Director Meeting on "The Health of Biomedical Research Institutions: Report of the Regional Meetings" . . . . . Dr. Raub

9:30 Human Fetal Tissue Transplantation Research: Overview and Background . . . . . Dr. Wyngaarden

9:45 Summary of September 14-16, October 20-21, and December 5 Meetings of the Human Fetal Tissue Transplantation Research Panel

Overview . . . . . Judge Adams

10:00 Individual Statements by the Human Fetal Tissue Transplantation Research Panel Members

10:00 . . . . . Dr. Ryan

10:05 . . . . . Dr. Walters

10:10 . . . . . Dr. Childress

10:15 . . . . . Dr. Delgado

10:20 . . . . . Mr. Bopp

10:25 . . . . . Dr. Clouser

MORNING SESSION (continued)

10:30 Coffee Break

10:45 Continuing Statements by the Human Fetal Tissue Transplantation Research Panel Members

10:45 . . . . . Ms. King

10:50 . . . . . Prof. Burtchaell

10:55 . . . . . Prof. Robertson

11:00 Summary of Considerations and Recommendations of Human Fetal Tissue Transplantation Research Panel--Scientific Issues

Chairman . . . . . Dr. Ryan

- **Assistant Secretary for Health (ASH) Question 5A: Should there be and could there be a prohibition on the donation of fetal tissue between family members or friends and acquaintances?**
- **ASH Question 5B: Would a prohibition on donation between family members jeopardize the likelihood of clinical success?**
- **ASH Question 9: For those diseases for which transplantation using fetal tissue has been proposed, have enough animal studies been performed to justify proceeding to human transplants? Because induced abortions during the first trimester are less risky to the woman, have there been enough animal studies for each of these diseases to justify the reliance on the equivalent of the second trimester human fetus?**
- **ASH Question 10: What is the likelihood that transplantation using fetal cell cultures will be successful? Will this obviate the need for fresh fetal tissue? In what time frame might this occur?**

General Discussion . . . . . Members, Advisory Committee to the Director and the Human Fetal Tissue Transplantation Research Panel

12:15 Lunch

AFTERNOON SESSION

1:15 Summary of Considerations and Recommendations of Human Fetal Tissue Transplantation Research Panel--Legal and Ethical Issues

Chairman . . . . . Dr. Walters

- ASH Question 1: Is an induced abortion of moral relevance to the decision to use human fetal tissue for research? Would the answer to this question provide any insight on whether and how this research should proceed?

- ASH Question 2: Does the use of the fetal tissue in research encourage women to have an abortion that they might otherwise not undertake? If so, are there ways to minimize such encouragement?

- ASH Question 3: As a legal matter, does the very process of obtaining informed consent from the pregnant woman constitute a prohibited "inducement" to terminate the pregnancy for the purposes of the research--thus precluding research of this sort, under HHS regulations?

- ASH Question 4: Is maternal consent a sufficient condition for the use of the tissue, or should additional consent be obtained? If so, what should be the substance and who should be the source(s) of the consent, and what procedures should be implemented to obtain it?

- ASH Question 6: If transplantation using fetal tissue from induced abortions becomes more common, what impact is likely to occur on activities and procedures employed by abortion clinics? In particular, is the optimal or safest way to perform an abortion likely to be in conflict with preservation of the fetal tissue? Is there any way to ensure that induced abortions are not intentionally delayed in order to have a second trimester fetus for research and transplantation?

- ASH Question 7: What actual steps are involved in procuring the tissue from the source to the researcher? Are there any payments involved? What types of payments in this situation, if any, would fall inside or outside the scope of the Hyde Amendment?

- ASH Question 8: According to HHS regulations, research on dead fetuses must be conducted in compliance with State and local laws. A few States' enacted version of the Uniform Anatomical Gift Act contains restrictions on the research applications of dead fetal tissue after an induced abortion. In those States, do these restrictions apply to therapeutic transplantation of dead fetal tissue after an induced abortion? If so, what are the consequences for NIH-funded researchers in those States?

AFTERNOON SESSION (continued)

	General Discussion	Members, Advisory Committee to the Director and the Human Fetal Tissue Transplantation Research Panel
3:00	Coffee Break	
3:15	Continuation of Discussion of Legal and Ethical Issues	
5:00	Adjourn	

Appendix II

December 15, 1988*

MORNING SESSION

9:00	Consideration of Report and Recommendations of the Human Fetal Tissue Transplantation Research Panel's Report	
	Chairman	Dr. Healy
	Speakers	Dr. Cooper Dr. Palade
	General Discussion and Recommendations	Members, Advisory Committee to the Director and the Human Fetal Tissue Transplantation Research Panel
10:30	Coffee Break	
10:45	Continuation of Advisory Committee Members' Discussion	
12:00	Adjourn	

*The Advisory Committee to the Director concluded its review of the Panel Report on December 14. Consequently, the Advisory Committee Meeting scheduled for December 15 was not held.

Meeting Participants

Appendix B

Appendix II

ADVISORY COMMITTEE TO THE DIRECTOR, NIH

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*These Committee members did not attend the December 14, 1988, meeting of the Advisory Committee to the Director, NIH.

Appendix II

Appendix II

ADVISORY COMMITTEE TO THE DIRECTOR, NIH

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Appendix II

HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH PANEL

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Presentations by Individual Members of the Human Fetal Tissue Transplantation Research Panel, December 14, 1988

Appendix C

STATEMENT TO THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH

December 14, 1988

Judge Arlin M. Adams

It is a pleasure to be here, and it has been a great pleasure to serve as chairman of the Panel. I concur with Dr. Wyngaarden that the Panel is broad-based, encompassing many of our disciplines. It was a very fine, courteous, and intelligent Panel. We had many disagreements, but we were never disagreeable.

The voting, as you probably have seen in the material that has been distributed, would favor going ahead with this type of research, but--and it is a strong "but," as far as I am concerned--NIH should do so only with carefully crafted guidelines and an additional provision for periodic reviews, because we are entering into a field where we do not know all of the answers.

As we proceeded with answering the questions that had been posed to us by Dr. Windom--and those questions are in front of you--we thought it insufficient merely to answer the questions, as difficult and as important as that task appeared to us, but to supply the members of the Advisory Committee with explanations or, as we put it, "considerations," which prompted the votes that were taken.

Those considerations appear immediately after the so-called "answers" to the questions. For example, Question 1 is posed and then the response of the Panel and, at the bottom, considerations for Question 1.

Finally, some of the members of the Panel--most of them--believed that we should permit individual members of the Panel to express their views in concurring or dissenting statements. They are immediately behind the answers to the questions and the considerations. I commend them to your attention.

The staff that you made available to us, Dr. Wyngaarden, was most courteous and extremely helpful. I personally am indebted to them and most particularly to Dr. Moskowitz, who was continuously available to us.

We are prepared to continue to assist you and this advisory group, as well as other members of the government as may be necessary to resolve these difficult matters.

Appendix II

Appendix II

STATEMENT TO THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH

December 14, 1988

Kenneth J. Ryan, M.D.

What I am presenting now is a personal viewpoint, which I believe is what each of the Panel participants will be doing until we get to the general discussion of the report itself.

The scientific community has itself been concerned with the ethical issues surrounding the use of cadaveric fetal tissue in transplantation research.

Evidence of this is that I was asked to deliver a lecture on the subject of the ethics of the use of such tissue at an international meeting of neuroscientists at MIT in March of this year. And, ironically, as I was driving home from the lecture, I turned on the car radio, and I heard about Assistant Secretary Windom's moratorium about the use of such tissue.

We are in a sense revisiting the atmosphere of 1974 and 1975, when the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which I chaired, was formed under the cloud of a congressional moratorium to publicly debate the then even broader issue of fetal research in general. The underlying tension then and now is that fetal tissue can be obtained from therapeutic interruptions of pregnancy or induced "abortions."

Our present Panel, which was formed 14 years later in 1988, like the original commission, was composed of individuals with diverse views and backgrounds. We have had to express these views and debate them in public. It is unlikely that much has been overlooked or omitted in the way of arguments pro or con on the use of cadaveric fetal tissue from abortion.

I personally applaud the tradition of using commissions or panels to work in public under the Sunshine Law and place the debate in a civilized and rational forum so we can deal fairly and democratically with the issues. Unfortunately, when the issue is abortion, we are more polarized than in most public policy debates. And as I have often said, it even stalks the halls of Congress.

There are, however, two legitimate principled positions on abortion itself, which can be defended and should be respected in a democratic society, and these issues are that abortion is moral; that is, a woman should not be forced to remain pregnant against her will; and that, conversely, abortion is immoral and the fertilized egg and fetus have a claim to life, which is absolute.

In any case, for the discussion, our Panel focused on the morality of separating the abortion itself from the use of fetal remains. I believe the only strident and dissonant note to our debate was some panelists who characterized scientists who use fetal remains as being as evil as the doctors who used tissue from the Nazi death camps.

While this has been amply rebutted in the material that has been distributed to you, I do wish to add that the reason the abortion debate is so difficult is that there are no close human analogies to the plight of the pregnant woman who has a conflict with the pregnancy in her body.

I would add that the trend in the last 15 years has been, from a medical point of view, to make abortion safer, quicker, and less expensive for women. There is no evidence that the procedure has been influenced in any way by the uses to which fetal remains are occasionally put, either for teaching or research.

Finally, the decision of the Panel was clear, that transplantation research could and should proceed if the research was kept separate from the decision-making, the techniques, and the economics of abortion, and if it was made non-commercial; that is, set up in a system similar to the transplantation of organs. This is what other countries, like Sweden, have already adopted.

I believe you have a fair report, amply argued, from the Panel, which I wholeheartedly commend to you as a response to Assistant Secretary Windom.

STATEMENT TO THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH

December 14, 1988

LeRoy Walters, Ph.D.

The guidelines on fetal tissue research that are included in our Panel's report constitute at least the ninth set of guidelines formulated on this topic since 1971. Committees or deliberative bodies involved in formulating earlier sets of guidelines represented numerous parts of the industrialized world, including the United Kingdom, the U.S., Australia, the Netherlands, France, Sweden, the Council of Europe, and Canada. There are remarkable similarities in the guidelines formulated in these diverse jurisdictions. In fact, there is an impressive international consensus on the ethical standards that should govern the use of fetal tissue for research. The positions adopted in the Panel's report are located squarely in the middle of this international consensus. We broke no new ground in approving this research in principle or in trying to isolate the research issue from the abortion decision. If we have contributed anything original in our report, it has been to update the scientific, ethical, and legal discussions and to provide a rationale for or explanation of the Panel's recommendations.

There is, of course, no guarantee that the eight committees and the one parliamentary assembly have reached a conclusion that is ethically correct. However, we are less likely to make a serious moral mistake when numerous groups of conscientious men and women from around the world have sought to study an issue with great care and have reached virtually identical conclusions about appropriate public policy.

My second and final comment has to do with the process through which the Panel's report and recommendations have been formulated. We have, I think, been fortunate to be able to arrive at such a substantial consensus in such a short time. We have had a fair-minded and vigorous chairman and a most attentive and diligent staff. The Panel members came from a diversity of backgrounds and represented numerous ethical viewpoints, yet we attempted to treat one another with respect. In some ways, the Panel deviated from the role originally envisioned for it. We held no deliberations in executive session because Dr. Wyngaarden courageously opened all of our meetings to the press and the public. Also, we were asked to finish our work in September, after a single 3-day meeting. In fact, we found it necessary to meet three times, especially if we were to provide an explanation for our recommendations.

Future *ad hoc* panels may not be so fortunate. In my view, the experience of our Panel points up the need for an ongoing ethics advisory committee or board within the Department of Health and Human Services. Ideally, such a body would be able to anticipate important ethical questions that are likely to confront NIH or the Department and to provide counsel that is at once timely, thoughtful, and balanced. Another possible role for such a standing body would be to provide recurrent review for fast-changing issues like the one before us today.

Appendix II

STATEMENT TO THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH

December 14, 1988

James F. Childress, Ph.D.

I am grateful for the opportunity I have had to serve on the Human Fetal Tissue Transplantation Research Panel and to appear here today. The first and fourth questions were two of the most important and divisive questions faced by the Panel. The first question invites us to consider whether the act of elective abortion disqualifies society from using the tissue of the aborted fetus, and the fourth question invites us to consider whether a woman's decision to abort disqualifies her from donating fetal tissue for use in transplantation research.

Regarding the first question, I would stress that different Panel members have very different views about why the act of elective abortion is morally relevant to the use of fetal tissue. Some view abortion as raising no moral problems; others view it as raising moral problems but not as absolutely wrong; and others view it as absolutely wrong. We were not asked to--and we could not--settle this issue of abortion. But whatever one thinks about abortion itself, the moral dispute about abortion in our society makes the source of fetal tissue morally relevant. Society faces a moral question about how to respect divergent views on this important matter. The majority of the Panel held--rightly in my judgment--that the fact that fetal tissue becomes available through an elective abortion should not lead society to reject its use in transplantation research. It is possible to use fetal tissue following elective abortions without complicity in abortions and without directly encouraging abortions.

The fourth question focuses on the sufficiency of maternal consent. The majority of the Panel held that maternal consent is both necessary and sufficient to transfer fetal tissue after an elective abortion (except where the father's objection is known). The Panel chose among several different ways to transfer human tissues: donation (express or presumed); abandonment; sales; and expropriation. The Panel clearly gave priority to transfer or acquisition of fetal tissue through express donation.

But who is the appropriate donor? And, specifically, does the pregnant woman's decision to abort disqualify her from being the donor? The Panel affirmed, and I strongly believe, that a woman who has a legal abortion remains the proper decisionmaker about the disposition and transfer of fetal remains. Societal disputes about the morality of her legal decision to abort should not disqualify her as a decisionmaker about donation. I quote from the Panel's rationale: "She still has a special connection with her fetus, and she has a legitimate interest in its disposition and use. Furthermore, the dead fetus has no interests that the pregnant woman's donation would violate."

Winston Churchill once remarked that democracy is the worst form of government except for all others. His comment is relevant here, too--the alternatives to express maternal donation of fetal tissue have even worse moral features. Of the possible ways to transfer fetal tissue, maternal donation is

the most congruent with our society's traditions, laws, policies, and practices, including the UAGA.

If we accept maternal donation as the best mode of transfer of fetal tissue, all things considered, and if we accept the moral relevance of abortion to the use of fetal tissue, for whatever reason, then it is important to develop procedures to separate as much as possible the abortion decision from the donation decision. And that is what the Panel's various recommendations attempt to do, for example, through the prohibition of remuneration for transfer, and the prohibition of the designation of transplant recipients.

Appendix II

WRITTEN STATEMENT PROVIDED TO THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH

December 14, 1988

Jane L. Delgado, Ph.D.

As the President and Chief Executive Officer of the National Coalition of Hispanic Health and Human Services Organizations, I feel it is important to bring to your attention the reasons why the deliberations of this Panel are of particular relevance to the Hispanic community:

- Almost one-third of U.S. Catholics are Hispanics.
- The majority of Hispanics (85 percent) are Catholic.
- According to a recent study (Henshaw and Silverman, 1988):
  - Hispanics represented 8.4 percent of women aged 15-44 and 12.8 percent of abortion patients in that age category.
  - Hispanic women were 60 percent more likely than non-Hispanics to have an unintended pregnancy terminated by abortion.
- Hispanics suffer disproportionately from diabetes and AIDS--diseases where an effective treatment might be developed from current fetal tissue transplantation research.
- Women's issues, Hispanic issues, and Hispanic women's issues are usually at best ignored and at worst maligned.

These facts were important considerations as we developed answers to the questions raised by Dr. Windom. Our deliberations, although generally collegial, unfortunately, were sometimes filled with not-so-polite accusations by articulate persons who used language to veil their own "feelings" while attacking others who were more candid in identifying "feelings" as the essential underpinning for values and beliefs. Besides these displays, I am also concerned about the inappropriate drawing of historical and situational parallels--most notably those to the Holocaust. Dr. Moscona's statement to this effect should be read carefully.

In summary, over the past several months I have had the opportunity to serve on this committee, review the testimony of experts in a variety of fields, and hear the range of concerns raised by members of this Panel. The answers have been developed by taking diverse ideologies and weaving them into a pattern which will benefit and enhance all of humanity. I concur with the responses developed by the Panel because they represent clearly understood, responsible positions.

Appendix II

STATEMENT TO THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH

December 14, 1988

James Bopp, Jr., Esq.

It is my pleasure to address the Director's Advisory Committee, and it has been, indeed, my distinct pleasure to serve on the Panel, which considered an issue about which there is a significant public interest.

You should note that there is, in fact, no consensus concerning the Panel's report. You will find in the documents prepared by the Panel a majority report of the Panel, and then you will find 11 members of the Panel filing concurrences and 4 members of the Panel filing dissents.

So at least 15 members of the 21-member Panel felt it necessary to explain and elaborate their views, put shadings on the recommendations that have been made by the Panel, some of which I think are important for this Advisory Committee to consider as they consider the majorities' recommendations.

Now, the question posed by the Assistant Secretary, in my view, can be summed up as whether transplantation research using human fetal tissue derived from induced abortion is an acceptable act for sponsorship by an agency of the Federal Government.

I think that the Panel's responsibility here was primarily ethical in nature. Since tissue for transplant was obtained from induced abortion, the essential ethical question before the Panel was whether or not the beneficial prospect of transplantation research is subverted by its association with induced abortion.

Some of the other members of the Panel, including myself, were guided by this ethical principle, that one may not take the life of a human being for the benefit of another human being.

Some of us proceeded on the assumption that abortion is, in fact, the taking of a human life and, thus, is morally objectionable except for the gravest of reasons.

Thus, in this inquiry, one of the ethical questions presented to me and to others of us is: Will fetal transplant lead some women to abort who would not have otherwise done so?

Some of us have concluded that it would, in fact, do so; and, thus, fetal tissue transplantation research, which could lead to this result, should not be funded by the Federal Government.

Now, it is reasonable to expect that abortion would increase, if fetal tissue transplantation became common, as a result of two distinct effects of this successful therapy: first, that it would provide a reason for some women to abort who would not have otherwise done so; and, secondly, that the market forces that can be expected to come into play would ensure that abortion clinics encouraged abortion.

As a preface to this, you have to understand that successful fetal tissue therapy involves an institutional relationship between abortion clinics and those who participate in this therapy.

It involves a contract with abortion clinics, people on site to gain the fresh tissue, consent from the woman, and reimbursement of expenses to the abortion clinic. In other words, the relationship necessitates a constant supply of fetal tissue from future abortions from abortion clinics and assurance that that supply will continue.

This, thus, is not a casual relationship, or an accidental one, but an intentional one requiring the most intimate cooperation between those involved in fetal tissue transplant or their agents who would use the tissue and the abortion clinic.

Now to the two effects. First, if fetal tissue transplant becomes common, this will influence some women to have an abortion. It is well-documented in the literature that ambivalence toward abortion is a common reaction of a woman facing a problem pregnancy.

There is a period of intense anxiety and ambivalence that is often experienced during the 24 hours preceding an abortion. This ambivalence is reflected in the fact that one-fourth to approximately one-half of women aborting find the decision difficult to make.

In addition, in studies of pregnant women who choose to abort and others who choose to deliver their children, approximately one-third to 40 percent of the women, whatever their ultimate decision, were reported to have changed their decision at least once, with women who aborted being significantly more likely to report their decision as a relatively difficult one, to rethink their initial choice, and to regret having to have made that decision.

Some women who make an initial decision to abort will change their minds at the last minute, with approximately 5 percent changing their minds after making an appointment to have an abortion and approximately 1 percent changing their minds at the abortion clinic itself.

Significantly, studies reveal that some 24 percent to 37 percent of women who abort do not make up their minds until just before the procedure. In addition, studies reflect that women, when they decide whether or not to abort, often consider multiple reasons, on the average four reasons, in deciding whether or not to have an abortion.

For those women who are ambivalent about abortion, that is, the 40 percent of pregnant women who have changed their minds at least once or who have found the abortion decision difficult, the pros and cons of the decision were somewhat evenly balanced, regardless of what decision is made. Most women who decide to abort are uncertain and uncommitted in their abortion decision. For them, abortion is a marginal good at best.

We also find that women, regarding their reasons to abort, consider the benefits or concerns of others. Thus, I would submit two facts: one, that if fetal tissue transplantation therapies became common, it would become common knowledge among women who were considering whether or not to abort that fetal

tissue transplant is a possible result of their abortion; and when you add a beneficent reason to the number of reasons that women consider when deciding whether or not to have an abortion, some would abort who would not have otherwise done so.

The Panel does acknowledge this result. The Panel admits that, "Transplantation and research with fetal tissue will become general knowledge" if it becomes successful.

They also acknowledge "that knowledge of the possibility for using fetal tissue in research and transplantation might constitute motivation, reason, or incentive for a pregnant woman to have an abortion."

Thus, I would submit that if fetal tissue transplant therapy became common and successful, that this would necessarily influence women, some women, to decide to have an abortion that would not otherwise occur.

Secondly, we cannot ignore the market forces that would be at work. Based on the testimony that we have heard before the Panel, if this therapy became successful, for instance, for Parkinson's disease or diabetes, the demand would greatly outstrip the supply.

Current levels of abortion can provide only enough tissue yearly for fetal transplant for those two conditions for less than 5 percent of those who would benefit from the therapy if successful. This necessarily would create financial incentives for abortion clinics to encourage abortion, even if they are only receiving reimbursement for their expenses.

Indeed, I would submit that these market forces will ensure what we have already come to know, that no one who is not otherwise obligated to follow NIH guidelines would follow them.

Indeed, as we sit here, fetal tissue transplants for Parkinson's disease is underway and has been conducted at the University of Colorado and at Yale during the period of time of the NIH moratorium, during which we were to develop voluntary guidelines to ensure that this research and ultimate therapy are conducted ethically.

Thus, in my view, abortion can reasonably be expected to increase as a result of NIH-funded research, if the research leads to successful therapies.

Now, let me turn briefly to the Panel report. The Panel does acknowledge that "it is of moral relevance that human fetal tissue for research has been obtained from induced abortion."

They then proceed to recommend guidelines which the Panel says is to prevent encouragement of abortion. But the Panel does not say why. The Panel does not explain why it is that guidelines should be adopted to prevent encouragement of abortion. They do hint, though, at some of the views of members of the Panel.

In one of the Considerations to one of the Answers, the Panel says that a majority of the Panel found "that it was acceptable public policy to support transplantation research from fetal tissue either because the source of the

tissue posed no moral problem"; thus, some members of the Panel did not view abortion as morally objectionable, "or because the immorality of its source could be ethically isolated from the morality of its use in research."

I would submit that those who would support guidelines to prevent the encouragement of abortion, but who do not view abortion as morally objectionable, have adopted an incoherent position. If abortion is not morally objectionable and if there are great benefits to be derived from fetal tissue, why is it that you would not encourage abortions?

Indeed, there is no moral or ethical objection to organ transplant from dead adults, provided proper consent is given, and, thus, we spent a lot of time and money encouraging organ transplant.

It is only if abortion is morally objectionable is it coherence to suggest, as the Panel attempts to, that abortion should not be encouraged to derive tissue therefrom.

Thus, in order to understand the report, it is important to know the view of those supporting its recommendations. And we find that view. In the Robertson concurrence, a majority of the Panel members who supported this report, nine so far, do not view abortion as morally objectionable, on the one hand; and, secondly, are perfectly prepared to disregard certain of these guidelines, if more fetal tissue is necessary for transplantation.

In the Robertson concurrence, a majority of the panelists supporting the report say that "if there were a substantial increase in the number of abortions, it still would not follow that fetal tissue transplantation research and therapy should not occur."

"Given the rudimentary development of early fetuses," up to 6 months old, I would add, "the potentially great benefits to recipients, and the legality of abortion, such transplants might still be ethically and legally acceptable."

A positive effect upon abortion increase is, thus, considered no obstacle to medical progress. The majority of panelists supporting the report are in favor of the guideline to prohibit research on fetuses conceived in order to be aborted for their use as fetal tissue because there appears to be no present need for it in research.

Quoting now from the majority of the Panel supporting the report, "In light of these supply considerations," the restriction is accepted. But, "if the situation changes so that the supply of fetal tissue from family planning abortions proves inadequate, the ban "should be reexamined."

Thus, I would suggest that a majority of the panelists supporting this report do not find abortion morally objectionable.

What conclusions can you derive from this fact concerning the report itself? Well, first, since the report provides no basis for its view that encouragement of abortion should not occur, we do not know the ethical basis upon which that report is based.

Secondly, for those on the Panel who believe that abortion is not morally objectionable, we can only conclude that they are recommending these guidelines as a temporary expedient to gain NIH funding, to gain Federal sponsorship, and to gain government approval for fetal transplantation research and therapy.

In any event, however, the guidelines will not prevent encouragement of abortion, as I have already explained. Thus, the guidelines do not separate the abortion decision from the use of tissue thereafter. That is, in fact, as the Panel acknowledges, inseparable if the research becomes successful.

Thus, it is my view, and some others, that fetal tissue transplant from induced abortion leads to ethically unacceptable results, the taking of a life of one human being for the benefit of another.

And research that can be expected to lead to that result should not be funded by NIH.

STATEMENT TO THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH

December 14, 1988

K. Danner Clouser, Ph.D.

Rather than focus on any of the details of our report, I would rather devote my 5 minutes to a more overarching matter which was never discussed as such by our Panel. I want to comment on the moral framework within which such discussions as the one we are engaged take place. There is no time here to defend the moral point of view I am about to describe, but rigorous arguments are available for doing so.[1]

I would urge the Advisory Committee to view the relevant moral issues before us from a moral framework more universal in scope, more cognizant of our society's plurality of values, beliefs, and lifestyles, and more basic than the special moralities from whom we have now and again heard on our Panel. The moral framework I am urging I believe to be the appropriate stance for decisions in the public arena. It is based on rationality, is applicable to all rational persons, and serves the mutual self-interest of all by deriving its moral rules from rationality. These rules proscribe us from causing specified harms to each other, and thus comprise a moral code which would have universal agreement, since all rational persons would avoid harm unless they had a reason not to.

This basic morality is itself a public policy. It is a policy that applies impartially to all rational persons who meet certain specifiable basic requirements such as being able to understand its moral rules and to act in accord with them. These persons comprise the moral community. It is only within and among this community that morality's demands make sense by having a basis in universal agreement and the means of being carried out. Rational persons do not much agree on what is good, but they do agree on what is harmful, that is, what a rational person would avoid unless he had an adequate reason not to. Consequently, rational persons would espouse moral rules prohibiting harm. It is to the interest of all to do so.

We should note that this basic morality is not to be confused with many other look-alikes. It is not a philosophy of life dedicated to the achieving of chosen goods; it is not an elite club delighting in its own secret rules and rituals; and it is not a religious morality based on metaphysical beliefs which not all persons by virtue of rationality alone would have to accept. Rather it is a basic morality, universal and public, that all rational persons by virtue of their rationality alone would espouse.

Now, from this general account of morality certain observations follow that are relevant to the proceedings and the report of our Panel.

1. This basic morality I have described is what is relevant in a pluralistic society because it deals with that on which rational persons might agree on the basis of rationality alone. It is devoid of

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[1]For example, Bernard Gert, Morality: A New Justification of the Moral Rules. Oxford University Press, 1988.

subjective goals, lifestyles, and metaphysical beliefs on which we could get little agreement.

2. Equally rational and moral persons can disagree on the weighting or ranking of evils (i.e., harms), and, consequently, disagree on their moral judgments about certain matters. This means that for many moral problems there is not necessarily one correct solution. And it is appropriate in those instances to settle a moral issue by consensus.

3. The moral community does not include those beings which do not understand the mutuality of morality nor how or why they should be moral. These beings could be trees, animals, or fetuses. This does not necessarily mean that we may treat those beings outside the scope of morality in any way we please, but it does mean that we have a profoundly different basis for our moral relationship with other rational persons than we do with those outside the scope of the moral community.

4. We in the moral community can of course grant rights to those beings outside. But why would we do that? Perhaps, for example, those beings would suffer, and many of us feel a kinship with those beings and want to avoid their suffering. But whatever our individual or personal reasons for wanting to grant certain rights to those outside, there are no universally compelling reasons as there are for our moral rules which pertain impartially to all rational persons within the moral community. So on these matters of our relationships to those beings outside the moral community we must struggle for consensus and compromise. If we ourselves feel a natural empathy for certain others outside the scope of morality, we might try to convince others to empathize--or we might compromise by agreeing to protect something for which they feel a natural empathy or regard. In short, there is nothing here to compel universal agreement, and equally moral, rational persons can and do disagree. And so it was that our Panel members disagreed, but we compromised, namely, by our efforts to insulate the abortion decision from the research and therapy possibilities--either as a protection for that which we felt some empathy or out of concession to those who did have strong empathetic concerns. This must not be written off as a weasel compromise unbecoming the grand enterprise of ethics. Rather it is an entirely appropriate procedure in areas not amenable to determination grounded strictly on rationality.

5. That there are disagreements on the treatment of those beings outside the scope of basic morality implies absolutely nothing about how we might therefore treat other fellow human beings. We are not on any sort of moral slippery slope whatsoever. Within the community of rational persons it is clearly immoral to cause each other harm--such as depriving them of life or liberty, or causing them pain, or deceiving them. And that is why analogies between what has happened to persons in the past and what is happening to fetuses now will not work.

In summary, in the public arena we must deal with basic morality which is founded on rationality. Certain basic rules follow from that rationality and are applicable to all rational beings within the moral community. And from this moral point of view the majority recommendations of the Panel are moral. However much special interests may see them as immoral, there is a strong and universal basis for regarding the recommendations as morally acceptable while recognizing that equally moral and rational persons can disagree on our relationship to those beings outside the moral community.

Those of us who do have strong empathies and concerns for those outside the moral community can of course continue to build a consensus for those particular interests. But the charge to our Panel is not the appropriate occasion.

Appendix II

Appendix II

STATEMENT TO THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH

December 14, 1988

Patricia A. King, J.D.

I appreciate the opportunity to speak with you today. As I feared when I saw my place in the line-up, many of the points that I wished to make have been more ably made by some who have preceded me, and so I will take this opportunity to depart from what I have prepared to just make a few points.

I would urge the members of the Director's Advisory Panel to adopt the recommendation of the Fetal Tissue Transplantation Panel because I believe that those recommendations represent not only a consensus of the Panel, but perhaps a consensus of broader opinion.

I say "consensus" because the vast majority of the Panel, despite our diverse backgrounds, views, and perspectives, were able to reach an agreement on the wording of recommendations and the wording of the considerations that we gave you.

That is not to say that we would not all have wished to have written our precise views and considerations, and some of us, indeed, tried to do that, in concurring opinions and dissents. But I emphasize that the document that you have before you does indeed represent, in my view, well-thought-out recommendations that the vast majority of us could indeed agree with.

There are a few additional points that I would like to make. I chose to speak today because I believe that the document insufficiently addressed some issues. For me, the document insufficiently pointed out the analogy between research with fetal tissues and organ transplantation, which is an accepted therapeutic procedure in our society.

It is no surprise that we ignored or gave insufficient attention to the organ transplantation analogy, since we were asked to respond specifically to ten questions.

Every good lawyer knows that the person who asks the question helps to shape the framework for the answer. That is something that I respect, and I like to think of myself as a good lawyer. But because the questions were worded in a particular fashion, it is no surprise that our answer, in trying to be responsive to our mandate, reflected the particular framework of the questions.

But in being responsive, I would stress that we ignored, in my view, the analogy to existing practices that we, as a society, have found acceptable. I believe that the issue of research with fetal tissue is analogous to organ transplantation. We are talking about using cadaveric tissue.

We are also talking about a very significant and promising area of research. We would not be here if we had not had some indication of the significant benefit that such research might bring. And, indeed, the Panel

heard nothing that would dissuade us of that view. To the contrary, our views have been re-enforced--this is an important and promising area of research.

In my view, because we did not focus on analogies to organ transplantation, we spent far too much time on the question of the association of fetal tissue research with the issue of abortion.

And, as a result, I believe that our efforts to develop principles by which this research might be ethically conducted is too related to the question of whether or not abortion will be encouraged.

I point out to you that the principles that we adopted, the principles of separation, and the ways in which we specify them, are principles that are present in the practice of therapeutic organ transplantation.

It is an area--therapeutic organ transplantation--that we have asked not be commercialized, for example, and our Federal law reflects that fact. Moreover, in therapeutic organ transplantation, we have separated the issues of obtaining organs, and the means by which we obtain those organs, from the question of who will receive the organs and, indeed, under what circumstances those recipients might be designated.

And so I repeat that I think that the guidelines that we have given you would support doing fetal tissue research, in my view, the guidelines are justified, and I would have found applicable if I had not been asked any questions concerning abortion.

Just a few final points. It seems to me that we should keep in mind that we are talking about NIH sponsorship and oversight of fetal tissue research. I emphasize this point because much of our discussion was premised on the fact that this research might prove so promising that other consequences would follow.

But I repeat that we are talking just about research. We do not know what we will find if this research is funded; and finally, it is very important for NIH to take the lead in funding this research, so that NIH can take the lead in setting up the guidelines by which this research will be conducted.

I note that there have been two attempts to do fetal tissue transplantation in the United States already, but I would still emphasize that it is important that NIH be clear about what its role is and about the justification for appropriate guidelines. And I have confidence that the scientific community will voluntarily adhere to those guidelines.

Appendix II

STATEMENT TO THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH

December 14, 1988

Professor James T. Burtchaell

I begin by noting three frustrations. The first is that the documentation resulting from our fall and winter work is substantial, and I am quite sure that the statement and concurring and dissenting documents that were sent to you were crafted with great stress and care, each word having been weighed.

I regret that those documents have been made available to the members of the Advisory Committee for so brief a time before this meeting. For busy people, I am sure it must have been very difficult to find appropriate time to read them and, thus, to appreciate much of what we are going to say today.

My second frustration is that while the questions put by the Assistant Secretary were primarily ethical in nature, a very large part of the response to them was based, not upon ethical, but upon legal, considerations.

And a great deal of that was done simply by setting aside the prospective victims of this research--that is, the aborted children--by simply excluding them, as has been said, from the moral community.

We always exclude from the moral community whomever we wish to exploit. The Fourteenth Amendment had to reverse one instance of that activity. The Nuremberg Code was a more recent rectification of that.

My third frustration regards something that we never spoke of. There would not be the human fetal tissue in such abundance available were it not for the 1973 Supreme Court decisions. Those decisions struck down existing legislation in 50 States and Federal legislation as well, and they have been severely criticized by very serious jurists.

Public opinion polling for the last 30 years demonstrates that there has not yet been a majority of public opinion in support of abortion on demand. And for the National Institutes of Health to presume that this is a dependable source of tissue for the indefinite future strikes me as improvident.

Four of the panelists strongly disagree with the primary recommendation of the Panel. I speak as one of them. I speak on behalf of three of our objections very briefly.

There is, first of all, no person who can fulfill the Nuremberg requirements for authentic voluntary consent. Consent to donate remains can be made by a human being in prospect of death or by someone who has custody of that human being: a parent of a minor child, a court-appointed guardian, a person given power of attorney. That power is only awarded for one purpose: protective care. It is quite clear that the act of abandonment implied in the abortion decision terminates such a trust, and it <u>is</u> a trust.

Therefore, in prospect of the unborn offspring's death, the mother has forfeited, or abrogated, her power to make such a decision on behalf of the still living child.

After death, the next of kin has a right, morally and usually legally, to dispose of their remains, no longer merely for the care of the now deceased unborn, yet, in conformity with the respect due to that deceased human.

The proposal of the Panel is almost unprecedented, to give that uniquely ante-mortem decision over another's remains to another human being, not as a caretaker, but as a person pursuing her own interests, and that is the explicit explanation given by a majority of those supporting this decision.

We have almost no antecedent for that except chattel slavery, and chattel slavery, even in the United States, never gave that large a selfish power over the one who was in control.

Our second objection is that, despite the attempts of the Panel to segregate the moral implications of abortion from the potential therapeutic usage, it does not work.

It is the same argument used by a banker who is laundering funds from drug transactions already completed. The function of the banker in no way affects those transactions, because they already took place. They would have taken place without the banker there ready to launder the funds. Nevertheless, the banker is an accessory: he is complicit by this institutionalized arrangement of interaction and association with those in the drug industry.

The more potent analogy, which is indeed distasteful to a number of our colleagues, comes from the very root of all contemporary literature on the protection of human subjects of research. One of the outrages brought to light in the medical trials at Nuremberg was the research use of cadaveric remains with the same disregard for victims we discern in the programs proposed to the Panel--because they were considered outside the moral community.

The explicit rationalizations given by the scientists engaged in that usage were, if not word-for-word, at least meaning-for-meaning, replicated in the justifications given for present fetal tissue research: "We had nothing to do with the source. Therefore, it is not a concern of ours." On the contrary, we argue that there is indeed complicity after the fact.

The third of our arguments has already been dealt with by Mr. Bopp: that for women facing the excruciatingly difficult and very ambivalent decision to abort, the prospect of bringing good out of tragedy, as they would see it, is going to be not insignificant.

And the financial incentives for those for whom abortion has now become an industry--practitioners who, in largest part, have already moved aside from the mainstream of the obstetrical profession--will prove to be, in its own right, a strong incentive.

We worked a great deal of time on our dissent. I hope that the discussion time provided throughout the rest of this meeting will allow us the opportunity to respond to the questions that it should naturally provoke.

Appendix II

STATEMENT TO THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH

December 14, 1988

John A. Robertson, J.D.

At the risk of sounding redundant, I would like to make a point that I do not believe has been made. The point is about burden of proof. Given the likely benefits of fetal tissue transplant research, the burden of showing that such research should not occur falls--and should fall--on its opponents. In the view of the Panel, the opponents have not met that burden.

The Panel's position recommending NIH support of fetal tissue research is based on the fact that more than 1.5 million elective abortions occur annually in the United States. Because this tissue will be available regardless of research needs and will otherwise simply be discarded, tissue from these abortions can be used for transplant research without involving researchers or recipients in the abortion itself. Indeed, one could reasonably argue that it would be unethical to discard this tissue rather than use it in research that could save many lives.

In making use of fetal tissue from induced abortions, the Panel has recommended a number of safeguards to assure that research needs do not influence the abortion decision. These include postponing requests to use the tissue until after the decision to abort has been made, prohibiting donations to family members, and prohibiting money payments for fetal tissue donation.

The Panel's view is that with these safeguards NIH support for fetal tissue transplant research would not signify approval of or encourage abortion or involve the Federal Government in supporting abortion. It simply recognizes the reality that abortions occur in large numbers, and that once having occurred, there may be better uses of fetal remains than incineration. The most relevant parallel is solid organ transplantation, which makes use of cadaveric organs from accident and homicide victims, without encouraging or approving the actions that make the organs available.

Given these considerations, persons who oppose NIH support of fetal tissue research should have the burden of showing that such great harm or such clearly unethical practices would result that the benefits of fetal tissue transplant research should be foregone. To that end, opponents claim that federal support of any fetal tissue transplant research will necessarily lead to more abortions, and that any increase in abortions, no matter how small or marginal, makes the program causing that increase unacceptable.

After careful consideration the Panel has found unpersuasive the notion that women, who otherwise would have decided not to abort, will choose to abort because tissue may be anonymously donated for research or therapy. The Panel heard no convincing evidence that a pregnant woman's decision against abortion would be changed by the prospect of anonymous tissue donation. The recommended safeguards further lessen the possibility of such influence.

To argue otherwise, as opponents do, requires a different perception of the motivations of women contemplating abortion and of the efficacy of the

recommended safeguards. But it also requires a further assumption--the assumption that federal research support will make fetal tissue transplants so successful and widely known that the prospect of anonymous tissue donation will inevitably alter the decision of pregnant women contemplating abortion.

But the assumption of widespread success, on which the opponent's claim of influence on abortion decisions rests, is itself highly questionable at this very early stage of clinical research. As you well know, there is no certainty or guarantee that fetal tissue transplants will work for any disease, much less that they will be successful for all diseases for which they offer hope. If they are successful, it may be that they will be successful only for certain patient subgroups, or that fetal tissue transplants will be a temporary way station to development of cell lines or biochemical substitutes that in 7-10 years replace fetal tissue transplants totally.

Nevertheless, opponents would ban all federally supported fetal tissue research at this early stage, and thus cut off further investigation that could lead to important findings in many areas, out of the hypothetical fear, which the Panel has rejected, that abortions will increase if the "best case" scenario of widespread success occurs. They would thus prevent federally sponsored research which may have little or no effect on abortion decisions, yet significantly help subgroups of patients. Indeed, they would even prevent the research that might lead to cell lines and other substitutes for fetal tissue, because of the speculative fear that "some" increase in abortions might occur if fetal tissue transplants were a stunning success.

But even if fetal tissue transplants turn out to be a stunning success, the opponents have presented no persuasive reasons to think that that success would have a <u>substantial</u>, as opposed to a <u>minor</u> or <u>marginal</u>, impact on the incidence of abortion. It is not enough to show that there will be <u>some</u> increase in the number of abortions that would not otherwise have occurred from widespread use of fetal tissue. Opponents have the burden of showing that the increase would be <u>substantial</u>, indeed, so substantial that the great benefits that may be possible from fetal tissue research should be foregone to avert this increase. None of the dissenting statements address the size of impact which they speculate would occur, arguing only that <u>some</u> increase or <u>an increment</u> in the number of abortions would result. Apparently their premise is that any increase in abortion, no matter how small, would render fetal transplants unacceptable.

Thus they are in the position of saying that any public policy that has the risk of increasing even slightly the number of abortions at some future time is unacceptable, regardless of the benefits to chronically ill patients. Needless to say, such a position applied to other public policies would ground or stop most progress, since many policies, from building roads, bridges, and airports to approving drugs, may cause the loss of human lives that would not otherwise have occurred--and not just fetal lives. In the case of policies that permit knives and guns to be sold, some of the increased deaths will be intentionally caused.

It is for these reasons that the Panel finds that persons opposed to fetal tissue transplant research have not met the burden of showing that such great harm or such clearly unethical practices would occur that such research should not go forward. Given the great good that is possible from fetal tissue research and the large number of abortions that will be occurring regardless of

tissue transplants, the Panel has found that it is acceptable public policy for the NIH to support such research, and recommends that this Advisory Committee so find as well.

Comments Prepared by Dr. George E. Palade on the Report of the Human Fetal Tissue Transplantation Research Panel

(for the record)

Appendix D

Appendix II

COMMENTS ON THE REPORT OF THE HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH PANEL

George E. Palade, M.D., Yale Medical School

In trying to provide answers to the questions raised by Dr. Windom, the Assistant Secretary for Health, the Panel on Human Fetal Tissue Transplantation Research had to deal with a difficult set of problems. So difficult that it was not possible to concentrate mostly, if not exclusively, on the central pertinent issue: to wit: Should the NIH support research on human fetal transplantation for experimental purposes, primarily for potential therapeutic applications?

The scope of the discussions was enlarged to include the much wider and currently divisive issue of the morality of abortion. This move by part of the members of the Panel generated minority opinions written with eloquence, zeal, and determination, but not always based on unquestionable arguments.

The key issue is the status of the human fetus. Is it a human person entitled to personal protection against everybody (including the prospective mother)? Is it a person whose rights are guaranteed by the Constitution of this country? In fact, a human fetus is not yet a person; it is a person in the making, and the time when it becomes a human person is still a matter of debate and argument.

This uncertainty explains, I believe, the decision of the Supreme Court in the widely known and so often discussed Roe v. Wade decision. Be it as it may, that decision is now the law of the country. Questioning it as immoral implies that we have an amoral or immoral Supreme Court. People may criticize the Court or disagree with some of its decisions, but I wonder how many are ready to label it immoral.

Equating abortion with feticide and feticide with homicide may generate impressive prose but leads to obvious inconsistencies. If feticide is homicide, why are the doctors performing the abortions not put on trial? And why are the women who become accessory to those crimes not treated accordingly?

If more than one and one-half million voluntary abortions are performed every year in this country, we should conclude that something is amiss in our society. The families, the churches, the synagogues, the schools, the media, and our system of health information and assistance are failing in their mission by that large figure. Addressing the causes that create and maintain this unhappy situation is an area in which zeal and crusading spirit would be most welcome.

Another issue of equal importance is the fate of those one and one-half million infants born, but unwanted by their mothers, if abortions become effectively forbidden. Is our society ready and willing to take care of them? We seem to have problems with the health maintenance, proper nutrition, and adequate education of those who are not unwanted.

By comparison with these major issues, the argument about the morality of the use of fetal tissue in transplantation experiments loses strength. The causes and the consequences of the current unhappy situation must be addressed.

Prevention of immorality or questionable morality, like prevention of disease, should be better than cure.

Notwithstanding its limited reproductive capacity, the human species has succeeded in performing the equivalent of a biological miracle: It started by being an endangered species and remained so through millennia, but the situation changed drastically over the last century. At present, Homo sapiens endanger all other species, itself, and the environment. It is clear that mankind does not need more numbers. It needs improvements in the quality of life, be it at the simple nutritional level in underdeveloped countries or at the level of broad education, ethics included, in economically advanced communities.

Perhaps some of the dogmas with which we have to cope in our time reflect our past condition as endangered species. Conceived by men or inspired by God, they responded to the needs of that condition: They were designed to make sure that the species loses as few individuals as possible.

Conditions change and so do dogmas, but they do not change in phase. Dogmas are slow in changing. In 1633, Galileo Galilei was condemned by the Catholic Church for heresy, obliged to deny his discoveries, and stop teaching. He also had to promise that he would denounce all who supported his ideas. Last year, the Church rehabilitated Galileo and recognized that back in 1633 he was right and the Church was wrong.

To redress the damage done by the dogma, it took 250 years, more than compelling evidence, and a courageous Pope. But the rehabilitation came much too late to do Galileo any good as a person. In a less formal way, the same applies for the victims of inquisition in Western Europe from the 15th to the 17th centuries and for the victims of the witch trials in the New England of the 17th and 18th centuries. Perhaps in a century--or less than a century--mankind will look at our current problems with a different understanding.

It does not mean, however, that dogmas must be altogether discarded. They are, in fact, an important element in the continuity of our civilization. They have done, in the past, more good than harm for us. Moreover, we should understand that dogmas have a hard time in periods of rapid change. We should help bring them closer to the realities of the human condition in our time.

Notwithstanding dissentions, abstentions, lively discussions, and passionate prose, the Panel provided useful answers to Dr. Windom's questions. The answers, supported by a large majority of the Panel's members, recommended that the NIH support experimental work with human fetal cell or tissue transplants; it identified the disease in which transplantation is expected to be beneficial (parkinsonism and juvenile diabetes, primarily), and defined in significant detail the conditions under which cadaveric fetal tissue should be collected and independent consent be obtained for its use in research from the pregnant woman. The conditions are designed to preclude commercialization of fetal tissue transplantation and to insure, within possible limits, that therapeutic use will not encourage more women to undergo abortion.

Of course, the entire development is built on a premise--the voluntary abortion--which remains questionable, even regrettable or repugnant for part of the public. Yet, as the majority of the Panel concluded, the use of cadaveric fetal tissue for biomedical research is "acceptable public policy" under our

current laws. This general position is essentially pragmatic: It tries to make the best out of an unhappy situation for which both the pregnant woman and a careless society are responsible. In any case, it provides the recommendations needed for setting in place regulatory and control mechanisms for a type of research that will remain highly vulnerable to public dissent, at least until truly beneficial results will be obtained.

The scientific basis for experimental therapy and other forms of biomedical research of direct health interest has been, in the meantime, considerably strengthened and enlarged.

Two Swedish Groups (A. Borklund and L. Olsen) have proceeded methodically to show that fetal transplants are viable and functional in rodents. And a group at Yale was able to demonstrate that collected brain tissue can be frozen for months without losing viability. This situation provides the researchers with the time needed to check the biochemical specificity of the tissue--which should include potential dopamine-secreting neurons--as well as the state of health of the intended graft, which should be free of either viral or bacterial pathogens. In addition, this reasonably long interval makes possible a satisfactory separation in time, space, and personnel between abortion and transplantation.

The Yale group has developed a detailed, carefully worked out protocol. Both groups--Swedish and American--have demonstrated feasibility in animal models, and the Yale group has obtained apparent cure of experimental parkinsonism in adult monkeys by transplantation of fetal monkey tissue containing potentially dopaminergic neurons. The Yale group has also succeeded in transplanting human fetal tissue in the striatum of normal monkeys and in demonstrating its survival and characteristic enzymic activity (tyrosine hydroxylase). In other words, the work has proceeded systematically, one step at a time, towards the final goal, which is transplantation of a human fetal explant taken from the appropriate region of the midbrain of a dead fetus to the part of the brain that needs dopamine-secreting neurons for its normal function in an adult human patient afflicted by parkinsonism. The final step was, in fact, performed on Thursday, December 8. Other transplantations will probably follow.

Notwithstanding the promise implied by the results of these preliminary (or preparatory) experiments, further experimentation will still be needed to define optimal conditions for each major step (tissue collection, storage, testing, and implantation) as well as for assessing the extent and the stability of clinical improvements. And the entire process will take time because of a relatively long period of latency (months) before the activity of the transplanted neurons can begin to favorably affect the disease.

The work on fetal pancreatic islets transplanted into juvenile diabetics is expected to follow similar lines; work on other diseases that may require neuron replacement is just beginning.

The Panel heard testimony of the desirability of using established cultured neuronal cell lines instead of tissue transplants, and experimentation is proceeding in this direction. Fetal cadaveric explants will still be needed to establish the cultures. And additional controls will have to be introduced to ascertain that the cells retain their specific activities in culture, in

spite of possible genotypic and phenotypic drift, and to prove that their growth can be adequately regulated in the brain. They may generate tumors.

The Panel has concentrated its attention on experimental therapeutic transplantation and has not considered other possible, biomedically important applications of fetal tissue transplants. But very recently, perhaps too recently for attracting the attention of the Panel, an important application of human fetal tissue transplantation was reported by Irving Weissman's laboratory at Stanford Medical School. The primary move came from a young M.D., Ph.D., J.D. MacClure, who--as a result of residency at the San Francisco General Hospital where he took care of AIDS patients--conceived the idea of transplanting human fetal lymphopoietic organs (thymus, lymph nodes, and liver) into mice homozygote for a severe combined immunodeficiency syndrome (SCID). These mice lack B cells and T cells; they do not reject the transplanted human cells, which establish themselves in their foreign host and produce a "hybrid" mouse (SCID/hu) provided with a human immune system.

The immediate potential use of these mice is as a convenient animal model for the study of the human acquired immunodeficiency syndrome (AIDS), but many other applications seem possible. The SCID/hu mice can allow the study of the human immune system response to other retroviruses. It can also provide an appropriate model for the study of the development of the human immune system and for exploring conditions that can prevent autoimmune disease or improve immunosurveillance against neoplastic cells. The SCID/hu mice open, in fact, much broader vistas for beneficial application than those considered in parkinsonisms or diabetes.

Dr. Windom's questions were formulated in conjunction with the current moratorium on Federal (NIH) funding of fetal research. The moratorium does not apply to research supported by private, non-Federal funds. Research done at Yale has been and continues to be supported by such funds. Therefore, legalistically, the work does not infringe on the moratorium. Why did the work of the Yale team move ahead of a decision on the moratorium instead of waiting for it? There are, I am sure, specific reasons. But we should realize that a democratic society like ours is organized in such a way as to use all possible drives and forces, altruistic or selfish, the desire to do good as well as the desire for self-promotion, greed as well as generosity, and harness them all to the slow, lumbering wagon of society's progress. Systems based entirely on idealistic considerations do not work in the long run. Sooner or later they are obliged to rediscover the virtues (or merits) of messy democracy by democratization.

Of course we should take advantage of this diversity of motivations and put them to work. But at the same time a reasonable regulatory system is definitely advisable to prevent abuse, to set standards, and to maintain quality. The NIH should enter the field for two reasons: The field is clearly promising--more promising than we believed a few months ago. And a regulatory system is needed given the sensitivity of part of the public in such matters. The NIH already has functioning mechanisms for quality control--scientific, ethic, and otherwise--of the research it supports. The NIH can set standards that will be followed by other agencies. It can also have power of enforcement as it has in the case of affirmative action. And it has the experience of reasonable and adaptable regulatory activity acquired in relation to recombinant DNA experimentation.

Report of the Human Fetal Tissue Transplantation Research Panel

December 1988

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GEORGETOWN UNIVERSITY

Consultants to the Advisory Committee to the Director, National Institutes of Health

Volume I

Arlin M. Adams
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December 12, 1988

James B. Wyngaarden, M.D.
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Shannon Building, Room 124
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Dear Dr. Wyngaarden:

The Assistant Secretary for Health, Dr. Robert Windom, posed a series of questions concerning the use of fetal tissue in medical research. You convened a panel to assist you in answering these questions. I am pleased to forward to you the answers to the questions as formulated by the panel; the considerations underlying the answers; and a number of dissenting and concurring opinions regarding the work of the panel.

Many members of the panel hold deep reservations about abortion. Yet, the United States Supreme Court has declared that a woman has a constitutional right in the first and second trimester of pregnancy to proceed with an abortion. Whatever doubt any of the panel members may have regarding the Supreme Court opinion, it still constitutes the law of the land. Thus, until the Supreme Court decision is reversed, all citizens are bound by it. Nonetheless, any activity which would serve as an inducement to women to have abortions must be dealt with extremely carefully and circumscribed to the extent possible.

Counterbalancing these concerns is the evidence brought to the panel's attention that a series of maladies might be substantially ameliorated by the prudent use of fetal tissue. Although complete proof that fetal tissue will be clinically useful has not been obtained, current evidence indicates that the use of such tissue might be beneficial in treating Parkinson's disease, childhood diabetes, Huntington's disease, and perhaps Alzheimer's disease.

The panel has carefully weighed concerns over abortion against concerns for medical research that could improve the lot of thousands of Americans. 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. Also, the need to separate completely the abortion procedure and the use of fetal tissue seems essential. Furthermore, Federal funding should be limited to situations that employ the most careful scientific approaches and the highest professional standards. As an additional condition for approval of this research, it is recommended that the 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.

Without Federal funding, other efforts to continue research with human fetal tissue would undoubtedly proceed without Federal supervision. Thus, if the NIH proceeds cautiously, and with carefully articulated safeguards, and a program of periodic review, there would be much greater assurance that the research will be undertaken with adherence to carefully crafted guidelines. Such an arrangement would protect pregnant women and fetuses in a far more thoughtful and intelligent manner than if the NIH did not participate. Based on available evidence, various safeguards can be instituted.

It has been a high honor to serve the National Institutes of Health and the Department of Health and Human Services, and I am confident that the members of the panel stand ready to continue to assist in any way that is deemed appropriate.

Respectfully yours,

Arlin M. Adams
Chairman, Human Fetal Tissue
Transplantation Research Panel

Appendix III

HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH PANEL

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Appendix III

REPORT OF THE

HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH PANEL

CONTENTS

VOLUME I

RESPONSE OF THE PANEL TO QUESTIONS POSED BY THE ASSISTANT SECRETARY FOR HEALTH

Question 1: Is an induced abortion of moral relevance to the decision to use human fetal tissue for research? Would the answer to this question provide any insight on whether and how this research should proceed? 1

Question 2: Does the use of the fetal tissue in research encourage women to have an abortion that they might otherwise not undertake? If so, are there ways to minimize such encouragement? 3

Question 3: As a legal matter, does the very process of obtaining informed consent from the pregnant woman constitute a prohibited "inducement" to terminate the pregnancy for the purposes of the research--thus precluding research of this sort, under HHS regulations? 4

Question 4: Is maternal consent a sufficient condition for the use of the tissue, or should additional consent be obtained? If so, what should be the substance and who should be the source(s) of the consent, and what procedures should be implemented to obtain it? 6

Question 5: Should there be and could there be a prohibition on the donation of fetal tissue between family members, or friends and acquaintances? Would a prohibition on donation between family members jeopardize the likelihood of clinical success? 8

Question 6: If transplantation using fetal tissue from induced abortions becomes more common, what impact is likely to occur on activities and procedures employed by abortion clinics? In particular, is the optimal or safest way to perform an abortion likely to be in conflict with preservation of the fetal tissue? Is there any way to ensure that induced abortions are not intentionally delayed in order to have a second trimester fetus for research and transplantation? 9

Question 7: What actual steps are involved in procuring the tissue from the source to the researcher? Are there any payments involved? What types of payments in this situation, if any, would fall inside or outside the scope of the Hyde Amendment? 11

Question 8: According to HHS regulations, research on dead fetuses must be conducted in compliance with State and local laws. A few States' enacted version of the Uniform Anatomical Gift Act contains restrictions on the research applications of dead fetal tissue after an induced abortion. In those States, do these restrictions apply to therapeutic transplantation of dead fetal tissue after an induced abortion? If so, what are the consequences for NIH-funded researchers in those States? 13

Question 9: For those diseases for which transplantation using fetal tissue has been proposed, have enough animal studies been performed to justify proceeding to human transplants? Because induced abortions during the first trimester are less risky to the woman, have there been enough animal studies for each of those diseases to justify the reliance on the equivalent of the second trimester human fetus? 14

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American Bar Foundation D1

Judith C. Areen, J.D.
Georgetown University D21

Robert Auerbach, Ph.D.
University of Wisconsin--Madison D27

David W. Barnes, Ph.D.
Environmental Health Sciences Center
Oregon State University D32

Judie A. Brown
American Life League, Inc. D37

Rebecca H. Buckley, M.D.
Duke University School of Medicine D50

Lisa Sowle Cahill, Ph.D.
Boston College D58

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Arthur L. Caplan, Ph.D.
Center for Biomedical Ethics
University of Minnesota. D66

Charles B. Carpenter, M.D.
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Ezra C. Davidson, Jr., M.D.
Charles R. Drew University of
Science and Medicine and
University of California, Los Angeles D82

Bernard M. Dickens, Ph.D., LL.D.
University of Toronto, Canada D90

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Robin Chandler Duke
Population Crisis Committee D112

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Thomas J. Gill III, M.D.
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Carol Lurie
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Alan Meisel, J.D.
University of Pittsburgh School of Law D174

Barbara Mishkin, Esq.
Hogan & Hartson D189

Robert Y. Moore, M.D., Ph.D.
Health Sciences Center
State University of New York at Stony Brook D194

Thomas H. Murray, Ph.D.
Center for Biomedical Ethics
Case Western Reserve University D197

Stuart A. Newman, Ph.D.
New York Medical College D205

Kathleen Nolan, M.D.
The Hastings Center D209

Lars Olson, M.D., Ph.D.
Karolinska Institute D219

Richard J. O'Reilly, M.D.
Memorial Sloan-Kettering Cancer Center D230

D. Eugene Redmond, Jr., M.D.
Yale University School of Medicine D231

Richard Riseberg
Public Health Service D245

Hans Sollinger, M.D., Ph.D.
University of Wisconsin D251

H. Fred Voss, Ph.D.
Hana Biologics, Inc. D252

Leslie C. Wong
Royal Marsden Hospital D267

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- *Federal Register* Notice Inviting Public Testimony at the Meeting

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American Association of Tissue Banks
Robert E. Stevenson, Ph.D. E1

American College of Obstetricians and Gynecologists
Col. Robert C. Park, MC USA E3

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American Diabetes Association, Inc.
Charles M. Clark, Jr., M.D. E10

American Paralysis Association
Margaret Brown, Ph.D. E15

Association of American Medical Colleges
Myron Genel, M.D. E16

Committee for Responsible Genetics
Stuart A. Newman, Ph.D. E25

Huntington's Disease Society of America
Madeline Bates, Ph.D. E30

International Institute for the Advancement of Medicine
James S. Bardsley, Jr. E31

Juvenile Diabetes Foundation International
Carol Lurie E33

Knights of Columbus
Carl A. Anderson E35

National Conference of Catholic Bishops
Bishops' Committee for Pro-Life Activities
Richard Doerflinger. E42

National Right to Life Committee, Inc.
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National Spinal Cord Injury Association
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Public Policy Council of the American Pediatric Society, the Association of Medical School Pediatric Department Chairmen, and the Society for Pediatric Research
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Appendix F: Background Paper Prepared for the Panel at the Request of the Panel Chairman, Judge Arlin M. Adams: "Using Human Fetal Tissue for Transplantation and Research: Selected Issues," A Paper Prepared by the Poynter Center for the Study of Ethics and American Institutions

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Appendix III

RESPONSE OF THE PANEL TO QUESTIONS POSED

BY THE ASSISTANT SECRETARY FOR HEALTH

FUTURE REVIEW OF PANEL RECOMMENDATIONS

These recommendations should be reviewed at appropriate intervals by the Secretary of Health and Human Services.

Appendix III

QUESTION 1. Is an induced abortion of moral relevance to the decision to use human fetal tissue for research? Would the answer to this question provide any insight on whether and how this research should proceed?

RESPONSE TO QUESTION 1

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.

This position must not obscure the profound moral dimensions of the issue of abortion, nor the principled positions that divide scholars, scientists, and the public at large. It is not the charge of this panel to attempt to settle the issue of abortion or to weigh the worthiness of competing principled perspectives on abortion itself. The panel notes that induced abortion creates a set of morally relevant considerations, but notes further that the possibility of relieving suffering and saving life cannot be a matter of moral indifference to those who shape and guide public policy.

Recognizing the moral convictions deeply held in our society, the panel concludes that appropriate guidelines are required even as the research proceeds. Accordingly, the following points are noted:

1. The decision to terminate a pregnancy and the procedures of abortion should be kept independent from the retrieval and use of fetal tissue.

2. 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.

3. Potential recipients of such tissues, as well as research and health care participants, should be properly informed as to the source of the tissues in question.

4. Procedures must be adopted that accord human fetal tissue the same respect accorded other cadaveric human tissues entitled to respect.

[Panel Vote: 18 Yes, 3 No, 0 Abstain]

CONSIDERATIONS FOR QUESTION 1

In reaching its answer to the first question, the panel weighed the proposition that the morality of abortion could be separated in principle from the morality of the uses to which fetal tissue from induced abortions might be put. It was noted that fetal tissue would be obtained as a result of lawful, constitutionally protected decisions and actions to terminate unwanted pregnancy, and that use of cadaveric fetal tissue from induced abortions for research or therapy was generally legal. But it was also noted that the lawfulness of decisions and actions can be distinguished from their morality.

On the morality of research use of fetal tissue from induced abortion, three positions were discussed during the panel's deliberations.

1. Abortion is morally acceptable, and thus the research and therapeutic use of fetal tissue derived from induced abortion is also morally acceptable.

2. Abortion is immoral and so is the use of fetal tissue obtained thereby. No amount of good achieved in research or therapy could erase institutional complicity in the immorality of abortion itself or in encouragement of future abortions. No efforts at separating the procurement and use of fetal tissue from the abortion decision and procedure could make the use of fetal tissue from induced abortion morally acceptable.

3. Abortion is immoral or undesirable, but as abortion is a legal procedure in our society and with appropriate safeguards can be separated from the subsequent research use of tissue derived therefrom, the use of fetal tissue in research and therapy is not seen as complicitous with the immorality of abortion.

A decisive majority of the panel found that it was acceptable public policy to support transplant research with fetal tissue either because the source of the tissue posed no moral problem or because the immorality of its source could be ethically isolated from the morality of its use in research. Considerations supporting this decision were the fact that these abortions would occur regardless of their use in research, that neither the researcher nor the recipient would have any role in inducing or performing the abortion, and that a woman's abortion decision would be insulated from inducements to abort to provide tissue for transplant research and therapy. Accordingly, the panel found it essential that abortion decisions and procedures be kept separate from considerations of fetal tissue procurement and use in research and therapy. In keeping with that separation, it is essential that there be no offer of financial incentives or personal gain to encourage abortion or donation of fetal tissue.

Because some persons opposed to abortion would not accept the use of fetal tissue from induced abortions regardless of these insulating measures, the interests of those persons in neither participating in the research nor in receiving fetal tissue transplants should be protected by informing them of the source of such tissue.

The majority's approval of the research use of tissue from elective abortions is not to be construed as a majority vote for the moral acceptability of elective abortion.

QUESTION 2. Does the use of the fetal tissue in research encourage women to have an abortion that they might otherwise not undertake? If so, are there ways to minimize such encouragement?

RESPONSE TO QUESTION 2

Research using fetal tissue has been conducted and publicized for over 30 years. There is no evidence that this use of fetal tissue for research has had a material effect on the reasons for seeking an abortion in the past. Some panel members were concerned that a more publicized and promising research program might have such an effect in the future. To minimize any encouragement for abortion as might arise from the use of fetal tissue in research, we recommend that the measures outlined above under Question 1 be implemented, as well as the following:

- The decision and consent to abort must precede discussion of the possible use of the fetal tissue and any request for such consent as might be required for that use.

- The pregnant woman should be prohibited from designating the transplant-recipient of the fetal tissue.

The foregoing recommendations are not to be construed as denying or in any way impeding a pregnant woman's access to information regarding the use of fetal tissue in research should she request this information.

[Panel Vote: 19 Yes, 1 No, 1 Abstain]

CONSIDERATIONS FOR QUESTION 2

The panel noted that the reasons for terminating a pregnancy are complex, varied, and deeply personal. The panel regarded it highly unlikely that a woman would be encouraged to make this decision because of the knowledge that the fetal remains might be used in research.

The panel concluded further that it was sound public policy to separate as much as possible the deliberations and decisions about the abortion from any discussion of the disposition of the fetal remains.

QUESTION 3. As a legal matter, does the very process of obtaining informed consent from the pregnant woman constitute a prohibited "inducement" to terminate the pregnancy for the purposes of the research--thus precluding research of this sort, under HHS regulations?

RESPONSE TO QUESTION 3

The panel agrees that a pregnant woman should not be induced to terminate pregnancy in order to furnish fetal tissue for transplantation or medical research.

The process for obtaining informed consent from a pregnant woman for fetal tissue research does not by itself constitute a prohibited inducement to terminate the pregnancy for the purposes of research. However, knowledge of the possibility for using fetal tissue in research and transplantation might constitute motivation, reason, or incentive for a pregnant woman to have an abortion. This would not constitute a prohibited "inducement," since it is not a promise of financial reward or personal gain, nor is it coercive.

However, because the panel believes strongly that we should keep transplantation and research on fetal tissue from encouraging abortion, the panel recommends that informed consent for an abortion should precede informed consent or even the provision of preliminary information for tissue donation.

Moreover, anonymity between donor and recipient shall be maintained, so that the donor does not know who will receive the tissue, and the identity of the donor is concealed from the recipient and transplant team.

Further, the timing and method of abortion should not be influenced by the potential uses of fetal tissue for transplantation or medical research.

In the long term, the problem alluded to by this question may be able to be addressed by deferring the discussion of possible tissue donation until after the abortion procedure has been performed. The feasibility of this approach to fetal tissue procurement should be reviewed on a regular basis by the Department.

[Panel Vote: 20 Yes, 0 No, 1 Abstain]

CONSIDERATIONS FOR QUESTION 3

As a preliminary matter, we assume that the informed consent mentioned in the question refers to the consent sought for the purpose of using the fetal tissue in research--as distinguished from the informed consent for the abortion itself. As we have emphasized in several places, in the consent process for termination of pregnancy, we believe there should be no mention at all of the possibility of fetal tissue use in transplantation and research. The one exception might be if the pregnant woman were to ask a direct question. And even then only general information should be given; there should be no promise that her fetal tissue either could or would be so used. Panel members individually take this stand either because they do not want to do anything that might encourage abortion or as a concession to those who do not want to risk encouraging abortion.

The heart of the question pivots on the meaning of "prohibited 'inducement.'" It is not clear which inducements are in fact prohibited by Department of Health and Human Services (HHS) regulations nor is it clear exactly what an inducement is. Therefore, some clarifications are in order to determine what would be a reasonable and defensible position in the matter.

An inducement could be a coercion, an incentive, or a reason. (1) Coercion is in any case unacceptable and would surely be prohibited. In order for consent to be valid it must at least be free, voluntary, and informed. (2) We would also find incentives to be unacceptable inasmuch as our panel recommends at every turn that we should (for reasons articulated elsewhere) keep fetal tissue transplantation and research from encouraging abortion. Also, incentives to terminate a pregnancy would probably be prohibited under HHS regulations, though it might turn on how strong, i.e., how irresistible, the incentive was. (3) However, with respect to reasons, it would be unrealistic not to consider the possibility that transplantation and research with fetal tissue may enter the balance of considerations of a pregnant woman in deciding whether to have an abortion. It would be unrealistic because transplantation and research with fetal tissue will become general knowledge; it will not be possible to keep the populace from knowing about it.

By no reasonable interpretation can sheer information constitute a "prohibited 'inducement.'" The point of labeling some inducements as prohibited is to avoid manipulation of persons by coercion (a threat of harm) or by incentives (the promise of personal gain) unrelated to the risks, harms, and benefits of the act itself. Thus, that fetal tissue could benefit others might be one of many reasons to be weighed in deciding whether to terminate a pregnancy. We clearly would be unable to keep such knowledge from functioning as a reason, and in any case it does not and should not be construed to constitute a "prohibited 'inducement.'"

QUESTION 4. Is maternal consent a sufficient condition for the use of the tissue, or should additional consent be obtained? If so, what should be the substance and who should be the source(s) of the consent, and what procedures should be implemented to obtain it?

RESPONSE TO QUESTION 4

Fetal tissue from induced abortions should not be used in medical research without the prior consent of the pregnant woman. Her decision to donate fetal remains is sufficient for the use of tissue, unless the father objects (except in cases of incest or rape).

The consent should be obtained in compliance with State law and with the Uniform Anatomical Gift Act.

Customary review procedures should apply to research involving transplantation of tissue from induced abortions.

[Panel Vote: 17 Yes, 3 No, 1 Abstain]

CONSIDERATIONS FOR QUESTION 4

There are several possible ways to transfer or acquire any human tissue: donation (express or presumed), abandonment, sales, and expropriation. Although each method of transfer has been used for some human biological materials in some contexts in the United States, our society has largely adopted express donation--by the decedent while alive or by the next of kin after his or her death--as the method of transfer of cadaver organs and tissues. In cases where the decedent while alive could not or did not express his or her wishes about donation, the Uniform Anatomical Gift Act (UAGA) allows express donation by the next of kin. Presumed donation (or presumed consent) is used in 12 States for the removal of corneas; the donation of corneas by the decedent and next of kin is presumed to have been made if there is no express objection. The panel believes that express donation by the pregnant woman after the abortion decision is the most appropriate mode of transfer of fetal tissues because it is the most congruent with our society's traditions, laws, policies, and practices, including the Uniform Anatomical Gift Act and current Federal research regulations.

When a woman chooses a legal abortion for her own reasons, that act does not legally disqualify her--and should not disqualify her--as the primary decisionmaker about the disposition of fetal remains, including the donation of fetal tissue for research. Objections to this conclusion are grounded in the assumption that the decision to abort severs kinship in any but the biological sense. Nonetheless, the panel concludes that disputes about the morality of her decision to have an abortion should not deprive the woman of the legal authority to dispose of fetal remains. She still has a special connection with the fetus, and she has a legitimate interest in its disposition and use. Furthermore, the dead fetus has no interests that the pregnant woman's donation would violate. In the final analysis, any mode of transfer of fetal tissue other than maternal donation appears to raise more serious ethical problems. For all these reasons, the pregnant woman's consent, or decision to donate, should be sufficient (within the limits identified below). The panel heard no compelling reasons why federally funded transplantation research should depart from ordinary and legal

practice in the disposition and use of cadaver tissues, including fetal cadaver tissues.

However, questions have been raised about whether additional consent is needed from other parties, such as the father or a hospital ethics committee or an institutional review board. We believe that the structure provided by the UAGA (revised 1987) is generally adequate but that a modification in policy is needed for the donation of fetal tissue. Where the decedent did not express his or her wishes, the UAGA authorizes "either parent of the decedent" to make a donation, unless there is a known objection to such a donation from the other parent (or from the decedent's spouse or adult children). As applied to the donation of fetal tissue, the UAGA provides that either parent may donate unless there is a known objection by the other parent. In the panel's view, the pregnant woman's consent should be <u>necessary</u> for donation--that is, the father should not be able to authorize the donation by himself, and the mother should always be asked before the fetal tissue is used. In addition, her consent or donation should be <u>sufficient</u>, except where the procurement team knows of the father's objection to such donation. There is no legal or ethical obligation to seek the father's permission, but there is a legal and ethical obligation not to use the tissue if it is known that he objects (unless the pregnancy resulted from rape or incest).

Review procedures have been developed for federally funded research involving human subjects. These review procedures would also apply to fetal tissue transplantation research, which must be reviewed and approved by Institutional Review Boards (IRBs) before it can proceed. Such research would fall under the purview of IRBs because human subjects would receive experimental transplants of fetal tissue in a research protocol. In addition, IRBs will need to consider the adequacy of the information disclosed to the pregnant woman who is considering whether to consent to tests (e.g., for antibody to the human immunodeficiency virus) to determine the acceptability of the fetal tissue for transplantation research. Nevertheless, the pregnant woman's consent to donate the tissue is legally sufficient and should be sufficient in federally funded transplantation research, as long as there is no known objection from the father (except in cases of rape or incest).

QUESTION 5. Should there be and could there be a prohibition on the donation of fetal tissue between family members, or friends and acquaintances? Would a prohibition on donation between family members jeopardize the likelihood of clinical success?

RESPONSE TO QUESTION 5

There should be no Federal funding of experimental transplants performed with fetal tissue from induced abortions provided by a family member, friend, or acquaintance. Absent such prohibition, the potential benefits to friends and family members might encourage abortion or encourage pregnancy for the purpose of abortion--encouragements that the panel strongly opposed.

Concerns regarding maternal welfare as well as the moral status of the human fetus and, therefore, the morality of abortion itself, militate against Federal practices or policies that could have the effect of in any way encouraging abortions for the purpose of benefiting family members or acquaintances.

There is no evidence now that a prohibition against the intrafamilial use of fetal tissue would affect the attainment of valid clinical objectives. Given the current state of scientific knowledge, the treatment of diabetes with intrafamilial transplants would be contraindicated. For other conditions that are considered to be candidates for fetal tissue transplantation, currently available scientific evidence allows no definitive conclusions to be drawn with respect to this question.

[Panel Vote: 19 Yes, 0 No, 1 Abstain (Note: One panel member was out of the room when this vote was taken.)]

CONSIDERATIONS FOR QUESTION 5

There was no plea from the scientists for doing intrafamilial transplantation. In fact, the experts gave testimony that there ought to be a prohibition. If circumstances change, however, there may be reasons to modify the prohibition.

The panel did not hear any compelling evidence that suggests that a relationship between the donor and the fetus would improve the likelihood of success. Repeatedly, testimony of the experts emphasized the lack of scientific justification for intrafamilial donation by reason of current state of knowledge of immunology and disease pathophysiology. In fact, some argued that relatedness may induce the potential for disease recurrence, e.g., diabetes mellitus. It was strongly urged that the Secretary for Health and Human Services review these recommendations at regular intervals.

QUESTION 6. If transplantation using fetal tissue from induced abortions becomes more common, what impact is likely to occur on activities and procedures employed by abortion clinics? In particular, is the optimal or safest way to perform an abortion likely to be in conflict with preservation of the fetal tissue? Is there any way to ensure that induced abortions are not intentionally delayed in order to have a second trimester fetus for research and transplantation?

RESPONSE TO QUESTION 6

If fetal tissue transplants become more common, the impact on the activities and procedures of abortion clinics will depend upon the demand for tissue and the regulations and safeguards that restrict tissue procurement. To minimize this impact, it is essential that requests to donate tissue be separated from consent to the abortion, and that no fees be paid to the woman to donate, or to the clinic for its efforts in procuring fetal tissue (other than expenses incurred in retrieving fetal tissue).

The most certain impact if fetal tissue transplants become more common is that abortion facilities will more frequently--perhaps even routinely--ask women to donate fetal remains for research and therapy after they have decided to abort the fetus. The abortion clinic will also coordinate retrieval and temporary storage of fetal remains with tissue procurement organizations, either retrieving the tissue themselves or permitting procurement agency personnel to do so.

The greatest pressure for change in abortion clinic practices beyond requesting women to donate fetal tissue would occur if abortion clinics and women could profit financially from procuring fetal tissue. Current Federal law and the law of many States prohibit the buying and selling of fetal tissue, though they do permit payment of expenses incurred in procuring tissue for transplantation. Enforcement of these laws, including clear guidelines about what constitutes procurement expenses, is essential to prevent pressure to abort and to donate fetal tissue.

One could contemplate a scenario in which demand outstripped the supply of fetal tissue from abortions to end unwanted pregnancies. More effective contraception, greater acceptance of pharmacologically induced abortions, and great success in treating major diseases (such as Parkinson's and diabetes) could make the demand greater than the supply. To accommodate this scarcity, mechanisms for distributing fetal tissue to the larger number of patients demanding it would have to be devised, such as now exist for distributing the scarce supply of hearts, livers, and kidneys to patients on waiting lists for transplants.

However, this situation alone would not change the activities and practices of abortion clinics. Pressures to conceive and abort for transplantation purposes would arise outside of or apart from the activities of such clinics. Adherence to rules that specify when the request to donate tissue is made and that ban sales of fetal tissue would also limit the impact of such demand on abortion clinics.

The future medical possibilities cannot be foreseen with clarity. If, however, presently unexpected conflicts arise in the future, the choice of the abortion procedure should always be dictated by the health considerations of the woman.

[Panel Vote: 19 Yes, 2 No, 0 Abstain]

CONSIDERATIONS FOR QUESTION 6

Predicting the impact on abortion clinics of a greater frequency of fetal tissue transplants is difficult and necessarily speculative at this time. The impact will depend upon many factors, including the extent of the demand for tissue, the number of abortions, the time at which viable fetal tissue may be obtained, the rules for obtaining consent, and rules against buying and selling fetal tissue. History, of course, will supply the most accurate answers, for no one can tell just how successful the research under consideration will be.

Ideally, permission to use tissues from the aborted fetus would not even be sought until the abortion itself had been performed. The timing of and the procedures associated with the abortion would be set and the abortion would be performed before the question of tissue donation was even raised. However, post mortem tissue quickly deteriorates, and, in most instances, (e.g., transplantation of neural tissue) cryogenic storage is not a scientifically effective alternative. Thus, the pregnant woman must be consulted before the abortion is actually performed. In such instances, it is always possible for the woman herself to consider procedural options that might render the fetal tissue more useful for research or therapy; possible, but, according to experienced persons, entirely unlikely.

It was the judgment of the panel that the concerns behind Question 6 are best addressed by strict adoption of a number of safeguards; safeguards that would eliminate or at least radically reduce profit motives and tendencies toward commercialization, and safeguards that would ensure the greatest possible separation between abortion procedures, facilities, and personnel on the one hand, and fetal-tissue research procedures, facilities and personnel on the other.

Where the panel was divided was on the question of which "scenario" to adopt in framing recommendations; a so-called "worst-case" situation in which demand so outstrips supply as to exert great financial and altruistic pressures, or a so-called "reasonable-case" situation in which modest medical objectives are met only over a long period. The energetic support of research by the NIH would, of course, affect the rate of progress in this area. The strictest principles of separation would be necessary in the "worst case" and would not be untoward in their effects even under current conditions.

QUESTION 7. What actual steps are involved in procuring the tissue from the source to the researcher? Are there any payments involved? What types of payments in this situation, if any, would fall inside or outside the scope of the Hyde Amendment?

RESPONSE TO QUESTION 7

Past experience with fetal tissue research usually has had the medical researcher directly requesting fetal remains for research from physicians performing abortions, usually in the same institution. Occasionally, medical researchers have requested fetal tissue from freestanding abortion clinics in the same city.

In these instances, it is assumed that the woman aborting has consented to donation of fetal remains, though it is possible that in some instances the tissue, which would otherwise be discarded, has been treated as abandoned and used without maternal consent. If consent was obtained, it would ordinarily have been obtained before the abortion occurred but after the decision to abort had been made.

More recently, agencies or organizations have developed to provide tissue, including fetal tissue, to researchers. These have been nonprofit agencies that have solicited fetal tissue from abortion facilities and paid them a small fee for each fetal tissue retrieved to cover the costs of retrieval, including time of staff and rental of space. They have then distributed the tissue to previously identified and approved researchers conducting legitimate medical research. These agencies have usually charged the researchers the cost they have incurred in procuring the tissue.

There sometimes have been payments made to abortion facilities and physicians who have provided fetal tissue for research. These payments are intended to cover the costs to the abortion facility of providing access to the procurement agency, including staff time in requesting consent and retrieving tissue, and use of the clinic space by employees of the procurement agency.

If Federal research funds were used to pay the cost of the abortion procedure that makes fetal tissue available for research, such payment would violate the Hyde Amendment. On the other hand, the use of Federal research funds to pay tissue retrieval agencies for the costs of retrieving fetal tissue after the abortion has occurred would not violate the Amendment. Those funds would not be used "to perform abortions," but to obtain fetal tissue from abortions that would otherwise be occurring. Similarly, Federal support of fetal tissue research activities other than the cost of fetal tissue retrieval would also not violate the Hyde Amendment.

[Panel Vote: 19 Yes, 2 No, 0 Abstain]

CONSIDERATIONS FOR QUESTION 7

The description of fetal tissue procurement procedures described here is based on information presented to the panel concerning past experience in obtaining fetal tissue and on information about new organizations that have arisen to provide fetal tissue for research and therapy. Some further development along these lines may be expected, with a strong emphasis on

nonprofit retrieval agencies and no payments for tissue procurement beyond expenses.

There is no evidence that women who abort are paid money or other consideration to donate fetal tissue. Payments to abortion facilities have purported to cover expenses involved in collecting tissue and making it available. To prevent abortion clinics from making profits from fetal tissue donation, specific rules for what counts as a reasonable payment for retrieval expenses may be required.

The Hyde Amendment prohibits the use of designated Federal funds "to perform abortions except where the life of the pregnant woman would be endangered if the fetus were carried to term." It would appear, therefore, that the Hyde Amendment is not violated by support of research with fetal tissue or payment of costs incurred in retrieving that tissue because those funds would not be paid "to perform abortions."

QUESTION 8. According to HHS regulations, research on dead fetuses must be conducted in compliance with State and local laws. A few States' enacted version of the Uniform Anatomical Gift Act contains restrictions on the research applications of dead fetal tissue after an induced abortion. In those States, do these restrictions apply to therapeutic transplantation of dead fetal tissue after an induced abortion? If so, what are the consequences for NIH-funded researchers in those States?

RESPONSE TO QUESTION 8

While the Uniform Anatomical Gift Act in every State permits donations of fetal remains with maternal consent (as long as the father does not object), the panel is aware of eight States (Arkansas, Arizona, Illinois, Indiana, Ohio, Louisiana, New Mexico, and Oklahoma) that have statutes that prohibit the experimental use of cadaveric fetal tissue from induced abortions. Provisions of one statute (that in Louisiana) have been struck down on constitutional grounds.

Six of the eight States prohibit experimentation on fetuses from induced abortion. By their terms, these statutes do not apply to nonexperimental therapeutic transplants, but arguably would apply only to experimental therapeutic transplants. However, if the subject of the research is deemed to be the recipient of the fetal tissue transplant, then it may be that these statutes do not apply to experimental therapeutic transplants because they are experiments on the recipient and not on the aborted fetus.

Two of the six States would ban any use of fetal tissue from induced abortions, whether experimental or not.

Several States also have laws requiring that maternal consent be obtained before fetal tissue may be used, and ban payments for fetal tissue or providing the abortion free as an inducement to obtain fetal tissue for research.

The consequences for NIH researchers in those States depend upon the meaning of the term "experimentation" in the statutes at issue. In at least two of the States no use could be made of aborted fetal tissue. In the other six they could be used for nonexperimental therapeutic transplants or for experimental therapeutic transplants that are reasonably viewed as experiments on the recipient of the transplant and not on the fetal tissue itself.

Researchers in States with statutes appearing to ban fetal tissue transplants may seek clarification of the law.

[Panel Vote: 20 Yes, 0 No, 1 Abstain]

CONSIDERATIONS FOR QUESTION 8

Research using tissue from dead fetuses is permitted in most States, because these States have statutes modeled on the Uniform Anatomical Gift Act, which treats fetal tissue like other cadaveric remains. The panel knows of only two States that prohibit all use of fetal remains from induced abortion. In six other States known to the panel, whether tissue from induced abortions may be used is dependent upon clarification of the statutory meaning of the term "experimental."

QUESTION 9. For those diseases for which transplantation using fetal tissue has been proposed, have enough animal studies been performed to justify proceeding to human transplants? Because induced abortions during the first trimester are less risky to the woman, have there been enough animal studies for each of those diseases to justify the reliance on the equivalent of the second trimester human fetus?

RESPONSE TO QUESTION 9

There is sufficient evidence from animal experimentation to justify proceeding with human clinical trials in Parkinson's disease and juvenile diabetes. Although fetal tissue of diverse ages may be scientifically and clinically advantageous for transplantation to relieve various pathologies, no abortion should be scheduled or otherwise accommodated to suit the requirements of research.

In terms of Parkinson's disease there is a wealth of positive data on graft efficacy from animal models. Extensive research has been conducted in rodents and in non-human primates. Additional testimony from some scientists suggested that further animal studies would be helpful. It is not known, for example, if there are any long-term adverse immunological effects of the grafts. It was also pointed out that the same disease processes that caused the initial dopamine neuron degeneration could also produce degeneration of grafted neurons. Testimony stressed the need for additional research, especially in terms of developing cell lines, as discussed in Question 10, below.

In terms of diabetes, there was presented a considerable body of data with animal models of diabetes supporting the efficacy of fetal islet transplants in man and suggesting that human clinical trials were timely and appropriate. Such trials are now in progress and are currently being evaluated.

Experts testified that in other disease states, such as Alzheimer's disease, Huntington's disease, spinal cord injury, and neuroendocrine deficiencies, promising results have derived from experiments using allografts in animal disease models. In these latter diseases, experts urged further animal studies before using human fetal tissue. Acceptable preliminary data would then need to be presented to an appropriate Institutional Review Board, NIH Initial Review Group, and National Advisory Council before Public Health Service funds would be obtained.

Research in diabetes, Parkinson's disease, and neural regeneration has found that first trimester fetal tissue is not only more apt, but optimal, for transplantation, since it survives better and contains cells at a stage of differentiation which is more appropriate for the therapeutic goals. Animal studies on other disorders have not revealed a transplantation protocol that would require the use of more mature fetal tissue.

Should that possibility arise and not be restricted by law, then tissue available from abortions that have already occurred during the second trimester may be used. But, to the extent that Federal sponsorship or funding is involved, no abortion should be put off to a later date nor should any abortion be performed by an alternate method entailing greater risk to the pregnant woman in order to supply more useful fetal materials for research.

[Panel Vote: 18 Yes, 2 No, 1 Abstain]

CONSIDERATIONS FOR QUESTION 9

A summary of current literature underlying this response is to be found in the Addendum. The scientific testimony presented to the panel is provided in the appendices.

QUESTION 10. What is the likelihood that transplantation using fetal cell cultures will be successful? Will this obviate the need for fresh fetal tissue? In what time frame might this occur?

RESPONSE TO QUESTION 10

In terms of alternatives to the use of fetal tissue for transplantation, an option that was presented to the panel was the use of established lines of cells that are maintained in culture. The scientific testimony was optimistic that transplantation using cell cultures may ultimately be successful. This use of cultured cells might obviate the need for tissue directly obtained from the fetus for some purposes of research and therapy. The time frame for use of defined cell lines for transplantation is estimated to be at least 10 years, given the problems of genetic engineering to have the cells synthesize chemical messengers and differentiate after grafting.

[Panel Vote: 21 Yes, 0 No, 0 Abstain]

CONSIDERATIONS FOR QUESTION 10

The evidence in the field and expert testimony indicate that an established cell line for transplantation in diabetes must be able to synthesize, store, and release appropriate amounts of insulin when the blood sugar exceeds normal limits. At the present time, it is possible to construct cell lines by genetic engineering which synthesize insulin, but the newly formed insulin is released immediately regardless of the level of blood sugar. The genetic information for the storage and controlled release of insulin is not available at the moment and thus cannot be inserted into these cells.

A second problem may occur even if a cell line could be developed which would synthesize, store and release insulin upon demand. A normal insulin-producing cell in the pancreas is surrounded by other cells which secrete hormones that control and modulate the secretion of insulin. Thus, it may require the development of additional cell lines to release these hormones and permit the normal secretion of insulin from an insulin-producing cell line.

In regard to Parkinson's disease, it is unknown whether the transplanted neural cells will be needed only to release a specific chemical messenger or whether the transplanted cells must contact other neural cells. If both properties are required, then these two different types of genetic information would have to be inserted into the cell line.

A final problem for the development of cell lines for transplantation into patients with either diabetes or Parkinson's disease is that genetic information would have to be inserted to permit the multiplication of the cells before transplantation and then stop multiplying after transplantation. If cell multiplication could not be stopped after transplantation, the cell line would form a tumor in the patient.

Appendix III

ADDENDUM

Appendix III

SUMMARY OF CURRENT LITERATURE UNDERLYING THE RESPONSE TO QUESTION 9

Prepared by Dr. Barry J. Hoffer

In terms of Parkinson's disease (PD), there is a wealth of positive data on graft efficacy from animal models. The possible clinical application of neural grafting in patients with PD was first suggested a decade ago when it was reported that striatal implants of dopamine-(DA)-rich ventral mesencephalic tissue from rat fetuses could improve the symptoms of a 6-hydroxydopamine-induced Parkinsonian syndrome in rats (Björklund and Stenevi, 1979; Perlow et al., 1979). It has since then been convincingly demonstrated that the functional recovery is dependent on graft survival and DA fiber ingrowth into the denervated striatum (Björklund and Stenevi, 1979; Björklund et al., 1980). The growth of the grafted DA neurons exhibits a high degree of specificity and the distributional pattern of the outgrowing fibers is reminiscent of that found in the normal brain (Björklund et al., 1983). The ingrowing graft-derived DA fibers form abundant synaptic contacts with host striatal neurons (Freund et al., 1985). The grafts are metabolically, physiologically, and biochemically active (Zetterström et al., 1986; Strecker et al., 1987; Rose et al., 1985) in that they exhibit transmitter synthesis, normal firing patterns, and organotypic DA release. Successful grafting of DA-rich ventral mesencephalic tissue from fetuses to the striatum has also been reported in nonhuman primates with MPTP-induced Parkinsonism. Survival of implanted DA neurons in the caudate nucleus or the putamen has been demonstrated microscopically in rhesus monkeys (Bakay et al., 1985), african green monkeys (Redmond et al., 1986) and common marmosets. Biochemical data have indicated a near-normal ratio of homovanillic acid (a major DA metabolite) to DA in the vicinity of the grafted cells indicating that in nonhuman primates as well, grafted dopaminergic neurons are able to normalize DA turnover in DA depleted areas of CNS. Such animals have shown a permanent reduction of both drug-induced motor abnormalities and of hypokinesia, rigidity and tremor.

A key finding supporting the recent clinical trials is that human fetal DA neurons are able to survive transplantation into the DA-denervated rat striatum, reinnervate the host brain and counteract Parkinsonian symptoms (Brundin et al., 1986, 1988; Strömberg et al., 1986, 1988).

The experiments with human donor to rat host ventral mesencephalic grafts indicate that the optimal donor age is 8 to 10 weeks. About 15,000 DA cells from each human fetus were found to survive grafting to the striatum of cyclosporin A treated rats (Brundin et al., 1988). Since it has been estimated (Lindvall et al., 1987) that the human putamen is normally innervated by about 60,000 DA neurons, grafting of ventral mesencephalic tissue from one fetus into this structure should be able to restore approximately 25 percent of the normal number of cells. Further estimates, taking into account the growth capacity of each individual human DA neuron, indicate that the DA innervation provided by mesencephalic tissue from one fetus would be able to reach 40 to 80 percent of the volume of the human putamen. The symptoms of PD do not appear until more than 70 percent of the DA neurons have degenerated (Berheimer et al., 1973); until this stage is reached, DA transmission is maintained through hyperactivity of remaining neurons and postsynaptic receptor supersensitivity (Ungerstedt, 1971). It is therefore realistic to believe that tissue from human fetuses implanted into the putamen, caudate nucleus, or both, would elicit a symptomatic improvement for a patient with PD.

Appendix III

Transplantation has also been considered as a possible "cure" for type I diabetes. In animal models, it has been known since the early sixties that it was possible to reverse the metabolic problems of diabetes by either whole pancreas or pancreatic islet transplantation (Lacy, 1984). Islet grafting was also shown to either prevent or arrest the development of diabetic complications, seen in animals with long lasting poorly controlled diabetes (Lacy, 1984).

Animal studies show that we are now in a position to isolate islets from the rodent pancreas and transplant them to unrelated animals without the need of recipient immunosuppression (Lafferty et al., 1983). Fetal pancreas can also be used as a source of tissue for transplantation (Lafferty et al., 1983). This tissue does not contain mature islets but does contain cells which give rise to islets. Grafts of fetal pancreas are relatively slow to reverse diabetes because the islet tissue must grow and differentiate before it can function.

Fetal pancreatic tissue, with appropriate treatment, can also be grafted without the need for recipient immunosuppression (Lafferty et al., 1983). The development of technology which provides the ability to graft without the need for immunosuppressive therapy, or at least using limited immunosuppressive therapy, makes islet or fetal pancreas transplantation a potential treatment for type I diabetes.

Studies have been carried out to determine whether human fetal pancreas, obtained from cadaveric donors, has the capacity to grow, differentiate and function in animals (Hullett et al., 1987; Tuch et al., 1988). These studies have involved the grafting of human fetal pancreas to animals with no functioning immune system (i.e., "nude" mice). The fetal pancreas does grow and develop insulin containing islets. The tissue also has the capacity to reverse a diabetic condition in these animals.

Since experimental studies have reached the stage of demonstrating that human fetal pancreas can grow, differentiate, and function in animals, it now seems scientifically justified to move to experimental studies in man, while continuing with research in animals.

Appendix III

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Additional Statements by Individual Panel Members

Appendix III

CONCURRING STATEMENTS

Judge Arlin M. Adams

The questions posed by Dr. Windom to the panel and the concerns underlying those questions raise a number of difficult and indeed anguishing issues for me.

I have been opposed to abortion except in very limited situations for a very long time. Yet, I recognize that the Supreme Court of the United States has declared that a woman has a constitutional right in the first and second trimester to proceed with an abortion. Although I have serious reservations regarding the Supreme Court opinion, both in its reasoning and in its ultimate result, I recognize that Supreme Court decisions in matters of this type constitute the law of the land. Thus, until those decision are reversed, all citizens are bound by them.

Nonetheless, any activity which would serve as an inducement to women to have abortions must, in my view, be dealt with in a most cautious fashion, and to the extent possible be carefully circumscribed.

Counterpoised against the concerns set forth above is the evidence produced during the hearings which indicate that there are a series of illnesses that might be substantially ameliorated by the prudent use of fetal tissue. Although proof of the efficacious use of such tissue is not yet established beyond all peradventure, every indication is that research in maladies such as Parkinson's disease, Huntington's disease, childhood diabetes, and perhaps Alzheimer's disease, can be considerably improved by the use of such tissue.

Consequently, at least for me, the problem has been weighing one major concern, my objections to abortions, against another major concern, making it possible to do medical research that could improve the lot of thousands of our citizens, in a sensible and rational fashion.

Certainly the prevention of any commercialization of this process would seem to me to be an absolute requirement. Also, the need to separate completely the abortion procedure and the use of the fetal tissue would seem to be an essential step, assuming that such a separation is possible. Further, it must be mandatory that any funding by the government be limited to situations which employ the most careful scientific approaches as well as the highest professional standards.

Based on the evidence that has been made available, I believe, at least preliminarily, that these various safeguards are possible in today's environment. Accordingly, I would insist as a condition to providing for any approval that the National Institutes for Health commit itself to conduct periodic reviews, from time to time and with great care, to insure that the concerns expressed herein, as well as concerns that may be uncovered as medical research proceeds, are carefully safeguarded.

One other element has tipped the balance so far as my vote is concerned in proceeding even with carefully crafted guidelines and on a periodic review basis only: I am troubled that without government funding there undoubtedly would be many efforts to use fetal tissue for medical research that would be completely unsupervised and not governed by any guidelines. Thus if the National Institutes of Health proceeds cautiously, and with carefully articulated

safeguards and a program of periodic reviews, there would be much greater assurance that carefully crafted guidelines will be put in place as an absolute condition to any research procedures. Such an arrangement would protect pregnant women and fetuses in a far more circumspect and intelligent manner than if the NIH did not participate in any way.

Appendix III

Dr. Aron A. Moscona
joined by: Professor John A. Robertson and Dr. LeRoy Walters

I wish to comment on the Statement of Dissent by Mr. James Bopp, Jr. and Professor James T. Burtchaell, distributed to the NIH Panel on Human Fetal Tissue Transplantation Research on October 21, 1988. This Statement refers to "instructive similarities" between Holocaust atrocities of the Nazis and elective abortions and transplantation research; it argues that transplantation research represents complicity in abortion and is, thus, "a perversion of both the scholar's and the healer's work" similar to the crimes of the Nazis and the Nazi "doctors."

Although voluntary elected abortion is within the pregnant woman's lawful right of choice and decision, this issue has become polarized by extremist views and beliefs. However, this panel was not convened to offer opinion on the abortion issue. Its task--specified by Dr. Windom's set of questions--was to evaluate research on fetal tissue transplantation in the context of laws, scientific-medical knowledge, and ethical and societal standards. It was the panel's majority opinion that existing medical knowledge justified funding of this research and that it could be lawfully and ethically conducted. The recommendations included complete insulation of the woman's choice and decision from influence by possible use of fetal cells in transplantation research and rigorous separation of the researchers from this process. As I see it, the essence of these recommendations was in accord with protection of individual freedom under the law and with uncompromising insistence that ethical-moral principles would be safeguarded in the pursuit of this new medical knowledge.

Dissent can make a positive contribution to our process. However, this Statement of Dissent is detached from reality in implying that the panel's majority position embraces moral complicity in deeds analogous to the Holocaust atrocities. Perhaps such a speculative analogy requires no comment. However, since it neglects the root causes which inspired and unleashed the atrocities of the Holocaust, this analogy not only is invalid, but is ethically repugnant and might be seriously misleading.

In a *New York Times* article (November 2, 1988), Julian Bond, the veteran of the 1960s civil rights struggle, comments on how the anti-abortion demonstrators compare themselves with the fight for black equality, claiming solidarity with the civil rights movement. Such comparisons, he says, are, at best, disingenuous and misleading attempts to "capture someone else's history" in a tactical maneuver to deny women constitutional rights. The attempt to bracket transplantation research in one context with the Nazi dictatorship's crusade to exterminate a people because of religion or creed is even more shockingly misleading: it closes its eyes to the "ideological" dogmas that, by denying human rights to one class of citizens, unlocked oppression and provided the warrant for genocide; and it exploits deeply lacerated memories and emotions in the service of an extremist position.

The Holocaust was not a medical research project to help Parkinson patients and rescue infants from fatal diseases. It was not scrutinized by peer reviews, examined by NIH panels, publicized by media, open to public questioning, debated in Congress, challenged by the Administration. The Holocaust victims did not board trains out of free will and choice; there were no clergymen, lawyers, ethicists, and social activists urging them to reconsider; they were not advised of constitutional rights or offered adoption as an alternative. They had no contraceptives against rape by racial prejudice and intolerance. At the gates

of Auschwitz, no one asked for "informed consent." Gas chambers were not a freely elected option to donate skin and hair to make lamp shades and mattresses for the Third Reich. The "medical experiments" did not involve freely surrendered clumps of embryonic cells lacking neural mechanisms for consciousness and pain. The "experimental" cruelties were not a main objective of the annihilation enterprise; they were just an incidental, opportunistic sideline of an obsessive "ideology" that denied human freedom and enslaved it to medieval hatreds in the name of world conquest. It was this unshakable "ideology," spawned of dogmatic religious intolerance, tribal feuds, and dark prejudices against one class of people that was the root cause and the sanction for the "final solution." This "ideology," above all the unspeakable deeds which followed, is the never-again-to-be-forgotten lesson and legacy of the Holocaust.

But this cardinal lesson is side-stepped by the Statement of Dissent in its use of the Holocaust to oppose transplantation research and elective abortions. Women do not choose abortion in the cause of racial extermination and fanatical nationalistic dogmas. They are dissuaded from contraception and family planning by beliefs and taboos. And equating freely surrendered abortus cells with tormented people poisoned with lethal insecticides defies reason and outrages morality. Is it negligence or a different frame of priorities that inspire such analogies? Or, are they meant to deny individual rights and freedoms in the name of preformed convictions. Is the Holocaust to be taken hostage in an assault on transplantation research? This is not constructive dissent. This might only feed ignorance, inflame passions, and inspire intolerance and extremism.

I trust that this was not the intent of the authors of the Statement of Dissent. But, in attempting to stigmatize the panel with "moral complicity," have they not strayed and lost sight of ethical and societal responsibilities?

Professor John A. Robertson
joined by: Dr. Robert C. Cefalo, Dr. James F. Childress, Dr. K. Danner Clouser, Dr. Dale Cowan, Dr. Barry Hoffer, Professor Patricia A. King, Dr. Paul Lacy, Dr. Joseph B. Martin, Dr. Aron A. Moscona, and Dr. Leroy Walters (Note: Dr. Walters does not accede to the final section, "Aborting to Obtain Tissue for Transplant.")

I concur in the panel's Report to the Assistant Secretary of Health. I write to provide a more complete rationale for some of the panel's positions and to address some issues not directly covered therein.

Clarifying the Issues

At the outset it is essential to separate out several issues that have become entangled in public, press, and scholarly commentary about fetal tissue transplant research.

The proposed research to be funded by NIH would make use of fetal remains from abortions that occur independently of tissue transplant research. Fetuses would not be kept alive or killed to obtain tissue. Nor would abortions be performed solely or primarily to get tissue for transplant. No fees would be paid to women to abort or to donate tissue, nor fees beyond actual expenses paid to abortion clinics to provide the tissue.

The main question before the panel is whether the NIH should support transplant research with fetal remains from the 1.5 million abortions performed annually to end unwanted pregnancies. If fetal remains may be used, the circumstances and procedures by which fetal tissue will be retrieved and distributed must then be addressed.

The Case for Funding Fetal Tissue Research

Transplantation research using fetal tissue from induced abortion should be funded because of its great clinical potential, and the ethically acceptable ways in which such tissue may be obtained.

Ample evidence was presented to the panel to justify proceeding with clinical research with fetal tissue transplants. Extensive animal studies have shown that clinical applications in humans are now justified for Parkinson's disease, and possibly diabetes. Promising results with fetal thymus transplants have also been shown. Given these clinical possibilities, there is an important role for the NIH to play in supporting such research so that progress in treating diseases affecting millions of persons may occur.

Fetal tissue research is permitted by current Federal research regulations and applicable law. Federal regulations permit research "involving the dead fetus, macerated fetal material, or cells, tissue, or organs excised from a dead fetus...in accordance with any applicable State or local laws regarding such activities."[1] The Uniform Anatomical Gift Act in all States treats fetal remains like other cadaveric remains and allows next of kin to donate the

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[1] 45 CFR 46.210. These recommendations resulted from the 1976 study of fetal research conducted by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Science Research.

tissue.[2] While eight States have laws banning experimental use of aborted fetuses, these statutes are of doubtful constitutionality.[3] One law has already been invalidated, and the others are vulnerable to challenge.[4] Advisory and review bodies in Great Britain, Sweden, Australia, and France have also approved such research when conducted under certain guidelines.[5]

Fetal tissue for clinical research may be made available in ethically acceptable ways. As noted, fetal tissue transplant research would use tissue retrieved from the 1.5 million legal abortions performed annually in the United States to end unwanted pregnancies. No need now or in the foreseeable future exists to have a woman conceive and abort to produce fetal tissue.

Given that these abortions will occur regardless of the needs of researchers, the research use of fetal remains from induced abortions performed to end unwanted pregnancies is ethically acceptable.[6] The researchers and recipients will have no role in the decision to abort or the abortion itself. The abortions at issue will occur regardless of research needs. If not used in research, fetal remains will be discarded. It is reasonable to conclude that the NIH may ethically fund transplant research with such tissue.

It should be emphasized that this conclusion is not determined solely by one's views about the morality of induced abortion. Because the abortion and subsequent research use occur independently, views about the immorality of abortion do not necessarily determine the morality of research with tissue from aborted fetuses. As evidenced by several members of the panel, persons opposed to abortion might reasonably view the research use of fetal remains as so separate and independent of the abortion as to be acceptable even if they disapprove of the abortion that makes the tissue available.

Similarly, the Catholic Church is not against all use of fetal tissue from induced abortions. A representative of the Bishop's Committee for Pro-life

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[2]Unif. Anatomical Gift Act, 8A U.L.A. 15-16 (West 1983 & Supp. 1987) (Table of Jurisdictions Wherein Act Has Been Adopted); 45 CFR 46.207(b).

[3]For an analysis of these laws, see King and Areen, Legal Regulation of Fetal Tissue Transplantation, 36 Clinical Research 205-209 (1988); Robertson, Fetal Tissue Transplants, 66 Washington Univ. Law Quarterly 1-65 (1988).

[4]Margaret S. v. Edwards, 794 F.2d 944 (5th Cir. 1986).

[5]Peel Committee on the Use of Fetuses and Fetal Material for Research (1972); British Medical Association, Interim Guidelines on the Use of Fetal Tissue in Transplantation Therapy (1988); National Health and Medical Research Council, Ethics in Medical Research Involving the Human Fetus and Human Fetal Tissue (1984); National Ethics Consultative Committee for Life and Health Sciences (France, 1984); Parliamentary Assembly of the Council of Europe (1986).

[6]While this claim is justified on utilitarian grounds, it also would not violate deontological concerns, because the abortion and subsequent use are so clearly independent. The question of whether such research would be acceptable if tissue could be obtained only from abortions performed for the purpose of providing fetal tissue raises issues that do not arise if the supply of tissue from family planning abortions is adequate. For discussion of those issues, see Robertson, Fetal Tissue Transplants, note 3 supra.

Activities of the National Conference of Catholic Bishops testified that "It may not be wrong in principle for someone unconnected with an abortion to make use of a fetal organ from an unborn child who died as a result of an abortion...."[7] The Vatican Instruction on Respect for Human Life in Its Origin and on the Dignity of Procreation forbids use of deliberately aborted fetuses only if they are not dead and the consent of the mother has not been obtained.[8]

The Case Against Research With Tissue From Induced Abortions

Some--but not all--persons opposed to abortion object to research with fetal remains from the million plus abortions that occur annually for reasons unrelated to fetal tissue procurement. They make three arguments, none of which withstand scrutiny as reasons not to proceed with fetal tissue transplants at this time.

Exploitation of the Fetus. Several of the right-to-life groups that testified before the panel argued that to use fetal remains in experimentation after an abortion had taken the fetus' life would be further "exploitation" of the fetus.[9] This objection is misguided. The abortion that makes tissue available occurs independently of the need for tissue. Also, fetuses are dead when tissue is retrieved for transplant. However one views the pre-abortion status of the fetus, once dead the fetus clearly lacks interests and can no more be exploited or harmed than can any cadaver.

Complicity in Abortion. A main argument of opponents of fetal tissue transplant research is that it will necessarily create complicity in past abortions.[10] But their account of complicity does not withstand scrutiny, and does not provide a sufficient basis for rejecting the benefits of research with fetal tissue obtained from elective family planning abortions.

The charge of complicity can appeal only to persons who think that family planning abortions are a moral evil. But even if one accepts that premise, it does not follow that use of fetal remains makes one morally responsible for or an accomplice in abortions that occur prior to and independent of later uses of fetal remains.

A researcher using fetal tissue from an elective abortion is not complicitous with the abortionist and woman choosing abortion. The researcher

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[7]Testimony of Richard Doerflinger, September 15, 1988, Panel Transcript, 240-41. However, he was concerned that use of fetal tissue could not "be institutionalized without threatening a morally unacceptable collaboration with the abortion industry." Id. at 241.

[8]Vatican Congregation for the Doctrine of the Faith, Replies to Certain Questions of the Day, p. 18 (St. Paul Editions, 1988).

[9]Testimony of Ms. Kay James, Panel Transcript at pp. 485-86.

[10]Dissenting statement of Rev. James Burtchaell and James Bopp, Esq., at pp. 66-72.

and patient will have no role in the abortion process.[11] They will not have requested it, and may have no knowledge of who performed the abortion or where it occurred. A third party intermediary will procure the tissue for the researcher. They may be morally opposed to abortion, and surely are not corrupted because they choose to salvage some good from an abortion that will occur regardless of their research or therapeutic goals.

A useful analogy is transplant of organs and tissue from homicide and accident victims. Families of murder and accident victims are often asked to donate organs and bodies for research, therapy and education. If they consent, organ procurement agencies retrieve the organs and distribute them to recipients unconnected with organ retrieval. No one would seriously argue that the surgeon who transplants the homicide or accident victim's kidneys, heart, liver, or corneas or the recipient who receives it become accomplices in the homicide or accident that made the organs available. Nor is the medical student who uses the cadaver of a murder victim to study anatomy an accomplice in that murder.

James Burtchaell's approach to the problem of complicity assumes that researchers necessarily applaud the underlying act of abortion, thereby allying themselves with it.[12] But one may benefit from another's evil act without applauding or approving of that evil. A may disapprove of B's murder of C, even though A gains an inheritance or a promotion as a result. The willingness to derive benefit from another's wrongful death does not create complicity in that death when the beneficiary has played no role in causing the death.[13]

Burtchaell and others try to shore up their complicity argument by drawing upon revulsion toward the unethical experiments that Nazi physicians carried out on concentration camp victims, which led to promulgation of the Nuremberg Code of human experimentation. But this analogy is inapposite. The Nazi experiments that were so revolting were carried out on live patients and clearly harmed them. Fetal tissue transplant research will be carried out with material from dead fetuses that have been lawfully aborted for reasons unrelated to the research. Unlike the Nazi experiments, the research in question does not harm fetuses. They are not aborted to advance research, and are dead when the research occurs.

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[11]Note that the complicity objection as framed by the opponents is a claim of complicity in abortions that have occurred in the past independent of research, and not a claim that fetal tissue research will lead to future abortions. That argument is treated separately.

[12]Burtchaell, Case Study: University Policy on Experimental Use of Aborted Fetal Tissue, 10 IRB: A Review of Human Subjects Research 7, 8 (1988). See also Robertson, Response to Burtchaell: Fetal Tissue Transplant Research Is Ethical, 10 IRB (forthcoming, 1988).

[13]The dissent also claims that use of tissue from aborted fetuses would "institutionalize a collaboration with the abortion industry" (p. 49), and create "an institutional partnership, federally sponsored and funded, whereby the bodily remains of abortion victims become a regularly supplied medical commodity." (p. 70). The terms "partnership" and "collaboration" imply active or intentional agreement and participation, and thus are a misleading way to describe a relationship in which independent tissue agencies will make fetal tissue that will otherwise be discarded available for research and therapy.

These references to the Nazi experiences are inapposite for two other reasons. One is that no doctors were tried or convicted at the Nuremberg war trials who had not directly researched on live persons before their death.[14] No one was prosecuted merely for making use of cadaveric remains from unethical experiments carried out by other physicians. Thus Nuremberg is no precedent for condemning the use of fetal remains made possible by independently occurring abortions.

The second reason is that reasonable persons clearly differ over whether benefits may ethically be drawn from the unethical experiments conducted on live persons in concentration camps under the Nazis. One could rely on Nazi-generated data while decrying the horrendous acts of Nazi doctors that produced the data without dishonoring those unfortunate victims.[15] Indeed, reliance on this data to save others could reasonably be viewed as retrospectively honoring the victims without justifying the horrors that produced the data. The Jewish doctors who made systematic studies of starvation in the Warsaw ghetto in order to reap some good from the evil being done to their brethren were not accomplices in that evil, nor are doctors and patients who now benefit from their studies.[16] Indeed, Burtchaell himself accepts that a physician may use a drug that has been produced by lethal experiments once the drug has been developed, despite the unethical process of developing it.[17]

If the complicity claim is doubtful when the underlying immorality of the act is clear, as with Nazi experiments and murder, it is considerably weakened when the act making the benefit possible is legal and its immorality is vigorously debated, as is the case with abortion. Given the range of views on this subject, perceptions of complicity with abortions that will occur regardless of tissue research should not determine public policy on fetal tissue transplants.

Legitimating and Encouraging Abortions. The dissent asserts that if fetal tissue transplants become common, "the incidence of abortion can reasonably be expected to increase from a combination of beneficent reasons motivating pregnant women who are ambivalent about abortion, and financial incentives

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[14]See, e.g., Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10, vols. 1&2 (Washington, D.C.: U.S. Government Printing Office, 1949); Leo Alexander, Medical Science Under Dictatorship, 241 New Eng. J. Med. 39 (1949).

[15]For example, scientists and officials at the EPA were divided over whether Nazi studies of certain gases could be cited in a proceeding related to a certain gas. Phillip Shabecoff, Head of E.P.A., Bars Nazi Data in Study in Gas, New York Times, March 23, 1988, p. 1. On the other hand, a University of Minnesota researcher has relied heavily on and would cite Nazi studies of hypothermia in his own studies of ways to save persons swept into icy seas. Minnesota Scientist Plans to Publish a Nazi Study, New York Times, May 12, 1988, p. 9.

[16]Leonard Tushnet, The Uses of Adversity: Studies of Starvation in the Warsaw Ghetto (New York: Thomas Yoseloff, 1966).

[17]Burtchaell, see note 12, supra. Yet Burtchaell finds that research use of cadaveric remains from those lethal experiments would not be acceptable, e.g., would create complicity. He makes no attempt to justify this distinction.

motivating abortion clinics."[18] To support this claim the dissent cites studies about women who are ambivalent about abortion and the motivations that influence the abortion decision.

Although the main appeal of this argument is to persons opposed to elective abortions, there are several reasons why this argument is not persuasive even to opponents of abortion. One is that the predicted impact on abortion practices is highly speculative, particularly at a time when few fetal transplants have yet occurred. There is no way to predict with certainty how fast the success of clinical research or the future demand for fetal tissue will progress. Judged by the progress of other research, it may take several years for effective clinical techniques for even a subgroup of seriously ill patients to be developed. Moreover, the research may lead to the development of cultured cells and other substances for transplant that minimize the need for fetal tissue in the future.

Nor is it clear that even successful use of fetal tissue will change individual or social practices concerning abortion. It is just as reasonable to think that successful fetal tissue transplants will have little effect on the incidence of family planning abortions, as that they will substantially increase them. The chief motivation for abortion is the desire to avoid the burdens of an unwanted pregnancy. As several physicians testified, even if fetal tissue transplants are successful, they will have no appreciable impact on the incidence of abortion.[19] A physician member of the panel noted that improving sex education and access to contraception would reduce abortion rates much more than banning fetal tissue transplants.[20]

The willingness of women to donate fetal tissue after abortion does not prove otherwise. Having decided to abort, a woman may feel better if she then donates the fetal remains. But this willingness does not show that tissue donation will lead to a termination decision that would not otherwise have occurred. Even if women consider donation before deciding to abort, the chance to donate will not necessarily lead to abortions that would not otherwise have occurred to any significant extent. One may acknowledge the ambivalence some women have about abortion, and still reasonably conclude that the desire to avoid the burdens of unwanted pregnancy and childrearing will continue to be the primary motivation to abort.

Yet even if <u>some</u> increase in the number of family planning abortions due to tissue donation occurred, it would not follow that fetal tissue transplants should not be supported. Surely it does not follow that <u>any</u> increase in the number of abortions makes fetal tissue transplants unacceptable. Automobile design, highway engineering, bridge building, drug licensing, and gun sales will lead to <u>some</u> loss of life as a result of the activity (in the case of gun sales, the deaths may even be intentionally caused). The risk that <u>some</u> lives will be lost, however, is not sufficient to stop those projects when the number of deaths is not substantial, when the activity serves worthy goals and when reasonable steps to minimize the loss have been taken. A more stringent policy

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[18] Dissenting statement at p. 55.

[19] Statement of Ezra Davidson, M.D., <u>Panel Transcript</u> at p. 420.

[20] Statement of Kenneth Ryan, M.D., <u>Panel Transcript</u> at p. 701.

is not justified for fetal tissue transplants just because the risk is to prenatal life from some increase in the number of legal abortions.

The dissent does not address the question of magnitude of impact. It asserts that "an increase" in the number of abortions will occur, but provides no convincing reasons to think that the increase will be substantial. Furthermore, it assumes that even a marginal increase in abortion should bar fetal tissue transplant research. As a result, the dissent would deny thousands of patients potentially important benefits to prevent a potentially marginal or insignificant increase in the number of abortions. Its stance would also bar fetal tissue research that could lead to developing cultured cells or direct chemical substitutes out of a speculative fear that "some" increase in abortions would occur.[21]

Other aspects of the concern about encouraging or legitimizing abortion are also unpersuasive. For example, the dissent's claim that abortion clinics would have financial incentives to persuade women who are ambivalent to abort is unconvincing because of the clear preference of the panel and existing law for prohibiting payments (other than reasonable retrieval expenses) for fetal tissue.[22] Nor would the use of fetal remains for transplant mean that a public otherwise ready to outlaw abortion would refrain from doing so. The continuing legal acceptance of abortion flows from the wide disagreement that exists over fetal status. If a majority were agreed that fetuses should be respected as persons despite the burdens placed on pregnant women, secondary benefits from induced abortion such as fetal tissue transplants would not prevent a change in the legality of abortion. Speculation about the legitimizing effect of tissue transplants should not stop the great good that fetal tissue transplants may provide.[23]

Maternal Consent for Fetal Tissue Donation

The acceptability of fetal tissue transplant research rests on the assumption that the tissue will be legally obtained for transplant. In the context of tissue and organ transplantation, this means that the consent of the woman (unless the father objects) be obtained. Maternal consent is a legal

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[21]If there were a substantial increase in the number of abortions, it still would not follow that fetal tissue transplant research and therapy should not occur. Given the rudimentary development of early fetuses, the potentially great benefit to recipients, and the legality of abortion, such transplants might still be ethically and legally acceptable.

[22]The panel has clearly recommended against buying and selling fetal tissue from women undergoing abortions and abortion clinics. See Panel Report, Responses to Question 1 and Question 6. Yet the dissent inaccurately states that the panel "has refused to recommend" such a restriction. Dissent at p. 63.

[23]It could also be said that the willingness to use organs from homicide, suicide, and accident victims might encourage or legitimate such deaths, or at least make it harder to enact lower speed limits, seatbelt, gun control, and drunk driving laws to prevent them. After all, the need to prevent fatal accidents, murder and suicide becomes less pressing if some good to others might come from use of victim organs for transplant. But the connection is too tenuous and speculative to ban organ transplants on that basis. It is similarly speculative and tenuous as a ground for banning fetal tissue transplants.

requirement for use of fetal remains under the Uniform Anatomical Gift Act and current Federal research regulations.[24] The previously cited Vatican Instruction also recognizes the importance of maternal consent to use of fetal remains from induced abortions.[25]

These rules should apply to donation of fetal remains for transplant research. A woman who aborts a pregnancy does not lose or forfeit all interest in an aborted fetus. She may care deeply about whether fetal remains--a product of her body and potential heir that she has for her own personal reasons chosen to abort--are contributed to research or therapy to help others. Given that interest, there is good reason to respect her wishes, as current law presently does. Her consent to donation of fetal tissue should be routinely sought.

The argument of some ethicists that her decision to abort disqualifies her from playing any role in disposition of fetal remains is not persuasive.[26] It overlooks her continuing interest in what happens to fetal tissue that results from her abortion. It also mistakenly assumes that a person who disposes of cadaveric remains acts as a guardian or proxy for the deceased, who has no interests, rather than as a protector of their own interests in what happens to those remains. Finally, it would lead to a policy of using fetal remains without parental consent or to a total ban on fetal transplants.[27]

Fetal Tissue Procurement Practices

The conclusion that fetal remains from family planning abortions may be ethically used in transplant research assumes that fetal tissue can be obtained and distributed for research use without close involvement in the abortion process. Current Federal regulations and solid organ procurement practices provide sufficient guidance here and should be followed for fetal tissue procurement.

A central feature of these rules is that the researcher has nothing to do with the decision to make the tissue available, including the decision to abort and determination of fetal death.

Another important feature is that consent to donate tissue be requested after the decision to abort has occurred. This will assure that tissue donation is not a prerequisite to having the abortion performed. Also, it will prevent the prospect of donating fetal remains from influencing the decision to abort, a clearly preferable policy when an adequate supply of fetal tissue is available from elective family planning abortions. Of course, there will be situations in which women may know of the possibility of tissue donation prior to being asked. In some cases, women considering abortion may inquire about donation of fetal remains. In those cases women should be informed of donation possibilities. As

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[24]See note 2 supra.

[25]See note 8 supra.

[26]Dissent at 2-5; Burtchaell, note 12 supra at p. 8.; Mary Mahowald, Placing Wedges Along a Slippery Slope: Use of Fetal Neural Tissue for Transplantation, 36 Clinical Research 220 (1988).

[27]Robertson, Fetal Tissue Transplants, note 3 supra.

a general rule, however, requests to donate fetal tissue should wait until the woman has clearly indicated her decision to abort.[28]

Laws and policies against paying women to abort or to provide fetal tissue for transplant, and against paying abortion facilities for fetal tissue, are desirable to remove any taint of commercialization or profit from the enterprise. The National Organ Transplant Act now makes payment of "valuable consideration" for the donation or distribution of specific fetal organs and "any subparts thereof" (which arguably includes tissue and cells) a Federal crime, as do many States.[29] Such laws are thought necessary to protect human dignity and to prevent exploitation. They will also allay fears that women are paid to conceive and abort to obtain fetal tissue.

Current bans on buying and selling fetal tissue do not--and should not--prohibit making reasonable payments to recover the costs of retrieving fetal tissue.[30] Tissue procurement agencies should be free to pay the costs of personnel directly involved in tissue retrieval, whether employees of the procurement agency or of the facility performing the abortion. For example, a tissue retrieval agency may reimburse the abortion clinic for using its space and staff to obtain consent for tissue donations and to retrieve tissue from aborted fetuses. However, the abortion facility should not charge the agency a fee beyond reasonable expenses incurred in retrieving fetal tissue at their facility.

For-profit firms that prepare, process, and distribute fetal tissue for research or therapy should be free to recoup their costs, including some "profit" to cover the costs of obtaining the capital that makes their services possible. Such payments are consistent with the role of for-profit physicians, hospitals, drug companies, air transport, and other services in solid organ transplantation, all of which also depend upon altruistic donation of cadaveric human remains.

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[28]This does not mean that it would be unethical to abort after having been made aware of donation options. See note 6 supra.

[29]42 U.S.C.A. #274e (West Supp. 1985); ARK. STAT. ANN §82-439 (Supp. 1985); ILL. ANN. STAT. ch. 38, §81.54(7) (Smith-Hurd 1983); LA. CIV. CODE ANN. art. 9:122 (Supp. 1987); OHIO REV. CODE ANN. §2919.14 (Page 1985); OKLA. STAT. tit. 63, §1-735 (1987); FLA. STAT. ANN. §873.05 (West Supp. 1987); MASS. GEN. LAWS ANN. ch. 112, §1593 (1964); ME. REV. STAT. ANN. tit. 22, §1593 (1964); MICH. COMP. LAWS ANN. §333.2690 (West); MINN. STAT. ANN. §145.422 (West Supp. 1986); N.D. CENT. CODE §14-02.2-02 (1981); NEV. REV. STAT. §451.015 (1985); R.I. GEN. LAWS §11-54-1(f) (Supp. 1987); TENN. CODE ANN. §39-4-208 (Supp. 1987); TEX. PENAL CODE ANN. §§42.10, 48.02 (Vernon 1974 and Supp. 1988); and WYO. STAT. §35-6-115 (1986); 18 PA. CONS. STAT. §3216 (Purdon 1983). See also Note, Regulating the Sale of Human Organs, 71 Va. L. Rev. 1015 (1985).

[30]The National Organ Transplant Act, for example, allows "reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of" the organs and tissue covered by that act. 42 U.S.C.A. #274 (e). Many state laws have similar exceptions.

Aborting to Obtain Tissue for Transplant

Central to the argument for NIH funding of fetal tissue transplant research has been the assumption that such transplants will not necessitate pregnancy and abortion to produce fetal tissue.

No need now or in the foreseeable future will exist to have a woman conceive and abort to produce fetal tissue. With 1.5 million abortions occurring annually to end unwanted pregnancies, the supply of fetal tissue for research and therapeutic needs appears to be adequate for many years to come. Nor is there presently any indication that fetal tissue antigenicity will be so important that a close genetic match between source and recipient will be necessary, which could lead family members to conceive and abort to obtain tissue for transplant.

In light of these supply considerations, at the present time a policy against aborting solely to obtain tissue for transplant, against donor designation of tissue recipients, and against fetal tissue donations to family or friends is desirable. It will not prevent needy patients from receiving fetal tissue transplants, and will quiet fears that women will be coerced or pressured into conceiving and aborting for transplant purposes, or that abortions solely to produce tissue for transplant will occur.

If the situation changes so that the supply of fetal tissue from family planning abortions proves inadequate, the ban on donor designation of recipients and aborting for transplant purposes should be re-examined. The ethical and legal arguments in favor of and against such a policy would then need careful scrutiny to determine whether such a policy remains justified.[31] In the meantime the fear that fetal tissue transplants will lead to abortions to obtain tissue for transplant should not prevent use of tissue from abortions not performed for that purpose.

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[31]When another person's life or health depends on it, the argument in favor of abortions to obtain tissue is much stronger than has generally been thought. See Robertson, note 3 supra.

Appendix III

DISSENTING STATEMENTS

Rabbi J. David Bleich

FETAL TISSUE RESEARCH AND PUBLIC POLICY

Questions focusing upon the morality of abortion are among the most emotion-laden and divisive issues of our time. The Supreme Court has ruled that, as a matter of law, the constraints that society may place upon performance of abortions are severely limited. Although the judiciary is empowered to declare the law, it does not function as an arbiter of morality. The morality of induced termination of pregnancy remains a contentious issue in our society.

The decision of the Supreme Court in Roe v. Wade serves to curtail legislative initiative designed to hamper a woman's right to make her own determination regarding the morality of induced abortion. There is, however, nothing in our law or in the mores of our society that argues for governmental action designed to support or to facilitate abortion. Quite to the contrary, it behooves all branches of government to maintain strict neutrality with regard to matters of controversy judicially declared to fall within the realm of private morality. Thus governmental agencies should neither grant their imprimatur--nor allow themselves to be perceived as granting their imprimatur--to the voluntary termination of pregnancy even when such a procedure is undertaken for the most noble of reasons. Support or encouragement of abortion by any Federal agency is ipso facto governmental endorsement of the moral nature of such procedures.

It has been tacitly assumed by the Advisory Panel from the very outset of its deliberations that our society should not lend its sanction to the performance of an abortion when the decision to induce an abortion is motivated solely by a desire to further scientific knowledge. Societal support of a woman's decision to conceive so that the fetus may be aborted for such purposes has been viewed by the Advisory Panel as equally repugnant. Moreover, although the goal may be realizable only to a greater or a lesser degree, the report of the Human Fetal Tissue Transplantation Research Panel is clearly predicated on the acknowledged, albeit unenunciated, premise that NIH-funded fetal tissue transplantation should not be conducted in a manner that might encourage the performance of any abortion that would otherwise not occur. To that end, the participants in the majority report of the Advisory Panel have unanimously recommended that there be no Federal funding of programs involving experimental transplants performed with fetal tissue derived from an abortion provided by a family member, friend, or acquaintance; that solicitation of consent for use of such tissue and even preliminary discussion of tissue donation be delayed until after a consent to the abortion has been signed; that anonymity between donor and recipient be maintained; and that the identity of the donor be concealed from the transplant team.

These mitigating safeguards notwithstanding, intellectual integrity compels recognition that the goal of preventing an increment in the total number of abortions performed is not totally attainable. The research proposals under discussion, if successful, will yield therapies designed to cure or to prolong the lives of countless numbers of individuals afflicted with life-threatening illnesses. Generation of the potential for preservation of life through the intermediacy of abortion must perforce diminish the odium associated with that procedure. As an instrument for good, the act of abortion cannot be perceived

as an unmitigated evil. A torn, tormented and guilt-ridden young lady struggling with the moral dilemma associated with a resolution of the question of whether "to abort or not to abort" will now have forced upon her one additional consideration to be added to the potpourri of social, economic, and moral forces pushing and tugging in opposite directions. Moreover, involvement of prestigious institutions and respected members of the scientific community coupled with implied governmental approval, as evidenced by the NIH funding of research in which utilization of the aborted fetus is crucial, combine to endow the abortion procedure with an aura of moral acceptability. Surely, in at least some instances, those factors will tip the decisionmaker's scales against preservation of the fetus.[1]

The Advisory Panel has endeavored to formulate recommendations designed both to safeguard fetal life and to permit support of potentially life-saving scientific research. The conclusions of the Advisory Panel reflect a balancing of those interests expressed through a policy of damage containment. Those conclusion represent an attempt to discourage abortion to the fullest extent possible short of an outright ban on fetal tissue transplantation. The goal of nonenhancement of abortion is illusory; the attempt at approximation is laudable.[2]

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[1]It is certainly not uncommon for women generally disposed against abortion to decide to terminate an unwanted pregnancy. Such women are reported to experience a significant degree of cognitive dissonance. See Michael B. Brachen, "The Stability of the Decision to Seek Induced Abortion," Research on the Fetus: Appendix, HEW Publication No. (OS) 76-128, p. 16-15. Thus it is not surprising that conflict during decisionmaking is reported as being quite prevalent. Ibid., p. 16-16. The percentage of women who undergo at least one change of decision with regard to abortion is reported to be approximately one third. Ibid., pp. 16-2 and 16-16. Given the vacillation which is known to exist, any relevant factor may become decisive in reaching a decision. Although, in the absence of statistical data, it is impossible to predict the percentage of women to whom beneficial aspects of participation in fetal tissue transplantation projects may become the factor in the absence of which a final determination to abort would not occur, it is certain that for at least some women this will be the case.

[2]Regrettably, the recommendations of the Advisory Panel fall short of maximum approximation of this goal. Federal funding conveys an unintended message of moral approval for every aspect of the research program. The distinction between moral approval of use of the product of an already completed abortion and the abortion itself is extremely subtle and, even if expressly formulated, unlikely to be fully appreciated. Nevertheless, if left unarticulated, many more women will be left with the erroneous impression that induced abortion is condoned by the Federal Government as acceptable. For at least some of those women, this erroneous impression will have a decided effect upon their determination to undergo an abortion. The NIH should certainly take appropriate measures to counteract any such misimpression. Meaningful measures should be taken to assure that literature describing fetal transplant programs, press releases, and public information programs spell out this point with utmost clarity. The method most effective in assuring that this information is actually received by women involved in fetal tissue donation is to include a legend or notice to this effect in the consent form signed by the donor. The consent form might simply state that solicitation of the consent does not

Appendix III

Opposition to Federal funding of research projects involving use of fetal tissue obtained by means of induced abortions focuses upon three considerations:

1) No benefit may be derived from an act of such inherent immorality; the benefit itself constitutes a malum per se.

2) Federal funding constitutes complicity and collusion in the antecedent abortion even if the abortion would have been performed in the absence of a research program for which utilization of the abortus is required. Since the implication of endorsement is a necessary concomitant of funding, funding must be eschewed in order to avoid the collusion inherent in the funding relationship.

3) Research of this nature will inevitably effect an increment in the total number of abortions performed. Hence governmental funding is, in effect, application of societal resources to activities that will result in loss of additional fetal lives.

It must be emphasized that these objections would not necessarily obtain in a situation involving organ tissue obtained from a homicide victim. Homicide is recognized by all, and commonly by the perpetrator himself, as a heinous offense and as a crime against society. From the societal perspective, homicide is aberrant behavior. Homicide is a crime and, if apprehended, the murderer will be prosecuted to the fullest extent of the law. Utilization of the body of the victim for scientific purposes could not conceivably be construed as an endorsement of the antecedent homicide. Nor could such utilization, or the contemplation of such utilization, possibly lead to an increase in the incidence of homicide. Abortion, on the other hand, is regarded in some sectors of our society as innocuous and condoned as a morally neutral act. Those who regard feticide as akin to homicide perforce view abortion, as presently performed, as socially sanctioned homicide. The wanton nature of the destruction of fetal life with societal approval imbues the moral offense with a gravity that greatly exceeds that of aberrant, socially condemned acts of homicide. Moreover, the sheer number of abortions required to sustain such research programs serves to magnify the immoral nature of the offense. We are confronted, not by isolated, individual acts of immorality in which the product of the act can be isolated from the act itself, but with programs and policies predicated upon the assumption that such acts are performed in inordinately large numbers, as a matter of course.

Each of the earlier enumerated objections is founded upon a cogent moral concern. Ceteris paribus each of those considerations may well be of sufficient moral gravity, in and of itself, to compel withholding of support for such research. However, the problem is rendered more complex by virtue of the fact that the lives of countless numbers of patients might be saved or prolonged by utilization of tissue derived from fetuses that would have been aborted regardless of whether or not such transplantation will take place subsequently. In this context, the question is not whether the procedure is or is not morally acceptable because of one or more of the previously enumerated considerations, but whether those considerations are of sufficient gravity to prevail over the

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necessarily signify that any person, institution, or agency involved in the transplant procedure, or in its funding, approves the abortion procedure by means of which the tissue has become available.

moral imperative associated with the preservation of human life. Stated somewhat differently, the issue is whether policies designed to preserve human lives may be put into place with the knowledge that the inexorable effect will be the snuffing out of an undeterminable number of fetal lives.

Resolution of this dilemma will, in part, hinge upon the weight to be given preservation of human life as a value within a system of values. If rescue of an endangered human life is to be accepted as the dominant value to which all others are subservient, and if the immediacy of danger is regarded as establishing an immediate duty taking precedence over duties less immediate in nature, a compelling case can be made for utilization of an abortus for the rescue of a life at risk here and now on the grounds that the duty of preserving that life is immediate whereas the obligation to prevent the taking of fetal life is less compelling since, at the present moment, no fetal life is as yet at risk.

If, however, a system of values is posited in which preservation of human life is not the dominant value, an entirely different moral calculus emerges. In such a system homicide remains an unparalleled evil. Nonfeasance and malfeasance may well be regarded as occupying entirely disparate moral planes; acts of commission may indeed be regarded as entirely different in nature from acts of omission. In such a system, prevention of homicide--and of feticide--may well occupy a dominant position. Thus, society's duty to prevent destruction of fetal lives--a duty to prevent grave evil--may indeed become a far more weighty concern than the duty to enhance longevity anticipation.

A system of ethics which does not recognize an obligation to employ extraordinary means in the preservation of human life does not posit preservation of human life as the paramount moral value. Renunciation of an obligation to employ extraordinary means is nought but a tacit acknowledgement that other values are at least equal to the value of human life. Inordinate expense, pain, loss of limb, separation from family and familiar surroundings have all been held to constitute extraordinary means. Those considerations reflect values that, in such a value system, need not be sacrificed for prolongation of life. It may well be contended that utilization of an abortus for such purpose is "extraordinary" if for no other reason than that it will lead to an increase in loss of fetal life or, to state the same proposition in different terms, because prevention of feticide constitutes a value at least equal to and, arguably, greater than prolongation of life.

Our society, in its institutions, mores, and public policies, certainly regards enhancement of longevity anticipation as but one value among many--an important value, to be sure, but hardly as the paramount value to which all others are subordinated. Failure to regard prevention of wanton destruction of nascent life as a value at least on par with much lesser concerns that are permitted to interfere with and to negate the value inherent in prolongation of human life can only be the product of either a failure to appreciate the sanctity of fetal life or of a certain inconsistency in moral reasoning.

Moreover, the duty of preservation of life is rendered far less compelling by virtue of the fact that the projects for which funding is presently sought are experimental in nature. The procedures, as applied to humans, are essentially untried and untested; therapeutic benefit is, as yet, undetermined. The cost in terms of fetal life is far more certain than the therapeutic benefit. Futhermore, the benefit to prospective patients cannot be regarded as immediate. Assuming that the contemplated research is fruitful and will lead to

development of therapies for various life-threatening illnesses, the benefits will be eventual rather than immediate. Procedures must be perfected and techniques honed before significant benefits can be anticipated.

To the extent that the duty to preserve life is compelling and takes precedence over other duties because the demand for rescue is present here and now, responsive action in the form of allocating societal resources for research programs cannot be subsumed under that imperative; scientific research cannot be regarded as commanded by virtue of the immediacy of the compelling demand to rescue human life.

The duty to embark upon such projects because of their lifesaving potential is thus diminished for two reasons: 1) the therapeutic efficacy of the procedure is unknown, and 2) the benefits will not accrue immediately but will become available only to future patients. The moral harm, on the contrary, is 1) known with a conviction approaching certainty, and 2) immediately attendant upon, and triggered by, implementation of the social policy under consideration. On balance, the duty to refrain from a course of action that will have the effect of increasing instances of feticide must be regarded as the more compelling moral imperative.

Appendix III

James Bopp, Jr., Esq. and James Tunstead Burtchaell, C.S.C., Ph.D.

HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH PANEL: STATEMENT OF DISSENT

The report of this panel is essentially a series of answers to ten questions posed to the National Institutes of Health by the Assistant Secretary for Health. With the other panelists we have participated in the discussions and the drafting process, and have cast our votes for or against the various answers.

In a larger sense, however, the sum of it all is a single question: whether transplantation research using human fetal tissue derived from induced abortions is an acceptable act for sponsorship by an agency of the Federal Government. That great issue has not been dealt with adequately by the Report. Indeed, we believe it has been avoided. Hence the need to file this Dissent.

The Assistant Secretary for Health has ranked the questions he set before us, in order of significance, as ethical, legal, and scientific.

To begin with the matter of last priority, the hasty and unmethodical nature of our scientific inquiry[1] accredits us to do little more than report: 1) that compassionate advocates of those afflicted by various handicaps, diseases, and injuries ardently champion the resumption of transplantation research; 2) that scientists and clinicians are more cautious in their hope than are the advocates, at this early stage of research, about the therapeutic results it might yield; and 3) that we might all be disposed towards the proposed research were there no ethical objection to the source of the fetal tissue. That this research might be scientifically promising has not been at issue among us, though our collegial competence to make such a judgment at this time is incomplete.

Indeed, it was obvious that the scientists selected by the NIH to give testimony were long-term NIH beneficiaries, and they did little to spread before us any of the serious opposition being raised in the scientific literature to

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[1]This panel has been asked to resolve matters of great import with much less time and resources than its two antecedent bodies, the Peel Commission in Great Britain (The Use of Fetuses and Fetal Material for Research: Report of the Advisory Group to the Department of Health and Social Security, Scottish Home and Health Department and the Welsh Office, 1972) and the DHEW Commission in the United States (Report and Recommendations on Research on the Fetus: The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1975). Of the former, Peter J. McCullagh writes: "The Peel Report . . . was the product of six meetings. Its reading provides no grounds to disbelieve this. . . . My advice to the reader who remains unconvinced of its superficiality is that, to paraphrase the Report's comments on foetal tissue use, 'there is no substitute' for reading the original in its entirety. No attempt was made, in writing the Report, to attribute sources to any of the categorical statements it contains." (The Fetus as Transplant Donor: Scientific, Social and Ethical Perspectives [New York: Wiley/Liss, 1987], 197). As for the latter report, Paul Ramsey has recounted how attempted evasions of the Freedom of Information Act and active disinformation by the NIH promoted its arrival at desired conclusions (The Ethics of Fetal Research [New Haven: Yale University Press, 1975], ch. 1).

such research. For instance, we heard little of the more cautionary view held among scientists and clinicians, that in many applications there have not been adequate animal research trials using subhuman primates.[2]

Ascending to the next level of concern: the legal questions put to the panel should probably be answered by a group that can address them more rigorously than we have. What we do find is a pattern of State legislation which suggests substantial support for prohibiting or restricting the use of aborted fetal tissue in research.

But since the panel's advice is asked about Federal sponsorship through funding, not just about criminal statutes, larger public policy concerns must also claim our attention. It is true, as advocates reminded the panel repeatedly, that abortion is currently legal. But it is also true that for over a decade it has been the policy of the Federal Government not to allow taxpayers' money to subsidize abortions--by the Hyde Amendment. With the action of the 100th Congress, there is no longer any direct Federal subsidization of abortion. Moreover, the 1988 presidential proclamation affirming the personhood and right to life of the unborn,[3] the Title X family planning regulations which separate family planning programs from symbiotic relationships with abortion providers, the repeated attempts of the several States to reinstate some of the restrictions on abortion struck down by the Wade and Bolton decisions, and the consistent rejection of abortion on demand by public opinion during the past thirty years[4] all cast a very dark shadow over any

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[2]See, for instance, R. J. Joynt & Donald M. Gash, "Neural Transplants: Are We Ready?" Annals of Neurology 22 (1987): 455-56; John R. Sladek, Jr. & I. Shoulson, "Neural Transplantation: A Call for Patience Rather than Patients," Science 240 (1988): 1386-88; Roy A. E. Bakay & Daniel L. Barrow, "Neural Transplantation for Parkinson's Disease," Journal of Neurosurgery 69 (1988): 807-810. In this regard, Dr. Thomas Gill was one of only two experts to address the panel that expressed this view. He gave four cogent reasons why further animal studies might be needed before human trials were begun. Statement of Thomas J. Gill, Panel Transcript, 15 September 1988, 40-41. These reasons to postpone human fetal transplant research were neither refuted nor discussed by the swarm of experts who urged no delay.

[3]Presidential Proclamation of 14 January 1988.

[4]Public opinion polls for nearly thirty years now manifest a stable ethical appraisal of abortion. One fifth of all adult Americans reject abortion except to spare the life of the mother. At the other end of the opinion spectrum, one fourth of the public accepts abortion on demand. The large population between those polar groups accepts abortion in the rare and difficult cases when pregnancy results from felonious intercourse (rape or incest). Abortion to avert the birth of a handicapped child usually receives less than a clear majority of affirmative opinion. These polls are frequently interpreted as showing that about 80% of all Americans accept abortion for some reasons. This is true but misleading, because the reasons they accept account for only perhaps 1% of all abortions performed. It is more accurate to read in the polls that 75% of the public considers about 99% of all present abortions to be unacceptable. This consistency of public opinion as manifest in Gallup, Harris, NORC, Yankelovich, Newsweek, and other polls has been chronicled by Professor Judith Blake of UCLA and Professor Raymond Adamek of Kent State University, the most capable analysts of opinion surveys on abortion in the 1960s and 1970s, and

government proposal to institutionalize a collaboration with the abortion industry.

Further reflection on the panel's responses and the Assistant Secretary's concerns makes it clear that both proponents and opponents understand that whether or not fetal tissue transplantation is scientifically plausible or legally permissible and/or well intentioned is beside the point if the procedure is ethically unacceptable to begin with. We cannot conclude, as the panel does, that because abortion and research that profits from abortion are legal and because the research is conducted with therapeutic intentions, it is therefore acceptable public policy for the government to sponsor it. This entirely sidesteps the ethical issue, or else it assumes that what is legal and well intentioned must be morally acceptable.

The question of overriding importance is whether the beneficial prospect of transplantation research is subverted by its association with elective abortion. For example, is the source of the fetal tissue inseparably linked to any uses subsequently made? Will fetal tissue transplants increase the probability that women who are ambivalent about carrying their pregnancies to term will abort? Even assuming that direct involvement or close cooperation between the transplant team and the abortion industry were avoidable, is there a more moral complicity between them? These are only a few of the questions which must all be answered satisfactorily in order for this research to be considered ethically acceptable.

1) First Argument: Lack of Rightful Consent[5]

Who can grant authentic consent for the use of electively aborted fetal remains? The panel proposes that the mother can do so. The usual understanding is that she would be acting as the parent/protector of her offspring, after she agrees to consent to the abortion. But when a parent resolves to destroy her unborn, she has abdicated her office and duty as the guardian of her offspring, and thereby forfeits her tutelary powers. She abandons her parental capacity to authorize research on that offspring and on his or her remains.

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in the 1980s, respectively. See Blake and Jorge del Pinal, "Predicting Polar Attitudes toward Abortion in the United States," in Abortion Parley, ed. James Tunstead Burtchaell (Kansas City: Andrews & McMeel, 1980), 27-56; Adamek, "Abortion Policy: Time for Reassessment," ibid., 1-26; Abortion and Public Opinion in the United States (Washington: NRL Educational Trust Fund, 1986). See also Burtchaell, Rachel Weeping (Kansas City: Andrews & McMeel, 1982), 96-105.

[5]Our remarks here are thus offered as primarily ethical, not legal. The Uniform Anatomical Gift Act appears to categorize unborn humans as subjects for research only if they are living. Consent for use of cadaverous fetal tissue is not treated under the ordinary legal norms for informed consent, but under those for disposition of human remains. But there are ethical obligations that restrict us from arbitrary seizure of another's bodies or property post mortem. For what follows on the subject of consent, see Burtchaell, "University Policy on Experimental Use of Fetal Tissue," IRB: A Review of Human Subjects Research 10,4 (July/August 1988): 7-11.

The late Paul Ramsey considered the plausibility of an aborting mother giving consent to have her unborn offspring's body used for research:

> The fundamental model for legitimate parental consent in place of a child's is . . . proxy consent that is medically on behalf of the child. . . . Parental consent is sought and is believed valid because parents are presumed to be "caretakers" for their infant children. Care is the attribute or virtue that qualifies parents as proxies, not strong or weak feelings, or strong or mild "interest" . . . It would be odd if we do not rescue from the deputyship of parents abortuses who have been abandoned by them as we would children abandoned in institutions.[6]

He concludes that it is "morally outrageous," "a charade," to give to an aborting woman any legitimate standing to act as a protective proxy for that child's body. Though he was speaking of research on a still-living fetus, the moral force of his comments applies as well to permission to use aborted fetal remains.

This same point was made clearly by the President of the United States only a week ago in his letter to the spokesman for the group of more than 800 signatories of an appeal not to permit fetal transplantation research from aborted remains:

> The use of any aborted child for these purposes raises the most profound ethical issues, especially because the person who would ordinarily authorize such use--the parent--deliberately renounces parenthood by choosing an abortion.[7]

Ours is an ancient obligation to treat human remains--body and property--with deference. The body may be a mere corpse and the estate mere chattels, but our treatment of them--insofar as they are identifiable with the person who left them behind--takes on the color of our relationship to that person. "If the body is indivisible from that which makes up personhood, the same respect is due the body that is due persons."[8]

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[6]Paul Ramsey, The Ethics of Fetal Research (New Haven: Yale University Press, 1975), 89-99 (emphasis in original).

[7]President Ronald Reagan, in a letter to Joseph R. Stanton, M.D., Brighton, Massachusetts, of the Value of Life Committee.

[8]U.S. Congress, Office of Technology Assessment, New Developments in Biotechnology: Ownership of Human Tissues and Cells--Special Report, OTA-BA-337 (Washington, DC: U.S. Government Printing Office, 1987), 130. This study, which enjoyed the consultancy of four members of our panel, stated that if the Congress were to be guided by the view quoted, it should incline to the policy that commercialized sale and purchase of body parts ought to be prohibited. Ibid., 15. This did prove to be the choice of the present Congress whose bill to that effect, the Organ Transplant Amendments Act of 1988,

How we treat human remains is both a function and a cause of our bond with human persons. No one who remembers Mussolini's body hanging by the heels from a Milan lamppost could doubt it. The partisans were dishonoring his person, and enacting defiance against any future tyrant. Creon's insistence that Polyneice's corpse lie exposed and Antigone's determination to bury her brother at peril of her own life, are both quite personal actions: towards the dead youth and towards all whose spirits crave rest. John Kennedy's funeral and the disposal of Adolph Eichmann's remains both illustrate how our treatment of bodies is, in a powerful way, our definitive treatment of those they embodied.

If we honor a fellow human while she is living we have no choice but to honor her body after death. To confiscate it discredits all ostensible dignity we accorded that person in vivo and orients us to treat still other persons with contempt. Stephen Toulmin mentions the importance and the moral relevance of the "fear that any relaxation in the general feelings of reverence towards the tissues and remains of the dead and dying could give the color of extenuation to other forms of callousness, violence and human indifference."[9] If my property is the extension of my person, then my body is my surrogate. Especially if one has had an ambiguous association with someone's death, to seize the dead person's remains for one's own purposes is the act that dissolves all ambiguity. When we forcibly requisition someone's body we are treating that person--not just his or her corpse--as of negligible dignity, or none.

There is nothing inherently unethical in research or experimentation upon the remains of humans who are victims of homicide, provided that consent is given, as is normally required, by the surviving guardian or next-of-kin and that the experiment does not enact indignity upon the deceased. But the very agents of someone's death are surely disqualified to act on the behalf or in the stead of the victim--disqualified as a man who has killed his wife is morally disqualified from acting as her executor. And in the case of a human abortus, it is the very guardians of the unborn who have collaborated in his or her destruction.

We must note one further point in this matter of maternal consent. The panel attempts to avoid this objection by proposing that the mother decides to donate her to-be-aborted offspring's remains for research in the way that a surviving relative can bury or otherwise dispose of a cadaver after death. Yet the panel recalls that tissue donation is commonly made either "by the decedent while alive or by the next of kin after his or her death."[10] As is well known, during one's lifetime no one but the person himself or herself can consent to donation of remains (unless empowered by protectorship of minor children or power of attorney or court-assigned wardship). To avoid the thrust of our argument about the abrogation of parental authority the panel treats the mother as one acting, not as a protector or proxy for her child, but as "next-of-kin." And since the scientific requirements for fetal tissue preservation practically require the consent to be made ante mortem, the panel's position associates itself with an ominous innovation: that within one's lifetime another person be

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P.L. 100-607, was signed on 4 November 1988, during our panel's term of service; see also 42 U.S.C., sec. 274e.

[9]Stephen Toulmin, "Fetal Experimentation: Moral Issues and Institutional Controls," Research on the Fetus: Appendix, 10-11.

[10]Panel Report. Answer to Question 4, Considerations.

legally permitted to assume authority, not as a protector exercising protective care, but as a survivor acting in her own interests. We can think of no sound precedent for putting a living human into the power of such an estranged person, not for his or her own welfare, but for the "interests" of the one in power.

Is This Research Dissociable from Abortion?

We were presented with four distinct ethical defenses of the use of tissue obtained through induced abortion. Firstly, objections to scientific use of abortion-supplied body parts have repeatedly been characterized as strongly felt sentiment, "deeply charged with emotion." "Emotivism" is the name for this kind of moral reflection, if it can be called reflection at all, which "understands" the warrants for serious moral judgments to rest ultimately upon rationally undiscussible and irreconcilable desires or feelings. Thus the measure of rightness for any moral claim is not its coherence with a rationally defensible set of practical principles or their position relative to some objective "good," but the degree of emotional vehemence behind it. "Good will" replaces the good; "sincerity" displaces rational argument. In the discussion of fetal transplantation research, determined and disciplined moral discourse has been so regularly confused with emotion that one may fairly ask whether some advocates of this research believe that all ethical conviction is nothing more than passionate and irrational feeling.[11]

Another vindication of fetal research with aborted tissue was grounded on the assumption that our inward dispositions alone determine the ethical value of our behavior. Several senior research sponsors expressed to the panel their indignation that the work to which they had dedicated years of goodwill could be considered exploitative. They resented having their integrity appraised by reference to anything but their good intentions.[12]

A third ethical stance dealt with the abortion/transplantation matter as one devoid of morally relevant considerations. Its advocates behold the prospect of relieving handicap and affliction as so incomparably beneficial that any moral deficits are irrelevant. As the director of the American Parkinson Association has been quoted as saying, "The majority of people with the disease couldn't care less about the ethical questions--they just want something that works."[13]

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[11]Dean Samuel Gorovitz, of Syracuse University, in his remarks to the panel, characterized those who oppose the use of fetal tissue from induced abortions for transplantation as "driven by a naive passion for simplicity . . . whose capacity to reason simply shuts down when they hear the word 'fetus'." Statement of Samuel Gorovitz, Panel Transcript, 15 September 1988, 479. Dr. Kenneth Ryan, the panel's chairman of scientific issues, is quoted in an article about the panel's deliberations as describing the antiabortion lobby as appealing to "a form of fundamentalism" that "foments hatred and violence." The Washington Post: Health, 18 October 1988, 4/19.

[12]See, e.g., Statement of Robert Stevenson, Panel Transcript. 15 September 1988, 543. One is reminded that it is not the goodness of the decisionmaker but the goodness of the decision that is morally relevant.

[13]In Richard John Neuhaus, "The Return of Eugenics," Commentary 85,4 (April 1988): 18.

These two approaches--which focus exclusively on the actor's motives or on the benefits to be derived from the therapy--take little account of the reason why we were called to consider these matters at Bethesda in the first place. The history of the abuse of human research subjects, from Tuskegee to Dachau to Willowbrook to Helsinki, cries out unambiguously that neither the goodwill of the researcher nor the prospective yield in beneficial knowledge has the slightest fingerhold on any moral right to relieve one human's affliction by exploiting another. That same abuse-marked history shows well that when scientists or therapists set out to exploit one group to benefit another, it is invariably the disadvantaged who suffer for the powerful.

It was the fourth defense of transplantation research that was most thoughtfully argued and the one which the panel adopted. After conceding that "(i)t is of moral relevance that human fetal tissue for research has been obtained from induced abortions," the panel endorsed the use of aborted fetal remains for transplantation based upon a utilitarian calculus[14] of the "significant medical goals" which the research seeks to achieve.[15] The panel thus sought to dissociate the research from abortion in numerous ways: informed consent for the research must be distinct from and subsequent to consent for the abortion; even preliminary information about tissue donation should be withheld from the pregnant woman before she consents to the abortion; the procedures of abortion should be kept independent from the retrieval and use of fetal tissue; no financial compensation should be offered to parents or providers for aborted remains; parents must not be permitted to designate or to know the identity of the beneficiaries of their aborted children's tissue; no abortion and donation should be permitted between relatives, lest a child be conceived for this purpose; and abortion procedures should not be altered to accommodate the transplantation.

The panel thus attempts to evade the ethical issue by sequestering fetal tissue research from the broader matter concerning abortion. The research problem is thereby reduced to a legal or scientific one, and the only moral problems left are procedural ones. Indeed, in its central recommendation, it reaches an ethical conclusion on legal and scientific grounds:

> 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,

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[14]Inexplicably missing from this utilitarian calculation are the morbidity and mortality risks to the recipient of the transplant, which are reported as "high." Rick Weiss (quoting Donald M. Gash of the University of Rochester), "Fetal-Cell Transplants Show Few Benefits," Science News 134 (1988): 324.

[15]That fetal tissue transplantation may be longer on promise than on results was reported at the annual meeting of the Society for Neuroscience (18 November 1988) where researchers conceded that few of the patients who have received fetal tissue transplants for Parkinson's disease have shown defined clinical improvement. In the case of those who have shown some improvement it was difficult to resolve whether the transplants were responsible. As a result, more animal studies were called for. Ibid.

> the panel concludes that the use of such tissue is acceptable public policy.[16]

The only significant ethical claim propounded in the Panel Report is a negative one: that human fetal tissue transplantation research is ethically so isolated from the abortion which delivers up its supplies that there is no moral connection between the two. It is that claim, which is stated but not argued, that we undertake here to discredit.

Advocates of this use of fetal tissue have acknowledged that induced abortion is a "tragedy," that they regret or even deplore it, but that the use of human flesh supplied by induced abortion implies no moral agency in that abortion. Research can then draw some benefit for medical science from what might otherwise have been an unrelieved tragedy. Death was not the scientists' doing. Indeed it was they who turned one victim's death into another victim's recovery. And by establishing various barriers between abortion and tissue use, they imply that a sort of moral autoclave will sterilize the tissue ethically so that it can be used without contamination by association with its method of supply.[17]

We contend that this attempt is futile, and that the appropriation of aborted human fetal remains for transplantation research effectively allies itself to the abortion industry in two distinct ways. We note that our argument runs in close concurrence with the dissenting statement of Rabbi J. David Bleich, a member of the panel.

2) Second Argument: An Incentive for Future Abortions

We must now ask whether the institutionalized use of aborted human remains will foreseeably constitute an endorsement that will effectively increase the incidence of abortion in our land.

This could be happen in two ways. First, fetal tissue transplantation would further entrench the abortion industry by the symbiotic relationship which would arise between it, the medical community, and the beneficiaries of fetal tissue transplants.[18] Second, the widespread use of fetal tissue

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[16] Panel Report, Answer to Question 1. In several of its segments the report reaches ethical conclusions grounded on considerations that are exclusively either legal or scientific.

[17] The panel makes its recommendations in the belief "that these abortions would occur regardless of their use in research, that neither the researcher nor the recipient would have any role in inducing or performing the abortion, and that a woman's abortion decision would be insulated from inducements to abort to provide tissue for transplant research and therapy." Panel Report, Answer to Question 1, Considerations. The panel however provides no evidence or analysis to support the belief that the guidelines will actually have such an effect. It thus assumes that which is most seriously contested.

[18] One witness before the panel predicted that "as various interest groups become accustomed to and dependent upon supplies of fetal tissue they will inevitably seek to enforce their right to this material." Idem (quoting Stuart A. Newman of the New York Medical College), "Forbidding Fruits of Fetal-Cell Research," Ibid. 134 (1988): 297.

transplantation could reasonably be expected to increase abortions, since knowledge of transplantation will induce some women to have abortions, who would otherwise not do so. In other words, this research may constitute complicity with abortion before the fact.

Successful fetal transplantation therapies will require the systematic acquisition of fetal tissue from abortion clinics and hospitals. To ensure that fetal tissues are fresh, the process of tissue acquisition must be integrated into the procedures of the abortion clinic, so that the woman's consent to the use of fetal tissue would be obtained before the abortion and the fetal remains collected and processed immediately afterwards. If this process is conducted by tissue acquisition personnel who are not abortion clinic employees, their presence on site at the clinic would be required.[19]

There would arise, therefore, a symbiotic relationship between the abortion industry and fetal tissue transplantation therapy. Transplants and transplant research could not proceed without the assurance that the abortion industry will continue to produce sufficient fetal tissue in the future. The nation's medical establishment would thereby reconcile itself with the abortionists it has so far disdained, and some of the most enterprising intellectuals in medical research and practice would enter into partnership with the abortion industry as the supplier of preference for one of their most venturesome, and perhaps promising, endeavors. The dignity and prestige this relationship confers upon the abortion trade should not be underestimated.

Beyond the institutional respectability which would be conferred upon the abortion industry is the effect of fetal tissue acquisition upon the practice and incidence of abortion. If fetal tissue transplantation from induced abortion becomes common, the incidence of abortion can reasonably be expected to increase from a combination of beneficent reasons motivating pregnant women who are ambivalent about abortion and financial incentives motivating abortion clinics.

Ambivalence toward abortion is a well documented reaction of many women when confronted with a problem pregnancy.[20] A period of intense anxiety and

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[19]The intimate relationship between tissue acquisition personnel and the abortion clinic was illustrated in the first fetal tissue transplant for Parkinson's disease by Dr. Curt Freed of the University of Colorado in November 1988. In order to obtain desirable fetal neural tissue, Freed spent four days at the abortion clinic "drinking coffee all day and looking at tissue that was unacceptable." Thomas H. Maugh II (quoting Freed), "Doctor Who Broke Restriction on Fetal Tests Under Attack," Los Angeles Times, 21 November 1988, I/3. During his time at the clinic, Freed was not only looking for the presence of "a portion of the brain tissue that hasn't been destroyed that is potentially useful," but also examining the fetal remains to ensure that the abortions were complete, a procedure normally performed by an abortion clinic employee. Leslie Bond (quoting Freed), "First U.S. Fetal Brain Tissue Transplant Performed," NRL News, 5 December 1988, 1.

[20]David C. Reardon, Aborted Women (Westchester, IL: Crossway, 1987), 71; Joyce L. Dunlop, "Counselling of Patients Requesting an Abortion," The Practitioner 220 (1978): 847; Michael B. Bracken & Stanislav V. Kasl, "Delay in Seeking Induced Abortion: A Review and Theoretical Analysis," American Journal of Obstetrics and Gynecology 121 (1975): 1008.

ambivalence is often experienced during the 24 hours preceding an abortion.[21] This ambivalence is reflected in the fact that from one-fourth[22] to approximately one-half[23] of women aborting find the decision difficult to make. In addition, in studies of pregnant women who chose to abort and others who chose to deliver their children, approximately one-third[24] to 40 percent of the women, whatever their ultimate decision, were reported to have changed their decision at least once, with women who aborted being significantly more likely to report their decision as a relatively difficult one, to rethink their initial choice, and to regret having to have made that decision.[25] Some women who have made an initial decision to abort will change their minds at the last minute, with approximately five percent changing their minds after making an appointment to have an abortion[26] and approximately one percent changing their minds at the abortion clinic itself.[27] Significantly, studies reveal that from 24 percent[28] to 37 percent[29] of women who abort do not make up their minds until just before the procedure.

Women's decision to abort is influenced by multiple reasons: four, on the average.[30] For those women who are ambivalent about abortion--that is, the 40 percent of the pregnant women who have changed their minds at least once and who have found the abortion decision difficult--"the pros and cons of the decision were somewhat evenly balanced" regardless of which decision is made.[31]

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[21]Carol Nadleson, "Abortion Counseling: Focus on Adolescent Pregnancy," Pediatrics 54 (1974): 768.

[22]Thomas D. Kerenyi, Ellen L. Glascock, and Marjorie L. Horowitz, "Reasons for Delayed Abortion: Results of Four Hundred Interviews," American Journal of Obstetrics & Gynecology 117 (1973): 307.

[23]Michael B. Bracken, "The Stability of the Decision to seek Induced Abortion," Research on the Fetus: Appendix, 16-3.

[24]Ibid., 16-16.

[25]Michael B. Bracken, Lorraine V. Klerman, and Mary Ann Bracken, "Abortion, Adoption, or Motherhood: An Empirical Study of Decision-Making During Pregnancy," American Journal of Obstetrics & Gynecology 130 (1978): 256-57.

[26]Editor's Note, Obstetrics & Gynecological Survey (1977), 97.

[27]Bracken, "Stability," 16-16.

[28]M. Diamond, P.G. Steinhoff, J.A. Palmore, et al., "Sexuality, Birth Control and Abortion: A Decision-Making Sequence," Journal of Biosocial Science 5 (1973): 347.

[29]Reardon, 15.

[30]Aida Torres and Jacqueline D. Forrest, "Why Do Women Have Abortions?" Family Planning Perspectives 20,4 (1988): 175.

[31]Bracken et al., "Abortion, Adoption or Motherhood," 256.

Most women who decide to abort are uncertain about and uncommitted to their abortion decision. For them, abortion is a "marginal good," at best.[32]

In the abortion decision, there are two important motives which may influence the choice: concern for self and concern for others. The most common motivation for abortion is self-centered concerns. In the most recent study of specific reasons which contributed to the decision to abort, a majority of women reported that they were influenced to have an abortion because they were concerned about how having a baby could change their lives, they could not afford a baby now, and they were having problems with a relationship or wanted to avoid single parenthood.[33] Some women also felt that they were unready for responsibility, or not mature enough, or had all the children they wanted.[34]

Concern for others is reflected in the decision of those women who said that others' wishes figured in their decision. More than one in five women chose to have an abortion at least in part because their husband or partner wanted them to.[35] About one-quarter of married women were influenced by their husband's desire for an abortion and more than one-quarter of those under 18 were influenced by their parents' wishes.[36] Thus women seeking abortion are influenced by a number of reasons, often in combination, that reflect both concern for self and concern for others.[37]

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[32]Reardon, 15.

[33]Torres and Forrest, 170.

[34]Ibid.

[35]Ibid., 176.

[36]Ibid.

[37]Recent court cases indicate that some women may also be motivated by malice. In Conn v. Conn, a court found that a pregnant woman was willing to carry the child to term if she could be sure that her husband, against whom she had filed a marriage dissolution action, could not gain custody of the child when born. She said she would carry the child to term if her husband would agree to put the child up for adoption by a third party, foreign to the marriage. Conn v. Conn, No 73C01-8806-DR-127, slip op. at 4 (Shelby County [Ind] Cir. Ct. June 27, 1988), rev'd, 525 N.E.2d 612 (Ind. Ct. App. 1988), aff'd and opinion of app. ct. adopted by order, No. 73S01-8807-CV-631 (Ind. July 15, 1988).

In addition, the self-centered reasons of some pregnant women are immature and even frivolous. In a court case where an unwed father attempted to prevent his girlfriend from having an abortion, the court found that the reasons why she sought an abortion included the desire not to be pregnant in the summertime so as to look good in a bathing suit and not have an impaired social life, and a desire not to share the father with anyone, including their baby. In the Matter of Unborn Child H, No. 84C01-8804-HP-185, slip op. at 2 (Vigo County [Ind] Cir. Ct., Apr. 8, 1988), rev'd sub nom. Doe v. Smith, No. 84A01-8804-CV-00112 (Ind. Ct. App. 1988).

Fetal tissue transplantation from induced abortions is possessed of strong potential to increase abortions by providing both selfish and selfless reasons for abortion.

The American Bar Foundation's Lori B. Andrews, a witness before the panel, has argued that a woman should be able to sell the tissue of the fetus she has agreed to abort,[38] in part because this will make more body parts available.[39] The sale of human embryos for cosmetic production has already been reported and kidneys for transplantation from live donors in Brazil and India have been advertised for sale to physicians in Germany.[40] One bioethicist who addressed the panel has acknowledged that "poor women in nations where markets are permitted in organs and tissues might seek abortion for financial gain."[41] Thus if more fetal tissue is needed, "policies aimed at maximizing the utilization of infants as donors could lead to increases in the number of elective abortions."[42]

Selfless motivation can also lead to an increased incidence of abortion. A person is motivated by concern for others when the person cares for the welfare of others, as a matter of genuine concern.[43] Concern for others is manifested when the person views her own welfare as bound up in the welfare of others, when the welfare of others is of positive concern to her in its own right, and when she gives so much weight to the welfare of others that she is prepared in principle to subordinate her own welfare to that of others.[44] In each of these cases, the person is motivated by concern for others, "<u>because their welfare is at issue</u>."[45] The motivation comes into operation when the person has "internaliz(ed) the welfare of another by way of prizing it on the basis of the relationship that subsists between them--a relationship that may be as tenuous as mere common humanity."[46]

It is reasonable to expect that this selfless motivation, when placed in the balance with all other reasons, will tip the balance in favor of abortion for some women who are ambivalent. Advocates for fetal tissue transplantation have themselves argued that this will provide "some solace" to those having

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[38]Lori B. Andrews, "My Body, My Property," <u>Hastings Center Report</u>, Oct. 1986, 28.

[39]Rorie Sherman, "The Selling of Body Parts," <u>National Law Journal</u>, Oct. 7, 1987, 32.

[40]Alan Fine, "The Ethics of Fetal Tissue Transplants," <u>Hastings Center Report</u>, June/July 1988, 7.

[41]Arthur Caplan, "Should Fetuses or Infants be Utilized as Organ Donors?" <u>Bioethics</u> 1 (1987): 135.

[42]<u>Ibid</u>.

[43]Nicholas Rescher, <u>Unselfishness</u> (London: Feffer & Simons, 1975), 9.

[44]<u>Ibid</u>.

[45]<u>Ibid</u>., 6 (emphasis in original).

[46]<u>Ibid</u>., 7.

abortions, since it will enable them "to help others with whose plight they can well empathize."[47] One physician who testified before the panel reported that women who are to abort consent to fetal tissue transplantation because they are "glad something positive could come out of it."[48] Indeed, one bioethicist claims that "There's a strong argument that intending to use tissue to relieve someone else's disease is a better ethical act than having an abortion just because you forgot to use a diaphragm."[49] Thus, a powerful human motivation will be thrown into the balance for women considering abortion: concern for others. The decision to abort, once difficult and troubling, becomes, for some, a noble and selfless act of "doing good for humanity."

In addition to concern for humanity in general there is concern for a family member. Reports have surfaced concerning women who considered getting pregnant to provide tissue to treat themselves or a family member,[50] and prominent bioethicists have argued that this is ethical.[51] This has led one proponent to conclude that a concern that "the use of fetal tissue for transplantation in such cases could become an incentive for abortion . . . appears well grounded,"[52] and another called it "a serious concern that ought to give us pause."[53]

The panel acknowledges that "knowledge of the possibility for using fetal tissue in research and transplantation might constitute motivation, reason, or incentive for a pregnant woman to have an abortion." As a result, the panel recommends that "even the provision of preliminary information for tissue donation" should not be volunteered to the pregnant woman.[54] This recommendation does not address the problem, however, as the panel itself inadvertently acknowledges. Proponents of fetal tissue transplantation from induced abortion claim that it holds "the promise of becoming a revolutionary therapy for millions of people suffering from a number of diseases."[55] Thus the panel admits that "transplantation and research with fetal tissue will become general knowledge." Even the relatively rare occurrence of infant organ transplant is now well enough known through reports in the media. As a result,

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[47]Caplan, 128.

[48]Statement of Lars Olson, Panel Transcript. 14 September 1988, 58.

[49]Karen Matthews (quoting Prof. Marjorie Schultz), "Fetal Cell Research Under Fire," Alameda Times, 27 March 1988, 1.

[50]"A Balancing Act of Life and Death," Time, Feb. 1, 1988, 49; Tamar Lewin, "Medical Use of Fetal Tissue Spurs New Abortion Debate," New York Times, Aug. 16, 1987, 1.

[51]Mary Anne Warren, Daniel C. Maguire, and Carol Levine, "Can the Fetus be an Organ Farm?" Hastings Center Report, Oct. 1978, 23-25.

[52]Fine, 6.

[53]Rick Weiss (quoting Kathleen Nolan of the Hastings Center), "Forbidding Fruits of Fetal-Cell Research," Science News 134 (1988): 297.

[54]Panel Report, Answer to Question 3.

[55]Statement of H. Fred Voss, 14 September 1988, Panel Transcript, 173.

many parents of dying infants are reported to request on their own that their child serve as an organ donor.[56] If many are helped by fetal tissue transplantation from induced abortions, the knowledge of it would be even more widespread, and thus, as the panel finds, "might be one of many reasons to be weighed in deciding whether to terminate a pregnancy."[57]

For those few women seeking abortion who are unaware of fetal tissue transplantation, current abortion practice suggests that they will be informed by abortion clinic personnel, reinforcing the abortion decision previously made and decreasing the number of those women who would change their minds. The vast majority of first trimester abortions are performed in free-standing clinics, many for profit, which offer no alternative solutions for an unintended pregnancy. Abortion clinic patients are counseled by abortion clinic employees, not physicians. The patient does not meet the physician until she is on the operating table, prepared for an abortion. Under current law, the pregnant woman can consent to abortion for any reason and this consent is obtained by abortion clinic employees.[58] The role of the abortion clinic counselor is to "support the patient and the [abortion] decision she has made"; counselors are admonished not to open "new issues of conflict, or to reawaken . . . ambivalence."[59] Thus abortion counselors act as "facilitators" who are not to "inform" their clients, but only to help them "make the choice for abortion with the least amount of pain and doubt."[60] The prospect of fetal tissue transplantation, therefore, offers a powerful argument in the hands of abortion clinic counselors: "doing good for humanity" is a powerful additional reason to go through with the abortion.

The actions by the Supreme Court are generally believed to have increased abortions in this country by legalizing them. A reasonable reckoning is that there are perhaps about five times as many abortions annually after Wade and Bolton as before.[61] We are persuaded, however, that the Court unwittingly had as much ethical influence as it did legal. The action which decriminalized abortion also drew the cloak of powerful moral approbation over a practice that had been inhibited even more by shame than by criminal penalty.

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[56]Caplan, 128.

[57]Panel Report. Answer to Question 3, Considerations. Ironically, while acknowledging that this information will serve to motivate some to abort, the panel thought it should be provided to her before the decision to abort, if she asked. Indeed, one panel witness argued that if a pregnant woman asks about fetal tissue transplantation there is a moral obligation to provide such information--"even when one knows in advance that it will sway [her into an abortion]." Statement of Alan Meisel, Panel Transcript, 15 September 1988, 463.

[58]Some institutions now obtain consent from the woman to use the fetal tissues at the same time the consent to the abortion is obtained. Statement of Robert J. Levine, Panel Transcript, 15 September 1988, 421.

[59]Nadleson, 768.

[60]Reardon, 270.

[61]Burtchaell, Rachel Weeping. 90-96.

It is willful fantasy to imagine that young pregnant women estranged from their families and their sexual partners and torn by the knowledge that they are with child but do not want that child, will not be powerfully relieved at the prospect that the sad act of violence they are reluctant to accept can now have redemptive value. Governmental sponsorship of research with tissue supplied by the abortion industry is likely to be the most persuasive, implicitly moral, accolade given to abortion since Roe v. Wade.

Fetal tissue transplantation can also be reasonably expected to increase abortions due to financial incentives motivating abortion clinics. If fetal tissue transplants are successful, the supply would not begin to meet the demand. For the transplant of fetal pancreatic tissue as a treatment for diabetes, for example, only 10,000 tissue recipients[62] could be benefited, based upon current abortion rates, whereas over 2,000,000 diabetic patients[63] might desire such transplants if the technique proved successful. For the transplant of fetal neural tissue for the treatment of Parkinson's disease, only 10,280 fetal transplants[64] could be expected from aborted fetal tissue compared with 300,000 to 500,000 patients who could potentially demand the benefits of such transplants.[65] Thus a dramatic disparity would exist between supply and demand: only .5 percent of diabetes patients could be treated with fetal transplants, and only 2.5 percent of those with Parkinson's disease.

If tissue supplied by abortion is adequate and if transplantation should be successful, it is expected to become big business. Hana Biologics estimates

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[62]The fetal pancreas most suitable for transplantation is retrieved from fetuses of 16 to 20 weeks gestation. Statement of Kevin Lafferty, Panel Transcript, 14 September 1988, 83. Approximately 50,000 abortions are performed during this period under current practices. Centers for Disease Control, Morbidity and Mortality Weekly Report, Feb. 1987, 12ss-13ss. Assuming a consent rate of 80 to 90 percent (Voss, 204), and a retrieval rate of 90 percent, then approximately 40,000 fetal pancreata from induced abortion in the United States would be available for transplant. Assuming four fetal pancreata are needed for one successful transplant (estimates range from one to two [Olson, 107-8] to 25 [Thomas H. Maugh II, quoting Brent Formby of the Sansum Medical Research Center, Santa Barbara, CA, "Use of Fetal Tissue Stirs Hot Debate," Los Angeles Times, Apr. 16, 1988, 28]), then only 10,000 transplants could take place yearly under current practices.

[63]Statement of Hans Sollinger, Panel Transcript, 14 September 1988, 100.

[64]The optimal fetal neural tissue for transplantation is of 7 to 10 weeks gestation. Olson, 65. Approximately 635,000 abortions are performed during this period. Stanley K. Henshaw, "Characteristics of U.S. Women Having Abortions, 1982-1983," Family Planning Perspective 19 (Jan./Feb. 1987): 6. Assuming a consent rate of 80 to 90 percent (Voss, 204) and a retrieval rate of nine percent (as experienced by the British Medical Research Council Tissue Bank, Written Statement of Leslie Wong, 12), approximately 51,400 fetal brains from induced abortions would be available for transplantation. If five to ten fetal brains are needed for sufficient neural tissue for one successful transplant (Statement of Thomas J. Gill, Panel Transcript, 14 September 1988, 46), sufficient fetal tissue would be available yearly for, at most, only 10,280 transplants.

[65]Statement of Harold Klawans, Panel Transcript, 14 September 1988, 278.

that the total potential market in treating diabetes and Parkinson's disease, using fetal tissue from induced abortions, exceeds $6 billion. Hana anticipates sales of insulin-producing cells in 1989 at a price of $5,000 per treatment.[66] Thus an extremely lucrative market would be created for fetal tissue from induced abortion which currently does not exist.

Abortion clinics gross perhaps $250 million annually from first-trimester abortions.[67] Currently, nonprofit fetal organ acquisition organizations offer $25 per fetal organ.[68] Since at least four fetal organs are currently being actively procured, the fetal pancreas, brain, adrenal gland, and liver,[69] abortion clinics stand to reap a substantial increase in revenue from each abortion.

The effect of these financial incentives, even at the current low price for fetal organs, would be dramatic and direct. With demand constant and overwhelming, the incentive to increase the supply of aborted fetal tissue will be great.[70] In this respect, transplants of fetal organs differ dramatically from transplants of organs from deceased adults. The number of dead adults is not likely to increase because there is a need for organ transplants. Homicides are not likely to be committed to gain access to human organs since society condemns and severely punishes such homicides. Abortions, however, are legal and, some claim, ethical. Some women who would otherwise decide not to have an abortion can be persuaded to do so. Abortion clinics will have substantial financial incentives to do so. Even some advocates of fetal tissue transplants from induced abortion admit that "successful therapeutic use of fetal brain tissue, once widely available, may indeed influence a woman's abortion decision," but they argue that "it would be improvident to legislate against them," since it is impractical to ascertain motives.[71] Indeed, under the current state of the law, States could not prohibit abortion clinic personnel

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[66]Karen Southwick, "Fetal Tissue Market Draws Profits, Rebuke," Health Week, Oct. 12, 1987, 1.

[67]Based on approximately 1,426,000 abortions a year at $175 per procedure. Henshaw, 6.

[68]Statement of Leatrice Ducat, Panel Transcript, 14 September 1988, 188.

[69]Voss, ibid., 190.

[70]Harvey Cohen, representing the American Academy of Pediatrics, recognized that "successful fetal transplantation therapies may lead to the demand for such tissue exceeding supply, as has occurred with other organ transplantation." His solution to the problem is the development of methods for growing fetal cells in the laboratory which could reduce the need for donors. Statement of Harvey Cohen, Panel Transcript, 15 September 1988, 547-48. Since fetal transplant therapy and therapy from cell cultures are both predicted to be available in a decade, and since therapies from cell cultures present no ethical concerns and can provide sufficient supply to meet an unlimited need for such tissue, there is no need to pursue fetal tissue transplants, which are ethically dubious, at best.

[71]Fine, 7.

from discussing fetal tissue transplants when obtaining consent to abortion[72] and the reasons for abortion are not subject to State regulation. Unless abortion clinics themselves are prohibited from purveying fetal organs, a restriction which this panel has refused to recommend,[73] substantial financial incentives will exist for abortion clinics to encourage abortions. Abortions, therefore, are bound to increase.[74]

A final troubling issue raised by fetal tissue transplantation from induced abortion is the potential for obtaining tissue from live fetuses. Fetal tissue degenerates as soon as it is without oxygen.[75] Therefore, fetal research using animals has involved removing tissues directly from living animal fetuses or abortuses. Some bioethicists argue that the use of organs or tissues from non-viable but live fetuses "is morally defensible if dead fetuses are not available or are not conducive to successful transplants."[76] In support of this view, other bioethicists, including some members of this panel, have suggested that a new definition of death--and of life--should be crafted: one based upon the degree of neocortical function of the child, particularly if post-mortem donation of tissue will not yield viable organs.[77]

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[72]Akron v. Akron Center for Reproductive Health, 462 U.S. 416, 442-445 (1983).

[73]While the panel recommends that "payments . . . associated with the procurement of fetal tissue should be prohibited," abortion clinics could be paid "reasonable expenses occasioned by the actual retrieval, storage, preparation and transportation of the tissues." Panel Report, Response to Question 1. Based upon current practices, the $25 fee per organ, which the panel characterized as "a small fee for each fetal tissue retrieved to cover the costs of retrieval, including time of staff and rental of space," ibid., Answer to Question 7, could amount to an additional fee of $100 per abortion, a potential increase in revenue of 57 percent to the abortion clinic.

[74]Several members of the panel claim that this predicted impact "is highly speculative" but then argue that it will not occur "to any significant extent." John A. Robertson et al., Concurring Statement, 36. That they consider a prospective increase in abortions, however, to be of negligible concern in the final analysis is revealed when they say that even "if there were a substantial increase in the number of abortions . . . such transplants might still be ethically and legally acceptable" (footnote 21). Since one principal effort of the panel was to ensure that fetal tissue transplantation did not encourage induced abortion, because, in part, of "the morality of abortion itself," a reasonably foreseeable increase in induced abortions, of whatever magnitude, should render the practice of fetal tissue transplantation morally unacceptable. With 40 percent of pregnant women at risk, however, there is likely to be a significant effect.

[75]Statement of Kevin Lafferty, Panel Transcript, 14 September 1988, 104-5.

[76]Mary B. Mahowald, Jerry Silver, and Robert A. Ratcheson, "The Ethical Options in Transplanting Fetal Tissue," Hastings Center Report, Feb, 1987, 12.

[77]John C. Fletcher, John A. Robertson, and Michael R. Harrison, "Primates and Anencephalics as Sources for Pediatric Organ Transplants," Fetal Therapy 1 (1986): 158; LeRoy Walters, "Ethical Issues in Fetal Research: A Look Back and A Look Forward," Clinical Research 36 (1988): 213. While these proposals are often suggested in the context of taking tissues from anencephalic infants, it

Some researchers in the field have already accepted this new definition of fetal life. One physician involved in fetal research expressed his view to the panel that fetal life does not exist until the three conditions of human personhood exist: cognition, volition, and sensation of pain, which are determined in the neocortex of the brain.[78] Thus he objected to the use of the word "life" to refer to fetal existence until viability.[79] During nonviability the fetus is not "alive" and thus fetal tissue could be taken from the fetus as if it were "dead."[80] With a need for fetal tissue "the fresher the better," these views provide a justification for taking tissues from live fetuses. When tissue procurement is to be conducted by abortion practitioners already committed to the destruction of these live fetuses, the potential for abuse becomes overwhelming.

The majority of the panel implies that fetal tissue transplants, if successful, could have the effect of encouraging abortion, since it recommends various "guidelines" by which it hopes to "minimize" such risk. This is a vain hope. Support for fetal tissue transplantation using aborted fetuses is premised upon the hope that fetal tissue transplantations will be successful, in large part due to NIH sponsorship, and thus will move from research to applied therapies. Whether it can then be conducted in an ethically appropriate manner is a critical question. NIH must consider not only the conduct of its sponsored research but the reasonably foreseeable consequences if its sponsored research leads to useful therapies.

In this case, the guidelines proposed by the panel will be irrelevant to the actual practice of fetal transplant therapy, since NIH regulations apply only to entities receiving NIH grant funds. Most abortion clinics receive no NIH funds and are not subject to its requirements. Nor is it reasonable to expect that most abortion clinics will voluntarily comply with NIH recommended guidelines; the market forces previously described, supported by the justifications already provided by those who favor such practices, provide powerful incentives to increase the supply of fetal tissue. Only the enactment of new laws, in all fifty States and the District of Columbia, could compel compliance with the guidelines recommended by this panel, an unlikely prospect and certainly one beyond the NIH's power.[81]

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would also be applied to "anencephalic fetuses--with the result that tissue or organ transplantation from such intact fetuses would become feasible." Walters, ibid.

[78]Statement of William Lyman, Panel Transcript, 15 September 1988, 428-29.

[79]Ibid., 430.

[80]Some would take this even farther, by applying "non-viable" "not only to anencephalic infants, but also to fetuses or individuals whose imminent death is unavoidable." Mahowald et al., "Ethical Options," 13. Since the imminent death of fetuses destined for induced abortion is, under current law, "unavoidable," then all live fetuses would be non-viable--thus dead--and subject to removal of their organs.

[81]The assumption that there will be any "voluntary" compliance with NIH guidelines by those not bound by them was discredited on 9 November 1988 when Dr. Curt Freed of the University of Colorado performed a fetal tissue transplant

Even for those bound by NIH regulations, two of the most significant guidelines recommended by this panel are either unenforceable or irrelevant. The panel recommends that the process of obtaining consent to the use of fetal tissue be deferred until after the decision to terminate the pregnancy has been made. Enforcement of this requirement would require NIH personnel to monitor counseling sessions in the abortion clinic, an unlikely and problematic process. In addition, the panel has recommended that the pregnant woman not be offered any financial incentive for consenting to the use of fetal tissue. This requirement is simply unenforceable. If an abortion clinic has agreed to sell fetal organs, it could reduce its price for abortion services, in effect splitting the proceeds from the sale of fetal organs with its patients. This lower price for abortion services, offered to all clients (but with the expectation that 80 to 90 percent would consent to the use of fetal tissues), would be a financial incentive for abortion, but one which could not be regulated. In addition, this recommendation is irrelevant. As noted above, it is the financial incentives to abortion clinics, not pregnant women, which are the larger problem.[82]

Thus the proposed procedural mechanisms will not ensure that the use of fetal tissue after induced abortions does not affect the decision to abort. One can reasonably expect that more induced abortions will result from the decision to use aborted fetal tissue[83] for transplantation.

3) Third Argument: Complicity with Abortions Already Performed

It is the assumption of the panel that transplantation research with fetal tissue from induced abortions neither implies nor fortifies a moral acquiescence in or complicity with the prerequisite abortions because the research occurs

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from an aborted fetus into a patient suffering from Parkinson's disease. Thomas H. Maugh II, "Doctor Who Broke Restriction on Fetal Tests Under Attack," Los Angeles Times, 21 November 1988, I/3. Dr. Freed, using private funds, ignored the NIH moratorium during which this panel was to develop guidelines for research. Freed is reported to have performed the transplant "strictly for scientific reasons." The transplant was praised by the chairman of the medical advisory board of the American Parkinson Disease Association as "courageous." "First Brain-to-Brain Transplant Patient Goes Home," UPI wire story, 24 November 1988. That there will be many "courageous" entrepreneurs prepared to ignore NIH guidelines if fetal transplantation should become successful, cannot be disputed.

[82]A further likelihood, when demand exceeds the supply of fetal tissue, is that fetal tissue will be imported from foreign countries. William Regelson, "A Wise Fetal Tissue Policy," The New York Times, 14 November 1988, A19. Voluntary NIH guidelines can be expect to play no part in abortion practices abroad.

[83]Indeed, some would argue that when the supply of fetal tissue is overcome by the demand for it, some of the guidelines recommended by the panel should be reconsidered with an eye towards deletion. John A. Robertson et al. Concurring Statement, p. 40. Thus some members of the panel seem to agree to certain guidelines only when they are irrelevant; they are prepared to revise them as soon as they might effectively restrict transplantation. That position is clearly grounded on expediency, not on any moral principle.

after the fact and cannot play any role in having caused them to occur. We cannot join the panel in this act of faith.

> For a scientist to claim that the ethical status of any experiment can be assessed in splendid isolation from its antecedents is as myopic as to maintain that its consequences are irrelevant.[84]

In its drift and its dimensions that claim yields instructive comparisons with the War Crimes Trial in Nuremberg known as "The Medical Case." There is a special irony in this for it was that Tribunal's "medical" trial which produced the Nuremberg Code of 1946, the great charter that initiated formal protection for human subjects of research. It inspired the Declarations of Helsinki in 1964 and 1975 that in turn begot virtually all of our present ethical norms for protecting human subjects in experimentation. Without Nuremberg and its judgment the world's conscience might never have gazed head-on at the intrinsic depravity of the doctors' defense.

In some respects the savagery and the genocidal ideology of the Nazi Holocaust defy any rational attempt at comparison with other instances of massive annihilation. Since, however, the Nuremberg Code stands as the inspiration and the progenitor of virtually every moral safeguard for human subjects of research, the world's conscience inevitably refers to the Nazi crimes as the explanatory context for construing and applying these ethical norms.

One lawyer who had taken part in prosecuting Nazis for war crimes explained how the German nation could have acted so savagely: "There is only one step to take. You may not think it possible to take it; but I assure you that men I thought decent men did take it. You have only to decide that one group of human beings have lost human rights."[85]

The insight of Nuremberg taught us that when we take possession of others, when their bodies are forcibly delivered up to be used as we wish, then no antecedent good will and no subsequent scientific yield will absolve us from having been confederates in their oppression.

The device of conscience whereby the Nazi physicians absolved themselves from moral association with the torment and abuse of their human subjects was a belief that they had had no say in how those subjects were delivered into their hands. The Nazi doctors had learned the ethic of their profession: that a physician may not relieve one human being's affliction at the cost of another fellow human's suffering. But they contrived to believe that if an associate had already done the subjugating and they then did the healing-oriented

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[84] McCullagh, 146.

[85] R.J.V. Pulvertaft, "The Individual and the Group in Modern Medicine," The Lancet 2 (1952): 841; cited in Jay Katz, Experimentation with Human Beings (New York: Russell Sage Foundation, 1972), 292.

research, they could divide the responsibility down the middle. The Tribunal and the world judged otherwise--and condemned the researchers for it all.[86]

The arguments of the physicians in defense of their experiments upon prisoners and patients are exemplified by the chief defendant, Dr. Karl Brandt. It was in the "interests of the community" confronted with "hard necessity," when many lives had to be protected from death and epidemics, that he and his colleagues were given leave by the State to experiment on human subjects put at their disposal. "There is no prohibition against daring to progress."

The traditional restrictions that protected human subjects from harm had to yield to this urgent community need. "In all countries experiments on human beings have been performed by doctors, certainly not because they took pleasure in killing or tormenting, but only at the instigation and under the protection of the State, and in accordance with their own conviction of the necessity of these experiments in the struggle for the existence of the people." This apparently inhumane treatment of their helpless fellow humans for the sake of research was admittedly brutalizing, but as Brandt's lawyer Dr. Robert Servatius (who would later appear as attorney for Adolph Eichmann) explained: "a measure may be as unavoidable as war and yet be abhorred in the same way."[87]

Most of the Nazi research subjects, of course, were still living, though their lives were forfeit, when they fell into the doctors' hands.[88] But there were many experiments that employed organs and tissue from cadavers: human muscle for culture media at the Hygienic Institute in Auschwitz; livers, spleens and pancreata for Dr. Kremer's experiments on site; hearts, brains, and other organs provided by Dr. Mengele for research in Berlin; testicles and heads sent

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[86]After elaborating its code of ethics for medical experiments the Tribunal proceeded to condemn defendants, not only for having acted as principals in criminal experiments, but even for having "taken a consenting part" in these and other atrocities. "Permissible Medical Experiments," ibid., 2:181-84.

[87]Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, vols. 1&2 (Washington, DC: U.S. Government Printing Office, 1949). For the quotations given in our text above, see "Final Plea for Defendant Karl Brandt by Dr. Servatius," 2:123-138; "Final Statement of Defendant Karl Brandt," 2:138-140.

[88]This type of research on doomed, living subjects may be compared to the research project presented to the panel by Dr. Ezra Davidson of UCLA as a model for incorporating ethical concerns into research protocols. With Federal funding in 1979 Dr. Davidson tested a diagnostic procedure, fetoscopy, on the unborn offspring of a series of black and Hispanic women intending to undergo elective abortions, to see how often it would cause a miscarriage; his defense was that the fetuses were already slated for death. Congress regarded this experiment as so unethical that in 1985 it banned for 3 years any use by DHHS of the regulation that had allowed it. Lifton's remark is apposite: "If one felt Hippocratic twinges of conscience, one could usually reassure oneself that, since all of these people were condemned to death in any case, one was not really harming them. Ethics aside, and apart from a few other inconveniences, it would have been hard to find so ideal a surgical laboratory." Robert Jay Lifton, The Nazi Doctors: Medical Killing and the Psychology of Genocide (New York: Basic, 1986), 295.

to Dr. Hirt in Strassburg for study, and brains for the work of Dr. Hallervorden.[89]

One sees, however, instructive similarities in the ways the Nazi researchers dealt with both live subjects and cadaverous remains:

> There was also a scramble for bodies and bones. When anatomy professor August Hirt set about assembling a collection of body casts for his institute, he requested that captured Russian Jews, both men and women, be brought to Strassburg alive so that he might arrange for a "subsequently induced death" in such fashion "that the heads not be damaged." They were not; the U.S. Army arrived unexpectedly to find 150 bodies still floating in formaldehyde.
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> Some German laboratory people also harbored a scientific curiosity about the Polish intelligentsia. When Dr. Witasek of Poznan and a group of his comrades in the resistance movement were executed, their heads were removed and sent in gunnysacks to Germany for study. Professor Julius Hallervorden, who was shipped six hundred preserved brains of "mercy death" victims for his research in neuropathology, testified after the war: "There was wonderful material among those brains: beautiful mental defectives, malformations and early infantile diseases. I accepted these brains, of course [he had requested them]. Where they came from and how they came to me was really none of my business." [One American professor commented that Hallervorden "merely took advantage of an opportunity."][90]

For both research groups, what lies within their grasp is anonymous "tissue," brains, pancreata, spleens. To an unblinded world those are the remains of Jewish, Gypsy, mentally handicapped, or unborn children: fellow victims sent nameless to destruction. It is the flesh of victims.

The carry-over in the analogy is the naive and vain belief that both groups of researchers and those they benefit are not pulled into the gravity field of responsibility for the violent act which supplies them with vanquished human bodies for study. The Nazi physicians were generally careful to keep the medical personnel involved in research separate from those responsible for

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[89]Lifton, 285-295; William Brennan, The Abortion Holocaust: Today's Final Solution (St. Louis: Landmark, 1983), 58-61.

[90]Leo Alexander, "Medical Science Under Dictatorship," New England Journal of Medicine 241 (1949): 40; Burtchaell, Rachel Weeping, 182-83.

killing.[91] They were much more explicit in their insistence that their experiments were going to bring some good out of tragedy. Dr. Hallervorden explained: "If you are going to kill all these people, at least take the brains out so that the material could be utilized." Dr. Hirt was of a similar mind: "These condemned men will at least make themselves useful. Wouldn't it be ridiculous to execute them and send their bodies to the crematory oven without giving them an opportunity to contribute to the progress of the society?" Likewise Dr. Rose: "The victims of this Buchenwald typhus test did not suffer in vain and did not die in vain." Countless numbers of people "were saved by these experiments."[92]

One perceives this same justification at work among researchers who derive their materials from induced abortion. Dr. Martti Kekomäki, whose experiments on the severed heads of late-abortion fetuses is widely known, has said: "An aborted baby is just garbage and that's where it ends up. Why not make use of it for society?"[93] Dr. Lawrence Lawn, of Cambridge University: "We are simply using something which is destined for the incinerator to benefit mankind."[94] And Drs. Willard Gaylin and Marc Lappé, associated with the Hastings Center, believe that the death of the "doomed fetus" "can be ennobled" through experimentation because the scientific results can be used for "the saving of the lives (or the reduction of defects) of other, wanted fetuses."[95]

"Abortion is a tragedy," says one transplant researcher. "But as long as it occurs, I believe it is immoral to let tissue and materials go to waste if it can cure people who are suffering and dying."[96] To compensate for the obvious lack of informed consent, both groups of doctors have supposed that those who gave their victims over to destruction should, by some grotesque contortion of human rights, be acknowledged as their protectors and empowered to hand over their remains. "All of us that work in fetal research feel that if someone has

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[91]As Dr. Hallervorden noted, there was a strict division of labor: "I gave them the fixatives, jars and boxes, and instructions for removing and fixing the brains, and then they came bringing them in like the delivery van from the furniture store." Bernhard Schreiber, The Men Behind Hitler: A German Warning to the World, trans. H.R. Martindale (Les Mureaux: La Haye-Mureaux, n.d.), 56. See also Lifton, 285,292.

[92]Brennan, 62.

[93]Naomi Wade, "Aborted Babies kept alive for Bizarre Experiments," National Examiner. 19 August 1980, 20-21.

[94]J. and B. Willke, Handbook on Abortion (Cincinnati, Hayes, 1975 [2nd ed.]), 131.

[95]Willard Gaylin and Marc Lappé, "Fetal politics: The Debate on Experimenting with the Unborn," Atlantic, May 1975, 69-70.

[96]D. Eugene Redmond, Jr., director of Yale Medical School's neurobehavioral laboratory, in The New York Times, 15 March 1988. This was the theme of some lay advocates who testified before the panel. See, e.g., Statement of Leatrice Ducat, Panel Transcript, 15 September 1988, 175-80.

decided to have an abortion and gives permission, it is all right to use that tissue to help someone else."[97]

What this line of thinking does not wish to recognize is that we can associate ourselves with others' moral agency after the fact. Consider a banker who judges narcotics use to be a tragedy, but agrees to accept the proceeds from the local drug network in order to make more capital available for home-owners and small businesses in the area. Who would or should believe that his readiness to accept those funds is not an act of acquiescent association--indeed, of partnership--in the human wastage and abuse that those moneys have already purchased? The banker has become a party to destruction even though it was complete before his subsequent involvement.

Elie Wiesel has said: "If we forget, we are guilty, we are accomplices. . . . I swore never to be silent whenever and wherever human beings endure suffering and humiliation. We must always take sides. Neutrality helps the oppressor, never the victim."[98] Wiesel is saying that even by acquiescent silence after the fact we can sign on as parties to a deed already done. But what we are considering here is no mere post mortem silence, no simple averting of the gaze after the fact. We are considering an institutional partnership, federally sponsored and financed, whereby the bodily remains of abortion victims become a regularly supplied medical commodity.[99]

The validity of our concern was suggested in 1974 by the chairman for ethical issues of this panel:

> Ought one to make experimental use of the products of an abortion system, when one would object on ethical grounds to many or most of the abortions performed within that system? . . . If a particular hospital became the beneficiary of an organized homicide-system which provided a regular supply of fresh cadavers, one would be justified in raising questions about the moral appropriateness of the hospital's continuing cooperation with the suppliers.[100]

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[97]Dr. Robert Gale of UCLA, in The New York Times, 16 August 1987.

[98]Excerpted from his 1986 Nobel Prize acceptance speech.

[99]Several members of the panel claim that a more apt analogy is the transplantation of organs from homicide or accident victims, whence they argue that "no one would seriously argue that the surgeon who transplants" becomes an accomplice "in the homicide or accident that made the organs available." John A. Robertson et al., Concurring Statement, p. 34. Such a serious argument could be made, however, if the surgeon contracted with the murderer to provide him organs for transplantation, to tell him when and where the organs would be made available, to arrange for the surgeon or his agents to be present to harvest the organs in "fresh" condition, and to reimburse the murderer for any expenses incurred in making the organs available. These are the types of arrangements that are routinely made to obtain fetal tissue.

[100]LeRoy Walters, "Ethical Issues in Experimentation on the Human Fetus," Journal of Religious Ethics 2 (Spring 1974): 41,48.

Our objections are congruent with the concern of 18 staff members at the Environmental Protection Agency who called for a halt in the application of Nazi research data from experiments with phosgene gas on prisoners of war. Their moral misgiving was that "to use such data debases us all as a society, gives such experiments legitimacy, and implicitly encourages others, perhaps in less exacting societies, to perform unethical human experiments."[101] When Dr. Robert Pozos of the University of Minnesota proposed to use the findings of the Dachau experiments in freezing prisoners alive, it was because "it could advance my work in that it takes human subjects farther than we're willing." Reaction was prompt. Daniel Callahan said, "We should under no circumstances use the information. It was gained in an immoral way." Abraham Foxman, national director of the Anti-Defamation League, added, "I think it goes to legitimizing the evil done. I think the findings are tainted by the horror and misery."[102]

The Nazi atrocities are now nearly a half-century behind us, and they are universally condemned, yet any impression of nonchalance about them is taken still today to be morally alarming. When the affliction is still underway in our own time, and has received only ambivalent repudiation in our society, any act of association speaks with much louder significance.

If, for the refining of his healing art, today's physician goes for his authorization to a mother who has abandoned her offspring to destruction, takes delivery of an insulted and mutilated body from the practitioner who dispatched the offspring, undertakes sponsored research upon those remains, publishes his results in professional journals, and then turns those findings to the resulting benefit of patients in pain--with all this being held together by a network of accounts payable and receivable--then he becomes party, even though after the fact, to all that it took to put that research subject's body at his disposal. He has effectively acquiesced in it all.

Is it possible, as the panel has apparently proposed, to fend off moral complicity by some sort of disclaimer, simply by asserting aloud that one's use of this tissue for research implies no approbation of the antecedent abortion? There is little to encourage such a hope. Consider that most explicit of disclaimers composed by Mr. Justice Blackmun fifteen years ago on behalf of the U. S. Supreme Court. The Court acknowledged in Roe v. Wade that the entire ethical and legal reality of abortion pivots on whether the unborn is a live human being entitled to the protections promised to all persons by the Constitution.[103] It then proceeded to strip the unborn of those protections. "We need not resolve," Justice Blackmun wrote, "the difficult question of when life begins."[104] But they did. The public disallowed the Court's disclaimer and saw it had indeed resolved that, being disposable at the will of another, the unborn was no fellow human. That was the confident inference we heard in so many testimonies presented to our panel: abortion is the law of the land, so it

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[101]Letter to Lee Thomas, Administrator of the Environmental Protection Agency, 15 March 1988. See also the letter to The New York Times, 19 April 1988, by Howard M. Spiro of Yale University.

[102]Chicago Sun-Times, 12 May 1988.

[103]Roe v. Wade, 410 U.S. 113, 156-7 (1973).

[104]Ibid., 159.

must be ethical.[105] So much for disclaimers when actions prevail over words. The commercial partnership between the abortion industry and fetal transplant therapy which this panel proposes will make equally implausible any disclaimer that they take no position on abortion.

Our argument, then, is that whatever the researcher's intentions may be, by entering into an institutionalized partnership with the abortion industry as a supplier of preference, he or she becomes complicit, though after the fact, with the abortions that have expropriated the tissue for his or her purposes. It is obvious that if research is sponsored by the National Institutes of Health, the Federal Government also enters into this same complicity.

Conclusion

An attentive reader of the Panel Report will note in it an unresolved inconsistency. It purports to address and resolve the question of primary ethical concern: Is the use of aborted fetal remains subverted by ethical complicity with elective abortion? This implies: first, that the panel considers elective abortion to be ethically suspect; and second, that the panel is as concerned as the Assistant Secretary for Health that its recommendations be governed by ethical inquiry and judgment.

A majority of the panelists who voted to approve this Report have asserted that even "if there were a substantial increase in the number of abortions, it still would not follow that fetal tissue transplant research and therapy should not occur. Given the rudimentary development of early fetuses [up to 6 months old], the potentially great benefits to recipients, and the legality of abortion, such transplants might still be ethically and legally acceptable."[106] A causative effect upon abortion increase is thus considered no obstacle to medical prospects. The same majority, in proposing a guideline to prohibit research on fetuses conceived in order to be aborted for their useful tissues, explains openly that the restriction is proposed because there appears to be no present market need for such a resource. "In light of these supply considerations," the restriction is accepted. But, "if the situation changes so that the supply of fetal tissue from family planning abortions proves inadequate, the ban . . . should be reexamined."[107]

The controlling convictions within this Report do not, as often implied, consider complicity with elective abortion to be significantly objectionable because they do not consider abortion to be objectionable. Nor do they reach their conclusion on grounds of ethical principle. The recommendation to proceed with this use of aborted fetal remains in research is grounded on a raw and ruthless determination "to achieve significant medical goals" no matter what the moral consequences.

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[105] See, e.g., Statement of Lynn Phillips, Panel Transcript, 14 September 1988, 288.

[106] John A. Robertson et al., Concurring Statement, note 21. A majority of those who support the Report have concurred in this Statement.

[107] Ibid., p.30.

Our conclusion is different because our grounds for judgment are different. Though there are scientific reasons for caution and though there are legal prohibitions in some States, it is not primarily on these grounds that the proposed research and experimental therapy could most clearly be judged unacceptable. It is on ethical grounds that it must be disapproved.

Research employing the remains of electively aborted fetuses is, in our judgment, ethically compromised

1) by the absence of authentic informed consent,

2) by the incentives it will offer for yet more abortions, and

3) by complicity with the abortions that supply the tissue.

It is additionally objectionable because of its dissonance from other elements of public policy.

For these reasons we consider it a perversion of both the scholar's and the healer's work, and we must respectfully dissent from the panel's principal conclusion.

Appendix III

GEORGETOWN UNIVERSITY

Department of Psychology

December 5, 1988

Dr. Jay Moskowitz
National Institutes of Health
Room 103 Shannon Building
Bethesda, Maryland 20892

Dear Dr. Moskowitz:

I have attempted, in my capacity as a member of the Fetal Tissue Transplant Panel, to provide good counsel in response to the questions propounded by Dr. Windom. My work on the Panel is now concluded, leaving me only with the task of recording my personal position on the matters considered.

To serve on the Panel at all required a willingness to accept the dispository rulings made by the Supreme Court in Roe v. Wade and subsequent decisions relating to abortion. Adopting any other attitude would have found members of the Panel doing no more than rediscovering their several positions on the question of abortion itself. Accordingly, I tried to address the public policy questions raised by Secretary Windom, apart from the question of the morality of abortion.

It is and has been my considered judgment that induced abortion is a moral wrong and that it cannot be redeemed by any actual or potential "good" secured by it. Thus, the possible medical benefits held out by research on tissues obtained by such measures cannot be exculpatory. I must, therefore, respectfully record my firm opposition to any form of Federal support for research making use of tissues obtained in this manner. I count on your good offices to make this letter part of the Panel's final report.

Yours sincerely,

Daniel N. Robinson
Professor and Chairman

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