

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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MEMORANDUM

September 9, 2015

To: Subcommittee on Oversight and Investigations Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Update on the Committee's Ongoing Investigation of Planned Parenthood Federation of America

I. INTRODUCTION

This memorandum serves as an update on the Committee's ongoing investigation into claims regarding the alleged sale of fetal tissue by affiliates of Planned Parenthood Federation of America (PPFA) to tissue procurement organizations (TPOs). The review has included bipartisan briefings by Planned Parenthood officials as well as representatives from StemExpress, Novogenix Laboratories, and Advanced Bioscience Resources - three TPOs that partner with Planned Parenthood affiliates and other healthcare providers to collect specimens to supply to researchers working with fetal tissue.

In addition to these briefings, the Committee has received documents and written responses to a series of questions it posed in writing to PPFA regarding its "practices relating to fetal tissue collection and sale or donation."¹ To date, the Committee has received no evidence to substantiate the allegations that Planned Parenthood has engaged in the sale of fetal tissue for profit. Furthermore, the Committee has received no evidence to support the allegations that fetal tissue was procured without consent, that Planned Parenthood physicians altered the timing, method, or procedure of an abortion solely for the purposes of obtaining fetal tissue, or that Planned Parenthood physicians performed intact dilation and evacuation in order to preserve fetal tissue for research. Thus far, the investigation has revealed that PPFA requires all affiliates to ensure compliance with all state and federal laws and that specific PPFA guidance requires affiliates to ensure that reimbursement for fetal tissue is limited to actual costs.

¹ Letter from Chairman Fred Upton, House Committee on Energy and Commerce, to Cecile Richards, President, Planned Parenthood Federation of America (July 17, 2015).

The Committee received evidence that the individuals making these unsubstantiated claims misrepresented themselves in order to gain access to Planned Parenthood personnel and facilities, and that the videos released by the Center for Medical Progress (CMP) are incomplete, selectively edited, and intentionally misleading.

II. THERE IS NO EVIDENCE THAT PLANNED PARENTHOOD OR ITS AFFILIATES HAVE VIOLATED ANY FEDERAL OR STATE LAWS

A. PPFA Requires All Affiliates to Comply With All State and Federal Laws, Including Laws Pertaining to the Donation of Fetal Tissue for Research

- i. PPFA Guidance to Affiliates Regarding Human Fetal Tissue Donation Specifically Advises That It Is Illegal to Receive “Valuable Consideration” for Fetal Tissue, and Requires Affiliates to Ensure that Reimbursement Represents Actual Costs*

The NIH Revitalization Act of 1993 established the legal standards governing fetal tissue donation.² The law states, “It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce.”³ The law further provides: “The term ‘valuable consideration’ does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.”⁴

Current PPFA guidance on fetal tissue donation tracks federal law, and it clearly and explicitly prohibits affiliates from receiving valuable consideration for fetal tissue. The guidance also requires affiliates to ensure that reimbursement represents actual costs incurred by the affiliate. The current PPFA guidance, revised in May 2015, provides as follows:

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 [Consortium of Abortion Providers] about steps to take to document and demonstrate actual cost. [emphasis in the original]⁵

² National Institutes of Health Revitalization Act of 1993, P.L. No. 103-43.

³ 42 U.S.C. § 289g-2(a).

⁴ 42 U.S.C. § 289g-2(d)(3).

⁵ Planned Parenthood Federation of America, Programs for Donation of Blood And/Or Aborted Pregnancy Tissue for Medical Research (May 2015).

The guidance also advises affiliates 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.”⁶

In a briefing with Committee staff, Dr. Raegan McDonald-Mosley, the Chief Medical Officer of PPFA, explained that PPFA accredits its affiliates. Affiliates are autonomous legal entities, with their own separate boards, executive personnel, and legal counsel.⁷

Dr. McDonald-Mosley further described how PPFA oversees its affiliates and verifies their compliance with its fetal tissue donation guidance. Each affiliate is independently responsible for ensuring compliance with the guidance, as well as with all applicable state and federal laws.

PPFA oversees its affiliates through an accreditation process, whereby each affiliate is reviewed at least once every three years. Affiliates are evaluated on a range of hundreds of possible elements of performance, including, as of 2013, compliance with PPFA’s fetal tissue donation guidance. Accreditation involves both offsite reviews of affiliate documentation as well as onsite reviews that include interviews with staff and direct observation of patient care.⁸ Non-compliance with PPFA required standards may affect an affiliate’s accreditation status and result in actions that jeopardize that affiliate’s ability to continue to use the Planned Parenthood trademark.⁹

Although the precise language of PPFA’s fetal tissue guidance has been revised over the years, affiliates have always been required to ensure that their tissue donation programs are in compliance with all state and federal laws, including the prohibition on receiving valuable consideration. For example, an earlier version of the guidance from 2001 provided to the Committee instructs affiliates that federal laws “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.”¹⁰ This guidance was reissued to affiliates in 2011.¹¹

⁶ *Id.*

⁷ Briefing by Dr. Raegan McDonald-Mosley, Chief Medical Officer, Planned Parenthood Federation of America, to House Energy and Commerce Committee Staff (Aug. 14, 2015).

⁸ *Id.*

⁹ Planned Parenthood Federation of America, U.S. House of Representatives Committee on Energy & Commerce, Subcommittee on Oversight & Investigations, Follow-Up Questions Dated August 20, 2015.

¹⁰ Planned Parenthood Federation of America, Memorandum to Affiliate Chief Executives, Affiliate Medical Directors, Patient Services Directors Re: Federal Regulations for Aborted Pregnancy Tissue Donation Programs (Apr. 4, 2001).

¹¹ Planned Parenthood Federation of America, Memorandum to Affiliate CEOs, Medical Directors, Patient Services Directors Re: Aborted Pregnancy Tissue Donation Programs (Jan. 26, 2011).

Several years ago, PPFA undertook an effort to revise their Manual of Medical Standards and Guidelines (the Manual) by removing those sections not directly related to clinical care.¹² According to Dr. McDonald-Mosley, the Manual is a desk reference for clinicians for directing medical care.¹³ It is intended to assist practitioners in providing regular care for a patient and is revised on a two-year cycle. As a result of this revision effort, the fetal tissue guidance was separated from the Manual and is now a standalone document.¹⁴ It is distributed to affiliates through the PPFA intranet. Dr. Deborah Nucatola, who is PPFA's Senior Director for Medical Services and has had primary responsibility for the Manual since July 2009, explained to Committee staff that guidance on fetal tissue donation was removed from the Manual as part of this process to streamline and remove non-clinical information.¹⁵

As of November 6, 2013, affiliates are now permitted to facilitate fetal tissue donation without prior approval from PPFA.¹⁶ PPFA distinguishes between "core services," which all affiliates are required to provide, such as well-women visits and education and prescribing for all FDA-approved methods of contraception, and services which are voluntary or optional for affiliates to offer.¹⁷ Earlier versions of the fetal tissue guidance instructed affiliates to "submit a written request to initiate an aborted tissue and/or blood donation program to PPFA for review and approval."¹⁸ According to PPFA, it "implemented this policy change as part of a broader effort to reduce the administrative burden on affiliates and support affiliate service expansion.

¹² Briefing by Dr. Deborah Nucatola, Senior Director of Medical Services, Planned Parenthood Federation of America, to House Energy and Commerce Committee Staff (Aug. 27, 2015).

¹³ Briefing by Dr. Raegan McDonald-Mosley, Chief Medical Officer, Planned Parenthood Federation of America, to House Energy and Commerce Committee Staff (Aug. 14, 2015).

¹⁴ Briefing by Dr. Deborah Nucatola, Senior Director of Medical Services, Planned Parenthood Federation of America, to House Energy and Commerce Committee Staff (Aug. 27, 2015).

¹⁵ *Id.*

¹⁶ Planned Parenthood Federation of America, U.S. House of Representatives Committee on Energy & Commerce, Subcommittee on Oversight & Investigations Follow-Up Questions Dated August 20, 2015.

¹⁷ Briefing by Dr. Raegan McDonald-Mosley, Chief Medical Officer, Planned Parenthood Federation of America, to House Energy and Commerce Committee Staff (Aug. 14, 2015).

¹⁸ Planned Parenthood Federation of America, Manual of Medical Standards and Guidelines: Programs for Donation of Blood And/Or Aborted Pregnancy Tissue for Medical Research, Education, or Treatment (June 2011).

This overhaul affected other services besides facilitation of tissue donation; PPFA no longer requires prior approval for an affiliate to offer certain other non-core services.”¹⁹

ii. *PPFA Guidance to Affiliates Includes Additional Requirements Pertaining to Fetal Tissue Transplantation Research, Although This is Not Required by Law*

Federal law imposes additional requirements on providers and on researchers when the donated tissue is used in federally funded research involving the transplantation of human fetal tissue for therapeutic purposes.²⁰ Under the statute, human fetal tissue may be used in federally funded research on the transplantation of fetal tissue if the attending physician declares in writing 1) that the woman’s consent for abortion was obtained prior to requesting or obtaining consent to donate the fetal tissue for research; 2) that the timing, method, or procedure used to terminate the pregnancy were not altered in order to obtain the tissue; 3) that the abortion was performed in accordance with applicable state law; and 4) the woman has been fully informed of the physician’s interest, if any, in the research, and of any medical or privacy risks associated with the tissue donation.²¹

According to the National Institutes of Health (NIH), the federal government has not funded any fetal tissue transplantation research since 2007.²² The federal rules relating to the timing and method of abortion are therefore not applicable to any recent fetal tissue donations in the United States. However, PPFA’s fetal tissue donation guidance nonetheless incorporates these requirements as recommended practices for affiliates. The 2015 PPFA guidance provides:

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.

¹⁹ Planned Parenthood Federation of America, U.S. House of Representatives Committee on Energy & Commerce, Subcommittee on Oversight & Investigations Follow-Up Questions Dated August 20, 2015.

²⁰ Congressional Research Service, *Fetal Tissue Research: Frequently Asked Questions* (July 21, 2015).

²¹ 42 U.S.C. § 289g-1(b)(2). The statute also requires that the patient sign a statement that 1) the donation is made without any restriction regarding the identity of individuals who may be recipients of transplantations of the tissue; and 2) the woman has not been informed of the identity of any such individuals. 42 U.S.C. § 289g-1(b)(1). The statute imposes additional requirements on researchers, which are not discussed here. 42 U.S.C. § 289g-1(c).

²² Letter from Jim R. Esquea, Assistant Secretary for Legislation, Department of Health & Human Services, to The Honorable Fred Upton, Chairman, House Committee on Energy and Commerce (July 14, 2015) (“Fiscal year 2007 was the most recent year NIH provided funding for this purpose.”).

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 will be no changes to how or when the abortion is done in order to obtain the blood or tissue.²³

The guidance further instructs affiliates that “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.”²⁴

Similarly, earlier versions of the PPFA guidance required the clinician to make a notation that: “[a]borted tissue was donated,” “[c]onsent for the abortion was obtained prior to requesting or obtaining consent for the tissue donation,” and “[n]o substantive alteration in the timing of terminating the pregnancy or of the method used was made for the purpose of obtaining the tissue.”²⁵ Previous versions of the guidance also required specific language in consent forms used for tissue donation. These versions were issued under the previous system, in which affiliates were required to seek service approval from PPFA for tissue donation programs.²⁶

Appended to PPFA’s May 2015 guidance is a recommended sample consent form, which prompts the patient who is donating tissue to affirm the following statements:

Before I was shown this consent, I had already decided to have an abortion and signed a consent form for it.

I agree to give my blood and/or the tissue from the abortion as a gift to be used for education, research, or treatment.

I understand I have no control over who will get the donated blood and/or tissue or what it will be used for.

²³ Planned Parenthood Federation of America, Programs for Donation of Blood And/Or Aborted Pregnancy Tissue for Medical Research (May 2015).

²⁴ *Id.*

²⁵ *See, e.g.*, Planned Parenthood Federation of America, Manual of Medical Standards and Guidelines: Programs for Donation of Blood And/Or Aborted Pregnancy Tissue for Medical Research, Education, or Treatment (May 2005).

²⁶ Planned Parenthood Federation of America, Manual of Medical Standards and Guidelines: Programs for Donation of Blood And/Or Aborted Pregnancy Tissue for Medical Research, Education, or Treatment (June 2011); Planned Parenthood Federation of America, Manual of Medical Standards and Guidelines: Aborted Pregnancy Tissue Donation Programs (March 2001).

I have not been told the name of any person who might get my donation.

I understand there will be no changes to how or when my abortion is done in order to get my blood or the tissue.

I understand I will not be paid.

I understand that I don't have to give my blood or pregnancy tissue, and this will not affect my current or future care at (affiliate name).²⁷

Earlier versions of the guidance included a substantially similar consent form, although use of the consent form was required rather than recommended under the previous system of service approvals by PPFA, and substantive deviations from the consent form required approval from PPFA Medical Services.²⁸

B. There Is No Evidence that Planned Parenthood Affiliates Knowingly Received Valuable Consideration in Exchange for Fetal Tissue

The Committee has received no evidence that any Planned Parenthood affiliate or employee ever received any “valuable consideration” for donated fetal tissue. The information and the documentary evidence received by the Committee support Planned Parenthood’s assertions that the few affiliates that have participated in fetal tissue donation comply with the requirement to limit reimbursement to reasonable payments associated with facilitating tissue donation.

In an August 27, 2015, letter to congressional leaders, PPFA President Cecile Richards listed the reimbursement rates at affiliates that are currently or were recently participating in fetal tissue donation.²⁹ At present, only two out of PPFA’s 59 affiliates are participating in fetal tissue donation, and only one affiliate is receiving any reimbursement for costs. An additional four affiliates facilitated fetal tissue donation for research in the past five years.³⁰ The California affiliate that is currently participating receives a reimbursement of \$60 per tissue specimen from a TPO. The other four affiliates, which had participated in fetal tissue donation programs in the past five years, either sought no reimbursement or had reimbursement rates ranging from \$45 to

²⁷ Planned Parenthood Federation of America, Programs for Donation of Blood And/Or Aborted Pregnancy Tissue for Medical Research (May 2015).

²⁸ See, e.g., Planned Parenthood Federation of America, PPFA Manual of Medical Standards and Guidelines: Programs for Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research, Education, or Treatment (June 2011).

²⁹ Letter from Cecile Richards, President, Planned Parenthood Federation of America, to Speaker John A. Boehner, et al (Aug. 27, 2015).

³⁰ Planned Parenthood Federation of America, U.S. House of Representatives Committee on Energy & Commerce, Subcommittee on Oversight & Investigations Follow-Up Questions Dated August 20, 2015.

\$55 per tissue specimen.³¹ The letter states, “[i]n every case, the affiliates report that these amounts were intended to recover only their costs, as allowed under the federal law and our guidance.”³² The evidence received by the Committee during the course of this investigation supports this assertion.

The May 2015 tissue donation guidance notes that affiliates “must be able to demonstrate the reimbursement represents its actual costs.” Dr. McDonald-Mosley explained that the way that each affiliate determines cost is fact-specific to that affiliate.³³ Dr. Nucatola stated that fetal tissue donation is not a revenue stream for affiliates, and that reimbursement should generally be reasonable for the impact it has on the clinic.³⁴

Both the statute governing fetal tissue donation and Planned Parenthood’s May 2015 guidance on pregnancy tissue donation outline the exceptions for reimbursement. The types of costs that may arise for clinics facilitating tissue donation include staff time to identify patients who are interested in donating fetal tissue, staff time spent explaining fetal tissue donation and securing consent, staff time spent drawing maternal blood samples, space in the pathology lab, storage of supplies, sterilization of equipment, and other related costs.

In a briefing with the Committee, Cate Dyer, the Chief Executive Officer of StemExpress, stated that it is her understanding that the valuable consideration requirement applies to all fetal tissue her company obtains.³⁵ The contracts between StemExpress and two Planned Parenthood affiliates state, “The reasonable costs associated with the services specified in this Agreement shall be fifty-five dollars (\$55.00) per POC [product of conception] determined in the clinic to be usable.”³⁶ According to Dyer, the reimbursement covers the space and storage at the Planned Parenthood facility, particularly within the lab and pathology departments, sterilization of equipment, and staff participation in consent and facilitating involvement in the clinic. Additionally, clinic staff is also involved in obtaining maternal blood samples for StemExpress, so that the company can screen for infectious diseases. Dyer stated

³¹ Letter from Cecile Richards, President, Planned Parenthood Federation of America, to Speaker John A. Boehner, et al (Aug. 27, 2015).

³² *Id.*

³³ Briefing by Dr. Raegan McDonald-Mosley, Chief Medical Officer, Planned Parenthood Federation of America, to House Energy and Commerce Committee Staff (Aug. 14, 2015).

³⁴ Briefing by Dr. Deborah Nucatola, Senior Director of Medical Services, Planned Parenthood Federation of America, to House Energy and Commerce Committee Staff (Aug. 27, 2015).

³⁵ Briefing by Cate Dyer, Chief Executive Officer, StemExpress, to House Energy and Commerce Committee Staff (Aug. 25, 2015).

³⁶ Services Agreement between Stem-Ex, LLC and Planned Parenthood affiliate (Apr. 1, 2010), and Services Agreement between Stem-Ex, LLC and Planned Parenthood affiliate (May 15, 2012).

that she believed Planned Parenthood is losing money on fetal tissue donation, given the amount of staff time involved and space StemExpress takes up at the clinics.³⁷

In a briefing with Committee staff, Dr. Ben Van Handel, the Executive Director of Novogenix Laboratories, confirmed that at the affiliate where Novogenix has a contract, Planned Parenthood set the price of \$45 for services rendered on a per specimen basis.³⁸ The contract between Novogenix and the Planned Parenthood affiliate states, “Novogenix will reimburse [the Planned Parenthood affiliate] for reasonable administrative costs associated with the identification of potential donors, as well as the obtaining of informed consent.”³⁹

Similarly, in a briefing with Committee staff, Advanced Bioscience Resources (ABR) confirmed that the reimbursement rate at the Planned Parenthood affiliate with which they partner is \$60 per patient product of conception.⁴⁰ The contract between ABR and the Planned Parenthood affiliate states:

[Affiliate] will provide, and ABR will pay the reasonable costs for, services and facilities ... associated with obtaining consents and with the removal of fetal organs and tissues from POCs [products of conception], 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.⁴¹

C. There Is No Evidence That Planned Parenthood Physicians Conducted Intact Dilation and Evacuation To Preserve Fetal Tissue

To date, the Committee has received no evidence that any physician employed by Planned Parenthood affiliates has performed an “intact” dilation and evacuation (D&E) to preserve fetal tissue for research. CMP claims suggesting that Planned Parenthood physicians are violating the Partial Birth Abortion Act in order to preserve fetal tissue for research appear to have no basis in fact.

³⁷ Briefing by Cate Dyer, Chief Executive Officer, StemExpress, to House Energy and Commerce Committee Staff (Aug. 25, 2015).

³⁸ Briefing by Dr. Ben Van Handel, Executive Director, Novogenix Laboratories, LLC, to House Energy and Commerce Committee Staff (Sept. 3, 2015).

³⁹ Specimen Donation Agreement Between Novogenix Laboratories, LLC and Planned Parenthood affiliate (Mar. 1, 2010).

⁴⁰ Briefing by Linda Tracy, President, Advanced Bioscience Resources, Inc., to House Energy and Commerce Committee Staff (Sept. 3, 2015).

⁴¹ Agreement between Advanced Bioscience Resources, Inc., and Planned Parenthood affiliate (Oct. 1, 2010).

There are three primary methods of surgical abortion: D&E, induction of labor, and hysterotomy. D&E is the only method available at Planned Parenthood facilities.⁴² In a briefing with Committee staff, Dr. McDonald-Mosley stated to the Committee that the confusion over “intact” fetuses is the result of deceptive video editing by CMP, and that she believes that the “intactness” that Planned Parenthood staff are referring to is the intactness of the tissue and specific organs. She noted that during most procedures, such as a D&E, the fetus is not delivered intact.⁴³ She stated there is no evidence that Planned Parenthood staff are removing the fetus in an intact manner.⁴⁴

Similarly, Dr. Nucatola explained that it would be rare for a patient to be sufficiently dilated to deliver an intact fetus.⁴⁵ When questioned whether it was possible to do a D&E resulting in an intact fetus, she stated that while possible, no Planned Parenthood physician would intentionally perform such a procedure because to do so would be illegal.⁴⁶

Representatives of all three TPOs also stated to the Committee that the donated fetal tissue specimens they receive do not include intact fetuses.⁴⁷

D. There Is No Evidence That Planned Parenthood Physicians Altered the Timing, Method, Or Procedure Solely for the Purpose of Obtaining Fetal Tissue for Research

To date, the Committee has not obtained any evidence that Planned Parenthood physicians altered the timing, method, or procedure of an abortion solely for the purpose of obtaining fetal tissue for research. The law requires physicians to certify that “no alteration of the timing, method, or procedures used to terminate the pregnancy was made solely for the purposes of obtaining the tissue.”⁴⁸ Although this section of the law applies only to federally funded research involving transplantation of human fetal tissue for therapeutic purposes, Planned

⁴² Briefing by Dr. Raegan McDonald-Mosley, Chief Medical Officer, Planned Parenthood Federation of America, to House Energy and Commerce Committee Staff (Aug. 14, 2015).

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ Briefing by Dr. Deborah Nucatola, Senior Director of Medical Services, Planned Parenthood Federation of America, to House Energy and Commerce Committee Staff (Aug. 27, 2015).

⁴⁶ *Id.*

⁴⁷ Briefing by Cate Dyer, Chief Executive Officer, StemExpress, to House Energy and Commerce Committee Staff (Aug. 25, 2015); Briefing by Linda Tracy, President, Advanced Bioscience Resources, Inc. to House Energy and Commerce Committee Staff (Sept. 3, 2015); Briefing by Dr. Ben Van Handel, Executive Director, Novogenix Laboratories, LLC, to House Energy and Commerce Committee Staff (Sept. 3, 2015).

⁴⁸ 42 U.S.C. § 289g-1(b)(2)(A)(ii).

Parenthood has voluntarily incorporated the principles of the law into its tissue donation guidance.⁴⁹ The PPFA May 2015 guidance instructs affiliates that “[i]t 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.”⁵⁰

There are limited methods of abortion. At Planned Parenthood affiliates, there are two methods of an early abortion: (1) a medication abortion, and (2) surgical abortion involving mechanical or manual aspiration.⁵¹ For abortions after approximately 13 weeks gestation, the only surgical abortion method available at a Planned Parenthood facility is D&E. A physician’s decision about which method to use is made in consultation with the patient.⁵²

PPFA has not identified any cases in which changes in methods for abortions were made for the purposes of fetal tissue donation.⁵³ It is reasonable for providers to make small adjustments in technique for clinical reasons, and such small adjustments would not constitute a change in method or procedure. As is common across the medical profession, techniques are different for each physician, and physicians commonly make clinical judgments to adjust their approach in the course of a surgery.⁵⁴

Dr. Nucatola confirmed that changing the position of the fetus is not a change in the method or procedure; instead, it often needs to be done for patient safety. Although she does not personally change the position of the fetus in her practice, she believes that some physicians may need to convert the fetus to breech position in order to perform the abortion procedure safely; it is a matter of skill and experience.⁵⁵

⁴⁹ 42 U.S.C. § 289g-1(b)(2)(A)(ii); Letter from Cecile Richards, President, Planned Parenthood Federation of America, to Speaker John A. Boehner, et al (Aug. 27, 2015).

⁵⁰ Planned Parenthood, Programs for Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research (May 2015).

⁵¹ Letter from Cecile Richards, President, Planned Parenthood Federation of America, to Speaker John A. Boehner, et al (Aug. 27, 2015).

⁵² *Id.*

⁵³ Briefing by Dr. Raegan McDonald-Mosley, Chief Medical Officer, Planned Parenthood Federation of America, to House Energy and Commerce Committee Staff (Aug. 14, 2015).

⁵⁴ Briefing by Dr. Deborah Nucatola, Senior Director of Medical Services, Planned Parenthood Federation of America, to House Energy and Commerce Committee Staff (Aug. 27, 2015); Letter from Cecile Richards, President, Planned Parenthood Federation of America, to Speaker John A. Boehner, et al (Aug. 27, 2015).

⁵⁵ Briefing by Dr. Deborah Nucatola, Senior Director of Medical Services, Planned Parenthood Federation of America, to House Energy and Commerce Committee Staff (Aug. 27, 2015)

All Planned Parenthood staff emphasized that patient safety is their top priority. Dr. McDonald-Mosley stated, “The ultimate goal is the safety of the patient.”⁵⁶ Dr. Nucatola said, “Patient safety comes first.”⁵⁷ PPFA’s August 27, 2015, letter reiterated the same message: “Our patient’s health is our paramount concern.”⁵⁸

E. There Is No Evidence That Fetal Tissue Was Ever Obtained Without Appropriate Consent

To date, the Committee has not received evidence that Planned Parenthood affiliates or employees have been involved in obtaining fetal tissue without appropriate consent. For donated fetal tissue that will ultimately be used in federally funded fetal tissue transplantation research, the law requires that informed consent of the patient be obtained prior to donation of fetal tissue, after a separate consent for the abortion procedure has been obtained.⁵⁹

Planned Parenthood has voluntarily incorporated the informed consent requirements into its guidance, and provides affiliates with a sample consent form that specifically tracks the requirements of the statute.⁶⁰ The consent form prompts the patient to affirm the following statement: “Before I was shown this consent, I had already decided to have an abortion and signed a consent form for it.”⁶¹

Dr. Nucatola explained the process, as she understands it, for obtaining informed consent for tissue donation at the Planned Parenthood health center where she works.⁶² First, a medical assistant counsels the patient in the counseling room and obtains informed consent for the abortion. The patient signs consent for the abortion before she knows the gestational age of the fetus. It is only after an exam to determine gestational age that a patient is given the option for tissue donation.⁶³

⁵⁶ Briefing by Dr. Raegan McDonald-Mosley, Chief Medical Officer, Planned Parenthood Federation of America, to House Energy and Commerce Committee Staff (Aug. 14, 2015).

⁵⁷ Briefing by Dr. Deborah Nucatola, Senior Director of Medical Services, Planned Parenthood Federation of America, to House Energy and Commerce Committee Staff (Aug. 27, 2015).

⁵⁸ Letter from Cecile Richards, President, Planned Parenthood Federation of America, to Speaker John A. Boehner, et al (Aug. 27, 2015).

⁵⁹ 42 U.S.C. § 289g-1(b)(2)(A)(i).

⁶⁰ Planned Parenthood, Programs for Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research (May 2015).

⁶¹ *Id.*

⁶² Briefing by Dr. Deborah Nucatola, Senior Director of Medical Services, Planned Parenthood Federation of America, to House Energy and Commerce Committee Staff (Aug. 27, 2015).

⁶³ *Id.*

At Planned Parenthood affiliates participating in fetal tissue donation, either Planned Parenthood staff or the tissue procurement organization are responsible for obtaining consent. Both StemExpress and ABR stated that there have been instances where their employees have obtained informed consent for the tissue donation, depending on timing and clinic staff availability.⁶⁴ According to officials from these companies, their staffs are trained in the process of obtaining patient consent.

Dyer explained that sometimes StemExpress employees obtain consent for tissue donation.⁶⁵ After the patient has consented to the abortion procedure, StemExpress can meet with those patients to review the donation consent and answer questions about the process. Regardless of whether the Planned Parenthood staff or the StemExpress staff obtain consent, the Planned Parenthood tissue donation consent form is used at the affiliate partnered with StemExpress.⁶⁶

ABR stated that for the most part, Planned Parenthood staff obtains consents.⁶⁷ Occasionally, ABR staff obtains consent for the fetal tissue donation in Planned Parenthood affiliates, always using the Planned Parenthood consent form.

Dr. Van Handel stated that Novogenix ensures that informed consent has been obtained for all tissue they procure.⁶⁸ However, Novogenix employees have no involvement in the consent process because they do not interact with patients.

StemExpress and ABR stated unequivocally that they have never procured fetal tissue from a medical waste bin, as was suggested by one of the CMP videos. Dyer, CEO of StemExpress, confirmed that everything is done with consent.⁶⁹ Linda Tracy, President of ABR, confirmed that tissue has never been obtained from the waste bin at ABR or a facility where ABR works.⁷⁰

⁶⁴ Briefing by Cate Dyer, Chief Executive Officer, StemExpress, to House Energy and Commerce Committee Staff (Aug. 25, 2015), and briefing by Linda Tracy, President, Advanced Bioscience Resources, Inc., to House Energy and Commerce Committee Staff (Sept. 3, 2015).

⁶⁵ Briefing by Cate Dyer, Chief Executive Officer, StemExpress, to House Energy and Commerce Committee Staff (Aug. 25, 2015).

⁶⁶ *Id.*

⁶⁷ Briefing by Linda Tracy, President, Advanced Bioscience Resources, Inc., to House Energy and Commerce Committee Staff (Sept. 3, 2015).

⁶⁸ Briefing by Dr. Ben Van Handel, Executive Director, Novogenix Laboratories, LLC, to House Energy and Commerce Committee Staff (Sept. 3, 2015).

⁶⁹ Briefing by Cate Dyer, Chief Executive Officer, StemExpress, to House Energy and Commerce Committee Staff (Aug. 25, 2015).

⁷⁰ Briefing by Linda Tracy, President, Advanced Bioscience Resources, Inc., to House Energy and Commerce Committee Staff (Sept. 3, 2015).

III. EVIDENCE INDICATES THAT THE CENTER FOR MEDICAL PROGRESS MISREPRESENTED ITSELF TO GAIN ACCESS TO PLANNED PARENTHOOD FACILITIES AND PERSONNEL

According to Planned Parenthood officials, CMP made a number of misrepresentations and may have broken several federal and state laws by accessing Planned Parenthood personnel and facilities in the course of creating the videos.

David Daleiden, an anti-abortion activist and the CMP Project Lead, created a fake tissue procurement company called BioMax Procurement Services (“BioMax”).⁷¹ According to Planned Parenthood officials, using BioMax as a front company, CMP was able to gain access to medical conferences, Planned Parenthood staff, Planned Parenthood facilities, and staff from legitimate tissue procurement companies in an attempt to discredit Planned Parenthood and its affiliates.⁷²

As explained in an August 27, 2015, letter sent from Cecile Richards to Speaker Boehner, in the course of their campaign, CMP officials may have violated state and federal laws by:

- violating federal tax laws by misrepresenting the Center for Medical Progress as a biomedicine or bioengineering organization in its application for nonprofit status;
- violating California criminal laws that prohibit forgery, fraud, and perjury by creating fake drivers licenses or obtaining official licenses fraudulently;
- violating California’s Invasion of Privacy Act by recording individuals without consent; and
- violating California’s penal code by making false charitable solicitations.⁷³

CMP may have also committed identity theft and/or credit card fraud.⁷⁴ Daleiden’s attorneys have advised a federal district court that he intends to invoke his Fifth Amendment right to refrain from self-incrimination in response to a lawsuit by the National Abortion Federation alleging that Daleiden and his associates violated federal and state laws.⁷⁵

⁷¹ Letter from Cecile Richards, President, Planned Parenthood Federation of America, to Speaker John A. Boehner, et al (Aug. 27, 2015).

⁷² Letter from Roger K. Evans, Senior Counsel, Law & Policy, Planned Parenthood Federation of America, to Chairman Fred Upton, House Committee on Energy & Commerce (July 20, 2015).

⁷³ Letter from Cecile Richards, President, Planned Parenthood Federation of America, to Speaker John A. Boehner, et al (Aug. 27, 2015).

⁷⁴ *Id.*

⁷⁵ Letter from Cecile Richards, President, Planned Parenthood Federation of America, to Speaker John A. Boehner, et al (Aug. 27, 2015); Civil Minutes, National Abortion Federation v. Center for Medical Progress (case no. 15-cv-03522-WHO) (Aug. 21, 2015).

In a briefing with Committee staff, Dr. Nucatola stated that she first met the individuals posing as BioMax in April 2014 at a booth at the annual meeting of the National Abortion Federation, and they exchanged business cards.⁷⁶ These individuals claiming to represent BioMax then contacted Dr. Nucatola to request a meeting to discuss fetal tissue donation. According to Dr. Nucatola's briefing to Committee staff, she agreed to meet with them not to establish a business relationship, but simply to help this new "company" understand more about Planned Parenthood and fetal tissue donation. Dr. Nucatola explained to Committee staff that she accepted the meeting because her patients often want the option to donate and she supports that option, as well as the research that the donations support. Dr. Nucatola also informed Committee staff that she has never been in a role to contract with a TPO and played no role with respect to the contract for fetal tissue donation at the affiliate where she was a provider.⁷⁷

BioMax also approached StemExpress under false pretenses, claiming to be a third party that could help source fetal tissue for research.⁷⁸ According to StemExpress, BioMax represented themselves as a company in the fetal tissue research business and signed a non-disclosure agreement with StemExpress. They subsequently violated the non-disclosure agreement, and StemExpress asserts that CMP or "BioMax" conducted themselves in a way that violated California law.⁷⁹

IV. EVIDENCE INDICATES THAT THE CENTER FOR MEDICAL PROGRESS IS RELEASING INCOMPLETE AND DECEPTIVELY MANIPULATED TAPES TO THE PUBLIC

On July 14, 2015, CMP began regularly releasing videos purporting to capture Planned Parenthood and TPO staff discussing violations of the federal law that governs fetal tissue donation. Thus far, CMP has released nine videos, six of which depict undercover videos with Planned Parenthood and TPO staff. The three remaining videos feature interviews with a former StemExpress employee.

CMP has released the "full footage" for the six undercover videos and seven transcripts purportedly capturing the entirety of the videos.

On August 27, 2015, PPFA released a forensic analysis conducted by Fusion GPS of the first four videos and accompanying transcripts (both the long and short versions) released by

⁷⁶ Briefing by Dr. Deborah Nucatola, Senior Director of Medical Services, Planned Parenthood Federation of America, to House Energy and Commerce Committee Staff (Aug. 27, 2015).

⁷⁷ *Id.*

⁷⁸ Briefing by Cate Dyer, Chief Executive Officer, StemExpress, to House Energy and Commerce Committee Staff (Aug. 25, 2015).

⁷⁹ Briefing by StemExpress to House Energy and Commerce Committee Staff (Sept. 2, 2015).

CMP between July 14, 2015 and August 4, 2015.⁸⁰ According to its website, Fusion GPS is a Washington D.C. based firm that “provides premium research, strategic intelligence, and due diligence services to corporations, law firms, and investors worldwide.”⁸¹ In conducting their analysis, Fusion GPS additionally commissioned the services of several qualified experts to review both the videos and the accompanying transcripts.⁸²

A. Fusion GPS Found That The CMP Videos Lack Credibility and Have “No Evidentiary Value”

Fusion GPS reviewed four “full footage” videos, which collectively totaled approximately 12 hours of video footage.⁸³ The Fusion GPS analysis found that, “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.” They concluded 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.”

The Fusion GPS analysis concluded that the videos have questionable “evidentiary value.”⁸⁴ The analysis states, “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.”

Fusion GPS also hired an independent transcription agency to examine and transcribe the four short and “full footage” videos released by CMP between the dates of July 14, 2015, and August 4, 2015.⁸⁵ Fusion GPS found all four transcripts by CMP “contain substantive omissions,” and one transcript “appears to be grossly edited.” Fusion GPS therefore concluded that the transcripts released by CMP “cannot be relied upon in official inquiries as a credible text record of what is said in the videos.”⁸⁶

B. The CMP Videos Repeatedly Omitted Representations by Planned Parenthood Staff About Compliance with the Law

⁸⁰ Letter from Cecile Richards, President, Planned Parenthood Federation of America, to Speaker John A. Boehner, et al (Aug. 27, 2015). *CMP Analysis*, Fusion GPS (Aug. 25, 2015).

⁸¹ Fusion GPS, *CMP Analysis* (Aug. 25, 2015).

⁸² *See*, Fusion GPS (online at www.fusiongps.com/) (accessed Sept. 4, 2015).

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ *See* TranscriptionWing (online at www.transcriptionwing.com) (accessed Sept. 4, 2015).

⁸⁶ Fusion GPS, *CMP Analysis* (Aug. 25, 2015).

Similar to the findings by Fusion GPS, Planned Parenthood also found that CMP deceptively edited the videos to suggest deliberate violations of the law.⁸⁷ According to briefings with Committee staff, the short videos deliberately omitted most mentions of efforts to comply with the law, discussions of fetal tissue donation as a not-for-profit activity, and conversations about the consent process. In a briefing, PPFA told Committee staff that without the master tapes, key questions could not be answered about them.⁸⁸

PPFA also reported that Dr. Nucatola emphasized that Planned Parenthood is not profit seeking at least 10 times, but nine of those statements were omitted from the short-form video.⁸⁹ A discussion of affiliates seeking to “break even” was also omitted. Additionally, Dr. Nucatola raised consent requirements 37 times, but none of those are in the short version of the video.

PPFA also stated that Melissa Farrell, the Director of Research at Planned Parenthood Gulf Coast, an affiliate captured in the undercover videos, referenced compliance with federal and state laws, but that is not included in the short video. Moreover, according to PPFA, Planned Parenthood Gulf Coast does not even have a fetal tissue donation program. Although the CMP video does not make this clear, the Gulf Coast affiliate had only a placental and decidua donation program in place.⁹⁰

V. IMPORTANCE OF FETAL TISSUE RESEARCH

The Committee has received evidence regarding the continuing importance of fetal tissue in basic scientific research. Although NIH has not funded human fetal tissue transplantation research since 2007, it continues to fund other research using fetal tissue.⁹¹ In fiscal year 2014, NIH funded \$76 million in research involving fetal tissue.⁹²

Since the 1930’s, fetal tissue has been used in a broad range of research that has led to lifesaving discoveries. In the past, human fetal tissue research has been critical in establishing permanent cell lines for use in vaccine research for diseases such as polio, hepatitis A, measles, mumps, rubella, chickenpox, and rabies. These established cell lines are currently being used to establish an Ebola vaccine.

According to information provided by the NIH, fetal tissue continues to be an important resource for biomedical research. Fetal tissue is used when scientists need a cellular system that

⁸⁷ Briefing by Dr. Raegan McDonald-Mosley, Chief Medical Officer, Planned Parenthood Federation of America, to House Energy and Commerce Committee Staff (Aug. 14, 2015).

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ Briefing by the National Institutes of Health to House Energy and Commerce Committee Staff (Sept. 1, 2015).

⁹² *Id.*

is less differentiated than adult cells.⁹³ According to the Department of Health and Human Services, “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.”⁹⁴

Some commentators have argued that technological advances have obviated the need for research using fetal tissue. When questioned about whether there are alternatives to fetal tissue for stem cell research, such as induced pluripotent stem cells derived from adult tissue, NIH acknowledged that such technology bears promise. However, according to NIH, the technology is not yet mature, and for the immediate future, fetal stem cells continue to play an important role in scientific research. Indeed, during the period while the new technologies are being developed NIH said that it is important to continue to have access to fetal tissue to validate these new methods.⁹⁵

NIH also explained the value of fetal tissue studies of diseases and conditions that affect fetal health and development, organ development, and neural development.⁹⁶ NIH noted that for the study of fetal growth and human development fetal tissue could not currently be replaced.

VI. CONCLUSION

The Committee’s ongoing investigation into Planned Parenthood’s fetal tissue donation program to date has uncovered no evidence that Planned Parenthood and its affiliates have violated the law. The Committee has received letters and documents and has conducted bipartisan briefings with individuals familiar with Planned Parenthood’s fetal tissue donation program. The information the Committee has gathered revealed that (1) there is no evidence that Planned Parenthood affiliates knowingly received valuable consideration in exchange for fetal tissue; (2) there is no evidence that Planned Parenthood physicians conducted intact dilation and evacuation to preserve fetal tissue for research; (3) there is no evidence that Planned Parenthood physicians altered the timing, method, or procedure solely for the purpose of obtaining fetal tissue for research; and (4) there is no evidence that fetal tissue was ever obtained without appropriate consent. Furthermore, the investigation has found that Planned Parenthood requires its affiliates to meet stricter standards than are required by federal law.

⁹³ *Id.*

⁹⁴ Letter from Jim Esquea, Assistant Secretary for Legislation, Department of Health and Human Services, to Senators Joni Ernst and Roy Blunt (Aug. 14, 2015).

⁹⁵ Briefing by the National Institutes of Health to House Energy and Commerce Committee Staff (Sept. 1, 2015).

⁹⁶ Briefing by the National Institutes of Health to House Energy and Commerce Committee Staff (Sept. 1, 2015).