

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927

Minority (202) 225-3641

September 30, 2015

Ms. Cecile Richards
President
Planned Parenthood Federation of America
434 West 33rd Street
New York, NY 10001

Dear Ms. Richards:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is continuing its investigation into practices related to the donation, collection, processing and distribution of human fetal tissue.

Planned Parenthood Federation of America (PPFA) provided a briefing to bipartisan committee staff on August 14, 2015. PPFA has also produced follow-up documents and information following that briefing. The committee appreciates the briefing and follow-up. The information has assisted the committee to better understand how PPFA and its affiliates operate and function, including with regard to the establishment and operation of programs for the donation of human fetal tissue. However, there are still a number of questions we have concerning how PPFA and its affiliates have implemented and managed programs related to the donation of such tissue.

The NIH Revitalization Act of 1993 (1993 law) is the primary federal law governing human fetal tissue research. This law was passed in the context of human fetal tissue transplantation. The 1993 law still either governs and/or guides the practice of human fetal tissue donation. The main elements of the law (1) prohibit valuable consideration for human fetal tissue, (2) ban altering the timing or method of the abortion procedure, and (3) require the patient's consent.¹

PPFA maintains that only a portion of the federal law governing fetal tissue research applies directly to fetal tissue donation. Specifically, the federal law prohibiting "valuable consideration" for fetal tissue applies to PPFA.² The informed consent requirement and

¹ 42 U.S.C. §289g-1; 42 U.S.C. §289g-2.

² 42 U.S.C. §289g-2.

prohibition against changing the timing and method of the abortion procedure, however, applies only to fetal tissue transplantation. PPFA claims that although it is “not legally required to follow the provisions in the 1993 law applicable to fetal tissue transplantation, [PPFA] does so voluntarily.”³

We understand that PPFA has provided guidance to its affiliates on the establishment and operation of programs to facilitate the donation of human fetal tissue. However, despite PPFA’s assertions that it complies with all applicable laws and ascribes to the highest ethical standards with regard to these programs, its guidance does not appear to be fully consistent with the requirements of the 1993 law. The language in the guidance is confusing, inconsistent, and even at times, inaccurate.

Further, PPFA’s guidance has undergone several iterations. For example, at one point, affiliates were required to obtain permission from PPFA before implementing a fetal tissue donation program. This requirement to obtain permission, however, apparently no longer applies, and it is not clear how PPFA assures that affiliates that adopt a fetal tissue program are following the applicable guidance. Also, we have been told that the guidance on fetal tissue donation programs has been removed from PPFA’s master Manual of Medical Standards and Guidelines because it did not pertain to essential “clinical” matters; yet, this explanation is not consistent with other documents that PPFA has provided to the committee.

Furthermore, PPFA has not produced any evidence regarding how affiliates are required to account for reimbursement costs related to fetal tissue donation. In 2001, PPFA directed any affiliate seeking to adopt a human fetal tissue program and which wanted to accept reimbursement for related expenses to employ an independent auditor to ensure that those reimbursed expenses were proper. This direction was reiterated to affiliates in 2011. Yet, this requirement for an independent audit is missing from the guidance which PPFA asserts currently governs affiliates with fetal tissue donation programs.

Your organization asserts that it has “extremely high standards, and any time those standards are not being met, [Planned Parenthood] takes swift action.”⁴ You also wrote to NIH that “Planned Parenthood adheres to the highest standards and follows all the laws.”⁵ Yet despite these assertions, there is little evidence to date that PPFA carefully monitors or oversees its affiliates’ fetal tissue donation programs. PPFA asserts that its reaccreditation process reviews the affiliates’ fetal tissue donation programs, but the documentation provided to committee to date does not support this claim.

To assist the committee’s inquiry, please provide the following documents and information by October 14, 2015:

³ Letter from Cecile Richards, President, PPFA, to Dr. Francis Collins, Director, NIH (July 29, 2015).

⁴ Letter from Roger K. Evans, Senior Counsel, Law & Policy, PPFA, to Rep. Fred Upton, Chairman, Energy & Commerce committee (July 20, 2015).

⁵ Letter from Cecile Richards, President, PPFA, to Rep. John A. Boehner, Speaker, House of Representatives, et al. (Aug. 27, 2015).

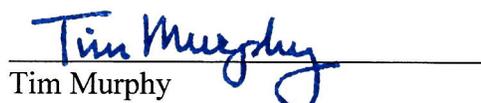
1. All communications and memoranda relating to or involving fetal tissue, including, but not limited to fetal tissue donation programs, collection, sale, research, law, and/or guidance, for the below custodians:
 - a. Cecile Richards, President and CEO, PPFA
 - b. Melvin Galloway, Executive Vice President & Chief Operating Officer, PPFA
 - c. Debra Alligood White, Senior Vice President & General Counsel
 - d. Roger Evans, Senior Counsel, Law & Policy, PPFA
 - e. Vanessa Cullins, Vice President of External Medical Affairs, PPFA
 - f. Leslie Kantor, Vice President of Education, PPFA
 - g. Raegan McDonald-Mosely, Chief Medical Officer, PPFA
 - h. Dr. Carolyn Westhoff, PPFA
 - i. Deborah VanDerhei, National Director, Consortium of Abortion Providers, PPFA
 - j. Kristin Flood, Director and Counsel, Health Regulatory Strategy, Consortium of Abortion Providers, PPFA
 - k. Karen Shea, Director of Medical Standards, PPFA
 - l. Deborah Nucatola, Senior Director of Medical Services, PPFA
2. All audits conducted of Planned Parenthood affiliates' fetal tissue donation programs.
3. All documents relating to waivers granted to Planned Parenthood affiliates to operate fetal tissue donation programs.
4. All completed accreditation assessments, including but not limited to, interview responses and completed accreditation indicators and elements of performance forms, for all Planned Parenthood affiliates that have had a fetal tissue donation program since January 1, 2001.
5. Identify all Planned Parenthood affiliates which have had a fetal tissue donation program since the passage of the NIH Revitalization Act of 1993.

An attachment to this letter provides additional information about how to respond to the committee's request. To fulfill its oversight responsibility, the committee reserves the right to propound additional questions and requests for information and documentation. If you have any questions regarding this request, please contact Charles Ingebretson with the majority committee staff at (202) 225-2927.

Sincerely,



Fred Upton
Chairman



Tim Murphy
Chairman
Subcommittee on Oversight and
Investigations



Joe Barton
Chairman Emeritus



Marsha Blackburn
Vice Chairman



Joseph R. Pitts
Chairman
Subcommittee on Health

Attachment

cc: The Honorable Frank Pallone, Jr., Ranking Member

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations

The Honorable Gene Green, Ranking Member
Subcommittee on Health