

United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
WASHINGTON, DC 20510-6250

KEITH B. ASHDOWN, STAFF DIRECTOR
GABRIELLE A. BATKIN, MINORITY STAFF DIRECTOR

September 28, 2015

The Honorable Sylvia Matthews Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Burwell:

We write to reiterate our request for information and documents from the Department of Health and Human Services (HHS) relating to HHS enforcement and oversight policies and procedures governing the research, transfer, and sale of human fetal tissue.

On August 14, 2015, HHS Assistant Secretary for Legislation Jim Esquea sent nearly identical letters in response to separate inquiries from Chairmen Johnson and Grassley¹ and Senators Ernst and Blunt² regarding the fetal tissue harvesting practices of Planned Parenthood Federation of America (Planned Parenthood), an HHS grant recipient. Mr. Esquea's response letter not only inadequately responds to the questions raised in our inquiries, but it also raises additional concerns about the adequacy of the Department's oversight of HHS grant recipients that engage in activities involving fetal tissue.

According to Mr. Esquea, when HHS funding recipients submit applications or accept grant awards, a representative from the organization receiving federal funds "certifies that researchers using these samples are in compliance with applicable legal requirements...."³ By accepting the award of federal funds, the 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."⁴ Mr. Esquea's letter further notes that HHS requires grant recipients to certify "no less than annually that they are in compliance with applicable legal requirements."⁵

The response we received from Mr. Esquea leads us to question whether, and to what extent, HHS actually verifies the accuracy of certifications submitted by private organizations

¹ Letter from Jim R. Esquea, Assistant Secretary for Legislation, U.S. Dep't of Health and Human Services, to the Senator Ron Johnson, Chairman, S. Comm. Homeland Security and Governmental Affairs, and Senator Charles Grassley, Chairman S. Comm. on Judiciary, Aug. 14, 2015.

² Letter from Jim R. Esquea, Assistant Secretary for Legislation, U.S. Dep't of Health and Human Services to Senator Joni Ernst and Senator Roy Blunt, Aug. 14, 2015.

³ Note 1, *supra*.

⁴ *Id.*

⁵ *Id.*

entrusted with federal taxpayers' dollars. According to Mr. Esquea, the National Institutes of Health (NIH) "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." He adds:

[HHS] know[s] of no violation of [laws governing human fetal tissue] 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.⁶

If HHS makes no effort to independently audit or otherwise verify such assertions by federal grantees, then we can certainly understand why the Department might lack *actual* knowledge of violations of applicable laws and regulations. In this event, however, we would seriously question the grounds for concluding that no violations have occurred, absent any effort by the Department to check the accuracy of certification documents submitted to HHS by third parties. In light of outstanding questions concerning the enforcement of federal laws governing fetal tissue, we ask that you please provide itemized responses to the letter dated August 7, 2015 from Chairmen Johnson and Grassley as well as responses to the following:

1. When an HHS grant recipient certifies to its compliance with all applicable laws and regulations relating to fetal tissue, does HHS conduct any additional oversight or investigation to ensure that such certification is accurate? Please explain (and discuss whether the Department's oversight practices and policies relating to other forms of research differ from its practices and policies relating to fetal tissue research).
2. Under 42 U.S.C. § 289g-1(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 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.)


⁶ *Id.*

- 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.
3. Please provide all analyses, reports, and reviews of Planned Parenthood's annual certification to HHS that it is in compliance with applicable legal and grant requirements for each year since 2010.
 4. Your August 14, 2015 letter states that HHS has not funded or conducted research on the transplantation of human fetal tissue for therapeutic purposes "in recent years." When did HHS last fund or conduct such research, which is subject to the requirements of 42 U.S.C. § 289g-1? Please list and describe all such research projects from the last year in which HHS did fund or conduct this type of research.

Please provide this material as soon as possible but no later than one week from today.

The Committee on Homeland Security and Governmental Affairs is authorized by Rule XXV of the Standing Rules of the Senate to investigate "the efficiency, economy, and effectiveness of all agencies and departments of the Government."⁷ Additionally, S. Res. 73 (114th Congress) authorizes the Committee to examine "the efficiency and economy of all branches and functions of Government with particular references to the operations and management of Federal regulatory policies and programs."⁸ The Judiciary Committee's jurisdiction includes "judicial proceedings, civil and criminal, generally," as well as "[r]evision and codification of the statutes of the United States."⁹ For purposes of this request, please refer to the instructions and definitions contained in the enclosure.

If you have any questions about this request, please contact Kyle Brosnan of the Homeland Security and Governmental Affairs Committee staff at (202) 224-4751 or Patrick Davis of the Judiciary Committee staff at (202) 224-5225 or Taryn Frideres of Senator Ernst's staff at (202) 224-3254. Thank you again for your assistance in this matter.



Ron Johnson
Chairman
Committee on Homeland Security
And Governmental Affairs

Sincerely,



Charles E. Grassley
Chairman
Committee on the Judiciary

⁷ S. Rule XXV(k); *see also* S. Res. 445, 108th Cong. (2004).

⁸ S. Res. 73 § 12, 114th Cong. (2015).

⁹ S. Rule XXV(l).

The Honorable Sylvia Burwell
September 28, 2015
Page 4



Joni K. Ernst
United States Senator

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

The Honorable Patrick Leahy, Ranking Member
Committee on the Judiciary

Enclosure