United States Senate
WASHINGTON, DC 20510

October 6, 2015

The Honorable Daniel R. Levinson
Office of the Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

Dear Inspector General Levinson:

We request that the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) conduct an audit of all fetal tissue research supported by HHS, specifically examining the Department's oversight of contractor and grantee compliance with the laws governing fetal tissue research.

Research involving human fetal tissue is primarily regulated by the NIH Revitalization Act of 1993 (NIH Act), the Health Research Extension Act, and the National Organ Transplant Act, 42 USC Sec. 289g-2. Federal laws make it unlawful to knowingly acquire, receive, or accept a donation of human fetal tissue for valuable consideration.

The Planned Parenthood videos recently released by the Center for Medical Progress raise serious concerns about potential violations of federal law prohibiting the transfer of fetal tissue for valuable consideration. The videos not only raise questions about Planned Parenthood's compliance with applicable laws and regulations, but also highlight potentially significant problems with HHS's oversight of practices in this market in general.

Our request to you follows receipt of an unacceptable response from the Department on August 14, 2015, which failed to address many of the substantive questions raised in the July 22, 2015 inquiry to HHS (both letters attached). The Department does not appear to have conducted any internal investigation of their own research practices or any audits or other oversight of their contractors, suppliers, and grantees with regard to their compliance with fetal tissue research laws and instead relied on assertions of compliance.

We request your assistance in answering questions that the Department did not answer, within the limits of your jurisdiction, including:

1. The attached letter from HHS dated August 14, 2015 states that NIH and FDA currently conduct and fund research involving fetal tissue samples. According to the letter, NIH and FDA obtain tissue samples from "non-profit organizations that have provided assurances to [HHS] that they are in compliance with all applicable legal requirements," and the third parties conducting research funded by FDA and

NIH have certified to HHS that they are in compliance with all legal requirements, including the ban on receiving valuable consideration for fetal tissue.

a. Please conduct an audit to determine, for fetal tissue used in connection with projects funded or conducted by HHS, what these third party entities have paid for fetal tissue, how prices are set, and how they determine whether they are in compliance with 42 USC Sec. 289g-2.
b. How does HHS verify third-party entities' certifications and/or assurances regarding compliance with 42 USC Sec. 289g-2? What kind of certifications and assurances do NIH and FDA obtain (i.e. who signs them, how often they are received, are they in writing, etc.)?
c. HHS' August 14, 2015, letter states that it also requires these third-party funding recipients to "be able to demonstrate their compliance with applicable legal requirements." With respect to compliance with 42 USC Sec. 289g-2, what does HHS require to demonstrate compliance? How often (if ever) has HHS invoked this requirement and asked a funding recipient to demonstrate compliance? Has HHS ever terminated an award based on noncompliance with 42 USC Sec. 289g-2?
d. Do NIH and FDA require any documentation to demonstrate compliance with 42 USC Sec. 289g-2, and if so, what documentation?

2. HHS' August 14, 2015, letter states that HHS has not funded or conducted research on the transplantation of human fetal tissue "in recent years" and currently knows "of no violation of [42 USC Sec. 289g-1] in connection with research done at our agencies." However, the letter does not clearly say whether HHS knows of any violations of 42 USC Sec. 289g-1 by third parties that conducted research with HHS funding.
   a. Does HHS have knowledge of any violations of 42 USC Sec. 289g-1 in connection with research conducted by third parties but funded by HHS?
   b. What has HHS done for past fetal tissue transplant research (if anything) to ensure third parties conducting HHS-funded research complied with 42 USC Sec. 289g-1, including verification of grantee/contractor certifications of compliance?
   c. When HHS conducted its own tissue transplant research in the past, what steps did it take to ensure compliance with 42 USC Sec. 289g-1, including verification of any third-party suppliers legal assurances or certifications?

3. Please review and respond to the remaining unanswered questions in the attached July 22, 2015, letter to Secretary Burwell and conduct any other investigation 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.

HHS OIG has a reputation for fulfilling its mission through thorough, nonpartisan audits and investigations. We look forward to working with your office to shed light on the many serious and alarming questions raised about fetal tissue research in recent months.

Sincerely,

Rand Paul

Roy Blunt

James E. Risch

Tim Scott

Dan Coats

James M. Inhofe

Ted Cruz

Jeff Sessions

Mike Rounds

Mike Crapo

Michael B. Enzi

David A. Perdue

Tom Cotton

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M. Michael Rounds

Bill Cassidy, M.D.

Ron Johnson

Mitch McConnell

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Rand Paul

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Ben Sasse

Jerry Moran

John Thune

Roger Wicker

Steve Daines

Deb Fischer