



The Honorable Joni Ernst
United States Senate
Washington, DC 20515

AUG 14 2015

The Honorable Roy Blunt
United States Senate
Washington, DC 20515

Dear Senator Ernst and Senator Blunt,

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 schizophrenia¹. 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

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.

Health Service Act, 42 U.S.C. § 289g-2, which governs the use of human fetal tissue. 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 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.

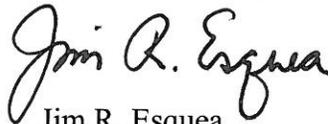
The Public Health Service Act (42 U.S.C. § 289g-2), prohibits knowingly acquiring, receiving, or otherwise transferring any human fetal tissue for valuable consideration if the transfer affects interstate commerce. Violation of this statute carries criminal penalties that apply to both those who supply 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-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 the other signatories to your letter.

Sincerely,



Jim R. Esquea
Assistant Secretary
for Legislation

cc: The Honorable Lamar Alexander
The Honorable Kelly Ayotte
The Honorable John Barrasso
The Honorable John Boozman
The Honorable Richard Burr
The Honorable Shelley Moore Capito
The Honorable Bill Cassidy
The Honorable Dan Coats
The Honorable Thad Cochran
The Honorable Bob Corker
The Honorable John Cornyn
The Honorable Tom Cotton
The Honorable Mike Crapo
The Honorable Ted Cruz
The Honorable Steve Daines
The Honorable Mike Enzi
The Honorable Deb Fischer
The Honorable Jeff Flake
The Honorable Cory Gardner
The Honorable Lindsey Graham
The Honorable Orrin Hatch
The Honorable John Hoeven
The Honorable Jim Inhofe
The Honorable Johnny Isakson
The Honorable Ron Johnson
The Honorable James Lankford
The Honorable Mike Lee

The Honorable Joe Manchin
The Honorable John McCain
The Honorable Mitch McConnell
The Honorable Jerry Moran
The Honorable Rand Paul
The Honorable David Perdue
The Honorable Rob Portman
The Honorable James Risch
The Honorable Pat Roberts
The Honorable Mike Rounds
The Honorable Marco Rubio
The Honorable Ben Sasse
The Honorable Tim Scott
The Honorable Jeff Sessions
The Honorable Richard Shelby
The Honorable Dan Sullivan
The Honorable John Thune
The Honorable Thom Tillis
The Honorable Pat Toomey
The Honorable David Vitter
The Honorable Roger Wicker