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ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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March 23, 2016

Dr. Lawrence Goldstein
Sanford Consortium for Regenerative Medicine
2880 Torrey Pines Scenic Drive
La Jolla, CA 92037

Dear Dr. Goldstein:

Thank you for appearing before the Select Investigative Panel of the Committee on Energy and Commerce on Wednesday, March 2, 2016, to testify at the hearing entitled "Bioethics and Fetal Tissue."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Wednesday, April 6, 2016. Your responses should be mailed to Rachel Collins, Investigative Counsel and Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Rachel.Collins@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Marsha Blackburn
Chairman
Select Investigative Panel of
the Committee on Energy and Commerce

cc: The Honorable Janice D. Schakowsky, Ranking Member, Select Investigative Panel of the Committee on Energy and Commerce

Attachment

Attachment — Additional Questions for the Record

The Honorable Marsha Blackburn

1. At the hearing, the claim was made that without fetal tissue, Zika virus research could not go forward. Only days later, the *Washington Post*[1] cited a *Cell Stem Cell* research project in which induced pluripotent stem cells were engineered to study the characteristics of the virus's infectious potential in developing neural tissue. Since the breakthrough study produced vital information, why the insistence that fetal tissue is required to develop a vaccine or to study the infection's progress?

2. First of all, you mention fetal cells related to spinal cord injuries – Why don't you tell us about any peer reviewed journal studies about the cures of spinal cord injuries from adult stems cells?

   You told us that fetal cells are essential to make astrocytes but you did not mention that adult neural stem cells can make astrocytes and perform what the fetal cells are doing. Aren't the fetal cells in your testimony just "nurse" cells to spew growth factors out to support iPS cells.

   Why did your testimony fail to mention that functional kidney "organoids" have already been grown using iPS cells and adult stem cells.

3. Prior to providing consent to donate fetal tissue, should a woman be advised that there is a possibility her child may be "born alive"?

   Is it not true that such information would allow a woman to provide a more informed consent prior to deciding whether to donate tissue, thereby making the consent more ethically sound?

   If you respond in the negative, please identify specific reasons why such information is ethically irrelevant.

4. In response to a question about "where do you guys get your fetal tissue," you testified that the "fetal neural stem cells that we obtain for our clinical trials come from our collaborating company called Neuralstem." You further testified that you "honestly don't know where they (Neuralstem) obtain their tissue." Since you are involved in transplantation research, do you know which DHHS regulations Title 45 Part 46 Regulations for an IRB were complied with? If so please provide these IRB approvals for the Panel.

   Do you currently obtain fetal tissue from sources other than Neuralstem? Have you obtained fetal tissue from other entities in the past?

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[1] See https://www.washingtonpost.com/national/health-science/evidence-of-zikas-risk-to-pregnant-women-continues-to-grow/2016/03/05/6c8e6152-e2aa-11e5-8c00-8aa03741dced_story.html.

The Honorable Joseph R. Pitts

Mr. Goldstein, you testified that the "form that says therapies for diseases such as Alzheimer's disease and all the rest have already been found, I agree, that is an inappropriate statement and it should not have been made on that form. I don't know who wrote it. That would not have made it past my IRB either." You were also asked where you get fetal tissue for your research. You responded that the fetal tissue neural cells come from Neuralstem and you don't know where they get the fetal remains from which to start the cell lines.

Following up on those statements:

1. How many research projects involving organs, tissue or cells from aborted babies have you participated in? Which of these were conducted in collaboration with Neuralstem?

2. Did you obtain IRB approval for all of the projects involving human fetal tissue, organs, cells or cell lines that you have conducted or in which you have participated? What standards did your IRB set for ethically obtaining human fetal tissue in each?

3. Please indicate the source of the fetal organs or cells for each project, the informed consent forms used in each (any patient-identifying information should be redacted), and the amount paid for each.

4. With regard to your collaboration with Neuralstem or any similar intermediary, please obtain the information requested in question 3 from Neuralstem (or any other intermediary).

5. You indicated a form presented at the hearing that overstated cures would not make it past your IRB. That same statement appears on forms that Planned Parenthood uses (according to this). You co-authored this study regarding Alzheimer's. In the study, published in 2012, you thank "Planned Parenthood of the Pacific Southwest for fetal brain specimens." Redacting any patient identifying information, please provide a copy of the informed consent forms used for each specimen (fetal organ, tissue, cells or cell lines).

The Honorable Janice D. Schakowsky

During the March 2, 2016 Select Investigative Panel hearing, questions were raised concerning the significance of recent fetal tissue donation to advancing our understanding of human development, disease, and illness and to conducting research on potentially lifesaving treatments and cures.

As a distinguished practicing scientist for 40 years, you have a wealth of experience working with a range of cells and tissue as part of your efforts to understand and treat Alzheimer's disease, spinal cord injury, ALS (sometimes called Lou Gehrig's disease), and kidney disease. You are also likely familiar with the work of other researchers who use fetal tissue to understand and seek treatment for a range of other illnesses or diseases.

1. While some of your research may use established cell lines, is there still a need for ongoing fetal tissue donation? (If your answer is yes, please provide some representative examples that illustrate the ongoing need for fetal tissue donation.)

2. Can anyone predict the types of cells or systems that will be necessary for answering particular research questions or developing new treatments or cures going forward?