October 7, 2016

The Honorable Marsha Blackburn
Chair
Select Investigative Panel
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

Dear Chairman Blackburn:

On behalf of the Association of American Medical Colleges (AAMC), the Association of American Universities (AAU) and the Association of Public and Land-grant Universities (APLU), we provide you with a response to the "Interim Update" report of July 14 by the Chairman and majority members of the Select Investigative Panel. The AAMC is a not-for-profit association representing all 145 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic and scientific societies. AAU is a non-profit association of 60 U.S. and two Canadian preeminent research universities founded to develop and implement effective national and institutional policies supporting research and scholarship, and public service in research universities. APLU is a research, policy, and advocacy organization representing 237 public research universities, land-grant institutions, state university systems, and affiliated organizations.

Our organizations urge the Panel to reconsider its characterization of research with fetal tissue in the report or to remove discussions of the scientific merit of such research from its final report as an acknowledgement that this line of inquiry extends beyond the Panel's charge. The characterization included in the interim report erroneously serves to discredit the past and current work of dedicated, ethical researchers who have used fetal tissue to try to improve the lives and health of infants, children, women, and men.

We have concerns with several aspects of the report but would like to address specifically the report's discussion, treatment, and depiction of the role of fetal tissue in past and current scientific research, especially in Section V of the report, entitled: "Biomedical Research and Fetal Tissue." This section presents a series of assertions dismissing the scientific merit of medical research with fetal tissue and its value to science and discovery. Virtually all of the input that the Panel has received from academic institutions, scientific societies, researchers, and associations has spoken about the importance of research with fetal tissue, both in its contribution to past research, including the development of vaccines, and its potential to enhance our knowledge and improve medical care for

diseases ranging from those related to fetal development to Alzheimer's disease, emerging diseases, and recovery from spinal cord injury. These individuals and organizations, as well as the AAMC, have provided the Panel with views on the importance of this research, and the AAMC is troubled that the report does not acknowledge this input.

The AAMC provided information to the Panel about the process of scientific discovery and the importance of exploring a variety of models and pathways to advance discovery, increase the understanding of mechanisms of disease, and enhance opportunity for translation of this knowledge into treatments. A multifaceted approach is crucial because no single scientific inquiry has a guaranteed or known outcome. As the AAMC wrote in its April 22, 2016 letter in response to the Panel's request for information about the use and importance of fetal tissue research:

> The AAMC believes where research pathways have been or can be discovered, such accomplishments reflect the strength of the research system as a whole. Research that looks promising today for one purpose may lead to discoveries in unexpected areas, provide insights about existing knowledge, or indicate that a new pathway should be explored. By closing the door on one type of research, we may never know what advances we might have attained. For every bit of knowledge or advance that has resulted from research using fetal tissue, alone or in combination with other research, there may be other questions and potential lines of inquiry that merit further exploration, using all available methods.
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> Scientists must consider and explore diverse paths, while leveraging available knowledge from the work and findings of previous research. When a particular approach appears successful, the research may illuminate other approaches that could lead to similar results or different outcomes. Similarly, researchers are unlikely to determine in hindsight whether their work could have been accomplished using another method. The testing of approaches in different scientific models, however, can be critical for understanding both the mechanisms of disease and the opportunities for translation and applicability of the knowledge for further clinical research.

Both specific information about the past and current use of fetal tissue in research and acknowledgement about the scientific process are notably absent from the interim report. Section V of the report, rather, presents arguments that purport to refute selective points made about the value of fetal tissue research historically, and concludes that such research is "outmoded technology" and not "mainstream science." However, public statements

from federal officials and academic researchers have catalogued the importance and promise of this research. This information is not reflected or referenced in the Panel's report.

We understand, from discussions with research institutions and from testimony before the Panel, that fetal tissue is fundamentally different than other types of cells such as adult stem cells, and researchers may not always have alternative tissues that could be used to answer certain research questions. As cells mature, changes to their DNA become permanent, limiting the type of tissues those cells may become. This is not true for fetal tissue, which can be used for research requiring undifferentiated cells or tissue.

The report is framed in part as a comprehensive argument against the possibilities for fetal tissue research in medical innovation and discovery, with misleading subsection headings such as "No Cures from Fetal Tissue." Few medical advances are categorized as "cures" and medical research models, on their own or even in combination with others, rarely result in "cures." If the criteria for further exploration, federal funding, or scientific inquiry were a demonstration that the technique or type of research had independently cured a disease, the available research approaches would be vanishingly small, and scientific progress toward improved health would stall indefinitely.

The Panel has cited the comparatively small number of federally funded grants using fetal tissue to study specific disease areas as definitive evidence that the research is not "necessary."[1] In a funding model where applicants must show that their proposed research is unique and not duplicative of other funded research, a concept that Congress has shown interest in ensuring, one would not expect to find all or even most investigators in one field exploring the same research method or pathway. For example, if it was evident which research pathway would lead to a cure for Alzheimer's disease, a slowdown of its progression, or a significant improvement in the lives of those affected, we would be in the enviable position of implementing known treatments, not continuing to search for answers.

The interim report's discussion of research on Zika infection focuses on vaccine development and draws analogies to research on cytomegalovirus or CMV, but does not address the potential role of fetal tissue in basic research to understand the

[1] From page 67 of the Panel's Interim Update report: "A query of NIH database of funded research reveals that in 2014, a total of 1,304 grants investigating Alzheimer's disease were awarded, yet only two employed human fetal tissue. Clearly, the vast majority of scientists studying Alzheimer's disease do not agree that human fetal tissue is vital for their research."

pathophysiology of either disease in human fetuses. The suggestion that research on fetal tissue is not necessary to understand a virus that has a devastating effect on developing fetuses is a potentially dangerous statement for the Panel to make. The director of the National Institute of Allergy and Infectious Diseases, Dr. Anthony Fauci, has raised similar concerns with the Panel's assertions in his testimony before Congress on the urgent need for funding to fight the virus. Further, the report's statement that "the ethical research tools we have in hand are more than powerful enough to fight Zika" suggests 1) that fetal tissue research is an "unethical research tool" and 2) that the Panel has determined what will be effective in stopping this virus, a claim no health authority or federal agency has yet made.

To assert that all scientific inquiry using fetal tissue is unethical, despite decades of legal, often federally-funded research by dedicated scientists following federal guidelines, serves to undermine the work they have done. Further, in an era where we have seen increased threats against the researchers and trainees that are working to improve health through this research we are concerned that this type of suggestion by a Panel made up of members of Congress may increase the physical risks potentially faced by these researchers.

The journal Nature last year (Dec. 7, 2015) published an excellent profile on research involving fetal tissue, including the use of cells from fetal organs to develop "humanized" research models, such as mice with functioning human liver and immune cells, important for research on hepatitis B and C. By focusing on past research and vaccine development alone and focusing on the lack of identifiable "cures," the Panel's report overlooked such examples of cutting-edge basic research. Just a few of the potentially life-saving examples of current research using fetal tissue include:

- Using fetal pancreas cells to create new pathways for treatment for diabetics;
- Creating a roadmap for the generation of new human thymus cells by studying fetal thymus cells, mechanisms that are important to understand and treat autoimmune diseases such as multiple sclerosis, type 1 diabetes, and rheumatoid arthritis;
- Researchers who work on tissue regeneration use fetal tissue to gain knowledge about normal tissue development with the hope to help people who currently rely on organ transplants or need daily medications to replace hormones that their organs no longer manufacture; and
- Scientists who focus on preventing and treating diseases such as infant leukemia can make faster progress because disease-causing mutations target fetal cells specifically.

The Panel's press release posted with the interim update report in July quoted a member of the majority, who said "[the Panel's] investigation is not about stopping fetal tissue research." We appreciate the public statement that this is not the intention of the Panel, but are concerned that the interim update report does not represent this intent. We are hopeful that the final report of the full Select Panel more clearly indicates that the Panel does not intend to try to stop fetal tissue research.

Sincerely,

Darrell G. Kirch, MD
President and Chief Executive Officer
Association of American Medical Colleges

Mary Sue Coleman, MD
President
Association of American Universities

Peter McPherson
President
Association of Public and Land-Grant Universities

cc: The Honorable Jan Schakowsky