

December 12, 2018

The Honorable Jim Jordan
Chair, Subcommittee on
Healthcare, Benefits, & Administrative Rules
Committee on Oversight & Government
Reform
United States House of Representatives
Washington, D.C. 20515

The Honorable Raja Krishnamoorthi
Ranking Member, Subcommittee on
Healthcare, Benefits, & Administrative Rules
Committee on Oversight & Government
Reform
United States House of Representatives
Washington, D.C. 20515

The Honorable Mark Meadows
Chair, Subcommittee on
Government Operations
Committee on Oversight & Government
Reform
United States House of Representatives
Washington, D.C. 20515

The Honorable Gerald Connolly
Ranking Member, Subcommittee on
Government Operations
Committee on Oversight & Government
Reform
United States House of Representatives
Washington, D.C. 20515

Dear Chairmen Jordan and Meadows, and Ranking Members Krishnamoorthi and Connolly:

As associations of leading academic medical centers and universities whose scientists conduct research to improve and save lives, the Association of American Medical Colleges (AAMC), the Association of American Universities (AAU), and the Association of Public and Land-grant Universities (APLU) respectfully write in support of the full spectrum of ethically-conducted research, including the use of fetal tissue in research and work to identify potential equivalents to fetal tissue. While we appreciate the Subcommittees' attention to exploring potential valid alternatives – and we support efforts to strengthen the evidence-base in developing such options – we wish to emphasize the importance of continued investment in research on cells already developed from fetal tissue and of scientists' continued access to new tissue or cell lines.

Fetal tissue research is essential, not only for developing therapies for adults, but also to better understand and treat diseases affecting developing fetuses. Understanding the unique processes at each stage of human development is important to translate discovery from basic research to applications that enhance health for all Americans. From therapies for end-stage breast cancer, diabetes, and Parkinson's disease to a promising vaccine for Ebola, vital medical research depends on continued use of fetal tissue under current laws and regulations. Fetal tissue continues to be an important resource for biomedical research.

Since the 1930s, fetal tissue has been used in a broad range of research that has led to lifesaving discoveries. In the past, human fetal tissue research has been critical in establishing permanent cell lines for use in vaccine research for diseases such as polio, hepatitis A, measles, mumps, rubella, chickenpox, and rabies. But cell lines themselves have limitations, and access to new fetal tissue remains critically important.

Research efforts are ongoing to identify potentially equivalent models to the current applications of fetal tissue research and therapies. Promising initiatives are underway, including induced pluripotent stem cells (iPSCs) and neonatal thymus-seeded humanized mice. However, the ability to identify, develop, and validate these potential alternative models would be hindered if access to fetal tissue is restricted. Furthermore, applications of fetal tissue research are diverse and distinct; even if viable equivalents are identified, evaluation of their fidelity would need to occur on a case-by-case basis. Scientific inquiry benefits from diversity of thought, methodologies, and models. While we should accelerate the development of new and potentially more effective research tools, we cannot arbitrarily abandon proven models in the interim.

Additionally, tissue from miscarriages is not a reliable source for research, as miscarriages most often occur as a result of a developmental abnormality or nonviable genetic condition, undermining the suitability of use of the tissue in many research settings. The emergency circumstances in which miscarriages occur mean that it is not an appropriate time to obtain consent or preserve the tissue under the best conditions for research use.

Fetal tissue has unique properties which have shown immense benefits as a resource for therapies and vaccines, but also as a gold reference standard in developmental biology and in generating new therapies. Medical researchers must continue to have access to this known unique resource while exploring alternatives to fetal tissue. The downstream consequences otherwise include:

- Slowing new research on vaccines not yet developed, for treatments not yet discovered, and for causes of diseases not yet understood.
- Hampering research that cannot be adequately controlled using immortalized cell lines which therefore requires tissue that has been obtained more recently.
- Restricting research only to organs or tissues for which cell lines currently exist, preventing new avenues of research exploring differences between tissue types.
- Restriction of access to new tissue necessary for the development and validation of novel research tools and technologies – essential to cutting-edge research.
- Organs and tissues are not just composed of a single type of cell, but rather an environment of multiple cell types; restrictions would prevent scientists from studying the behavior of cells as they exist in our bodies.
- In order to study fetal diseases like congenital cytomegalovirus infection, congenital zika virus infection, congenital heart disease, and others, fetal tissue is necessary. A classical example is fetal rubella virus infection, which produces developmental delay, blindness, deafness, and congenital heart disease. We no longer need to study congenital rubella because a vaccine made using a fetal tissue cell line (WI-38 cells) has virtually abolished rubella from the Americas.

A vital part of the United States research system's success is ensuring that we stay competitive in progress and are able to collaborate effectively among investigators and laboratories. Diversity of approaches in research gives hope to those suffering and plants the seeds for our nation's future development and economic growth.

Our organizations fully support the ethical use of human tissue, including fetal and placental tissue, cell lines including iPSCs, adult and embryonic stem cell lines, genetically modified or

synthetic organisms, and other approaches to further scientific understanding and improve the health of all. As organizations representing physicians and scientists, our members work every day to save and improve lives. We urge lawmakers to support their ability to continue this important work by ensuring continued access to fetal tissue for research that has the potential to save countless lives.

Sincerely,

Association of American Medical Colleges
Association of American Universities
Association of Public and Land-grant Universities

The Association of American Medical Colleges is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members are all 152 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

AAU is a not-for-profit organization of 62 leading public and private research universities in the United States and Canada. AAU member universities are on the leading edge of innovation, scholarship, and solutions that contribute to the nation's economy, security, and well-being. The 60 AAU universities in the United States award nearly one-half of all U.S. doctoral degrees and 55 percent of those in the sciences and engineering. AAU works to maintain the productive partnership between the nation's research universities and the federal government.

APLU is a research, policy, and advocacy organization representing 235 public research universities, land-grant institutions, state university systems, and affiliated organizations. Founded in 1887, APLU is North America's oldest higher education association with member institutions in all 50 states, the District of Columbia, four U.S. territories, Canada, and Mexico. Annually, member campuses enroll 4.7 million undergraduates and 1.3 million graduate students, award 1.2 million degrees, employ 1.2 million faculty and staff, and conduct \$42.7 billion in university-based research.