July 11, 2019

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

We write to express our collective and strong opposition to the new policies on research using human fetal tissue announced by the Department of Health and Human Services (HHS) on June 5, 2019. These policies would impose substantial barriers to and limit the use of an essential biomedical research resource that has led to many advances in human health and remains critical for the development of new treatments for a wide range of serious diseases.

Decades of thoughtful deliberation on fetal tissue research has provided an ethical and regulatory framework for valuable medical research to progress, enabling the discovery of therapies that would not otherwise have been possible. The ethical considerations fall heavily in favor of permitting fetal tissue research, conducted in accordance with longstanding federal rules. The new restrictions on NIH intramural research using fetal tissue and the new redundant ethics reviews for extramural research will disrupt important biomedical research and delay the development of new treatments for patients.

Human fetal tissue research advances science, improves human health, and saves lives

Research using human fetal tissue has been critical for scientific and medical advances that have saved the lives of millions of people, including the development of vaccines against polio, rubella, measles, chickenpox, adenovirus, rabies, and treatments for debilitating diseases such as rheumatoid arthritis, cystic fibrosis, and hemophilia. Fetal tissue was also essential for the development of a therapy to prevent the transmission of HIV (Truvada). It remains critical for ongoing clinical research on potential treatments for Amyotrophic Lateral Sclerosis (ALS), spinal cord injury, Parkinson's disease, and human development. Fetal tissue is a source of cells for potential treatments of major public health problems.

Fetal tissue has unique and valuable properties that often cannot be replaced by other cell types. Cells from fetal tissue are more flexible and less specialized than cells from adult tissue and can be more readily grown in culture. This is part of the reason why fetal tissue is used in the generation of many of the vaccines made today.

Fetal tissue research cannot be replaced

While there have been some advances in recent years that have reduced the need for fetal tissue in certain areas of research, it remains critically important in many other areas. Fetal tissue remains an essential resource for studying complex interactions between cells, and it is critical for studying developmental tissues. Fetal cell lines are not a substitute for fetal tissue because the lines are limited to a small number of cell types and are inadequate for studying complex interactions between cells. Similarly, organoids and stem cell model systems are simplistic models that only mimic certain aspects of human development. Finally, tissue from spontaneous abortions is not a reliable substitute for tissue from induced abortions because they often result from genetic defects, developmental abnormalities, or other conditions that undermine the usefulness of the tissue.

Fetal tissue research is critical for research on early human development

The new policies on research using fetal tissue will hinder the development of critical new treatments for newborns. Fetal tissue is necessary to understand human development and allows researchers to more fully understand congenital defects such as those of the heart and nervous system. The use of donated fetal tissue has been critical for understanding how Zika virus crosses the placenta and impacts human brain development. The insights gained through studies of Zika virus in human fetal tissue are guiding the development of therapies to prevent transmission of the virus. The study of human fetal tissue also provides an unparalleled window into the complexity of human tissue development, helping researchers understand how birth defects arise and how they can be prevented.

There are well-established and rigorous regulatory frameworks for fetal tissue research

The existing legal and ethical frameworks for fetal tissue research provide rigorous and appropriate oversight, ensuring that the tissue is obtained legally and with donor consent. The framework requires that:

- Donors must provide informed consent before donating tissue.
- Patients must be informed of any known medical risks.
- Primary investigators conducting fetal tissue transplantation research are required to sign a statement that they are aware that “the tissue is human fetal tissue; the tissue may have been obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth; and the tissue was donated for research purposes” and certify that this information has been shared with other members of the research team.
- Federal law makes it illegal to profit from acquiring, receiving, or transferring fetal tissue for research.

Given these requirements – in addition to two levels of peer review to assess the scientific and technical merit of any proposal, its potential significance, and the approach to the research, among other factors – convening yet another review panel would be redundant and will delay medical research that could lead to new treatments. We are deeply concerned that additional delays resulting from the new policies will also lead scientists to abandon promising ideas that otherwise will go unexplored in the U.S. The new policies also will slow and potentially derail the administration's efforts to seek other biomedical resources to minimize the use of fetal tissue, since any new options would need to be evaluated against the gold standard – fetal tissue.

As organizations representing scientists, clinicians, and patients who are driven by a desire to improve the health and well-being of all, we share your interest in promoting the highest ethical standards in federally supported research. However, we are concerned that these new policies will undermine critical work to alleviate human suffering from disease and disability. As you continue to evaluate the regulations and rules for research using fetal tissue, we urge you to consider the scientific and medical significance of fetal tissue research and the rigorous ethical framework already in place.

Thank you for considering our views. Nearly everyone is a patient or future patient; we all rely on biomedical research to develop new treatments for the world's most devastating diseases. Now is not the time to stifle progress.

Sincerely,

AIDS Action Baltimore
AIDS Foundation of Chicago
AIDS Treatment Activists Coalition
Alliance for Aging Research
American Academy of HIV Medicine
American Academy of Neurology
American Academy of Pediatrics
American Association for the Advancement of Science
American Association of Anatomy
American Association of Colleges of Pharmacy
American Institute of Biological Sciences
American Physiological Society
American Society for Investigative Pathology
American Society for Reproductive Medicine
American Society of Hematology
American Society of Human Genetics
American Thoracic Society
Americans for Cures
Associated Medical Schools of New York
Association for Research in Vision and Ophthalmology
Association of American Medical Colleges

Association of American Universities
Association of Independent Research Institutes
Association of Public and Land-grant Universities
Boston University
Brown University
Coalition for the Life Sciences
Columbia University Irving Medical Center
Cornell University
Council on Governmental Relations
Duke University
Endocrine Society
Equity Forward
Federation of American Societies for Experimental Biology (FASEB)
Fellowship in Family Planning
Global Healthy Living Foundation
Harvard University
HIV Medicine Association
HIV/STI Intervention and Prevention Studies (HIPS) Program
HIV+Aging Research Project-Palm Springs
Housing Works, Inc.
Infectious Diseases Society of America
International Society for Stem Cell Research
ISCT, International Society for Cell & Gene Therapy
Jacobs Institute of Women's Health
Johns Hopkins University
Massachusetts General Hospital
Massachusetts Institute of Technology
Medical College of Wisconsin
National Alliance for Eye and Vision Research
National Alliance on Mental Illness
National Center for Health Research (NCHR)
National Minority AIDS Council
National Multiple Sclerosis Society
National Women's Health Network
New York University
North American Society for Pediatric and Adolescent Gynecology
Northwestern University
Princeton University
Research!America
Rutgers Biomedical and Health Sciences
Sexuality Information and Education Council of the United States (SIECUS)
Society for Maternal-Fetal Medicine
Society of Family Planning

Stanford University
Texans for Cures
The American Association of Immunologists
The American Society for Cell Biology
The Elizabeth Glaser Pediatric AIDS Foundation
The Michael J. Fox Foundation for Parkinson's Research
The Nebraska Coalition for Lifesaving Cures
Treatment Action Group
Tuberous Sclerosis Alliance
UC San Diego Health
UCLA
Union of Concerned Scientists
United States People living with HIV Caucus
University at Buffalo Jacobs School of Medicine and Biomedical Sciences
University of California San Diego
University of California San Francisco
University of California System
University of California, Irvine
University of Chicago Medical Center
University of Illinois at Chicago
University of Massachusetts Medical School
University of Michigan
University of Oregon
University of Pittsburgh
University of Washington
University of Wisconsin-Madison
UW Medicine
Yale University