December 21, 2018

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:

On behalf of the millions of patients throughout the nation and around the world, as well as the scientific and medical communities dedicated to advancing human health, the undersigned organizations and institutions write to express our collective and strong support for the continued investment in important fetal tissue research. This research is critical for the development of new treatments for a wide range of serious diseases.

Public policy that facilitates ethically responsible research is in the best interest of patients worldwide. Decades of thoughtful deliberation on the conduct of fetal tissue research has provided an ethical and policy framework for valuable medical research to progress, leading to the discovery of new treatments. At this time, the ethical considerations strongly confirm the need to continue federally supported fetal tissue research, in accordance with current federal rules. Additional restrictions on this lifesaving research would be disruptive to biomedical research and devastating to patients.

you some essential scientific facts and information for your consideration.

Fetal tissue research cannot be replaced with existing alternative research models

Claims that other cells can be used to replace fetal tissue in biomedical research are patently incorrect. In fact, cells in fetal tissue have 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. The study of human fetal tissue provides researchers with incomparable insights into how birth defects arise and how they can be prevented as well as an unparalleled window into the complexity of human tissue development, including why serious congenital defects sometimes arise. 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. As representatives of the scientific and medical communities we are obligated to correct the record.

<u>Induced pluripotent stem cells (iPSCs) and organoids cannot replace fetal tissue research</u>

Assertions that iPSCs and organoid models can replace fetal tissue research are simply false. These cells and model systems may reduce the need for fetal tissue to address certain questions, but they cannot replace it. Organoids can only be used to model certain aspects of human development that can be studied in culture (growing in laboratory dishes).

There are many disease processes or therapies for which studies in tissue culture are not sufficient - in vivo studies are required. This is particularly true of diseases that involve interactions between different tissues or complex combinations of cell types.

Organoids lack immune cells and tend to mimic early fetal development, making them inadequate for modeling immune responses to infection, inflammation, or later stages of fetal development.

There is a general inability to form a functional human immune system with organoids or with iPSCs, or to model the complex interactions between different kinds of immune cells and supporting cells in lymphoid organs. For this reason, diseases that affect the immune system, such as HIV, are studied by

human immune system can develop. Cord blood cells can be transplanted into NeoThy mice to transiently form other components of the blood forming system but in the NeoThy mouse this occurs in mouse blood-forming tissues, not in human tissues. Consequently, the

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 on-going clinical research for Amyotrophic Lateral Sclerosis (ALS), spinal Fetal tissue is medically necessary to best understand human development. It is vitally important for testing new therapies and as a source of cells for new cell therapies that offer the potential to improve the treatment of major public health problems.

As you conclude your review of fetal tissue research, we urge you to allow this important research to continue to support the families who are relying on biomedical research to develop new treatments for diseases that affect their loved ones and millions of other people around the world. Thank you for your consideration.

Sincerely,

AIDS Foundation of Chicago
AIDS Treatment Activist Coalition
Alliance for Aging Research
American Academy of HIV Medicine
American Academy of Neurology
American Association for the Advancement of Science
American Association of Anatomists
American Association of Colleges of Pharmacy
American Association of Immunologists
American Physiological Society
American Society for Cell Biology
American Society for Investigative Pathology
American Society for Reproductive Medicine
American Society of Hematology
American Thoracic Society
Americans for Cures
Association of American Medical Colleges
Association of American Universities
Association of Independent Research Institutes
Association of Public and Land-grant Universities
AVAC
Axis Advocacy
Bailey House, Inc.
Christopher and Dana Reeve Foundation
Coalition for the Life Sciences
Columbia University Irving Medical Center
Council on Governmental Relations
Endocrine Society
Federation of American Societies for Experimental Biology
Global Healthy Living Foundation

Harvard University
HIV Medicine Association
HIV+Aging Research Project-Palm Springs
Housing Works
Infectious Diseases Society of America
International Foundation for Autoimmune & Autoinflammatory Arthritis
International Rectal Microbicide Advocates
International Society for Cell & Gene Therapy
International Society for Stem Cell Research
Johns Hopkins University
Lupus and Allied Diseases Association
Massachusetts General Hospital
Nashville CARES
NASTAD
National Multiple Sclerosis Society
New York University
NMAC (Formerly known as the National Minority AIDS Council)
Project Inform
Research!America
Rutgers Biomedical and Health Sciences
Society for Neuroscience
Society of Family Planning
Stanford University School of Medicine
Stony Brook University
Texans for Cures

The Nebraska Coalition for Lifesaving Cures
The State University of New York System
Treatment Action Group
Tuberous Sclerosis Alliance
University at Buffalo- The State University of New York
University of California System
University of Michigan
University of Minnesota
University of Pittsburgh
University of Washington
University of Wisconsin Madison
Washington State University
Weill Cornell Medicine
Yale University