January 7, 2021

The Honorable Joseph Biden, Jr. President-Elect 1401 Constitution Ave NW Washington, DC 20230

Dear President-elect Biden,

On behalf of the scientific, medical, and patient communities dedicated to advancing medical knowledge and improving human health, we congratulate you on your election and urge you, upon taking office, to swiftly rescind the human fetal tissue (HFT) research restrictions and policy changes that the Department of Health and Human Services made in 2019. These changes have halted all intramural HFT research and obstructed new extramural research involving HFT. Scientists and ethicists have repeatedly reviewed the use of HFT in research and have consistently concluded that HFT is an essential resource for biomedical research. HFT has led to many scientific and medical advances that have saved millions of lives. It remains critical for the development of new treatments for a wide range of serious diseases, including COVID-19.

We encourage you to immediately revoke the 2019 <u>Department of Health and Human</u> <u>Services policy</u> that banned intramural NIH research and imposed an additional and unnecessary barrier for extramural research using HFT, and restore the previous process for approving these projects. As a result of the flawed 2019 policy, highly worthy, scientifically meritorious research was not funded, creating a chilling effect on the broader scientific community. The NIH guide notices that implemented the HHS policy (<u>NOT-OD-19-128</u> and <u>NOT-OD-19-137</u>) must be revoked to restore the integrity of the peer review process and lift the unnecessary barriers to promising biomedical research using HFT.

Additionally, we encourage you to commission an expert report on the scientific and medical value of HFT research. In 2018 and 2019, many of our organizations provided feedback during the Trump administration review of HFT research. While the details of the review were never publicly released, we are confident that an independent and rigorous evaluation of the scientific and ethical merits of HFT research would find that it will continue to advance scientific research and contribute to the development of new treatments.

Cells derived from HFT are currently being used to support the development of multiple treatments and vaccines for COVID-19. While the Trump Administration's arbitrary restrictions on HFT research did not extend to the particular cell line used in COVID-19 research, this research demonstrates the significance of HFT as a research tool for life-saving biomedical research. The restrictions put in place by the Trump administration could delay future advances, vaccines, and anti-viral therapies that would otherwise have been developed through the current generation of HFT research.

HFT has unique and valuable properties that often cannot be replaced by other cell types. Cells from HFT 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 HFT is used to generate vaccines and to study infectious diseases like COVID-19, Zika, HIV, and other viruses. HFT also remains necessary for ongoing research to understand human development and its impact on disease. It is needed to validate model systems to study the progression of diseases and evaluate new therapeutics. It remains critical for ongoing clinical research on potential treatments for amyotrophic lateral sclerosis (ALS), spinal cord injury, and Parkinson's disease. While some have argued that advances in recent years have reduced the need for HFT in certain areas of research, it remains crucial for many others.

The longstanding review process for HFT research that was in place prior to the Trump administration ensured that research using HFT was scientifically meritorious, legal, and ethically sound. This ethical and legal framework remains the standard for HFT research and prohibits individuals from profiting from acquiring, receiving, or transferring HFT for research.

As organizations representing scientists, clinicians, and patients driven by a desire to improve the health and well-being of all, we appreciate your commitment to public health, biomedical research, and evidence-based policies. We look forward to working with you and your administration and thank you for considering our views on the significance of research using human fetal tissue.

Sincerely,

Academic Pediatric Association **AIDS Action Baltimore AIDS** Alabama **AIDS Foundation Chicago** AIDS Treatment Activists Coalition (ATAC) Alliance for Aging Research American Academy of Neurology American Academy of Pediatrics American Association for Anatomy American Association for the Advancement of Science American Brain Coalition American Institute of Biological Sciences American Pediatric Society American Society for Cell Biology American Society for Investigative Pathology American Society of Hematology American Society of Human Genetics American Thoracic Society Americans for Cures

Association of American Medical Colleges Association of American Universities Association of Independent Research Institutes Association of Medical School Pediatric Department Chairs Association of Nurses in AIDS Care Association of Public and Land-grant Universities AVAC Axis Advocacy **Boston University Cascade AIDS Project** Coalition for the Life Sciences Columbia University Irving Medical Center **Council on Governmental Relations** Duke University School of Medicine **Elizabeth Glaser Pediatric AIDS Foundation** Equality California Equality North Carolina Fred Hutchinson Cancer Research Center GLMA: Health Professionals Advancing LGBTQ Equality **Global Healthy Living Foundation** Harvard University HealthHIV **HIV Medicine Association** HIV+Aging Research Project-Palm Springs Housing Works, Inc. Infectious Diseases Society of America International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis) International Society for Cell & Gene Therapy (ISCT) International Society for Stem Cell Research Jacobs Institute of Women's Health Johns Hopkins University Medical College of Wisconsin NASTAD National Alliance for Eye and Vision Research National Alliance on Mental Illness National Coalition for LGBT Health National Working Positive Coalition New York University Northwestern University Feinberg School of Medicine Pediatric Policy Council **Prevention Access Campaign** Princeton Research!America Rutgers, The State University of New Jersey

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