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April 7, 2021

The Honorable Xavier Becerra, JD Secretary of Health and Human Services U.S. Department of Health and Human Services 200 Independence Ave., SW Washington, DC 20201

Transmitted via email: Xavier.Becerra@hhs.gov

Dear Secretary Becerra,

The Federation of American Societies for Experimental Biology (FASEB) advances health and well-being by promoting research and education in biological and biomedical sciences through collaborative advocacy and service to our 29 member societies and the 130,000 individual scientists they represent. Rigorous research depends upon a range of resources, including financial support, a well-qualified and diverse workforce, and access to appropriate experimental models.

Fetal tissue research has played a critical role in scientific advances that have saved and enhanced the lives of millions of people. These include development of vaccines against polio, rubella, measles, chickenpox, adenovirus, rabies, and most recently, COVID-19. Similarly, development of treatments for debilitating chronic diseases such as rheumatoid arthritis, cystic fibrosis, and hemophilia have depended on human fetal tissue. Human fetal tissue research has also helped scientists better understand the impact of Zika and other viruses on fetal development as well as other aspects of fetal medicine. All of these advances have depended upon the unique properties of cells derived from human fetal tissues that cannot be replaced by other cell types.

In <u>June 2019</u>, the Trump Administration directed the Department of Health and Human Services to implement changes to its requirements and National Institutes of Health (NIH) grants policy that essentially halted federally funded research involving human fetal tissue from elective abortions. This policy prevented the acquisition of new fetal tissue into the NIH intramural program following exhaustion of existing resources.

The updated policy allowed existing research using human fetal tissue conducted through the NIH extramural research program to continue. However, new grant applications and grant renewals were subjected to an additional layer of review by an ethics advisory board appointed by HHS following the typical two-tier review process to assess scientific merit and rigor. The requirement for this additional review had an immediate chilling effect on this field of research with 13 of 14 proposals reviewed being rejected for funding during the <u>inaugural convening</u> of the NIH Human Fetal Tissue Research Advisory Board.

Full members: The American Physiological Society • American Society for Biochemistry and Molecular Biology • American Society for Pharmacology and Experimental Therapeutics • American Society for Investigative Pathology • American Society for Nutrition • The American Association of Immunologists • American Association for Anatomy • Society for Developmental Biology • American Peptide Society • Association of Biomolecular Resource Facilities • The American Society for Bone and Mineral Research • American Society for Clinical Investigation • Society for the Study of Reproduction • The Society for Birth Defects Research & Prevention • The Endocrine Society • American College of Sports Medicine • Genetics Society of America • The Histochemical Society • Society for Glycobiology • Association for Molecular Pathology • Society for Redox Biology and Medicine • Society For Experimental Biology and Medicine • American Aging Association • U. S. Human Proteome Organization • Society of Toxicology • Society for Leukocyte Biology • American Federation for Medical Research • Environmental Mutagenesis and Genomics Society Associate members: The American Society of Human Genetics FASEB urges you to rescind the policies and procedures overseeing human fetal tissue research implemented by the prior administration. This includes restoring the ability of researchers within the NIH intramural research program to procure human fetal tissue for new and continuing projects and eliminating the requirement for a third tier of review by an ethics advisory board for research involving human fetal tissue proposed by extramural researchers. Similarly, we urge continued active and transparent engagement with the research community to ensure policies overseeing this important work advance scientific discovery and human health.

Sincerely,

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Louis B. Justement, PhD FASEB President