December 18, 2018

The Honorable Alex M. Azar, II
Secretary
U.S. Department of Health and Human Services (HHS)
200 Independence Avenue, SW
Washington, DC 20201

Re: Review of Alternatives to Fetal Tissue Research

Dear Secretary Azar:

We are writing on behalf of the HIV Medicine Association (HIVMA) and the Infectious Diseases Society of America (IDSA) regarding the Department of Health and Human Services review of the use of fetal tissue to conduct biomedical research. Specifically, the review is already negatively impacting HIV and infectious diseases (ID) research projects planned or underway. Our Societies represent more than 16,000 physicians, researchers, scientists and other healthcare professionals, including many who work on the frontlines of HIV and infectious diseases providing prevention and care and conducting research in communities across the country. We are concerned that pausing or restricting the use of fetal tissue in current and future research will be a major setback to important work to develop an HIV cure and to develop more effective vaccines as well as HIV and ID medications.

The HHS review of fetal tissue research has reportedly already delayed critical HIV and ID studies. There are no existing alternative research models that can replace fetal tissue research being conducted to prevent, treat and cure HIV. Fetal tissue research is the gold standard for allowing researchers to fully model the formation of human blood and immune system cells in human tissues. The increased plasticity, viability, robustness, and immune privilege characteristics are specific, unique properties of fetal tissue-derived stem cells which highly recommend their use over other sources of stem cells. Being able to realistically model human blood and immune system cells is critical to developing medications effective at stopping replication of HIV and studying mechanisms to permanently control or eliminate the virus from a person's body.

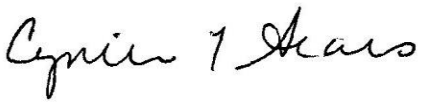
Fetal tissue is a unique source that gives rise to a particular type of stem cell which cannot be found in any other source tissues. The growth ability of fetal tissue-derived stem cells is much different than embryonic stem cells including possessing a better safety profile and without risk of creating uncontrollable growth or cancer tissue. They are different than adult tissue-derived stem cells as they are more robust, in addition to

being immune-privileged. These properties provide an excellent opportunity for scientists to study how to overcome the devastating complications of stem cell and full organ transplantation, namely, rejection and graft-versus-host-disease. The ability to study fetal stem cell development and biology as well as their potential in clinical applications could result in research advances within a few years which would otherwise take several decades. Research with fetal tissue-derived stem cells holds great promise to achieve success in HIV cure studies.

While significant advances in biomedical research have transformed HIV from a fatal to a chronic condition for those with access to HIV treatment, people living with HIV must have lifelong, uninterrupted access to a regimen of at least three antiretrovirals to suppress the virus, stay healthy and prevent disease progression. Due to a number of factors including stigma and discrimination and barriers to treatment including cost, just over 50 percent of people living with HIV are virally suppressed in the U.S. Further, nearly 40,000 new HIV cases continue to occur annually in the U.S. The ongoing evolution of HIV treatment modalities in addition to the development of an HIV vaccine and cure are critical components of the clinical armamentarium needed if we are to end new HIV infections and improve outcomes for all people living with HIV.

We urge HHS not to undercut the promise offered by fetal tissue research to reduce the impact of the HIV epidemic currently affecting 1.1 million Americans and 36.9 million individuals worldwide living with HIV. Protect the integrity of biomedical research by ensuring that decisions regarding research and research methods are driven by science and not stymied by ideology. The health and lives of millions of Americans including those living with and at higher risk for HIV depend on sound, data-driven science policy. Please contact the HIVMA Executive Director Andrea Weddle at aweddle@hivma.org or IDSA Senior Program Officer, Science and Research Policy Jaclyn Levy, MS at jlevy@idsociety.org with questions regarding our comments.

Sincerely,



W. David Hardy, MD
Chair, HIV Medicine Association

Cynthia L. Sears, MD, FIDSA
President, IDSA

CC: Brett Giroir, MD, Assistant Secretary for Health, HHS
Francis Collins, MD, PhD, Director, National Institutes of Health (NIH)
Anthony Fauci, MD, Director, NIH National Institute of Allergy and Infectious Diseases