October 27, 2017

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Planning and Evaluation
Strategic Planning Team
ATTN: Strategic Plan Comments
200 Independence Avenue, SW
Room 415F
Washington, DC 20201

Dear Strategic Planning Team Members,

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide feedback on the Department of Health and Human Services (HHS) draft Strategic Plan for Fiscal Years (FY) 2018 – 2022. Composed of 31 scientific and professional member societies collectively representing over 130,000 biological and biomedical researchers, FASEB was pleased to see the inclusion of Strategic Goal 4: Foster Sound, Sustained Advances in the Sciences in the draft plan. Advances in biological and biomedical research have improved the health of Americans, and the opportunities for additional progress are enormous. The U.S. is the world leader in this crucial area of research, in no small part due to the efforts of several agencies within HHS, including the National Institutes of Health (NIH).

FASEB’s long-standing interest in fostering sound, sustained advances in the sciences has resulted in numerous consensus statements and reports that we believe will aid HHS in the refinement of the proposed strategic plan, goals, and objectives. In Sustaining Discovery in Biological and Medical Sciences: A Framework for Discussion, a 2015 consensus report that examined the opportunities and challenges facing federally funded research in the U.S., FASEB proposed several recommendations relevant to Objective 4.2: Expand the capacity of the scientific workforce and infrastructure to support innovative research. This report has served as a critical resource for the biological and biomedical research community, with NIH leaders using several of the recommendations as a framework for recent policy changes implemented to ensure a robust biomedical research workforce and maximize federal investments in research.

Earlier this month, FASEB released another report relevant to the strategies outlined in Objective 4.2. Maximizing Shared Research Resources identifies the challenges encountered by providers
and users of shared research resources and facilities, and offers recommendations for improvement. Therefore we appreciate the Department’s commitment to explore ways to leverage shared research resources and facilities to enhance researchers’ access to the most cutting-edge research technologies while ensuring proper stewardship of federal funds.

FASEB is also actively engaged in the development of solutions to balance the promotion of ethical and responsible research with regulatory oversight for research involving human and animal subjects. A 2013 survey of over 1,300 individual scientists helped FASEB identify key areas for which there are duplicative and/or contradictory regulations affecting the conduct of research. Not surprisingly, many of the identified regulatory burdens pertained to research activities using animal and human subjects. FASEB’s findings informed the National Science Board in its effort to identify opportunities to reduce investigators’ administrative workload for federally funded research, and a related study by National Academies of Science, Engineering, and Medicine. Recently, FASEB partnered with the Association of American Medical Colleges, Council on Government Relations, and the Foundation for Biomedical Research on a report and recommendations intended to promote ethical and responsible research while streamlining regulations guiding research with animal subjects.

While FASEB appreciates the demonstration of the Department’s commitment to research throughout the proposed strategic plan, we are concerned about the inclusion of the statement, “The research pursued under this strategic goal is to be conducted consistent with the understanding that human subjects protection applies to all human beings from conception to natural death.” This statement implies a desire by Department leadership to restrict research activities involving fetal tissue or embryonic stem cells, a position strongly opposed by FASEB.

Fetal tissue remains a critical resource to further researchers’ understanding of how human tissues develop and are affected by disease. Critical scientific advances – such as the development of vaccines against polio, rubella, measles, chickenpox, adenovirus, and rabies, and treatments for debilitating diseases such as rheumatoid arthritis, cystic fibrosis, and hemophilia – depend on research using fetal tissue. Because of their potential to produce any cell type in the body in unlimited quantities, embryonic stem cells are also a vital resource for research. For decades, embryonic stem cells have been used to test new drugs and have led to innovative new approaches for treating deadly and debilitating diseases, including spinal cord injury, heart failure, and diabetes. Current regulations provide oversight and ethical guidance for this research, and statutory limits on funding for such research would severely impede progress
towards understanding the underlying biology and the development of possible treatments for a wide range of serious and incurable diseases. Inclusion of this language in the HHS strategic plan is counterintuitive to the stated goals.

Thank you for considering our comments on the draft HHS Strategic Plan for FY 2018 – 2022. Please do not hesitate to contact me if FASEB can provide further assistance or resources as you continue to develop and refine the goals in Strategic Goal 4.

Sincerely,

Thomas O. Baldwin, PhD
FASEB President