Written Testimony of the American Society for Pharmacology & Experimental Therapeutics

Submitted to the House and Senate Appropriations Subcommittees Labor, Health and Human Services, Education & Related Agencies

Fiscal Year 2013 Appropriations for the National Institutes of Health

The American Society for Pharmacology and Experimental Therapeutics (ASPET) is pleased to submit written testimony in support of the National Institutes of Health (NIH) FY 2013 budget. ASPET is a 5,100 member scientific society whose members conduct basic, translational, and clinical pharmacological research within the academic, industrial and government sectors. Our members discover and develop new medicines and therapeutic agents that fight existing and emerging diseases, as well as increase our knowledge regarding how therapeutics affects humans.

ASPET recommends a budget of at least $32 billion for the NIH in FY 2013. Research funded by the NIH improves public health, stimulates our economy and improves global competitiveness. Sustained growth for the NIH should be an urgent national priority. Flat funding or cuts to the NIH budget will delay advances in medical research, jeopardizing potential cures, eliminate jobs, and threaten American leadership and innovation in biomedical research.

A $32 billion budget for the NIH in FY 2013 will provide a modest 4% increase to the agency and help restore NIH to more sustainable growth. Currently, the NIH cannot begin to fund all the high quality research that needs to be accomplished. After several years of flat funding and spending cuts enacted in 2011, the NIH’s funding environment has reached a critical point:

- Adjusted for inflation, the FY 2012 budget and the President’s FY 2013 budget proposal are $4 billion lower than the peak year of FY 2003;
- The number of research project grants funded by NIH has declined every year since 2004, and NIH is projected to fund 3,100 fewer grants in FY 2012-2013 than in FY 2004;
- Success rates have fallen more than 14% in a decade and are projected to decline further in FY 2012 and FY 2013.

If flat funding continues or if additional cuts are mandated to the NIH budget for FY 2013 and beyond, research that improves the quality of life will be delayed or stopped, and fewer clinical trials will be conducted. International competitors will continue to gain on this highly innovative U.S. enterprise, and we will lose a generation of young scientists who see no prospects for careers in biomedical research. Flat or reduced funding for NIH will mean that the agency would have to dramatically reduce new awards and many research projects in progress would not receive sufficient funding to complete ongoing work, thus representing a waste of valuable research resources.
An FY 2013 NIH budget of $32 billion would help to begin to restore momentum to NIH funding. A $32 billion FY 2013 NIH budget will help the agency manage its research portfolio effectively without too much disruption of existing grants to researchers throughout the country. The NIH, and the entire scientific enterprise, cannot rationally manage boom or bust funding cycles. Scientific research takes time. Only through steady, sustainable and predictable funding increases can NIH continue to fund the highest quality biomedical research to help improve the health of all Americans and continue to make significant economic impact in many communities across the country. An FY 2013 NIH budget of $32 billion will help NIH move to more fully exploit promising areas of biomedical research and translate the resulting findings into improved health care.

**Diminished Support for NIH will Negatively Impact Human Health**

Diminished funding for NIH will mean a loss of scientific opportunities to discover new therapeutic targets and will create disincentives to young scientists to commit to careers in biomedical science. A difficult federal funding environment becomes more problematic as economic difficulties have led to less investment by the pharmaceutical industry and diminished venture capital needed by the biotech industry. Previous investments in NIH research have been instrumental in improving human health. However, a greater investment in research is needed to help improve the lives of many afflicted by chronic diseases:

- Parkinson’s Disease is estimated to afflict over 1 million Americans at an annual cost of $26 billion. The discovery of Levodopa was a breakthrough in treating the disease and allows patients to lead relatively normal, productive lives. It is estimated that treatments slowing the progress of disease by 10% could save the U.S. $327 million a year. Current treatments slow progression of the disease, but more research is needed to identify the causes of the disease and help to develop better therapies.

- More than 38 million Americans are blind or visually impaired, and that number will grow with an aging population. Eye disease and vision loss cost the U.S. $68 billion annually. NIH funded research has developed new treatments that delay or prevent diabetic retinopathy, saving $1.6 billion a year. Discovery of gene variations in age-related macular degeneration could result in new screening tests and preventive therapies.

- One in eight older Americans suffer from Alzheimer’s disease at annual costs of more than $200 billion. It is estimated that by 2050 more than 14 million Americans will live with the disease with projected costs of $1.1 trillion (in 2012 dollars). Although there are new clinical candidates for Alzheimer’s disease in development, more basic research is needed to focus on new molecular targets and potential cures for this disease. Inadequate funding will delay and prevent improved treatment of the disease.

- Heart disease and stroke are the number one and three killers of...
Cardiovascular disease costs the U.S. more than $350 billion annually. Death rates from cardiovascular disease have fallen by 50% since 1970. Statin drugs that reduce cholesterol help to prevent heart disease and stroke, decrease recurrence of heart attacks and improve survival rates for heart transplant patients.

- Cancer is the second leading cause of death in the U.S. The NIH estimates that the annual cost of the disease is over $228 billion. NIH research has shown that human papillomavirus (HPV) vaccines protect against persistent infection by the two types of HPV that cause approximately 70% of cervical cancers. NIH funded researchers are using nanotechnology to develop probes that could pinpoint the location of tumors and deliver drugs directly to cancer cells. NIH funded basic research built the foundation for one of the most revolutionary FDA approved new treatments for melanoma and helped launch the era of modern personalized medicine.

- NIH-funded investigators discovered an enzyme that may act as a tumor suppressor, therapeutic target, and clinical biomarker in patients with colorectal cancer. Clinical trials are now underway to study its role as a possible novel chemoprevention approach to prevent colorectal cancer and determine the utility of the enzyme as a prognostic and predictive marker for staging patients with disease. The enzyme is also being used as a vaccine target to prevent recurrent disease. Studies are underway evaluating this enzyme’s role in regulating appetite and as a possible novel therapeutic target to prevent obesity, diabetes, and metabolic syndrome.

- Finding new uses for existing drugs is difficult but could be life saving and cost effective. NIH-funded researchers using new bioinformatic approaches have discovered that a drug designed to treat heartburn also inhibited the growth of human lung tumors in laboratory mice. Without adequate support for NIH funding, this type of discovery may become impossible and potential clinical benefits will not be realized.

- There are almost 7,000 rare diseases, each afflicting fewer than 200,000 individuals. More than 350 drugs have been approved for rare diseases since passage of the Orphan Drug Act in 1983. The number of new drugs in development is increasing rapidly as researchers gain a better understanding of the underlying molecular and genetic causes of disease. Diminished support for NIH will prevent new and ongoing investigations into rare diseases that FDA estimates almost 90% are serious or life-threatening.

NIH-funded studies have also indicated that adopting intensive lifestyle changes delayed onset of type-2 diabetes by 58%, and that progesterone therapy can reduce premature births by 30% in at-risk women. Historically, our past investment in basic biological research has led to many innovative medicines. The National Research Council reported that of the 21 drugs with the highest therapeutic impact, only five were developed without input from the public sector. The significant past investment in the NIH has provided major gains in our knowledge of the human genome, resulting in the promise of pharmacogenomics and a reduction in adverse drug reactions that currently represent a major worldwide health concern. Already, there are several

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examples where complete human genome sequence analysis has pinpointed disease-causing variants that have led to improved therapy and cures. Although the costs for such analyses have been reduced dramatically by technology improvements, widespread use of this approach will require further improvements in technology that will be delayed or obstructed with inadequate NIH funding.

**Investing in NIH Helps America Compete Economically**

A $32 billion budget in FY 2013 will also help the NIH train the next generation of scientists. This investment will help to create jobs and promote economic growth. Limiting or cutting the NIH budget will mean forfeiting future discoveries to other countries.

Worldwide, other nations continue to invest aggressively in science. China has grown its science portfolio with annual increases to the research and development budget averaging over 23% annually since 2000. And while Great Britain has imposed strict austerity measures to address that nation’s debt problems, the British conservative party had the foresight to keep its strategic investments in science at current levels. The European Union, despite austerity measures and the severe debt problems of its member nations, has proposed to increase spending on research and innovation by 45% between 2014 and 2020.

NIH research funding catalyzes private sector growth. More than 83% of NIH funding is awarded to over 3,000 universities, medical schools, teaching hospitals and other research institutions in every state. One national study by an economic consulting firm found that federal (and state) funded research at the nation’s medical schools and hospitals supported almost 300,000 jobs and added nearly $45 billion to the U.S. economy. NIH funding also provides the most significant scientific innovations of the pharmaceutical and biotechnology industries.

Inadequate funding for NIH means more than a loss of scientific potential and discovery. As we have noted, failing to help meet the NIH’s scientific potential has led to a significant reduction in research grants and the resulting phasing-out of high quality research programs and jobs lost.

**Conclusion**

ASPET appreciates the many competing and important spending decisions the Subcommittee must make. The nation’s deficit and debt problems are great. However, NIH and the biomedical research enterprise face a critical moment. The agency’s contribution to the nation’s economic and physical well being should make it one of the nation’s top priorities. With enhanced and sustained funding, NIH has the potential to address many of the more promising scientific opportunities that currently challenge medicine. A $32 billion FY 2013 NIH budget will allow the agency to begin moving forward to full program capacity, exploiting more scientific opportunities for investigation, and increasing investigator’s chances of discoveries that prevent, diagnose and treat disease. NIH should be restored to its role as a national treasure, one that attracts and retains the best and brightest to biomedical research and provides hope to millions of individuals afflicted with illness and disease.

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