

**Statement of Hugh Auchincloss, M.D., The American Association of Immunologists,
to the House Appropriations Subcommittee on Labor, Health and Human Services,
Education and Related Agencies, Regarding the FY 2006 Budget
for the National Institutes of Health
April 15, 2005**

The American Association of Immunologists (AAI), a not-for profit professional association representing more than 6,500 research scientists and physicians who are the world's leading experts on the immune system, appreciates this opportunity to comment on the FY 2006 Budget for the National Institutes of Health (NIH). AAI is very grateful to the members of this subcommittee and to its Chairman, Mr. Regula, and ranking member, Mr. Obey, for their continuing leadership and strong support for biomedical research, for the NIH, and for the scientists who devote their lives to preventing, treating, and curing disease.

The importance of immunology

The study of immunology impacts a wide range of infectious diseases (e.g., influenza/flu, SARS, West Nile Virus, tuberculosis, and HIV/AIDS) and chronic diseases (e.g., cancer, heart disease, diabetes, and rheumatoid arthritis.) The immune system can protect its human or animal host from illness or disease, either entirely (by attacking the virus or bacteria successfully) or partially (resulting in a less serious illness). But even a healthy immune system cannot fight off all bacteria or viruses, some of which overwhelm the body's defenses, resulting in illness or death. Because the immune system works by recognizing and attacking "foreign invaders" (i.e., viruses, bacteria, tumors) inside the body, it can also cause problems: it will reject transplanted organs and bone marrow (seeing them as foreign) and, if it is working improperly, attack its own tissue, resulting in an "autoimmune" disease such as multiple sclerosis, Type I diabetes, or lupus.

Thus, the immunologist's role is to understand how the immune system works and to discover ways to defend against new public health challenges such as 1) emerging bacteria and viruses (e.g., the Avian flu); 2) re-emerging bacteria (e.g., tuberculosis); 3) drug resistant bacteria (e.g., causing antibiotic-resistance); and 4) chronic disease (e.g., studying how the immune system can be activated to fight cancer). Immunologists have also been urgently researching ways to protect humans and animals from natural and engineered pathogens that could be used for bioterrorism.

AAI's members include the world's leading immunologists. While our members work in academia, government, and industry, many are medical school professors and researchers who use grants from NIH, and in particular from the National Institute of Allergy and Infectious Diseases (NIAID) to support their research.(1) NIH funding, and the rules governing its use, directly impact virtually every researcher at virtually every research institution in the United States, and enhance (or impede) the advancement of virtually all biomedical research in this nation.(2)

The NIH budget after the "doubling"

AAI is grateful to the members of this subcommittee for supporting the successful bipartisan

(1) Many AAI members also receive grants from the National Cancer Institute, the National Institute on Aging, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Heart, Lung, and Blood Institute, the National Institute of General Medical Sciences, and other NIH Institutes and Centers.

(2) According to NIH, nearly 84% of the funds appropriated to NIH in FY 2006 "will flow out to the extramural

effort to double the NIH budget (from \$13.65 billion in FY 1998 to \$27.18 billion in FY 2003). This “doubling” represented an unprecedented commitment by the federal government to preventing and curing disease, and allowed biomedical researchers to begin new and innovative research made possible by recent advances, including in genomic sequencing. But scientific research takes time, and the doubling of the NIH budget will have been for naught if researchers are unable to complete ongoing studies or retain the personnel in whom they have invested.

Although the NIH budget increased slightly in FY 2004 (as a result of converting prior years’ funds from construction to research), NIH’s FY 2005 program level increased just 2% (to \$28.4 billion) over FY 2004, considerably below the 3.3% “Biomedical Research and Development Price Index (“BRDPI”) (projected estimate of the cost of inflation for biomedical research). (3) For FY 2006, the picture is even bleaker. The President’s proposed budget of \$28.845 billion includes an increase of just 0.7% (\$196 million). This increase is severely below the FY 2006 “BRDPI” of 3.3%. Coupled with the effect of FY 2005, this budget’s failure to even keep up with inflation is poised to have a tremendously deleterious effect:

- NIH anticipates funding 38,746 competitive, peer-reviewed, investigator initiated research project grants (RPGs) in FY 2006, 402 fewer than in FY 2005.
- No inflation increases are expected for competing or non-competing grants.

AAI believes that these sub-inflationary “increases” are beginning to dismantle the doubling benefit and squander the nation's previous investment. Such funding “increases” will harm the advancement of biomedical research, in particular by making establishing or maintaining a career as an independent investigator more difficult, by decreasing NIH’s intramural budget (undermining the effort to attract excellent scientists to NIH), and by failing to increase pre-and post-doctoral compensation (harming efforts to attract bright young people to scientific careers).

AAI’s recommended increase for NIH budget for FY 2006: 6% (2.7% above inflation)

AAI strongly believes that there is currently great opportunity to capitalize on many important research advances that have resulted from the doubling of the NIH budget, and that increased investment in research is not only fiscally prudent but necessary to preserve past investment.

AAI urges this subcommittee to increase the NIH budget by 6% for FY 2006. Such an increase, which is only 2.7% above the BRDPI (biomedical inflation), would ensure the funding of quality basic research that will lead to more translational opportunities and swifter clinical application.

The NIH Roadmap for Medical Research (“Roadmap”)

The President’s FY 2006 budget request for the NIH Roadmap is \$333 million, an increase of \$98 million over FY 2005. While AAI believes that the Roadmap addresses some important issues, including a trend toward multidisciplinary, interdisciplinary research, AAI is concerned that the Roadmap funding increase consumes 50% of NIH’s total funding increase for FY 2006.

(2, *continued*) community, which supports work by more than 200,000 research personnel affiliated with approximately 3,000 university, hospital, and other research facilities.” FY 2006 NIH Budget

(3) The BRDPI was developed by the U.S. Commerce Department and is updated annually by the NIH Office of Science Policy. It indicates how much the NIH budget must increase to maintain purchasing power. NIH reports that the BRDPI is projected to increase by 3.3% during FY 2005 and by 3.2% during FY 2006 and FY 2007.

AAI urges this subcommittee to fund the Roadmap initiative separately so that needed funds will not be taken from the NIH institutes. Further, AAI believes that all Roadmap funds, including the Director's Pioneer Awards, must be awarded through a rigorous peer review process.

Biodefense research

AAI supports the President's request for \$1.694 billion for biodefense research, an increase of 3.2% over FY 2005.⁽⁴⁾ NIH's biodefense research effort has focused thus far on two areas: a) basic research on the biology of microbial agents that could be used for bioterrorism and the properties of the host's defense mechanisms against, and response to, infection; and b) applied research for the development of new or improved diagnostics, vaccines, and therapies needed in the event of bioterrorism. While much has been accomplished in the last three years, there is much left to do. AAI supports, in particular, NIAID's plan to aggressively pursue research to protect against the creation or modification of organisms designed to increase virulence.

Construction and renovation of biocontainment (BSL3) laboratories

AAI supports the use of \$30 million for construction of an additional Regional Biocontainment Laboratory (presumably at Biosafety Level 3 -"BSL3") (the 18th National or Regional Biocontainment Laboratory). AAI also supports using these funds to build or renovate several smaller, local-level laboratories to BSL3 standards. BSL3 laboratories (which are used for less dangerous select agents than BSL4 laboratories), have many advantages: they can be used for research on many hazardous agents; they can be housed in many different physical buildings; and they cost less to operate than BSL4 facilities. Additional BSL3 laboratories will help provide prompt access to researchers who work on certain select agents and other pathogenic bacteria, viruses, and fungi, and will provide needed protection for both researchers and the local community.

AAI also believes that ensuring adequate training in the use of new BSL4/BSL3 laboratories is as important as their construction. AAI supports ongoing efforts by NIH to address laboratory biosecurity issues and urges the subcommittee to support programs to train graduate students, post-doctoral fellows, and senior investigators to work in biocontainment labs. Such programs could be in the form of brief training periods or as supplements to existing training grants.

AAI also urges this subcommittee to include supplementary funds for additional security costs mandated by the government for facilities where research on select agents and other biohazards is conducted. In addition, scientific personnel (and their laboratories) who are on the front lines against both disease and bioterrorism need protection from animal rights terrorists.⁽⁵⁾

Research, Management and Services (RM&S) budget and government outsourcing

AAI strongly supports the President's FY 2006 budget proposal to increase the Research, Management and Services (RM&S) budget by \$11 million (to 5% of the NIH's budget). The

⁽⁴⁾ An additional \$97 million has been budgeted in the Public Health and Social Services Emergency Fund to support research on countermeasures against nuclear, radiological, and chemical threats. When adjusted for non-recurring construction, NIH biodefense research will increase by \$175 million (11%) in FY 2006.

⁽⁵⁾ Immunologists depend heavily on the use of animal models in their research and therefore are vulnerable to animal-rights terrorists. The illegal methods used by some to further an animal-rights/anti-medical research agenda threaten the safety of scientists, delay the progress of important research, and divert precious resources. Without the use of animals, theories about immune system function and treatments that might cure or prevent disease would have to be tested first on human subjects, something our society - and our scientists - would never countenance.

RM&S budget supports the management, monitoring, and oversight of both intramural and extramural research activities (including NIH's excellent and highly regarded peer review process). For FY 2005, AAI recommended precisely this percentage be devoted to RM&S and we are pleased to see this amount included for FY 2006. In AAI's view, this increase should be sufficient to enable NIH to supervise a budget of increasing size and complexity and to ensure that NIH funds are well and properly spent.

AAI continues to be concerned about the "outsourcing" of NIH jobs. While certain NIH jobs might be appropriate for outsourcing, it would not be appropriate for program administrative staff, many of whom are highly experienced, dedicated, and have historical knowledge and understanding of NIH programs and policies, ensuring greater efficiency in the long run.

HIV/AIDS research

AAI supports the creation of the Center for HIV/AIDS Vaccine Immunology, which will focus on collaborative projects addressing key immunological roadblocks to the discovery and development of a safe and effective HIV/AIDS vaccine.

Attracting bright students to biomedical research and retaining young researchers

AAI has long been concerned about our nation's ability to attract bright young students to careers in biomedical research, and has worked to increase compensation for post-doctoral fellows. These scientists, who perform critically important work in the research environment, are significantly underpaid and often receive few or no employment benefits. Given that many post-doctoral scientists are in their thirties, are married, have children, and are trying to buy homes, save for their children's college educations, and save for retirement, ensuring their adequate compensation is essential to our ability to "grow" the next generation of scientists.

AAI supports NIH's plan (March 2001) to implement recommendations of the National Academy of Sciences regarding the need for better compensation for post-doctoral fellows. (See NIH NOT-OD-01-027). While NIH did increase stipends for the Ruth L. Kirschstein National Research Service Awards (NRSA) for FY 2002 and FY 2003 by 10% per year, in FY 2004 NIH increased NRSA awards for post-doctoral fellows by only 1% to 4%, and in FY 2005, by only 2.2% (institutional awards) and 0.9% (individual awards). These two recent "increases" have caused NIH to fall short of its goal of increasing stipends by 10% per year over five years or until entry level post-doctoral fellows earn \$45,000 per year (from FY 2002 level of \$31,092).

The President's FY 2006 budget for NIH would increase NRSA stipends for post-doctoral fellows with 1-2 years' experience by 4%, with a \$500 increased allowance for health insurance coverage. While this is a step in the right direction, it is an insufficient increase and does not include all post-doctoral fellows. We strongly urge this subcommittee to help NIH increase both pre- and post-doctoral stipends further and to explore ways to provide important employment benefits - including health insurance, pensions and Social Security, and vacation and sick leave time - to both NRSAs and the post-doctoral fellows supported by NIH extramural grants.

Cultivating diverse populations of graduate students, post-doctoral fellows, and faculty

Attracting talented, diverse young students to careers in science has long been a priority for AAI. With many top educational and research institutions witnessing a rise in the number of under-

represented minority undergraduates, it is imperative that NIH continue funding programs which encourage these students to pursue careers in science (research and/or teaching). AAI supports increasing the number of underrepresented minority faculty and urges the members of this subcommittee to continue to support NIH diversity programs such as the NRSA fellowship award for minority students and the Minority Access to Research Careers (MARC) program administered through the NIH's National Institute of General Medical Sciences (NIGMS).

The politicization of science

AAI remains concerned about reports that various federal scientific advisory panels have been dismantled or reorganized, and that certain federal agency reports have been changed or edited, in an effort to ensure political compatibility with specific political positions. AAI believes strongly that it is in the best interests of the public, the government which serves them, and the advancement of science that members of government scientific advisory panels be selected on the basis of the excellence of their science, and not on the basis of their political affiliations, voting history, or religious views. Millions of lives – as well as the prudent use of taxpayer dollars - depend on government officials receiving – and taking - the very best and most independent scientific advice that is available. We urge this subcommittee to provide oversight which ensures that funds are expended only to enhance independent scientific advice.

Making good use of NIH Funds

While AAI's testimony is replete with examples of excellent uses of NIH funds, there are two areas in which AAI believes funds are being used unwisely.

1. NIH is currently implementing a new system for the archiving and public dissemination of manuscripts resulting from NIH-funded research. Although NIH has estimated the cost of the project to be \$2 million, there is no official cost estimate. Scholarly publishers, including AAI, estimate (based on their own publishing costs) that this project could cost as much as \$50 million annually. AAI believes that this archiving system, which is duplicative of, but inferior to existing private archives, represents a poor use of federal funds and that its dissemination activities may violate copyright agreements between authors of scientific manuscripts and the scientific journals which peer-review and publish their work.

2. AAI is very concerned that there will be substantial new personnel costs incurred by NIH as a result of the departure of scientists and others whose morale has been damaged by the imposition of harsh new conflict of interest rules. AAI is also concerned about the rules' effect on NIH's efforts to recruit and retain the very best scientists and employees, and on NIH's ability to ensure communication between its scientists and the rest of the scientific community (including industry), an imperative if NIH's goal is to advance research "from the bench to the bedside".

Conclusion

AAI stands ready to assist Members of Congress on any matter involving the immune system, vaccine development, or biomedical research. While immunologists continue to research many traditional areas, they are also expanding their work to embrace newer, urgent scientific needs. With increasing scientific challenges and opportunities before us, biomedical researchers are in need of this subcommittee's strongest possible support. AAI appreciate your support of research and the scientists who conduct it, and hope you will contact AAI if we can be of assistance.