Written Testimony of the American Society for Microbiology submitted to the House Appropriations Subcommittee on Labor, Health and Human Services and Education on FY 2007 Funding for the National Institutes of Health

The American Society for Microbiology (ASM) is pleased to submit the following statement on the FY 2007 appropriation for the National Institutes of Health (NIH). The ASM is the largest single life science Society with over 42,000 members who are involved in basic biomedical research, research and development activities, and diagnostic testing in university, industry, government and clinical laboratories.

The ASM is deeply concerned that the President's proposed FY 2007 budget falls far short of adequately funding biomedical research supported by the NIH. Under the President's FY 2007 budget request, 18 of the 19 Institute budgets are reduced in real dollars. These proposed reductions come at a time when more, not less, research is needed to address pressing health problems. Funding for the NIH in recent years has fallen substantially in constant dollars, foreshadowing a troubling future for biomedical research and for progress against health challenges from emerging and entrenched infectious diseases and chronic diseases. The continued toll on human life from chronic diseases, new threats from pandemic diseases and the potential dangers from bioterrorism make the ASM firmly believe that now is not the time to perpetuate the decline in funding of the past three fiscal years for the NIH. Biomedical research supported by the NIH is critical to the discovery of new knowledge and understanding which underpins development of medical treatments and vaccines. As the US population ages and as global stability is threatened by pandemics, basic research which can only be supported by the NIH is essential to the well being of the world. However, basic biomedical research and the recruitment and training of the next generation of researchers will be weakened if funding for the NIH stagnates and does not keep pace with inflation for a fourth year.

The ASM commends Congress for the past decades of substantial and sustained funding for the NIH, an investment which is key to global health and benefits all Americans medically and economically. The ASM is pleased that the Senate recently has taken steps to increase the NIH budget for FY 2007. The ASM urges Congress to continue to recognize the medical, economic, and strategic importance of adequately funding the NIH and recommends at least a 5 percent increase for the NIH in FY 2007, an appropriation of \$29.75 million. This level of funding is the minimum amount necessary to sustain the current rate of research progress and offset biomedical research inflation.

Biomedical Research Benefits Public Health Preparedness and the Economy

In the past year, there have been tragic reminders that being unprepared protects neither the public health nor the economic and strategic interests of the United States. Increased support for biomedical research is needed because new knowledge and technology are the pillars of preparedness against biological threats. Each day we face local, national, and global threats to health, safety, and well-being. To counter these threats, the NIH's

resources are focused on preserving and improving health in this country and elsewhere through innovative, cutting-edge research. Declining cancer, heart disease and stroke mortality, extended HIV/AIDS life expectancies, and massive genome databanks are evidence of the power of biomedical research. Research supported by the NIH is responding to the realities of 21st century medicine, developing predictive and preemptive medical capabilities to overcome expected health resource shortages and unforeseen dangers like newly identified microbial pathogens.

Research funded by the NIH also contributes to the nation's competitiveness and economic strength, which is clearly rooted in basic science that generates commercially viable products and technologies. Biomedical research advances scientific knowledge, expands the high-technology workforce of the nation, and enhances innovation among the country's private sector companies. Roughly 84 percent of the proposed FY 2007 NIH budget will support the extramural science community through research grants and contracts. This funding will sustain work by more than 200,000 research personnel affiliated with approximately 3,000 hospitals, universities, private companies, and other research facilities.

Infectious Disease Research Needs Increased Support

Inadequate increases in funding for biomedical research weakens our national defenses against infectious diseases, which despite some medical victories persist as the second leading cause of death worldwide, accounting for 26 percent of all deaths. Infectious diseases particularly affect years of healthy life lost because they cause approximately two thirds of deaths among children less than five years of age. Our ability to combat infectious diseases depends on basic research of how microbes spread, how they are harbored in the environment, and how they cause disease. The National Institute of Allergy and Infectious Diseases (NIAID) supports research that is essential to developing strategies to prevent, diagnose and treat infectious diseases here and abroad. NIAID funding supports both intramural and extramural researchers in academia and the private sector searching for new therapies, diagnostics, vaccines, and other technologies that improve health care for infectious diseases. This critical work also focuses on highpriority homeland security initiatives, includes influenza preparedness and counterbioterrorism. Unfortunately, the proposed FY 2007 budget leaves funding for the NIAID flat, about \$4.4 billion or 0.3 percent over the FY 2006 appropriation. With additional resources the NIAID could fund more promising initiatives and restore funding for research projects.

The Threat of Pandemic Influenza

Biomedical research and preparedness save lives and, in the case of pandemic influenza, the number of lives saved could be significant. Anticipating dire possibilities if the H5N1 avian influenza virus mutates sufficiently to move easily from human to human, the Department of Health and Human Services (DHHS) and other federal agencies recently introduced the National Strategy for Pandemic Influenza. The ASM commends this plan as a prudent response to what could become a lethal global event. Fearsome pandemics have ravaged human populations three times in the past century: the 1918-19 Spanish influenza that took more than 40 million lives worldwide, the 1957 Asian

influenza, and the 1968 Hong Kong influenza. Those unusually virulent viral strains contained genetic material from avian influenza viruses like the current H5N1 virus. Confirmed reports of H5N1 related deaths in birds and mammals are coming from an expanding list of nations, where millions of domestic and wild fowl have died or been destroyed. In just the four months since the introduction of the National Strategy for Pandemic Influenza, H5N1 has spread to 37 nations. At present about 186 humans have contracted the disease, more than half of whom have died. Feared for their facile ability to infect and kill, influenza viruses are always with us. Every year, seasonal influenza causes 250,000 to 500,000 deaths worldwide. In the United States, this highly communicable disease annually causes an average 36,000 deaths, more than 200,000 hospitalizations, and, when calculated with pneumonia, an estimated \$37.5 billion in direct and indirect costs. Together influenza and pneumonia are the leading infectious cause of deaths in the United States, ranked seventh among all causes of death. The Centers for Disease Control and Prevention has estimated that if pandemic flu arrives in the United States, 90 million people will become ill and almost 2 million people could die. The global potential for profound loss, millions of human lives and billions in financial costs, clearly demands that our public health institutions be ready with the most effective preventive and therapeutic measures against influenza.

The ASM strongly supports the critically important NIH influenza initiatives. Researchers sponsored by the NIAID are focusing on effective vaccines and antivirals as prioritized in the national strategic plan, which calls for pandemic vaccine within six months of detection, as well as enough antiviral treatment. Scientists supported by the NIAID have completed a successful clinical trial of an experimental inactivated H5N1 influenza vaccine. Research efforts in the DHHS Plan also include the development of new vaccine delivery systems and higher capacity cell-based production methods. Recent advances supported by the NIAID include the institute's Influenza Genome Project, collecting to date the full genomic sequences of more than 830 influenza viral isolates from human patients and building a repository databank for use by other scientists.

Progress Against Infectious Diseases

There are numerous research programs at the NIH that battle a long and growing list of infectious diseases which deserve increased support. Biomedical research consistently yields new ways to treat or prevent diseases. The following are just a few examples of new science advances:

Scientists supported by the NIAID have collaborated to develop a tissue culture cell system in which the whole hepatitis C virus can be grown, which will allow researchers to better understand how Hepatitis C Virus (HCV) replicates and causes infection. HCV is a major cause of chronic liver disease with over 170 million infected people worldwide and can progress to cirrhosis of the liver, leading to liver cancer and failure. Two studies by the NIAID have shown that anti-cancer drugs show promise as potential antiviral drugs and merit further exploration. A vaccine to protect adults and adolescents against illness due to *Bordetella* pertussis infection, or whooping cough, has proved more than 90 percent effective in a large-scale clinical trial, which could help stem the increase in

pertussis cases in the United States. The NIAID has supported a clinical trial of a vaccine against pneumococcal disease, which is a major cause of illness and death in children worldwide.

Biomedical research must remain focused on major killers like HIV/AIDS, tuberculosis and malaria, which together are responsible for more than 5 million deaths each year. Despite extensive prevention programs, an estimated 14,000 people are newly infected with HIV daily. Twenty-five years after physicians first described AIDS as a new disease, more than 40 million people are living with HIV. The bacterium that causes TB currently infects about one-third of the world's population. Multi-drug resistant (MDR) TB increased 13.3 percent in the United States from 2003 to 2004, the largest single year increase in MDR TB since 1993, presenting significant challenges to treatment and control of TB in the United States and abroad. Extensively drug-resistant (XDR) TB has increased in the industrialized nations from 3 percent of MDR TB cases in 2000 to 11 percent in 2004. Two new engineered TB vaccines developed with support of the NIAID have entered clinical trials and a number of TB drug candidates are ready for clinical testing. Scientists continue to pursue a wealth of genomic data to understand malaria pathogenesis and to uncover new molecular targets for both drugs and vaccines for malaria which has an incidence of 300 to 500 million cases a year.

The NIAID funds extensive, multifaceted programs focused on these devastating diseases. In the past year, advances include: the new Center for HIV/AIDS Vaccine Immunology to address what is proving to be the very difficult task of finding HIV vaccines, with clinical sites in England, Africa, and three US states; a clinical trial of two topical microbicides to assess effectiveness in stopping HIV transmission; and detection of a cellular protein that helps the tuberculosis microbe resist standard antimicrobials.

Emerging Diseases and Biodefense Research

A world influenced by rapid transit and global markets challenges not just US competitiveness, but also our public health networks and our national sense of security. We no longer can view far-flung disease outbreaks as remote or theoretical threats to our well-being. The Administration has requested \$1.9 billion in FY 2007 funding for the NIH's biodefense efforts in recognition that the ability to counter bioterrorism depends on progress in biomedical research and the support of scientific capacity to respond to new biological threats. In 2005, the NIAID awarded two additional grants to research consortia aimed at new vaccines, therapies, and diagnostics, completing a national network of ten Regional Centers of Excellence for the NIAID Biodefense and Emerging Infectious Diseases Research program. Research targets include anthrax, plague, smallpox, West Nile fever, botulism, hantaviruses, viral hemorrhagic fevers and many other less-common diseases. The NIAID also began clinical trials of an experimental DNA vaccine against the West Nile virus, which first appeared in the United States in 1999; two NIAID-supported teams identified how Nipah and Hendra viruses attack human and animal cells, both emerging viruses that cause serious respiratory and neurological disease; and NIAID researchers and their university partners determined which host-cell enzymes Ebola viruses can hijack to infect humans.

Conclusion

To sustain the pace of research discovery, we must continue to enhance the research capacity and productivity of the nation's biomedical research enterprise. We must be prepared for the predictable diseases and build sufficient research capacity to detect and respond quickly to unexpected health threats. The 2002-03 outbreak of Severe Acute Respiratory Syndrome (SARS) is a prime example of this balance, a rapid international response occurred to the sudden reality of a novel pathogen, which spread to more than two dozen countries. Biomedical scientists drew upon vast reserves of earlier viral research and quickly developed three distinct SARS vaccines now being evaluated, with the first human clinical trial opening just 21 months after SARS appeared as a new disease. Increased funding for biomedical research will strengthen our public health preparedness, our technological competitive edge and our ability to improve the quality and length of life for people. We urge Congress to provide at least a 5 percent increase for the NIH budget for FY 2007 to help accomplish these goals.