Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

March 23, 2010

James C. Greenwood
President & CEO

The Honorable David R. Obey
Appropriations Subcommittee on Labor,
Health and Human Services, Education,
And Related Agencies
2358 Rayburn House Office Building
Washington DC 20515

The Honorable Todd Tiahrt
Appropriations Subcommittee on Labor,
Health and Human Services, Education,
And Related Agencies
1016 Longworth House Office Building
Washington DC 20515

Dear Chairman Obey and Ranking Member Tiahrt:

On behalf of the Biotechnology Industry Organization (BIO), I am writing to encourage your support for programs and initiatives of great importance to the American public, the advancement of public health, and the innovative biotechnology that will help meet our nation's unmet medical needs. In particular, as you develop the Fiscal Year 2011 Labor, Health and Human Services, Education and Related Agencies Appropriations Act, we respectfully request that you consider and support the following:

National Institutes of Health (NIH)

As you are very aware, NIH is the nation's premier biomedical research agency. The work it conducts and supports provides a critical foundation for further biomedical investment and innovation in both the public and private sectors. Over many years, and under your leadership, Congress wisely has supported NIH and increased funding for its essential mission. For example, in its swift move to address the global economic downturn through the American Recovery and Reinvestment Act (ARRA), an additional $10 billion was included for NIH. These funds have allowed the agency to issue an additional 13,000 research grants that will create or sustain an estimated 50,000 jobs. In addition, the base funding Congress provides the NIH creates 350,000 high-wage/high- skill biomedical research jobs.

BIO urges Congress to continue its historically strong investment in the nation's biomedical research enterprise by supporting consistent growth in NIH funding. The experience of the past decade demonstrates the problems caused by cyclical periods of rapid funding growth followed by periods of stagnation. Since the doubling of the NIH budget between 1998 and 2003, funding has failed to keep pace with biomedical research inflation and, as a result, the success rate of meritorious research proposals has fallen to one in ten, down from one in three in 2003. Consistent sustainable growth in NIH funding is critical to knowledge development that contributes to advancing better health for all Americans.

Specifically, BIO requests that the Committee provide NIH with a 3.2%, or $1 billion, increase for FY 2011.

Technology Transfer at NIH

According to NIH, "technology transfer is a vehicle through which the fruits of NIH intramural research are transferred to industry to be developed ultimately into preventive, diagnostic, and therapeutic products to advance public health." The future development of innovative products and technologies depends on an efficient system of technology transfer that is transparent and

accessible to small, as well as large private sector organizations. BIO urges the Committee to request an NIH report on how best to enable government scientists and small biotechnology companies to work more efficiently together to foster the development of breakthrough medical products. This report should include information on how the technology transfer program currently works, how many licensing agreements have been made, timelines from application to transfer of technology, and examples of 'best practices' and successful partnerships, as well as any problems the program is facing fiscally, programmatically, or otherwise.

Pandemic Influenza Preparedness

Important work has begun to prepare the nation for an influenza pandemic, and BIO appreciates the efforts and support of Congress and the President for this work. Full funding of the HHS Pandemic Influenza Plan is essential to ensure the strong and sustainable public-private partnership needed for successful pandemic preparedness.

The Federal government has made significant progress in expanding domestic capacity to respond to public health emergencies, but the H1N1 threat has revealed that additional steps are needed to ensure that the country is prepared for a full-blown pandemic.

Last year's appropriation of $7.65 billion in emergency funds to HHS for pandemic influenza preparedness, in response to the H1N1 epidemic, supported a number of important activities, including development of new vaccines and antivirals, production of drug delivery devices, communication strategies, and investments in new testing capabilities.

The HHS 2008 Guidance on Antiviral Use During an Influenza Pandemic, as well as an April 2008 Institutes of Medicine report, recommended that upwards of 100 million courses of antivirals should be ready for deployment for both pre- and post-exposure prophylaxis of high-risk individuals such as healthcare and emergency service personnel. To achieve these goals, we encourage HHS to begin stockpiling antivirals for the protection of these critically important first responders.

The President's FY 2011 budget directs HHS to spend $330 million in unobligated emergency funds to continue pandemic preparedness activities. To ensure that we are adequately prepared for future events, it is critical that these funds are made available and used to support advanced development of life-saving medical countermeasures and diagnostics as well as to replenish and increase the supply of essential pharmaceuticals, drug delivery devices, and medical supplies in the Strategic National Stockpile (SNS).

Pandemic / Seasonal Influenza Media Campaign

In light of the recent decision by the Advisory Committee on Immunization Practices (ACIP) to recommend universal influenza immunization, BIO urges Congress to appropriate $30 million in additional funding specifically for the CDC to implement a comprehensive national media campaign on the importance of annual influenza immunization. This is particularly important because the FDA recently announced that the A (H1N1) pandemic influenza strain will be included in the annual 2010 – 2011 seasonal vaccine. Pandemic influenza strains continue to circulate globally and in the U.S., with a disproportionate impact on the young and healthy, and the annual threat of seasonal strains persists. Immunization rates remain alarmingly low among adults and children (only 30% of high-risk adults and just 17.4% of healthy young adults aged 19-49 receive annual influenza immunizations. In addition, only 26.5% of children aged 6 months to 18 years receive an annual influenza vaccination). BIO believes that the CDC is uniquely

positioned to lead this effort because of its strong credibility among Americans as one of the nation's leading public health agencies. New funds are essential to this effort, as CDC's current $1.8 - $2.8 million influenza awareness campaign budget is insufficient to cover the costs of a large scale, national campaign to educate the public about the new immunization recommendation.

Section 317 Immunization

BIO requests that the Committee provide $865.6 million for CDC - $800 million for the Section 317 Immunization Program and $65.6 million for related CDC program operations. The increase would be used to augment vaccine purchase grants to state and local health departments, to cover new vaccines and expanded recommendations from public health experts for existing vaccines. Additional funding would also be used to strengthen state and local infrastructure to support vaccination programs and increase vaccine uptake rates.

Bioterrorism and Emergency Preparedness

The Pandemic and All-Hazards Preparedness Act (PAHPA) of 2006, which was strongly supported by BIO, created the Office of the Assistant Secretary for Preparedness and Response (ASPR) to improve coordination and oversight of Federal public health and emergency preparedness activities. The Act also established the Biomedical Advanced Research and Development Authority (BARDA) within ASPR to facilitate the development of medical countermeasures and vaccines. Many promising technologies for national preparedness have languished between early-stage research and commercialization. Because the U.S. government is the only potential purchaser for these products, strong support and funding partnership is urgently needed to ensure that these technologies continue along their development process and are not abandoned because of lack of financial viability.

In FY 2010, Congress transferred all remaining balances in the Project BioShield Special Reserve Fund (SRF) from the Department of Homeland Security to the Department of Health and Human Services (HHS), and subsequently funded BARDA activities from these funds. In addition to the $305 million transferred to fund the advanced development activities of BARDA, an additional $304 million was transferred to the NIH budget.

BIO is concerned that the transfer of money from the SRF to the NIH undermines the original intent of the program. As you know, the funds appropriated under Project BioShield were placed into the SRF to be used over the course of 10 fiscal years. Prior to last year, funds from the SRF had not been transferred for activities beyond BioShield's originally intended purpose of advanced development and procurement of medical countermeasures. BIO respectfully requests that the Committee not use SRF monies for any activities not related to the advanced development and procurement of medical countermeasures, to preserve the original intent of Project BioShield.

The development of life-saving medical countermeasures is lengthy, costly, and risky. To demonstrate that the Federal government is a strong and reliable partner in countermeasure development, it is important that funding be robust and available on a multi-year basis. This is needed to attract biotechnology and pharmaceutical companies to invest and develop products that would not have a market without government support. BIO recognizes the current constraints on domestic spending; however, we are concerned that the continued funding of development activities from the SRF places the long-term viability of the program at risk. Recent independent analysis has concluded that funding BARDA advanced development at $1.7

billion yearly would be required through FY 2015 to ensure that BARDA has a 90% chance of developing one successful medical countermeasure for each of the eight key bioterrorism threats facing the U.S. For FY 2011, BIO urges the Committee to appropriate $609 million for BARDA, as well as provide report language directing the Administration to work with the private sector, including our industry, to develop a long-term strategic plan to address funding concerns. The chronic underfunding of the advance development efforts of BARDA threatens the ability of the US to protect its citizens from the threats posed by chemical, biological , radiological, or nuclear threats whether intentional, accidental, or naturally occurring.

Strategic National Stockpile

The Strategic National Stockpile (SNS) was established in 1999 to ensure the availability of a large quantity of essential medical supplies in the event of a public health emergency. An influenza outbreak, a terrorist attack, or a large-scale natural disaster will require rapid access to large quantities of pharmaceuticals, drug delivery devices, diagnostic reagents, and other medical supplies. However, adequate quantities of some items may not be readily available unless they have been stockpiled in advance.

For example, leading up to the H1N1 outbreak, there were fewer than 30 million needles and syringes in the stockpile, enough to inject less than 10% of the population at one time. The FY 2009 Supplemental Appropriations Bill included funding to expand significantly the number of pharmaceuticals, drug delivery devices, diagnostic reagents, and other medical supplies available to support the H1N1 immunization campaign. As a result, manufacturers were able to meet the demand for products; however, the strain on the supply chain was significant.

In light of the limits of the existing manufacturing surge capacity for pharmaceuticals, drug delivery devices, and other medical supplies, BIO urges the Committee to provide sufficient funding to enable the SNS to acquire products that can be developed and procured in advance of a public health emergency and to enable the SNS to acquire additional products necessary to respond to emerging infectious disease outbreaks during a declared public health emergency such as vaccines and diagnostics.

Thank you for your consideration of these requests. Should you have any questions or comments, please feel free to contact me or Patrick Carroll, Director of Federal Government Relations, at (202) 962-6696.

We look forward to working with you throughout the appropriations process.

Regards,

James C. Greenwood

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President and CEO