

September 17, 2008

James C. Greenwood  
President & CEO

The Honorable Robert C. Byrd, Chairman  
United States Senate  
Committee on Appropriations  
S-131 The Capitol  
Washington, DC 20510

Dear Chairman Byrd,

On behalf of the Biotechnology Industry Organization (BIO), I am writing to encourage your support of programs and initiatives of critical importance to our country. As Congress prepares a Continuing Resolution for Fiscal Year (FY) 2009, I urge you to provide the Food and Drug Administration (FDA) and National Institutes of Health (NIH) with the resources necessary to keep pace with rapidly evolving biomedical science and make sound regulatory decisions in a timely and efficient manner. Congress recognized that the FY 2008 funding levels were not adequate to meet the needs at the FDA and NIH and, as such, additional money was included in the FY 2008 Supplemental for these Agencies. To ensure adequate funding for FY 2009, I urge you to include \$30.38 billion for the NIH and \$2.04 billion for the FDA.

In addition to FDA and NIH, I urge you to provide additional funding in the Continuing Resolution for the Public Health and Social Services Emergency Fund (PHSSEF). The President recently submitted an amended budget request proposing an increase of \$905 million for the PHSSEF in FY 2009. We support this amended budget request. The additional funds are for the advanced development of new medical countermeasures and activities. Of these funds requested, \$50 million will remain available until the end of FY 2010 to support the delivery of medical countermeasures. The proposed funding is critical to ensure the success of the bipartisan effort to establish the Biomedical Advanced Research and Development Authority (BARDA) and its mission to facilitate the development of needed medical countermeasures against bioterrorist threats, pandemic influenza, and other naturally-occurring biological threats.

BARDA manages the advanced development of medical remedies for biodefense and infectious diseases within HHS. BARDA takes a systematic approach for the development and purchase of the highest priority vaccines, drugs, therapies, and diagnostic tools necessary for public health and medical emergencies. Although the advanced research and development fund was authorized to over \$1 billion for FY 2006-2008, and additional funds as needed in future years, funding to date has been far below



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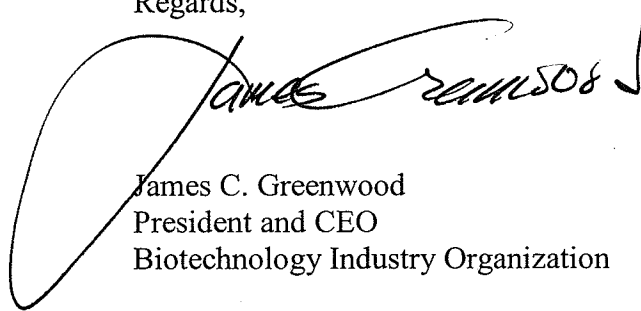
that level considering the complexity and risk of medical countermeasure development and the importance of this mission to national security and public health preparedness.

As evidence of what level of funding is necessary for this national security and public health mission, an analysis conducted by the Center for Biosecurity indicates that for BARDA to have a 90% chance of ultimately developing successful countermeasures for each requirement set forth in the Public Health Emergency Countermeasures Enterprise (PHEMCE) Implementation Plan, over \$3 billion would be required in FY 2009 funding.

In summary, I respectfully request that you provide an increase for the Food and Drug Administration, National Institutes of Health, and Public Health and Social Services Emergency Fund as part of the FY 2009 Continuing Resolution.

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

Regards,

A handwritten signature in black ink, appearing to read "James Greenwood", with a large, sweeping flourish that loops back under the signature.

James C. Greenwood  
President and CEO  
Biotechnology Industry Organization