

June 24, 2010

The Honorable Nancy Pelosi  
Speaker  
United States House of Representatives  
H-232, The Capitol  
Washington, D.C. 20515

James C. Greenwood  
President & CEO

Dear Speaker Pelosi:

On behalf of the Biotechnology Industry Organization (BIO), I am writing to express our opposition to the proposed offsets within the FY2010 Supplemental Appropriations Act from funds directed for pandemic influenza and the BioShield Special Reserve Fund (SRF). We urge these funds not be rescinded so that they are available to support identifying, developing and procuring medical countermeasures for the prevention and treatment of pandemics and injuries or diseases which could result from chemical, biological, radiological or nuclear attacks.

A response to a pandemic or biological weapon attack cannot be mounted overnight. The severity of the threat warrants robust disease surveillance, epidemiologic investigation, the development of medical interventions as well as communications programs and services. Ongoing, advanced funding has been responsible for expanding the nation's domestic vaccine production capacity, influenza surveillance and laboratory testing capability, and planning at the federal and state and local levels. These investments were critical to mitigating the impact of the H1N1 influenza A outbreak in this country. The country mounted a successful response only with the aid of the H1N1 supplemental funding, existing vaccine manufacturing capacity and know-how and a well-informed, established public health infrastructure. Even with these advantages the healthcare system strained to respond to a relatively mild disease outbreak. The recent experience with H1N1 illustrated gaps in the nation's preparedness for a more severe disease emergency, such as a biological attack.

The threat of a severe flu pandemic is also real. It could take the form of a mutation of H1N1 or H5N1 or a currently unknown virus. The Department of Health and Human Services has stated that the H1N1 virus is still circulating, and it is unknown if the virus will resurface in a more severe form in the 2010-2011 flu season. Therefore, we urge you not to reduce contingency funding to replace antivirals which were used under an Emergency Use Authorization during the H1N1 pandemic, along with the supply which has expired; and for procurement of personal protective equipment, syringes, and other necessary supplies. In addition, contingency funding is needed so that vaccine production can be modernized, pandemic plans can be updated and enhanced influenza surveillance maintained, and continued research into rapid diagnostics and medical countermeasures can be undertaken.



Regarding the SRF, the Congress recognized the importance of preparedness for an intentional or accidental biological attack when in 2004 it passed the Project BioShield Act (P.L. 108-276) to procure medical countermeasures to “treat, identify and prevent harm from any biological, chemical, radiological or nuclear agent” that might be used to harm the American people. In establishing the SRF, Congress acknowledged that without guaranteed government commitment to countermeasure procurement, private companies with the expertise needed to develop drugs, vaccines, diagnostics and devices would be unable to assume the risks inherent in the development process.

The availability of SRF funds is essential to ensure the continuation of countermeasure production. Without confidence that the government is committed to procuring countermeasures, companies will have to consider abandoning, or significantly scaling back, efforts to produce biosecurity products, especially if their private investors conclude that a long-term investment in product development is untenable without government funds available to purchase the products. The SRF serves as a concrete demonstration of the federal government’s commitment to procuring medical countermeasures. Diminishing or eliminating the SRF would call into question the credibility of that commitment, and by doing so make it difficult for the private sector to create and maintain jobs in the countermeasure arena.

We understand that these are extremely difficult budgetary times. However, using pandemic funds and the SRF as offsets for the FY2010 Supplemental Appropriations Act or to fund any other program unrelated to their missions would have a devastating impact on efforts to plan and respond to pandemics or to develop countermeasures for chemical, biological, radiological, and nuclear threats. We urge you to oppose any use of pandemic or SRF funds for any purpose other than they were intended.

Sincerely,



James C. Greenwood  
President and CEO

Cc: The Honorable Steny Hoyer, Majority Leader  
The Honorable John Boehner, Republican Leader  
The Honorable David R. Obey, Chairman, Appropriations Committee  
The Honorable Jerry Lewis, Ranking Republican, Appropriations Committee