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BIOTECHNOLOGY
INDUSTRY ORGANIZATION

James C. Greenwood
President & CEO

July 25, 2011

The Honorable Michael J. Rogers
133 Cannon HOB
U.S. House of Representatives
Washington, DC 20515

Dear Representative Rogers:

On behalf of the Biotechnology Industry Organization (BIO), I am writing with our support for H.R. 2405, the Pandemic and All-Hazards Preparedness (PAHPA) Reauthorization Act of 2011. I commend you for introducing this bill, and look forward to working with you on this important measure.

BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. Our members play a central role in ensuring the effective development of countermeasures to protect our nation's citizens against biodefense threats.

We strongly support the simultaneous reauthorization of Project BioShield and the Special Reserve Fund (SRF) with the reauthorization of PAHPA. Because the government represents the sole marketplace for the vast majority of medical countermeasures (MCMs), the funding available through the SRF is vital for private companies, considering the high cost and significant time commitment associated with the development and manufacture of these products.

BIO is also encouraged by the bill's provisions clarifying the regulatory process at the Food and Drug Administration (FDA) for MCMs. H.R. 2405 requires FDA to develop regulatory management plans, provide technical assistance, and adhere to specific timelines, providing MCM sponsors with a more transparent and consistent path to licensure. These provisions will help accelerate MCM development and approval, improving the nation's preparedness in the face of a public health crisis or chemical, biological, radiological, or nuclear (CBRN) event.

BIO looks forward to working with you for passage of H.R. 2405. Thank you.

Sincerely,

James C. Greenwood
President & CEO