BIOTECHNOLOGY
INDUSTRY ORGANIZATION

July 13, 2007

Dr. Susan Coller
Policy Analyst
Office of Public Health Emergency Preparedness
330 Independence Avenue, SW
Room G640
Washington, DC 20201

Dear Dr. Coller,

The Biotechnology Industry Organization (BIO) appreciates the opportunity to provide comments to the Department of Health and Human Services (HHS) on the HHS Public Health Emergency Medical Countermeasure Enterprise Implementation Plan for Chemical, Biological, Radiological, and Nuclear Threats (the Implementation Plan). BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products.

The Implementation Plan is helpful in providing increased transparency and clarity on the timing, priority, and size of acquisition plans. We believe additional information and guidance are needed so the appropriate incentives and environment will foster medical countermeasure (MCM) development. Therefore, we provide the following comments.

Acceleration of Acquisition Timelines

We believe the Implementation Plan should identify strategies for accelerating the Request for Proposal (RFP) review and award process. The time between RFP issuance and reward has at times been very long. This adds uncertainty to an already challenging market and increases the difficulty of attracting investment dollars. Faster review times are needed to enable companies to make more informed risk management decisions and provide a more predictable and attractive investment environment.

Strategies should also be identified to accelerate the generation of RFPs for both near-term and mid-term acquisitions. The identification of near-term and mid-term priorities and the estimates of funding are helpful. However, because the United State government will be the primary purchaser of most MCMs, industry and investors need a more clear articulation of potential contract size in order to make informed investment decisions and sustain and justify development projects for mid-term acquisitions.

Additionally, since a substantial number of high-priority MCMs are identified as mid-term (FY 09-13) acquisition targets, it will be important for the nation's preparedness goals to ensure processes are in place to enable the RFP process to proceed expeditiously through the transition between FY 2008 and FY 2009. Specifically, strategies should be identified to develop and issue – prior to FY 2009 - RFPs for mid-term acquisition targets even if the funding for those acquisition would not be available until FY 2009. Unnecessary process delays in RFP issuance and review would result in delays in availability of MCMs. Delays in RFP issuance will further challenge the business environment, as additional uncertainty and time will compound the risk environment for companies and their investors.

The Project BioShield and Pandemic and All-Hazard Preparedness Act provided statutory mechanisms for other expedited procurement processes. In cases where the routine acquisition processes are not sufficient to meet the nation's security needs, strategies should be identified to exercise these authorities as appropriate.

Funding and Incentives

Funding constraints appear to be a major inhibitor to development of a more detailed and robust acquisition strategy. The overriding factor that should inform activity should be the expeditious strengthening of our national security and public health. The appropriate and prudent use of available funds should be focused on achieving this result, and this should be the basis of future requests for additional funding.

Robust funding is needed throughout the countermeasure development lifecycle. Lack of strong funding for the array of MCMs identified as priorities creates a challenging environment for companies to make informed investment decisions and attract investors. Importantly, because biotechnology product development is a lengthy - as well as costly - endeavor, companies must make risk decisions years in advance. A lack of clarity of the market and funding size at the present time for products HHS desires to acquire in the coming years will adversely affect the probability that companies can support and justify their continued development.

In addition to the need for robust funding, we encourage HHS to develop strategies to enhance domestic market opportunities wherever possible. For example, States and local governments, first responders, businesses, and civilians may have interest in the availability and acquisition of MCMs. Sound strategies in this area may serve to complement Federal stockpiling and attract investment.

We appreciate the awareness of HHS of the value of enhanced partnering among companies in the development of MCMs. We encourage OPHEMCE to continue to facilitate partnerships between those companies developing innovative end stage products and those investing in new delivery or enabling technologies. Market forces often bring companies together to create product innovations. However, both policymakers and industry have noted that the dynamics in the biodefense marketplace are unique and would benefit from agency support for collaboration among the players. It is also critical

to note that a lack of a clear and robust market can hamper the goal for more partnering among companies – particularly partnering with large companies - as opportunity costs can challenge investment in MCMs.

Additionally, while the Implementation Plan appropriately identifies the importance of response capabilities, there remains a strong need for prevention. Ensuring that prophylaxis strategies are incorporated for an array of threat agents will serve to promote a comprehensive, proactive, and robust strategy.

The new advanced research and development authorities of the Biomedical Advanced Research and Development Authority (BARDA) will be extremely valuable and helpful in supporting advanced research and development and managing development risks. However, a clear articulation of acquisition needs, robust funding, and streamlined and accelerated RFP processes remain necessary components to fulfill the intent of Project BioShield and the Pandemic and All-Hazards Preparedness Act.

Thank you again for the opportunity to comment on the Implementation Plan. We look forward to participating in the upcoming Stakeholders Workshop and commenting on the draft BARDA Strategic Plan.

Respectfully submitted,

Chris Colwell
Director, Healthcare Regulatory Affairs