

# Alliance for Biosecurity

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The Honorable Fred Upton  
Chairman  
Committee on Energy and Commerce  
U.S. House of Representatives  
2125 Rayburn House Office Building  
Washington, DC 20515

The Honorable Frank Pallone  
Ranking Member  
Committee on Energy and Commerce  
U.S. House of Representatives  
2322A Rayburn House Office Building  
Washington, DC 20515

November 30, 2016

Dear Chairman Upton and Ranking Member Pallone:

On behalf of the Alliance for Biosecurity, we write today in strong support of the newly revised version of the *21<sup>st</sup> Century Cures Act*, which includes a section (Subtitle H) on Medical Countermeasures Innovation. Subtitle H would support preparedness for potential public health emergencies by increasing accountability and streamlining the contracting process for medical countermeasures (MCMs). Ensuring that these essential programs are sufficiently funded and effectively managed is critical to sustaining our national security.

Biosecurity companies tackle some very complex scientific puzzles, which are no less challenging than those faced by the biopharmaceutical sector as a whole but face a much more limited market. The medical countermeasures enterprise represents the government's commitment to develop and procure the products necessary to protect our national interests and encourage further innovation by the private sector. A combined and concerted effort among government agencies has greatly improved our preparedness capabilities over the last decade, but as these programs must evolve to ensure that they continue to function efficiently.

Given that MCMs are essential to our national security and that private sector partners play a critical role in their development, the contracting process must be expeditious. Government funded projects progress at a slower pace than privately funded ones due to unpredictable funding and a lengthy contracting process. Subtitle H of the *21<sup>st</sup> Century Cures* bill addresses this concern by taking steps to make the contracting process more transparent, predictable, and flexible and by removing the requirement that OMB review all contracts already approved and funded by HHS. These reforms will speed up the procurement process and facilitate the public private partnerships necessary for countermeasure development.

The Medical Countermeasures Innovation section of the bill also encourages private sector development of MCMs by including the material threats identified by the Department of Homeland Security in a Priority Review Voucher program. This model has proved successful in encouraging the development of vaccines and therapeutics for neglected tropical diseases and rare pediatric diseases and its application to MCMs for material threats is an important step toward ensuring necessary products are developed,

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approved, and stockpiled for use in a potential disease outbreak or chemical, biological, radiological and nuclear (CBRN) attack.

The Alliance for Biosecurity strongly supports the passage of the revised version of the *21<sup>st</sup> Century Cures Act* and the inclusion of the Medical Countermeasures Innovation section (Subtitle H) that will help improve these critical programs that contribute to greater public health security and ensure preparedness against CBRN threats. If you should have any questions please contact Maureen Hardwick (202-230-5133, [Maureen.Hardwick@dbr.com](mailto:Maureen.Hardwick@dbr.com)).

Respectfully,



Maureen Donahue Hardwick  
Alliance for Biosecurity Secretariat and Legal Counsel

cc: *The Honorable Paul Ryan, Speaker of the U.S. House of Representatives*  
*The Honorable Nancy Pelosi, Minority Leader of the United States House of Representatives*