



DEPARTMENT OF THE ARMY  
JOINT PROGRAM EXECUTIVE OFFICE  
FOR CHEMICAL AND BIOLOGICAL DEFENSE  
5101 HOADLEY ROAD  
ABERDEEN PROVING GROUND, MD 21010-5424



APR 01 2016

The Honorable Susan W. Brooks  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Congresswoman Brooks,

Thank you for your letter requesting my perspective as the Joint Program Executive Officer for Chemical and Biological Defense regarding Food and Drug Administration (FDA) priority review vouchers. I appreciate hearing from you on this important aspect of facilitating and expediting development of medical countermeasures.

I support establishing a new priority review voucher (PRV) program for medical countermeasures for items on the Department of Homeland Security (DHS) Material Threat List. I believe such a program will incentivize investment and partnership, thereby benefiting the Department of Defense (DoD) in the advanced development of products that are essential to the Warfighter. Today there are few economic or regulatory incentives to encourage industry to innovate in the chemical and biological defense medical countermeasure market space. In general, chemical and biological defense medical countermeasures will be utilized in rare, emergency situations and, accordingly, the market for product sales is unlikely to yield a high return-on-investment. A new PRV program can inspire additional innovation in this market and greatly enhance the DoD's ability to rapidly deliver certain medical treatments and prophylaxis to the warfighter.

Because this issue is so important to my mission space, I have been in discussions, along with my DoD leadership, with House Armed Services Committee staff to determine the best approach to getting a PRV program specifically for DoD's validated chemical and biological threat list. Although the DHS' materiel threat list overlaps to a large degree with DoD's validated chemical and biological threat list, there are some differences based on the distinct missions of DoD. Lastly, the only additional recommendation I would make is to consider adding 'prophylaxis' or 'vaccines' to 'treatments' in the title of Section 8 ("Priority Review to Encourage Treatments for National Security Threats") to affirm the point that both pre-exposure and post-exposure capabilities are required to address this tremendous threat to the Nation.

Thank you again for your letter and for your efforts to incentivize innovation.

Sincerely,

  
DOUGLAS W. BRYCE  
Joint Program Executive Officer  
for Chemical and Biological Defense