

Congress of the United States
House of Representatives
Washington, DC 20515

September 10, 2007

Secretary Michael O. Leavitt
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

We are writing to express concern with the delays in the Department's implementation of Project BioShield and its related efforts to assure National preparedness against anthrax attacks. In March 2006, you testified to the Senate Committee on Health, Education, Labor and Pensions that anthrax remains a top threat and priority for your Department. Yet six years after the 2001 anthrax mail attacks, there remains a serious shortage of the types and quantities of medical countermeasures that could protect the American people from another attack.

An existing mandate requires the Department to procure enough vaccine to inoculate 25 million people and maintain 200,000 doses of anthrax therapeutics. However, in December 2006, the Department terminated its contract with VaxGen to procure 75 million doses of rPA vaccine. We discussed this issue with Department officials during an April 18, 2007, hearing held by the Committee on Homeland Security's Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, and we remain concerned that this cancellation impedes development work and sends the wrong signal to private sector companies who would seek contracts under BioShield. Unfortunately, at least three companies – VaxGen, Acambis, and Hollis Eden – have already made decisions to exit the biodefense market. Some of companies have told us that the Department's inability to effectively manage contracts have caused them to reconsider participating in Project BioShield.


Without the timely issuance of RFPs and significant contract awards, there will be few countermeasures to procure in the mid- and long-term. The Department recently issued a pre-solicitation notice for rPA vaccine (SS-DHHS-BARDA-07-01) which was posted on May 14, 2007, and closed on June 11, 2007. We ask that you please provide the Committee with your preliminary assessment of the efficacy of this notice. How many responses did the Department receive? Do you believe that procurement may come soon? Do you have a timeline for issuing an RFI or an RFP?

We are also concerned about the impact that the Department's implementation plan will have on the procurement of anthrax antitoxins. On April 18, 2006, the

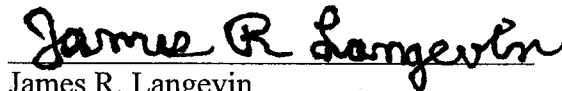
Department released its implementation plan for the development of countermeasures against biological, chemical and radiological threats. This implementation plan makes both anthrax vaccine and broad spectrum antibiotics a near-term acquisition goal. The implementation plan, however, delays the next round of acquisitions for anthrax antitoxins, a type of countermeasure that could counter multi-drug resistant anthrax, until at least Fiscal Year 2009 and perhaps as late as Fiscal Year 2013. We believe that given the Department's history of delays in essential procurements, and widely documented problems in communications and transparency, the Department must pursue a more aggressive timeline for preparedness against an anthrax attack.

We look forward to discussing this issue with you further. Please contact Dr. Chris Beck, of the Committee on Homeland Security, at 202-226-2616 if you have questions. We request a response in writing by no later than October 10, 2007.

Sincerely,



Bennie G. Thompson
Chairman
Committee on Homeland Security



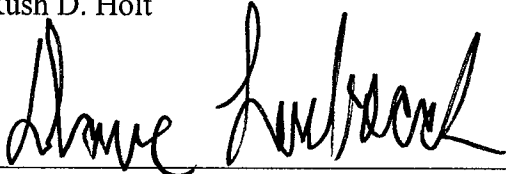
James R. Langevin
Chairman
Subcommittee on Emerging Threats,
Cybersecurity, Science and Technology
Committee on Homeland Security



Rush D. Holt



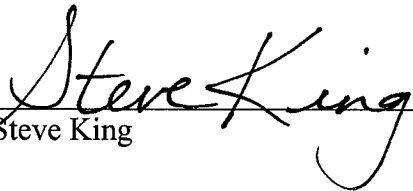
Leonard L. Boswell



David Loebbeck



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