

Alliance for Biosecurity

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November 27, 2009

Secretary Janet Napolitano
Department of Homeland Security
U.S. Department of Homeland Security
Washington, DC 20528

Dear Secretary Napolitano,

We write on behalf of the Alliance for Biosecurity to express support for the "Proposed Guidance for Protecting Responders' Health During the First Week Following a Wide-Area Anthrax Attack" (Docket No. DHS-2009-0091) published in the Federal Register on October 27, 2009. The DHS Guidance contains sound recommendations for protecting first responders; the Alliance supports these recommendations, and we commend the Department of Homeland Security for being proactive and thoughtful in this area.

The events of 9-11 demonstrated the extraordinary professionalism of the U.S. first responder community. The dedication of these individuals is such that in the event of a wide-area anthrax attack first responders are likely to expose themselves to considerable dangers in performing their duties. It is essential that the final DHS guidance establishes practices that ensure every effort to adequately protect these individuals is undertaken.

Ensuring that first responders are adequately protected in the event of an anthrax event requires thorough planning and preparation well in advance of the event, as well as availability of medical countermeasures and other tools. With respect to planning, the proposed guidance makes a significant contribution to local authorities' efforts to plan for a potential anthrax event. With respect to advance preparation, the proposed guidance notes correctly that it is critical that first responders have voluntary access to pre-exposure prophylaxis (PEP) such as vaccination prior to any anthrax event, and access to vaccines and antibiotics for prophylactic and treatment purposes during an event.

We also note below five issues that we believe should be considered by DHS when formulating policy guidelines designed to protect first responders and others from anthrax and other biological agents.

First, in designing policies to protect first responders and other Americans from anthrax, DHS should, after consultation with appropriate public health authorities, consider recommending not only vaccines and antibiotics, but also monoclonal or polyclonal antibodies and anti-toxins. Combined with vaccines and antibiotics, these countermeasures represent the full arsenal of tools that could be made available to protect and treat first responders. Relying on only some of these tools may risk leaving first responders vulnerable under several possible anthrax use scenarios, such as an attack with an anthrax strain developed to be antibiotic-resistant.

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Second, we support the proposed Guidance's recommendation that voluntary anthrax vaccination be available to first responders. We further suggest that the proposed Guidance's anthrax vaccine recommendations be strengthened, assuming CDC supports the clinical rationale for doing so. First responders, particularly members of Tier 1 and 2, will be at significantly elevated risk for exposure to anthrax, and we believe that a vaccinated responder community is critical to ensuring continuity of operations in the event of an anthrax attack. Furthermore, we believe that voluntary vaccination should be available to first responders just as it is to WMD-CST teams. Given the confusion and disruption that will be associated with a wide-area anthrax attack every effort to prepare first responders and other critical personnel in advance of an attack is essential. We would also note that expiring anthrax vaccine doses in the Strategic National Stockpile may represent a missed opportunity to leverage U.S. biosecurity preparations. Instead of being allowed to expire, these already-purchased doses could be used to provide voluntary vaccination to first responders.

Third, we recommend that the final guidance (perhaps in the form of an Appendix) provide additional information on anthrax vaccination. State and local authorities often lack up-to-date data on anthrax vaccination – for example, most states' anthrax guidance indicates, inaccurately, that a vaccine is not available – and DHS can address this challenge by including relevant information in its Guidance. Similarly, we recommend that emergency responder training provided by DHS include a course on the uses of anthrax vaccine.

Fourth, we recommend periodic review by the Department of Homeland Security of the final Guidance to assess the status of existing knowledge to determine whether updated guidance on protecting first responders during a wide-area anthrax attack is necessary.

Fifth, U.S. government funding for research and development of new countermeasures has been inadequate, and the country has a shortage of needed medical countermeasures as a result. DHS has made material threat determinations for several threat agents, but many of the corresponding countermeasures have not yet been sought by the government and therefore have not been fully developed by industry. If there is an event involving one of these agents, authorities will be extremely limited in their ability to protect the health of first responders. The Alliance for Biosecurity urges increased investment in research and development on medical countermeasures, so as to ensure that first responders and others can be protected from the full range of DHS-identified biological threats.

The Alliance for Biosecurity is a collaboration of pharmaceutical companies and biotechnology companies working to develop vaccines and medicines for our nation's Strategic National Stockpile. The Alliance mission is to work in the public interest to promote a robust and sustainable research and development infrastructure necessary to prevent and treat the infectious disease threats that present security challenges in the 21st Century.

It is critically important that DHS and other federal agencies involved in security and public health provide education and direction to local authorities on preparation and planning for chemical, biological, radiological, and nuclear (CBRN) threats, including the threat of anthrax. The Alliance for Biosecurity thanks DHS for taking action to assist local authorities in disaster preparation, and we support the proposed guidance.

Respectfully submitted on behalf of the Alliance,



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