Choking BioShield: The Department of Homeland Security’s Stranglehold on Biodefense Vaccine Development
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One of the bright milestones toward the development of a vibrant biodefense vaccine industry was the passage of the Project BioShield Act of 2004. That statute was designed “to provide protections and countermeasures against chemical, radiological, or nuclear agents that may be used in a terrorist attack against the United States.” The most prominent parts of that legislation were its procurement provisions designed to address the key significant impediment to biodefense vaccine production – lack of a significant market. These provisions encourage the development of effective vaccine countermeasures by establishing the Special Reserve Fund of $5.6 billion to be spent over ten years to purchase for the nation’s Strategic National Stockpile (SNS) the “next generation of countermeasures against” a broad array of chemical, biological, radiological, and nuclear [CBRN] agents, all of which were seen by Congress as weapons that could be deployed against the United States in the War on Terror. Due to the substantial expense and risk of bringing a vaccine to market, along with the infrequency with which these diseases occur naturally, pharmaceutical manufacturers have little to no incentive to invest without BioShield funds.

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In order for a portion of the BioShield Special Reserve Fund to be released for the purchase of a countermeasure for SNS, a series of actions must occur. The first action, however, (and the one on which all later actions are based) is that “the Homeland Security [DHS] Secretary, in consultation with the [Health and Human Services (HHS)] Secretary and the heads of other agencies as appropriate,” must make a “determination” of “current and emerging threats of CBRN agents” that “present a material threat against the United States . . .” Once that “material threat assessment” is made, various government agencies, up to and including the President, through a series of decisions, then determine whether promising countermeasures may be purchased with the Special Reserve Fund to address those identified threats.

The BioShield Act established no procedure for DHS to employ in supervising the making of the material threat determinations. Despite what was an obvious Congressional invitation to determine summarily what are widely recognized to be dozens of CBRN threats to the United States, DHS has employed an opaque, bureaucratized, lengthy process for determining material threats. Since the statute’s passage, DHS has made only the following four material threat determinations: anthrax, smallpox, botulinum toxin, and radiological/nuclear devices. At a July 12, 2005 Congressional hearing, DHS officials promised that by the close of the 2005 fiscal year (September 30, 2005), additional material threat determinations would be

made concerning plague, tularemia, and viral hemorrhagic fevers. As of December 20, 2005, well into the 2006 government fiscal year, however, no further material threat determinations have been made beyond the original four.

Because there have only been material threat determinations pertaining to four CBRN agents, BioShield’s Special Reserve Fund can only be used for countermeasures directed to those agents. Accordingly, only three contracts have been let using the Special Reserve Fund since BioShield’s enactment in July 2004 – two directed to the purchase of anthrax vaccines and one for the delivery of pediatric doses of liquid potassium iodide (to be used in the event of the release of radioactive iodine). Even if a promising countermeasure were to meet the other requirements for purchase under the statute, it would be ineligible for procurement if there were no corresponding finding that the agent to which it was directed was a “material threat.”

DHS’ lassitude in supervising the making of material threat findings is mystifying. The legislative history of the statute is replete with references to a myriad of agents, beyond the four agents now identified, posing a substantial threat to the United States. Moreover, the Center for Disease Control and Prevention (CDC) has a long established and widely recognized hierarchy of highly damaging biological agents that are likely to be deployed by terrorists against the United States. CDC’s Category A agents, ranked as the most dangerous to the United States,

11 Id.
include anthrax, botulism, plague, smallpox, tularemia, and viral hemorrhagic fevers (including Ebola and Marburg). Only three of those agents have as yet been identified under the BioShield bureaucracy as posing a material threat. When one looks at the Category B and C agents identified by the CDC, there are over twenty more agents which ultimately will need to be addressed with medical countermeasures. At the rate the “material threat” findings have been made to date, it could be years before BioShield procurement funds can be used to purchase products designed to counter the as yet undesignated agents.

Leaving the CDC’s findings to the side, scholarship on terrorist threats abound with long standing and well recognized findings about a significant number of CBRN agents likely to be deployed against the United States. Jessica Stern, for example, in her 1999 classic, The Ultimate Terrorists, lists two dozen chemical agents that have been historically deployed by terrorists going all the way back to World War I. Not one of these chemical agents has been certified under DHS’ leadership. Nor has DHS even committed to making such designations in the future.

Quite ironically, under other provisions of the BioShield statute concerning HHS funding for research (which does not require a “material threat” finding), grants have been made for the development of countermeasures relating to tularemia, Ebola, and plague. Yet, none of these agents has yet been designated as a material threat. If HHS has already commenced funding for research in this area, one would assume that there is substantial evidence available to DHS demonstrating that these agents should be so designated.

Substantial National Institutes of Health (NIH) funding outside of the BioShield appropriations is being committed to the development of medical countermeasures for agents not

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yet declared to be “material threats.” For example, the Mid-Atlantic Regional Center of Excellence for Biodefense and Emerging Infectious Diseases is researching countermeasures for tularemia as part of a five-year grant from the National Institute of Allergy and Infectious Diseases, which is supported by funding wholly apart from monies appropriated under the BioShield statute. Simultaneously, plague vaccine research is being performed by the University of Maryland School of Medicine’s Center for Vaccine Development that is funded by an NIH U19 grant, again a project being done wholly apart from the BioShield Act.

The BioShield Act is an impressive starting point for the creation of a vibrant biodefense vaccine industry. It has many problems that must be corrected both administratively and legislatively, however. Certainly, foremost among those problems is DHS’ bureaucratic quagmire in identifying CBRN agents posing a material threat to the United States (thereby delaying the use of procurement efforts for well recognized CBRN dangers to this country).

No legislative fix is needed. What is required is aggressive Congressional prodding to have DHS abandon its unnecessary administrative morass. It requires directing the agency to follow the well worn path already trodden through scholarship and the work of the CDC to list quickly the full panoply of CBRN agents as material threats. Such an expedited effort would be an encouragement to both researchers and the vaccine industry that a broad array of efforts might be funded over the next decade by the BioShield Special Reserve Fund.

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18 Center for Vaccine Development, Nataro Lab, University of Maryland School of Medicine, http://medschool.umaryland.edu/cvd/natarolab/natarolab.html (last visited Nov. 30, 2005).
Finally, it should be noted that the legislation introduced in April 2005 as a corrective to the BioShield Act (S. 975, or the Project BioShield II Act of 2005) places the major procurement responsibility principally in the hands of DHS, reducing substantially the role of HHS. Supposedly, this displacement is in reaction to industry supporters of BioShield II who view “HHS as having a contentious relationship with the biopharma industry.” However, given the difficulties DHS has had with effectively carrying out its single major mission under the existing legislation, Congress should think long and hard before it puts the entire biodefense vaccine apparatus under DHS.

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21 Id. at 2.