



Decades of lonely lament by public health advocates about the state of the vaccine industry are now over. Suddenly (since the tragedy of September 11 and scary reports from chicken farms in Southeast Asia), Washington insiders are bemoaning the industry's tribulations as well. Republicans and Democrats alike seem to want pharmaceutical and biotech industries to use some of their expertise creating vaccines against anthrax, smallpox and AIDS, not to mention making sufficient quantity of usable flu shots.

**THE BIOTERROR–INFECTIOUS DISEASE CONNECTION**

Four years ago, the US government responded to newly perceived bioterror threats with impressive alacrity, ramping up spending at NIH, procuring quantities of vaccines and making it easier to cut around red tape to get the work done. Last year Congress passed Project Bioshield which authorized \$5.6 billion to buy bioterror “countermeasures” (including vaccines). A principal goal of the legislation was to demonstrate to industry that a paying market exists for bioterror products. But company representatives and others said it was not enough to overcome the considerable disincentives for private investment in countermeasures.

This year, US Senator Joe Lieberman from Connecticut and his staffer, Chuck Ludlam, set to work on second generation legislation—Bioshield II. The Lieberman office was wise to recognize that the real problem is not just about getting industry engaged in bioterror, it's about addressing longstanding market breakdown in the vaccine and other health technology fields and marshalling private sector know-how in the biggest public health battles of the day. AVAC and a large group of public health advocacy organizations were very happy that Bioshield II included an array of incentives for infectious disease products like AIDS vaccines, along with countermeasures against weapons of terror.

The term “kitchen sink” could have been invented for Bioshield II. This legislation incorporates most of the industry-stimulating ideas that have been floating around for several years. These include expanded procurement programs, a selection of five tax credits, extended patent rights and liability protections. Title IV of the bill, stunningly named “The Valley of Death” provision, would offer an array of benefits to engage small companies. The most controversial provision of the bill would grant a “patent-exchange” to companies who could swap a patent on an AIDS or anthrax vaccine for extension of their patent on a blockbuster drug like Viagra® or Lipitor®.

Bioshield II is a commendable effort and a very complex bill. (In fact, the bill summary from the Senator's office warns readers that to fully understand the bill, “one needs command of a broad range of disciplines: the science of evolving threats; zoonotic diseases and bioagriculture threats; biopharma industry economics; procurement, tax, patent, and liability law; ... regulatory policy; animal models, human clinical trials, adjuvants, and vaccine industry issues; ...antitrust, export license, and visa law; Nunn–Lugar programs...”)<sup>1</sup>

Congress should act on Bioshield II but take the time to look at the complexities and clean up the loose ends. We have a few concerns.

First, lawmakers need to review the legislation to make sure it would not inhibit rapid global delivery of the infectious disease products whose creation it seeks to stimulate. Provisions like the extended market exclusivity period may not have a negative impact on access to AIDS vaccines because, due to the technological complexity involved, these products are not likely to go generic soon after licensure. The story is different with urgently needed drugs to treat global infectious diseases. If applied to global markets, schemes like an extended market exclusivity period may keep prices high and delay widespread



access to the product unless other measures—such as voluntary licensing, price tiering, increased purchase capacity and access to approved generics—are in place.

Our understanding is that the liability protection provisions in Bioshield II would apply to claimed injuries during clinical trials. This is an important protection for AIDS vaccine makers, and it should stay in the bill. Some kind of administrative system is needed, similar to that now in place for marketed childhood vaccines, that reviews the liability claims of trial volunteers and provides compensation where justified. Still, we encourage lawmakers to make sure liability protection for industry is not overly broad. For example, we have been told that, under the bill, if vaccine makers are found “negligent,” victims would be compensated by the

government rather than the company. We are not sure that expansive level of corporate protection is justified.

Finally, the patent exchange provision is perhaps the bill’s most potent incentive for industry, but it’s a political nonstarter. It might have a place in a world in which seniors and others don’t have to empty their pocketbooks to buy expensive on-patent drugs. Removal of the provision will make the bill less of a political liability for would-be supporters.

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SIDEBAR FOOTNOTES

<sup>1</sup> Office of Senator Joe Lieberman, Bioshield II, S.975; Section by Section

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**FOR MORE INFORMATION**

- + Bioshield II, Senate Bill 975 can be found online at <http://thomas.loc.gov>
- + The section by section description of the bill is online at <http://lieberman.senate.gov/newsroom/reports/bioshieldsectionbysection.pdf>