

BioShield II: One Step Forward, One Step Back?

— by Paul Ferrari —

After a flurry of activity throughout the summer and fall of 2005, Congress adjourned in late December without passing a new, comprehensive BioShield II legislative package to induce broader industry participation in the development of medical countermeasures for use in response to chemical, biological, radiological, or nuclear (CBRN) attacks against the United States. Companies engaged in CBRN countermeasure development received a significant incentive, however, in the form of the Public Readiness and Emergency Preparedness Act of 2005,¹ which was signed into law on December 30, 2005, and provides sweeping liability protections.

BioShield I

Several BioShield II bills were introduced in Congress in 2005 with the goal of improving upon the Project BioShield Act of 2004 (BioShield I).² BioShield I amended the Public Health Service Act³ and the Federal Food, Drug, and Cosmetic Act (FDCA)⁴ to provide industry with incentives to take on the risks inherent in developing new CBRN medical countermeasures. Most prominently, BioShield I:

- authorizes the appropriation of \$5.593 billion for fiscal years 2004 through 2013 for the procurement of “security countermeasures”⁵ for the Strategic National Stockpile (SNS) and authorizes the procurement of countermeasures not yet approved, licensed, or cleared by the Food and Drug Administration (FDA);
- simplifies the National Institutes of Health’s (NIH) procedures for reviewing proposals and issuing grants and contracts for qualified countermeasure research and development (R&D);



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- grants FDA the ability to authorize the interim emergency use of investigational drugs, biological products, and devices to respond to CBRN emergencies; and
- provides streamlined government contracting procedures to accelerate the acquisition of CBRN countermeasures for the SNS.

The U.S. government has channeled its efforts primarily into developing therapeutics and vaccines for use against biological agents thought to pose the most immediate threats because of their virulent effects, their ability to spread rapidly through the population, or because they have been used already in terrorist attacks. Priority under BioShield I has been given, therefore, to developing next-generation countermeasures for biological agents such as anthrax, smallpox, botulinum toxin, Ebola virus, pneumonic plague, and tularemia. Less emphasis has been placed on developing countermeasures for chemical, radiological, or nuclear threats, but the Department of Health and Human Services (HHS) has purchased existing medical products for the SNS with nonBioShield funds to counter some of these threats.

HHS has issued only three procurement contracts using BioShield I funds: 1) an \$877.5 million contract to VaxGen Inc. for 75 million doses of a purified recombinant protective antigen anthrax vaccine, which still is under development, 2) a \$122.7 million contract to BioPort Corporation for five million doses of an adsorbed anthrax vaccine, and 3) a \$5.7 million contract to Fleming & Company for 1.7 million pediatric doses of a liquid potassium iodide drug for treatment of exposure to radioactive iodide.

BioShield I has failed to produce its desired effect, however, as only a relatively limited number of small companies currently are developing CBRN countermeasures. Critics of BioShield I identify four reasons for industry’s reticence to invest resources in the CBRN countermeasures market.

First, the government’s decisionmaking process is time consuming and opaque. HHS is responsible for administering the BioShield program, but the commitment of procure-

ment funds requires a complicated and lengthy series of “material threat” assessments and findings involving the Department of Homeland Security (DHS), HHS, and the White House.

Second, BioShield funds cannot be used to support R&D efforts. Procurement payments can be made only upon delivery of the final product. Therefore, even if a company receives NIH funding for early research efforts and later secures a BioShield procurement contract, it still must absorb all intervening development, product approval, and production ramp-up costs, creating a funding void that some have called a “valley of death.”

Third, companies that have not received procurement contracts but that continue to develop CBRN countermeasures on their own lack any assurance that the government will ever procure their products in quantities sufficient to allow for a reasonable return on their investments. This is particularly troublesome because meaningful commercial markets for most CBRN countermeasures do not exist.

Fourth, BioShield I fails to provide liability protection against lawsuits that might be brought by individuals treated with CBRN countermeasures. Companies have been especially concerned about liability exposure because clinical studies cannot be conducted for ethical reasons for most CBRN countermeasures, and FDA approval will rest largely on animal data. In addition, some of the products that are procured for the SNS will not even have been approved, licensed, or cleared by FDA before being stockpiled and perhaps used in emergencies.

BioShield II

Of all of last year’s BioShield II bills, one introduced in January 2005 by Sen. Judd Gregg (R-NH) with the backing of Senate Majority Leader Bill Frist (R-TN) (S. 3),⁶ and a second introduced by Sen. Joe Lieberman (D-CT) in April 2005 (S. 975),⁷ garnered the most attention. These two bills contain a number of mechanisms for addressing BioShield I’s shortcomings. Both propose limited tort liability reforms, tax credits for R&D activities and manufacturing capacity investments, and exemptions from existing antitrust laws to facilitate more direct communications between industry and government.

S. 975 calls for lengthening the periods of marketing exclusivity available for eligible approved CBRN products beyond what currently is provided for under the FDCA. Both S. 3 and S. 975 contain provisions to restore more of a countermeasure’s patent life that is lost to product development and to FDA’s product review cycle than now

is available under the FDCA and the Patent Act of 1952.⁸ Most controversially, S. 975 also includes novel provisions that could provide a company that successfully develops an FDA-approved CBRN countermeasure an additional six months to two years worth of patent extension, either for the countermeasure itself, or for any other drug in the company’s portfolio. Some observers believe that as written, S. 3 will accomplish the same result.

Sen. Richard Burr (R-NC), Chairman of the Subcommittee on Bioterrorism and Public Health Preparedness of the Committee on Health, Education, Labor, and Pensions (HELP Committee), reconciled the various BioShield II bills into a single bill that he introduced on October 17, 2005 (S. 1873).⁹ S. 1873 cleared the HELP Committee on October 24, 2005, but moved no further.

S. 1873 would create a Biomedical Advanced Research and Development Agency (BARDA) headed by a bioterrorism czar reporting directly to the Secretary of HHS. BARDA would serve as the focal point of authority for the federal government’s entire CBRN countermeasure advanced R&D efforts and also would oversee the development of vaccines to respond to naturally-occurring epidemic/pandemic infectious disease outbreaks (e.g., avian influenza). The inner workings of BARDA and all related entities would be shielded from public scrutiny and disclosure normally available under the Federal Advisory Committee and Freedom of Information Acts. BARDA initially would be funded with \$1 billion from monies appropriated under BioShield I. The reconciliation bill also attempts to bridge the “valley of death” by giving the Secretary of HHS discretionary authority to make progress payments of up to 25% of a contract’s total value, provided predetermined milestones are met.

S. 1873 also includes provisions comparable to some of those contained in the S. 3 and S. 975 bills. It creates, for example, exemptions from current antitrust laws, and provides grants to spur increased CBRN and epidemic/pandemic countermeasure R&D and production efforts and rebates to encourage investment in manufacturing surge capacities. S. 1873 also extends liability protections to manufacturers, distributors, state and local administrators, and healthcare providers against lawsuits arising from the use of qualified security countermeasures or epidemic/pandemic products, provided that the harm is not the result of willful violations of the law, and calls for the creation of a fund to compensate healthcare workers and emergency first responders who might be harmed as the result of the administration of epidemic/pandemic or CBRN countermeasures.

Sen. Burr dropped the patent restoration and extension provisions contained in the S. 3 and S. 975 bills, yielding to stiff opposition from the generic drug industry, the drug benefits management industry, and nonpharmaceutical companies concerned with containing escalating employee and retiree healthcare costs. S. 1873 holds forth the possibility, however, that a CBRN drug or biological countermeasure could be granted orphan drug status and thus could receive 10 years of marketing exclusivity instead of the seven years now available under section 527 of the FDCA.¹⁰ The Secretary of HHS would have to determine that the countermeasure is “a priority ... to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent (including organisms that cause an infectious disease) or toxin identified as a material threat” by the Secretary of HHS, in which case the countermeasure would be considered necessary to treat a “rare disease or condition” within the meaning of section 526 of the FDCA.¹¹

PREP Act of 2005

Although Congress was unable to pass BioShield II legislation in 2005, companies involved in CBRN countermeasure development and production received a considerable measure of relief with the 11th-hour enactment of the Public Readiness and Emergency Preparedness Act of 2005 (PREP Act),¹² which had its genesis in Congress’ year-end preoccupation with addressing the possibility of an avian influenza pandemic and incorporates many of the liability provisions from S. 1873.

The PREP Act grants immunity to manufacturers and distributors of covered epidemic/pandemic and CBRN countermeasures,¹³ state and local officials and related entities responsible for directing the distribution and use of the countermeasures, and persons qualified to prescribe, administer, or dispense the products from “all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure,”¹⁴ provided that the Secretary of HHS first declares that a grant of immunity is necessary.¹⁵ The Secretary’s declaration must be based on a determination that “a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency.”¹⁶ The declaration must specify the particular diseases, conditions, or threats, and the particular countermeasure or countermeasures affected by the grant of immunity.¹⁷ The Secretary also

must specify the period of time during which the immunity attaches, the populations of people eligible to receive the covered countermeasure, and the geographic area or areas of the country in which the products can be distributed, used, and administered under the protection of the liability umbrella.¹⁸

The scope of the PREP Act’s immunity provision is sweeping. It “applies to any claim for loss that has a causal relationship with the administration to or use” of a covered product, “including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.”¹⁹ The PREP Act also exempts the Secretary’s declarations of the need for liability protection from judicial review and preempts all state laws.²⁰

Individuals harmed by the administration or use of a qualified countermeasure can overcome the PREP Act’s immunity protections only if they can prove by “clear and convincing evidence” that the offending party engaged in “willful misconduct.”²¹ Willful misconduct is defined as “an act or omission that is taken (i) intentionally to achieve a wrongful purpose, (ii) knowingly without legal or factual justification; and (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.”²² The PREP Act also empowers the Secretary to issue an interim final rule to restrict the definition of willful misconduct even further.²³

Individuals cannot bring a lawsuit against a manufacturer or distributor if the alleged action or omission is regulated by the PREP Act or by the FDCA, and if neither the Secretary of HHS nor the U.S. Attorney General initiates an enforcement action against the manufacturer or distributor, or if an enforcement action is initiated, but is terminated or resolved without resort to final, formal action, such as a criminal prosecution, an injunction, a product recall, repair, or replacement, a debarment, or a suspension or revocation of an approval, license, or clearance.²⁴ In essence, plaintiffs are barred from bringing a suit unless either FDA or the Department of Justice first determines that an act of willful misconduct has occurred.

If a potential plaintiff clears these hurdles, the only available legal recourse is a newly-created federal cause of action “for death or serious physical injury proximately caused by willful misconduct.”²⁵ All lawsuits must be filed in the U.S. District Court for the District of Columbia.²⁶ The PREP

Act directs that the plaintiff's first stop must be before a three-judge panel, which will rule on any motions to dismiss or motions for summary judgment,²⁷ which effectively empowers the panel to determine in each instance whether the plaintiff has met the demanding "willful misconduct" standard, and only those cases that do will be assigned to a trial judge. If the panel dismisses the lawsuit for failing to meet the "willful misconduct" standard, the plaintiff can be assessed the defendant's legal fees and expenses.²⁸

Finally, the PREP Act directs that a fund will be created to compensate individuals suffering injuries directly caused by the administration or use of qualified countermeasures during a period in which the PREP Act's immunity provisions are in effect.²⁹ Congress is to provide the necessary funds on an emergency appropriations basis,³⁰ and the PREP Act directs the Secretary to issue regulations when appropriate to define the types of injuries eligible for compensation, the value of the compensation to be provided, and the procedures that are to be followed in administering the fund.³¹ Accepting compensation from the fund will preclude an individual from later filing a lawsuit under the PREP Act.³² Any actions taken by the Secretary related to the compensation fund will be exempted from judicial review.³³

The Road Ahead

The PREP Act's liability protections will provide companies engaged in the development and production of CBRN countermeasures with welcome and necessary relief. Whether this alone will induce industry to initiate new CBRN countermeasure development projects, however, is questionable. Nothing has been done to streamline the government's decisionmaking processes or to make the government's actions and intentions more transparent. Nor has anything been done to address the financial risks entailed in crossing the "valley of death" alone, or in developing CBRN countermeasures without knowing whether the government eventually will purchase the products in sufficient quantities. Until these issues are addressed, industry will continue to view the government's CBRN efforts with skepticism.

The prospects for enactment of a more comprehensive BioShield II law in 2006 are uncertain, but likely better than they were last year. With the contentious issue of liability settled for the moment, passage of BioShield II legislation theoretically should be easier. BioShield II is reportedly high on the list of legislative priorities for Sens. Frist and Burr, and a revised bill most likely based on S. 1873 could be introduced as early as February or March. Even if the Senate

passes BioShield II legislation expeditiously, it is unclear how the bill will be received in the House of Representatives. The House has tended to defer to the Senate on bioterrorism issues, but all parties face the additional pressure of a shortened calendar because of the congressional November mid-term elections. Absent an intervening event such as another terrorist attack, another year could pass without any further progress on the BioShield front. Δ

¹ Pub. L. No. 109-148, 119 Stat. 2680 (Dec. 30, 2005).

² Pub. L. No. 108-276, 118 Stat. 835 (July 21, 2004).

³ 42 U.S.C. § 243 *et seq.*

⁴ 21 U.S.C. § 301 *et seq.*

⁵ A "security countermeasure" is defined as "a drug, ... biological product, ... or device ... that the Secretary [of HHS] determines to be a priority" and necessary "to treat, identify, or prevent harm from any biological, chemical, radiological, or nuclear agent identified as a material threat ... or to treat, identify, or prevent harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product or device against such an agent." 42 U.S.C. § 247d-6b(c)(1)(B).

⁶ S. 3, 109th Cong. (2005).

⁷ S. 975, 109th Cong. (2005).

⁸ 35 U.S.C. § 101 *et seq.*

⁹ S. 1873, 109th Cong. (2005).

¹⁰ 21 U.S.C. § 360cc.

¹¹ S. 1873, § 5(a), 109th Cong. (2005); 21 U.S.C. § 360bb.

¹² Pub. L. No. 109-148, 119 Stat. 2680 (Dec. 30, 2005) (reprints of Pub. L. No. 109-148 were not readily available at the time this article was written, so all citations to the statute herein refer to the final bill as enacted, H.R. 2863, Division C, 109th Cong. (2005)).

¹³ The PREP Act's definition of "covered countermeasure" includes "security countermeasures" as the term is defined by BioShield I, see *supra* note 5, as well as unapproved drugs, biological products, and devices authorized for emergency use pursuant to section 564 of the FDCA, 21 U.S.C. § 360bbb-3, H.R. 2863, § 319F-3(i)(1).

¹⁴ *Id.* § 319F-3(a)(1), (i)(2).

¹⁵ *Id.* § 319F-3(b)(1).

¹⁶ *Id.*

¹⁷ *Id.* § 319F-3(b)(1), (2)(A).

¹⁸ *Id.* § 319F-3(b)(2)(B)-(D).

¹⁹ *Id.* § 319F-3(a)(2)(B).

²⁰ *Id.* § 319F-3(b)(7).

²¹ *Id.* § 319F-3(d)(1).

²² *Id.* § 319F-3(c)(1)(A).

²³ *Id.* § 319F-3(c)(2).

²⁴ *Id.* § 319F-3(c)(5).

²⁵ *Id.* § 319F-3(d)(1).

²⁶ *Id.* § 319F-3(e)(1).

²⁷ *Id.* § 319F-3(e)(5).

²⁸ *Id.* § 319F-3(e)(9).

²⁹ *Id.* § 319F-4(a).

³⁰ *Id.*

³¹ *Id.* § 319F-4(b)(4)-(5).

³² *Id.* § 319F-4(d)(5).

³³ *Id.* § 319F-4(b)(5)(C).

