From BioShield To The PREP Act And Beyond: Developing A Market For Infectious Disease And Bioterror Countermeasures

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McKenna Long & Aldridge LLP has had the privilege over the last few years of taking a leading role in the development of a market for infectious disease and bioterror countermeasures to protect the health of the public in the United States and abroad. Since even before President Bush's 2003 State of the Union speech in which he called for Project BioShield legislation to protect the population from public health disasters and attacks, we have worked with leading pharmaceutical, vaccine, biotechnology, diagnostic, and defense technology companies, the U.S. Congress and Administration officials, and the financial community to assist in developing a working market to supply countermeasures to governments. This article briefly reviews some of the latest occurrences in this field and how legislation and legal government affairs work are helping to make a true "bioshield" a reality.

The market for countermeasures goes beyond the borders of the United States. The global nature of infectious diseases such as avian flu and SARS and the war on terror, combined with the strategic partnerships of the United States, underscores the "no limits" nature of the public health and biodefense market. As the European Union is still working on finding a coordinated approach to these threats, officials from both the U.S. and EU are calling for greater US-EU cooperation in the areas of bioterrorism countermeasures and public health disasters, as stated at the Transatlantic Conference on Biosecurity in June 2005. As U.S. companies face European competition, the growing demand for medical countermeasures and detection/rapid-response technologies will most likely ensure an expansion of the existing customer base and emerging markets for U.S. biodefense companies.

Reorientation Of Biomedical Companies Toward Biodefense Market

Our firm has witnessed a significant shift of biomedical companies toward the biodefense area. Companies with platform technologies founded originally with the goal of developing therapies for cancer, hypertension, heart disease or against non-bioterror agents are now seeking biodefense funding from governments and are applying their technologies to the growing field of counter-bioterrorism.

Most companies pursuing government opportunities in the biodefense field find that they need expert legal counsel in the fields of government contracting and government affairs. Aside from these basic concerns, the unfamiliarity of many of these companies with export control – especially with deemed export rules – will also lead to more need for legal counsel in this area, especially since the Department of Commerce has pledged to focus its enforcement activities on life sciences. The magnitude of the work yet to be done is underscored by the estimate that more than 300 organizations comprising more than 12,000 individuals work now in biodefense and have access to biological agents with biowarfare/bioterror applications.

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Increasing Government Demand For Biodefense And Public Health Protection

The Project BioShield statute was signed into law in July 2004. BioShield was devised as a $5.6 billion, 10-year term procurement mechanism to finance the stockpiling of biological, chemical, nuclear and radiological countermeasures.

The process of BioShield procurement starts with the Department of Homeland Security (DHS) issuing a Material Threat Determination (MTD) in order to prioritize ongoing biodefense activities, including subsequent rounds of BioShield acquisitions. The MTD is the basis of the assessment of public health consequences issued by the Department of Health and Human Services (HHS) regarding the need for countermeasures in order to define requirements and release Requests for Proposals (RFPs). MTDs have been issued for four agents: anthrax, smallpox, botulinum toxin, and radiological/nuclear devices. DHS is currently working on MTDs for plague, tularemia, toxic industrial chemicals, radiological devices, chemical nerve agents, and hemorrhagic fever viruses.

According to the July 12, 2005 testimony of Dr. John Vitko, Jr., Director, Biological Countermeasures Portfolio, S&T Directorate at DHS, DHS will release MTDs in the winter of 2006 for all six Category A agents from the Centers for Disease Control (CDC) threat list; all 12 Category B agents; five representative Category C agents, and a number of candidate drug-resistant and emerging threats. These MTDs will provide many opportunities for biodefense companies to tap into BioShield funding.

Most of the homeland security R&D allocation goes to the National Institute of Allergy and Infectious Disease's (NIAID) biodefense work consisting of basic research and preclinical development. An estimated $10 million in FY05 supported development of countermeasures for Category A threat agents. In addition, NIAID expanded its network of university research hospital-based sites (so-called Vaccine Treatment and Evaluation Units or VTEU) conducting clinical trials of promising vaccine candidates and therapies for infectious diseases. Since 9/11, CDC has also received substantial capacity upgrades and increased funding for biodefense research. Upcoming RFPs will provide federal funding for upgrading or retrofitting existing manufacturing facilities for certain vaccines produced in the private sector.

Since its creation in 2003, DHS has spent an estimated $5 billion on civilian biodefense. Modeled after DARPA, the Homeland Security Advanced Research Projects Agency (HSARPA) is actively involved in funding late stage countermeasures development. HSARPA also joined the Small Business Innovative Research (SBIR) program and pledged two solicitations per fiscal year.

A third major player is the Department of Defense (DOD) with an estimated $1.1 billion spent on civilian biodefense efforts since FY01. Traditionally oriented toward protecting the war fighter, that distinction is no longer clear considering the many efforts undertaken to protect homeland security. About $1.5 billion is being sought for chembio defense in FY06 and the recently released Quadrennial Defense Review also projects $2.1 billion from 2007 to 2011 for the development of medical countermeasures against chemical and biological threats including genetically engineered bioterror agents.

The Latest Building Block: The PREP Act Offers Liability Protection

On December 30, 2005, President Bush signed into law the "Public Readiness and Emergency Preparedness Act" (PREP Act) as part of the 2006 Defense Appropriations Act. Through this legislation, the U.S. Congress has provided a key tool to protect the nation from infectious diseases and other threats that could potentially cripple the U.S. and, indeed, the global economy. As a result of the PREP Act, vaccine and countermeasure developers who are seeking procurement opportunities associated with Project BioShield are now better protected from the mass of lawsuits that have basically eviscerated the U.S. vaccine and countermeasure manufacturing base, leaving it ill prepared for threats such as avian influenza.

Many companies have long shied away from developing devices, vaccines and other countermeasures against naturally occurring and man-made threats to human health because of the fear of crippling litigation and findings of liability. Following the anthrax attacks of 2001, the recognition that terrorists are actively pursuing biological and chemical weapons, and that a nightmare scenario of an uncontrollable influenza pandemic is all too realistic, the U.S. realized that it needs to control the liability threat. Without doing so, most agreed that the U.S. would leave itself unacceptably exposed to such threats.

To address the liability concerns in a responsible manner, Congress passed the PREP Act. Passage of the PREP Act is the culmination of an effort begun by McKenna Long & Aldridge in January 2002 on behalf of a number of clients. The firm has had an extensive role in assisting with both the drafting of the PREP Act and the legislative strategy that led to the passage of the Act.

The PREP Act offers targeted liability protections to those involved in the development, manufacturing and deployment of pandemic and epidemic products and security countermeasures. The Act creates a shield of immunity for claims arising out of, related to, or resulting from the administration or the use of a covered countermeasure (i.e., vaccines, countermeasures, devices and certain other products). The immunity covers a wide range of uses, including design, development, testing, manufacturing, distribution, administration, use and other activities so that the protections can be applied as broadly as possible.

The immunity created by the Act can be overcome, but only upon a showing of willful misconduct that proximately caused a serious injury or death. The Act creates a single new Federal cause of action in relation to claims arising out of the use of pandemic and epidemic products and security countermeasures. To meet the "willful misconduct" exception, a plaintiff must show that acts or omissions were undertaken to "intentionally achieve a wrongful purpose." *Most significantly, prior to any claim of willful misconduct, the Food and Drug Administration or Department of Justice MUST take and complete a specific enforcement action establishing the willful misconduct.* Plaintiffs must specifically detail their claims, and there are mandatory penalties for counsel that file a frivolous or baseless suit. If claims can proceed, there are other restrictions, such as a limit on damages and reductions for collateral benefits received by a plaintiff.

The liability protections under the PREP Act are triggered when the Secretary of HHS makes a declaration that a disease or other threat constitutes a public health emergency, or that there is a credible risk of such a threat. This flexibility allows the Secretary to be proactive and gear up the nation's infrastructure for threats that are real, but may not be occurring in the immediate future.

As a matter of policy, this legislation is expected to impact the ability of the U.S. to develop the tools it needs to be prepared for a naturally occurring or terrorist-related public health emergency. The recent media attention on avian influenza and the devastating consequence of being unprepared make clear why this legislation is so important.

Prospects For The So-Called "BioShield II"

Up next in the legislation pipeline is "BioShield II" or the Biodefense and Pandemic Vaccine and Drug Development Act of 2005 (S. 1873). Sponsored by Sen. Richard Burr (R-NC), BioShield II is designed to shortcut safety testing for new vaccines and drugs in case of a pandemic and to protect vaccine makers and the pharmaceutical industry from legal liability for vaccine injuries. The proposed bill would also create a new federal agency, the Biomedical Advanced Research and Development Agency (BARDA), that would act "as the single point of authority" to promote advanced research and development of drugs and vaccines in response to bioterrorism and natural disease outbreaks, while shielding the agency from public Freedom of Information Act (FOIA) requests. BARDA would be exempt from long-standing open records and meetings laws that apply to most government departments. This legislation is slated to be addressed in 2006.

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