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# CONGRESS ENACTS SUBSTANTIAL LIABILITY PROTECTIONS FOR PUBLIC HEALTH EMERGENCIES

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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 (H.R. 2863). Through this legislation, the United States Congress has provided a key tool to protect the nation from infectious disease and other threats that could potentially cripple the U.S. and, indeed, the global economy. Vaccine and countermeasure developers are now better protected from the mass of lawsuits that have essentially eviscerated the U.S. vaccine and countermeasure manufacturing base, leaving America ill-prepared for threats such as Avian Influenza. With the implementation of these targeted and responsible protections, the U.S. is now in a far better position to revitalize its domestic capability to produce the tools needed to secure the health and well-being of its citizens.

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. The anthrax attacks of 2001 and the all-too-realistic nightmare scenario of an uncontrollable influenza pandemic inspired Congress to take action on the liability deterrent.

The PREP Act builds on — and was informed by — similar product liability reforms, including the SAFETY Act, which is a provision of the Homeland Security Act of 2002 providing liability protection for developers and consumers of anti-terror technologies.

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In short, 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). This 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 related 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 which file frivolous or baseless suits. 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 Health and Human Services 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 prepare the nation’s infrastructure for threats that are real, but may not be occurring in the immediate future.

A number of alternative remedies are available to potential plaintiffs, such as pre-event and post-event compensation funds. These funds will provide compensation for persons who were injured by a covered countermeasure. This program has two purposes: 1) to ensure that victims do not go uncompensated, and 2) to ensure that plaintiffs’ lawyers do not abuse the American judicial system to the point where manufacturers stay away from providing countermeasures.

The PREP Act has been described by both the media and members of Congress as one of the farthest reaching piece of tort reform ever to pass into law; its protections are substantial. It will allow the U.S. to more rapidly 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 consequences of being unprepared underscore the importance of this legislation.