

## Major Liability Protections Passed to Help Protect the U.S. from Pandemic Threats

On December 30, 2005, President George W. 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. As a result of the PREP Act, vaccine and countermeasure developers 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. 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.

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 needed 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. Our 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 builds on - and was informed by - our role in similar efforts on product liability reforms, including the [SAFETY Act](#).

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

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### HOT LINKS

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### CONTACTS

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relating 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 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 gear up 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 resulting from the use of a covered countermeasure. This program has two purposes: 1) to ensure that victims do not go uncompensated, and 2) to ensure that plaintiff’s 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 the most far reaching piece of tort reform ever to pass into law. Its protections are substantial.

As a matter of policy, this legislation is expected to impact the ability of the United States 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 consequences of being unprepared make clear why this legislation is so important.

Should you have any questions about the impact or operation of the PREP Act, please contact John Clerici at 202.496.7574.

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