



# Liability Protection for Public Health Countermeasures

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# The Liability Threat



- 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 was all too realistic.
- Existing mechanisms to address liability (e.g., P.L. 85-804; SAFETY Act, etc.) proved inadequate or unworkable.

**GHSI Public Health Emergency  
Medical Countermeasures Workshop**  
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U.S. Department of Health and Human Services  
Office of the Assistant Secretary for Preparedness and Response



# The Solution



# The PREP Act

- **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).**
- **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.**
- **The Obama Administration has made very effective and very responsible use of the PREP Act in its response to the Novel H1N1 (nH1N1) Pandemic.**



# The Liability Protections Provided by the PREP Act



# The PREP 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).
- 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 PREP Act

- 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 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.”



# The PREP Act

- *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.

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# HHS Declaration



# The PREP Act

- 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.



# PREP Act Declarations

- Pandemic Influenza Vaccines – January 26, 2007
  - Modified on Nov 21, 2007 (adding H7 and H9)
  - Modified on Oct 10, 2008 (adding H2 and H6)
  - Modified on June 25, 2009 (adding nH1N1)
  - Modified on Sep 9, 2009 (additional provisions)
- Pandemic Influenza Antivirals Oct 10, 2008
  - Modified on April 26, 2009 (adding nH1N1)
- Anthrax – October 1, 2008
- BOT – October 10, 2008
- Smallpox – October 10, 2008
- ARS – October 10, 2008
- Protective Equipment/Respirators – Dec 18, 2008



# Compensation Mechanism



# The PREP Act

- 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 compensation 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.
- If Plaintiffs elect compensation, they may NOT pursue other remedies.
- HHS Working Group, under HRSA, formed to implement Compensation Fund for in response to nH1N1 Pandemic
  - Funds appropriated as part of FY 2009 Supplemental Appropriations funding nH1N1 response



# Remaining Challenges



# Consideration for International Sales

- PREP Act protects only against US liability, however, protection is not limited to USG procurements unless noted in Declaration (i.e., June 2009 modification limits PREP Act protection to USG Contracts only)
  - Having procurement flow through USG provides maximum protection
- Absent PREP Act, vendors must seek indemnification, cross waivers, and limitation of liability provisions.
  - Only as strong as contractual protection and limited to the assets of the provider
- SAFETY Act may also provide some protection for bioterror products, but not pandemic



# Consideration for Donations

- Donations have always presented challenges
  - Wyeth/Aventis donations of smallpox vaccine in 2001 triggered expansion of P.L. 85-804
- Liability concerns mainly US issue, however, donations may expose companies to liability in the US for foreign donations and sales
  - Especially a concern for unapproved products
- Proactive, International cooperation is key
  - May include funneling donations through USG
  - US State Department has dedicated resources to assist
  - World Health Organization is trying to facilitate international agreements where possible

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# Conclusion



# The PREP Act

- 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.
- The PREP Act has had a direct, meaningful impact on 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 response to the nH1N1 Influenza Pandemic and the devastating consequences of being unprepared has made clear why this legislation is so important.



**THANK YOU**

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