

The PREP Act: Significant Liability Protection a Reality

**Session VII: Liability Constraints, Concerns, and
Unknowns**

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The Liability Threat: What will make your company a target?

Many companies are concerned about liability resulting from assisting in a public health emergency.

Volunteer Protection Act of 1997

- Doesn't protect organizations (corps or nonprofits)
- Doesn't protect people who are being paid
- Volunteer can be sued by sponsoring organization
- States can limit protection significantly and opt out in cases involving only state residents
- Gross negligence; willful, wanton and reckless misconduct; criminal actions and others excluded;
- Operation of motor vehicles, watercraft and aircraft excluded
- Joint and several liability eliminated only for non-economic damages

Significant protection if your activities fall within the PREP Act

The PREP Act

- provides limited immunity from suit under Federal and State law
 - to persons involved in the design (Universities), development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing (doctors), administration and use (first responders and healthcare professionals)
 - of countermeasures (FDA-regulated products: vaccines, drugs, medical devices) and
 - to persons who are program planners – city officials, Governors
- for claims arising out of, related to, or resulting from the administration or the use of the countermeasure
- if a declaration has been issued for the countermeasure.

Victims are compensated through a compensation fund.

PREP Act Declaration

- The Secretary of Health and Human Services may make a declaration when he finds that a disease or other threat constitutes a public health emergency, or that there is a credible risk of such a threat.
- The Secretary considers the “desirability of encouraging” the design, development, clinical testing, manufacture, and other activities related to the countermeasure.
- The liability protections under the PREP Act are triggered subject to the conditions prescribed by the Secretary in the declaration.

Claims Not Covered

- Claims not *causally* related to the administration or use by an individual of a covered countermeasure
- Claims related to injuries not covered by the conditions in the declaration (e.g., Countermeasure used for purposes other than those listed in declaration)
- Claims occurring before a PREP Act Declaration is issued
- Claims of willful misconduct that proximately caused a serious injury or death – for these claims the PREP Act creates a new Federal Cause of Action **AFTER** the plaintiff **REFUSES** reasonable compensation.
- 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

- The PREP Act has been described as the most far reaching piece of tort reform ever to pass into law: its protections are necessary to protect US businesses who are willing to sell products for emergencies.
- Since January 2006, one declaration for H5N1 vaccines and a supplement for H7 and H9 vaccines has been issued.

Current GAPS

- **EMTALA** – Waiver that can last the entire duration of disaster for Pandemic Flu but not bioterror incident or other catastrophe
- **Standard of Care** – Not all medications or medical devices may be available
- **Volunteer Liability** – Most state laws do not extend good Samaritan liability to businesses or non-profit entities that assist communities in preparing for or responding to public health emergencies.

Federalized Volunteers (e.g., licensed medical practitioners under the National Disaster Medical System (NDMS) who are made "special government employees")

Protected under the Federal Tort Claims Act

Federal Employees Compensation Act

Conclusion

We've come a long way but have much more to do!