

Immunity under Public Readiness and Emergency Preparedness (PREP) Act
Prepared by Office of General Counsel
Texas Department of State Health Services (DSHS)
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ISSUE: What is the PREP Act and what immunity does it provide?

ANSWER: The federal Public Readiness and Emergency Preparedness (PREP) Act, 42 United States Code sec. 247d-6d, creates immunity from tort liability for “covered persons” who are involved in administration and use of “covered countermeasures”. Immunity is provided only when the Secretary of the US Department of Health and Human Services (HHS) issues a declaration specifying the public health emergency, category of disease, covered countermeasure, effective time period, population, geographic area, and additional qualified persons.

DISCUSSION: A covered person is immune from suit and for loss caused by, arising out of, relating to or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration has been issued with respect to such countermeasure. A covered person is a: 1) manufacturer of a countermeasure; 2) distributor of a countermeasure; 3) public or private program planner (including state or local government) who supervises or administers a program using a countermeasure; 4) qualified person authorized under state law to prescribe, administer, or dispense a countermeasure; or 5) official, agent, or employee of a person or entity described in 1-4. The Act does not create immunity for willful misconduct, i.e., intentional wrong, knowing lack of justification, or disregard of obvious risk of harm.

Each declaration must be reviewed to determine the particular disease, covered countermeasure, and other details. Declarations are found at www.hhs.gov/disasters/discussion/planners/prepact/. As of August 2009, declarations have been issued for pandemic influenza vaccine; pandemic antivirals; and pandemic influenza diagnostics, personal respiratory protection devices, and respiratory support devices and for countermeasures for anthrax, botulism, smallpox, and acute radiation syndrome. (Also see one page summary concerning H1N1 influenza and immunity under the PREP Act.)

For certain countermeasures regulated by the US Food and Drug Administration (FDA), FDA may issue an emergency use authorization (EUA) that allows use of an unapproved device or product or allows an unapproved use of a device or product during an emergency when there are no adequate, approved, and available alternatives. EUAs are found at www.fda.gov/RegulatoryInformation/Guidances/ucm122044.htm. EUAs must also be reviewed for any additional requirements placed by an EUA on covered countermeasures under the PREP Act. For example, HHS has issued two PREP Act declarations about the use of antivirals, Tamiflu and Relenza, and FDA has issued an EUA concerning the same antivirals.

Frequently asked questions about the PREP Act are found at www.hhs.gov/disasters/emergency/manmadedisasters/bioterrorism/medication-vaccine-qa.html.