



# STATE OF NEW YORK DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Richard F. Daines, M.D.  
*Commissioner*

James W. Clyne, Jr.  
*Executive Deputy Commissioner*

September 1, 2009

Dear Planning Partner:

As requested at the New York State Department of Health's H1N1 Vaccination Planning Meeting with Provider Professional Society Representatives on August 20, 2009, I am writing to provide information on the liability protections provided by the Public Readiness and Emergency Preparedness ("PREP") Act (Public Health Service Act § 319F-3, 42 U.S.C. § 247d-6d).

The PREP Act authorizes the Secretary of Health and Human Services ("Secretary") to issue a declaration providing broad immunity from tort liability for claims relating to the administration or use of countermeasures to specified health conditions, diseases or threats. Immunity from tort liability means that no legal tort claim (except, as discussed below, claims of willful misconduct) may be pursued in a United States Federal or a State court.<sup>1</sup>

The Secretary has issued three PREP Act declarations relevant to Novel H1N1 Influenza, which cover the use of: (i) vaccines for pandemic influenza, including Novel H1N1 Influenza (74 Fed. Reg. 30294 (2009)); (ii) oral Tamiflu and Relenza inhalation powder for Novel H1N1 Influenza (74 Fed. Reg. 29213 (2009)); and (iii) Personal Protective Equipment and respiratory support devices for patients with pandemic influenza (73 Fed. Reg. 78362 (2008)). The declarations are available on the internet at <http://www.hhs.gov/disasters/discussion/planners/prepact/>. These PREP Act declarations apply to certain categories of "covered persons," including licensed health professionals or other individuals who are authorized under state law to prescribe, administer, or dispense the covered countermeasures.

As a result, providers administering novel H1N1 vaccine should receive PREP Act coverage for those activities. In addition, providers dispensing Tamiflu® (oseltamivir phosphate) or Relenza® (zanamivir) from the Strategic National Stockpile should receive PREP Act immunity for the distribution of the antivirals as long as the guidelines

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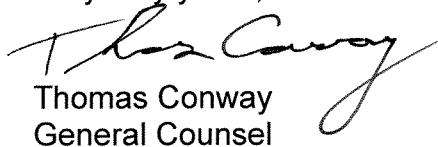
<sup>1</sup> Instead, the PREP Act authorizes an emergency fund to provide compensation for certain eligible individuals. To date, Congress has not appropriated any funds for this purpose.

set forth in the applicable Emergency Use Authorizations are followed.<sup>2</sup> Private providers should also receive PREP Act protection for dispensing privately obtained Tamiflu and Relenza for novel H1N1 influenza, including off-label uses, as long as reliance on the private providers is part of the state or local emergency response plan.

The broad protections provided by the PREP Act do have some restrictions. Immunity is not available for (i) claims based on activities that fall outside the scope of the declaration (e.g., the effective date or specified geographic area); (ii) claims of loss that are not based on a causal relationship to the administration or use of a covered countermeasure; (iii) claims filed under foreign law in courts outside the United States; and (iv) lawsuits other than tort claims (e.g., violations of civil rights laws or labor laws). As mentioned above, PREP Act protections also do not apply in the event of death or serious physical injury caused by willful misconduct. Suits based on willful misconduct, however, may be avoided by reporting any injuries caused by the covered products to local or state public health authorities or the Secretary within seven days of learning of the injury.

We strongly recommend that you discuss this information with your legal counsel. Please note that the PREP Act is a relatively recent statute that has not yet been tested in any court of law. Please also be advised that PREP Act declarations may change at any time without notice.

Very truly yours,

  
Thomas Conway  
General Counsel

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<sup>2</sup> As you are probably aware, the Food and Drug Administration ("FDA") has issued EUAs for the use of Tamiflu and Relenza for uses and populations that are not covered under the current FDA license for those drugs.