

[Declaration Under the Public Readiness and Emergency Preparedness Act for Zika Virus Vaccines \(DHHS Notice\)](#)

Provides liability immunity to individuals and entities administering Zika Virus vaccinations.

Updated last **May 23, 2017**
for the 2/6/2017 notice.

WHAT IT DOES

The [Public Readiness and Emergency Preparedness \(PREP\) Act](#), passed in 2005, provides immunity from legal liability for claims related to the administration of countermeasures (i.e. vaccines) against certain diseases. The statute authorizes the Secretary of the Department of Health and Human Services ([DHHS](#)) to issue a declaration granting liability immunity with regard to a specific disease or health threat, after determining that the disease or threat constitutes a public health emergency or presents a credible risk of causing such an emergency.

This Declaration ([FR 82 10365](#)), effective August 1, 2016, extends the PREP Act liability shield to countermeasures related specifically to Zika virus:

- The Secretary of DHHS has determined that there is a credible risk that Zika virus may create a public health emergency in the future.
- As required by the PREP Act, the Secretary of DDHS has considered the desirability of encouraging the design, development, manufacture, distribution, etc. of Zika virus vaccines/countermeasures before extending liability protections.
- Individuals protected from liability include the manufacturers and distributors of Zika vaccines, government program planners, and any person authorized by law to prescribe, administer, or dispense countermeasures.
- The Secretary has extended liability protection related to the manufacture, testing, development, distribution, administration, and use of the following Zika vaccine types:

(1) Whole-particle inactivated virus vaccines

(2) Live-attenuated vaccines

(3) mRNA vaccines

(4) DNA vaccines

(5) Subunit vaccines

(6) Peptide vaccines

(7) Virus like particles vaccines

(8) Nanoparticle vaccines.

- The Declaration bars lawsuits that allege negligence in creating the vaccine on the part of manufacturers, or negligence in administering vaccines on the part of health care providers. The Declaration also bars injury claims related to the operation of a vaccine distribution site (for example, slip-and-fall injuries at a distribution center). Immunity does not extend to willful misconduct.

- Liability immunity is in effect for 24 months from the effective date of the Declaration. An additional 12 months of liability protection is extended to return the vaccine to manufacturers after the emergency declaration has expired.
- Individuals who sustain serious physical injury as a direct result of using Zika countermeasures may be eligible to receive benefits from the Countermeasures Injury Compensation Program ([CICP](#)). Individuals who want to receive benefits from CICP must support their claims with “compelling, reliable, valid, medical and scientific evidence” that the Zika vaccine/countermeasure directly caused their injuries.

RELEVANT SCIENCE

[Zika virus](#) is a mosquito-borne virus in the same family as West Nile virus, dengue, and yellow fever virus. The disease is transmitted primarily through the bite of infected *Aedes* mosquitos, but transmission through sexual contact and blood transfusion is also possible.

Most people who contract the disease exhibit [no symptoms](#); others present mild symptoms such as mild fever, rash, joint pain, conjunctivitis, headache, and malaise. Symptoms usually last from two to seven days. There is currently no vaccine for Zika virus, and no effective antiviral treatment exists. The disease is usually mild, however, and typically requires no more than bedrest and administration of over-the-counter medicines to relieve symptoms.

Although the disease is usually not life-threatening, Zika virus has been linked to certain serious health complications. Zika has been associated with congenital brain defects in infants, including [microcephaly](#) (stunted brain development, which can lead to cognitive impairments and related problems), if a woman is infected with the virus while pregnant. Zika may also trigger [Guillain-Barre Syndrome](#), a disorder which causes the body’s immune system to attack its own nerves. Guillain-Barre Syndrome causes temporary muscle weakness and paralysis, and may lead to permanent and/or life-threatening complications. According to the World Health Organization ([WHO](#)), “[i]ntense efforts are continuing to investigate the link between Zika virus and a range of neurological disorders.”

BACKGROUND

The Public Readiness and Emergency Preparedness (PREP) Act was first passed in 2005. The objective of the law is to facilitate and incentivize development of drugs and vaccines in times of public health emergency, by protecting drug manufacturers from financial liability associated with rushing new drugs to market. The statute gives the Department of Health and Human Services the ability to declare that a particular disease presents or could cause a public health emergency, and may extend liability immunity to individuals and entities developing countermeasures for that specific disease.

ENDORSEMENTS & OPPOSITION

At present, there have not been any publicly reported endorsements of or opposition to the specific PREP Act declaration extending liability protections to Zika virus vaccines.

However, the PREP Act as a whole is controversial as a liability shield for pharmaceutical companies. Proponents of the statute believe that it incentivizes companies to develop and market drugs in response to a public health emergency by decreasing the risk of lawsuit. Opponents say that the PREP Act gives too much protection to drug companies, allowing them to market potentially unsafe products; they also claim that the compensation system denies consumers adequate remedy for injuries sustained as a result of receiving unsafe drugs.

Endorsement:

- Former Senator Bill Frist: This [concept](#) “strikes a reasonable balance where those who are harmed will be fairly compensated and

life-saving products will be available in ample supply to protect and treat as many Americans as possible.”

Opposition:

- [Former Senator Edward Kennedy](#): “Without a real compensation program, the liability protection ... provides a Christmas present to the drug industry and bag of coal to everyday Americans.”
- [The Association of Trial Lawyers](#): “At a time when we see the egregious things that are being done by major drug companies, the last thing in the world that the consumer needs is immunity for drug manufacturers to act with impunity.”

STATUS

This Declaration is effective as of August 1, 2016.

RELATED POLICIES

Zika virus is most prevalent in the tropics, and the [CDC has issued travel advisories](#) for multiple countries in the Caribbean, South America, Central America, and Oceania. Zika was first detected in the United States in December 2015 with a case reported in Puerto Rico; Florida reported its first case of Zika virus in August 2016. On February 1, 2016, the [WHO declared Zika virus an international public health emergency](#) due to lack of information surrounding the disease and suspected links to serious birth defects. In November 2016, the WHO declared the emergency [over](#), but stressed that Zika should be viewed as an important and ongoing threat.

Eight similar [declarations](#) have also been issued by the Department of Health and Human Services and are active as of May 23, 2017. Liability immunity currently exists for countermeasures developed and administered against the following diseases: Nerve agents and certain insecticides, Zika virus, Ebola, pandemic influenza, anthrax, acute radiation syndrome, botulinum toxin, and smallpox.

In 2012 the New York Supreme Court upheld PREP Act protections for a lack of informed consent claim ([Parker v. St. Lawrence County Public Health Department](#)). St. Lawrence County, during their vaccination program in response to the [H1N1 influenza](#) outbreak, accidentally failed to obtain parental consent before vaccinating a kindergartener. The lower court allowed the parent’s claims of negligence and battery to proceed, saying that the PREP Act did not protect against lack of informed consent claims. The New York Supreme Court reversed, finding that the PREP Act protects countermeasure administrators from a wide range of state tort claims.

PRIMARY AUTHOR

Cole Wilhelmi, JD/MA Candidate


EDITOR(S)

Jenny Wang, JD/MA Candidate; Aubrey Incorvaia, MPP

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