

Federal PREP Act Provides Legal Immunity to H1N1 Vaccine Makers and Others

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Although millions of doses of the newly-created H1N1 vaccine have been shipped nationwide,¹ it may be too late for many Americans seeking inoculation against swine flu. A majority of the United States is already in the midst of a very active influenza season and much of the illnesses are the result of swine flu infections. The Centers for Disease Control and Prevention (CDC) reports that 46 states are currently experiencing widespread influenza activity – the majority of which are cases tied to the 2009 H1N1 influenza A virus.² Visits by children and adults to physician offices due to flu-like symptoms are higher now than what has typically been seen at the peak of past flu seasons, and resulting hospitalizations continue to rise.³

Many Americans hoping to receive a swine flu vaccination shot or nasal mist spray have been waiting in long lines at local health care clinics recently and growing frustrated by the minute. The United States has contracted with five suppliers⁴ of seasonal influenza vaccine to also supply the H1N1 vaccine, however only four makers have been approved by the U.S. Food and Drug Administration (FDA).⁵ The U.S. Department of Health and Human Services (HHS) had initially predicted it would have distributed nearly 40 million doses of the vaccine by the end of October, but only 22 million doses have been delivered.⁶ And although the CDC and other federal agencies assure the public that the delivered vaccine is safe, much of the nation struggles with whether to actually get inoculated.⁷ Makers of the vaccine were concerned as well; however, they were concerned about the potential legal ramifications that could result if individuals were harmed by vaccine side effects. In response to such concerns, HHS Secretary Kathleen Sebelius employed existing federal law to provide legal immunity from tort liability to swine flu vaccine manufacturers and others in the event claims and lawsuits were filed alleging individuals suffered detrimental side effects from the shots.

¹ U.S. Dep't of Health & Human Servs., Flu.gov, *2009 H1N1 Influenza Vaccine Supply Status*, <http://www.flu.gov/individualfamily/vaccination/supply.html> (last updated Oct. 16, 2009) (as of Oct. 14, 2009, 5,885,900 doses of the H1N1 vaccine were shipped to states).

² Centers for Disease Control & Prevention, *2009 H1N1 Flu: Situation Update*, <http://www.cdc.gov/h1n1flu/update.htm> (last updated Oct. 23, 2009).

³ *Id.*

⁴ Four manufacturers have been approved by the FDA to supply H1N1 vaccine: CSL Limited, MedImmune, LLC, Novartis Vaccines and Diagnostics Limited, and Sanofi Pasteur, Inc. GlaxoSmithKline has yet to gain approval for its vaccine from the FDA even though it has a contract with the government.

⁵ See Reuters, *H1N1 Vaccine Makers Struggle With U.S. Shot*, Oct. 27, 2009, available at http://www.msnbc.msn.com/id/33494844/ns/health-cold_and_flu.

⁶ *Id.*

⁷ See Elizabeth Landau, *To Vaccinate or Not? Some Wary on H1N1 Choice*, CNN.COM, Oct. 9, 2009, <http://www.cnn.com/2009/HEALTH/10/09/h1n1.vaccine.skepticism/index.html?iref=newssearch>.

Background

On April 26, 2009, then-Acting Secretary of HHS, Charles E. Johnson, issued a nationwide public health emergency declaration in response to rising human infections from the H1N1 virus.⁸ Made pursuant to Section 319 of the Public Health Service Act (PHSA),⁹ the declaration is a proactive and precautionary measure that allows the HHS Secretary to take appropriate action to respond to a public health emergency, including making grants, entering into contracts, and investigating the cause, treatment, or prevention of the disease or disorder.¹⁰ Since that time, current HHS Secretary Kathleen Sebelius has renewed the declaration twice, on July 24, 2009, and again on October 1, 2009.¹¹ Meanwhile, as reported cases of H1N1 infections grew worldwide, the World Health Organization (WHO), raised the worldwide pandemic level to Phase 6 on June 11, 2009.¹² A Phase 6 alert, the highest assigned by the WHO, is characterized as a global outbreak of the disease and an indication that a global pandemic is underway.¹³ Since that time, the H1N1 virus has continued to spread, with the number of countries reporting cases nearly doubling.

While the influenza pandemic progressed, the FDA, in conjunction with HHS, took steps to procure a supply of vaccine to inoculate Americans against the H1N1 virus. On September 15, 2009, the FDA announced that it had approved four vaccines to combat the virus.¹⁴ Due in part to the fast-track nature of developing, manufacturing, and supplying the United States with enough doses of the H1N1 vaccine to cover nearly everyone, makers of the drug expressed concern regarding legal liability that could arise if individuals filed suit claiming the vaccination caused harmful side effects – a lesson learned from a 1976 vaccination fiasco.

After an outbreak in 1976 of a swine flu virus that sickened soldiers at Fort Dix, New Jersey, health officials feared that the United States was on the verge of another influenza epidemic similar to the 1918 wave of deadly Spanish flu.¹⁵ As a result, nearly 40 million

⁸ Public Health Emergency Declaration issued by Charles E. Johnson, Acting Secretary of the Dep't of Health & Human Servs., Apr. 26, 2009, http://www.hhs.gov/secretary/phe_swh1n1_april_2009.html.

⁹ 42 U.S.C. § 247d-6d (West 2009).

¹⁰ U.S. Dep't of Health & Human Servs., *HHS Pandemic Influenza Plan*, available at <http://www.hhs.gov/pandemicflu/plan/appendix.html> (last accessed Oct. 22, 2009). See also U.S. Dep't of Health & Human Servs., *HHS Pandemic Influenza Plan*, available at <http://www.hhs.gov/pandemicflu/plan/appendix.html> (last accessed Oct. 22, 2009).

¹¹ Public Health Emergency Declaration issued by Kathleen Sebelius, Secretary of the Dep't of Health & Human Servs., July 24, 2009, http://www.hhs.gov/secretary/phe_swh1n1.html. See also Jackie Calmes and Donald G. McNeil, Jr., *Swine Flu Is Widespread in 46 States as Vaccines Lag*, N.Y. TIMES, Oct. 25, 2009, http://www.nytimes.com/2009/10/25/us/politics/25flu.html?_r=1.

¹² Centers for Disease Control & Prevention, *A Pandemic Is Declared*, <http://www.cdc.gov/h1n1flu/updates/071709.htm> (last accessed Oct. 25, 2009).

¹³ World Health Org., Global Alert and Response, *Current WHO Phase of Pandemic Alert*, http://www.who.int/csr/disease/avian_influenza/phase/en (last accessed Aug. 6, 2009).

¹⁴ U.S. Food & Drug Admin., News Release, *FDA Approves Vaccines for 2009 H1N1 Influenza Virus: Approval Provides Important Tool to Fight Pandemic*, Sept. 15, 2009, available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm182399.htm>.

¹⁵ Mike Stobbe, Assoc. Press, *Legal Immunity Set for Swine Flu Vaccine Makers*, MSNBC.COM, July 17, 2009, available at http://rss.msnbc.msn.com/id/31971355/ns/health-swine_flu.

individuals received a vaccination shot. But the virus never spread, and instead, nearly 500,000 people developed a rare inflammation of the nervous system known as Guillain-Barre Syndrome, which led to several deaths.¹⁶ Lawsuits were filed by those claiming there was a causal link between the vaccination and the nervous system disorder. In an effort not to have history repeat itself, makers of the 2009 H1N1 influenza vaccine received immunity from liability that could result from similar claims of adverse side effects being made by individuals.

PREP Act Overview: Legal Immunity for Vaccine Makers and Others

Enacted in 2005, the Public Readiness and Emergency Preparedness Act (PREP Act),¹⁷ authorizes the HHS Secretary to issue a PREP Act declaration that provides immunity from tort lawsuits for manufacturers, administrators, and distributors of vaccines as well as other “qualified persons” who prescribe, administer, or dispense countermeasures, unless they acted with willful misconduct.¹⁸ Covered countermeasures may include vaccines, antidotes, medications, medical devices, and other items used to respond to pandemics or biological or chemical threats.¹⁹ If people are subsequently injured by countermeasures covered by the PREP Act, the legislation provides for a compensation fund to pay for individuals’ out-of-pocket expenses, medical expenses, lost wages and a death benefit to survivors. A PREP Act declaration is specifically for the purpose of providing immunity from tort liability and is not otherwise dependent on other emergency declarations.²⁰

The payment mechanism and compensation fund is different from the one created in the 1980s in response to children being harmed by side effects caused by other types of vaccines. In 1986, Congress enacted the National Childhood Vaccine Injury Act (Vaccine Act), which, in turn, created the National Vaccine Injury Compensation Program (VICP), a no-fault compensation system in the form of a Trust Fund designed to encourage manufacturers to produce childhood vaccines while providing a shield against potential liability in rare instances where an injury results from vaccination.²¹

¹⁶ *Id.*

¹⁷ Pub. L. No. 109-148, 109th Cong. (2005).

¹⁸ *Id.*; 42 U.S.C. 247d-6d at § 319F-3; “Willful Misconduct” is defined as an act or omission that is taken: (1) intentionally to achieve a wrongful purpose; (2) knowingly without legal or factual justification; and (3) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit. *Id.* at § 319F-3(c). See also Emily McCormick, editor, *Frequently Asked Questions about Federal Public Health Emergency Law*, (Sept. 2009), based on the Apr. 28, 2009, teleconference FEDERAL PUBLIC HEALTH EMERGENCY LAW: IMPLICATIONS FOR STATE & LOCAL PREPAREDNESS AND RESPONSE, at 9-10.

¹⁹ *Id.*

²⁰ Tort claims precluded by a PREP Act declaration include claims such as (1) any type of loss including death; physical, mental or emotional injury; fear of such injury; or property damage or loss, including business interruption loss, with any causal relationship to any stage of development, distribution, administration or use of the covered countermeasure. See U.S. Dep’t of Health & Human Servs., *Public Readiness and Emergency Preparedness Act Questions and Answers*, <http://www.hhs.gov/disasters/emergency/manmadedisasters/bioterrorism/medication-vaccine-qa.html> (last accessed Oct. 27, 2009).

²¹ Pub. L. No. 99-660; 42 U.S.C. §§ 300aa-1 *et seq.* (West 2009); see also Craig A. Conway, *Federal Court Reverses Denial of Vaccination Compensation Claim*, HEALTH L. PERSPECTIVES, July 23, 2009, available at [http://www.law.uh.edu/healthlaw/perspectives/2009/\(CC\)%20Vaccine.pdf](http://www.law.uh.edu/healthlaw/perspectives/2009/(CC)%20Vaccine.pdf).

By comparison, the PREP Act authorizes Congress to appropriate funds to compensate individuals harmed by countermeasures specifically named by the Secretary of HHS. In June 2009, the Secretary added the H1N1 vaccine to the list of covered countermeasures which include countermeasures for Anthrax, Botulism, Pandemic Antivirals (Tamiflu and Relenza), Small Pox, and Acute Radiation Syndrome.²² Additionally, Pandemic Influenza Diagnostics, Personal Respiratory Protection Devices, and Respiratory Support Devices are covered.²³ To date, however, Congress has not appropriated funds likely due to the lack of any reported side effects caused by influenza antivirals or the H1N1 vaccine.

Who is Given Immunity from Tort Liability?

A declaration issued by the HHS Secretary provides immunity for “covered persons” involved in the administration, distribution, and use of a covered countermeasure.²⁴ Those “covered persons” may, at the Secretary’s discretion, include:

- Manufacturers of countermeasures;
- Distributors of countermeasures;
- Program planners of countermeasures (i.e., individuals and entities involved in planning and administering programs for distribution of a countermeasure);
- Qualified persons who prescribe, administer, or dispense countermeasures (i.e., healthcare and other providers); and
- The United States.²⁵

Immunity also covers officials, agents, and employees of any of the aforementioned entities or persons.

Limitations on Immunity from Liability

The legal immunity provided under the PREP Act is not without limitations. As previously mentioned, death or serious injury²⁶ caused by willful misconduct is not covered. Additionally, immunity is not available for claims based on activities that fall

²² See McCormick, *supra* note 18 at 9-10; see also Pandemic Influenza Vaccines, 72 Fed. Reg. 4170, 67731 (2009), 73 Fed. Reg. 61871 (2009), 74 Fed. Reg. 30294 (2009); Pandemic Influenza Antivirals, 73 Fed. Reg. 61861 (2007), 74 Fed. Reg. 29213 (2007); Anthrax Countermeasures, 73 Fed. Reg. 58239 (2008); Botulinum Toxin Countermeasures, 73 Fed. Reg. 61864 (2008); Acute Radiation Countermeasures, 73 Fed. Reg. 61866 (2008); Smallpox Countermeasures, 73 Fed. Reg. 61689 (2008).

²³ *Id.* See also Pandemic Influenza Diagnostics, Personal Respiratory Protection Devices, and Respiratory Support Devices: 73 Fed. Reg. 78362 (2008).

²⁴ See McCormick, *supra* note 18 at 9-10; See U.S. Dep’t of Health & Human Servs., *Public Readiness and Emergency Preparedness Act Questions and Answers*, <http://www.hhs.gov/disasters/emergency/manmade-disasters/bioterrorism/medication-vaccine-qa.html> (last accessed Oct. 27, 2009).

²⁵ 42 U.S.C. 247d-6d, sec. 319F-3(i)(2)-(6) (West 2008).

²⁶ A “serious injury” is life-threatening, or results in or required medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. See 42 U.S.C. 247d-6d, sec. 319F-3(i)(10) (West 2008).

outside the scope of the declaration which the HHS Secretary has the discretion to define, including the effective dates of the immunity and geographic area for which immunity will be available.²⁷ In terms of the declaration issued for the H1N1 vaccine, Secretary Sebelius conferred immunity to manufacturers and distributors until February 2013. She placed no geographic limitations on the declaration.²⁸

Further, immunity will not be available for claims based on those who administer the vaccine inconsistently with stated uses. According to HHS, the H1N1 vaccines are covered only when they are administered and used as (1) licensed or approved by the Food and Drug Administration (FDA); (2) authorized for investigational use by the FDA; or (3) authorized under an Emergency Use Authorization (EUA) by the FDA.²⁹

Emergency Use Authorization (EUA)

An Emergency Use Authorization (EUA) may be issued by the FDA to allow either the use of an unapproved medical product or an unapproved use of an approved medical product during a pandemic or other emergency.³⁰ Pursuant to Section 564 of the Food, Drug, and Cosmetic Act, amended by the Project BioShield Act of 2004,³¹ an EUA is authorized for such products for use in diagnosing, treating, or preventing serious or life-threatening diseases or conditions caused by biological, chemical, radiological, or nuclear agents, if certain statutory criteria are met.³²

Once the HHS Secretary has declared a public health emergency justifying the emergency use of a drug or medical product, the FDA Commissioner may authorize an EUA after consulting with the National Institutes of Health (NIH) and the CDC to determine that certain criteria have been met, including:

- That the agent specified in the declaration of emergency can cause a serious or life-threatening disease or condition;
- That, based on the totality of scientific evidence available, it is reasonable to conclude that the product would be effective in diagnosing, treating, or preventing the life-threatening disease or condition;

²⁷ See *Public Readiness and Emergency Preparedness Act Questions and Answers*, *supra* note 24.

²⁸ *Id.*

²⁹ *Public Readiness and Emergency Preparedness Act Questions and Answers*, *supra* note 24. See also U.S. Dep't of Health & Human Servs., Flu.gov, *Coverage Under the Public Readiness and Emergency Preparedness (PREP) Act for H1N1 Vaccination*, http://www.flu.gov/professional/federal/vaccine_liability.html. Immunity is also not available for claims filed under foreign law in courts outside the United States but will be available for U.S. claims based on events that took place outside the United States. Immunity is also not available for lawsuits other than tort claims such as violations of civil rights laws, labor laws, or other claims with no causal connection to a tort claim. See *id.*

³⁰ *Public Readiness and Emergency Preparedness Act Questions and Answers*, *supra* note 24. See also Centers for Disease Control & Prev., *Interim Questions and Answers About Emergency Use Authorization*, Apr. 26, 2009, <http://www.cdc.gov/h1n1flu/eua/qa.htm> (last accessed Oct. 27, 2009).

³¹ Pub. L. No. 108-276, 108th Cong. (2004).

³² Centers for Disease Control & Prev., *Interim Questions and Answers About Emergency Use Authorization*, Apr. 26, 2009, <http://www.cdc.gov/h1n1flu/eua/qa.htm> (last accessed Oct. 27, 2009).

- That the known and potential benefits of the product outweigh the known and potential risks of the product when used to diagnose, prevent, or treat the serious or life-threatening disease or condition that is the subject of the declaration; and
- That there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition.³³

Once issued, the EUA remains in effect for one year unless revoked. Both the emergency declaration as well as any issued EUA issued under that declaration may be renewed if justified after a year. For unapproved products, federal law requires the FDA Commissioner to establish conditions he or she finds necessary to protect the public health. For example, conditions could include a requirement to disseminate information to healthcare providers or dispensers of the drug, as well as consumers, the extent to which it is known that the potential benefits and risks of a specific drug or product is known, alternatives available as well as those risks and benefits, and requirements to report adverse events, data collection, and analysis.³⁴

Earlier this year, the FDA authorized the emergency use of influenza antivirals Tamiflu, Relenza, and Peramivir IV, as well as certain types of respirators, influenza diagnostic tests, and the swine flu test kit.³⁵

A PREP Act Declaration Versus a Section 319 PHSA Declaration: The Difference?

Prior to issuing a PREP Act declaration, the HHS Secretary must determine that a disease or public health condition constitutes a public health emergency – or that there is a significant risk of a future emergency. This determination is made independent of a public health emergency declaration under Section 319 of the PHSA.³⁶ Put simply, a PREP Act declaration triggers the Act’s immunity for legal liability and a Section 319 or other statutory declaration is not needed for immunity to take effect.

Conversely, pursuant to Section 319 of the PHSA, the HHS Secretary may issue a declaration of a public health emergency based upon a determination that (1) a disease or disorder presents a public health emergency; or (2) a public health emergency, including significant outbreaks of the disease or bioterrorist attacks, otherwise exists.³⁷ Recent examples of Section 319 declarations include ones in response to the terrorist events in New York and Washington, D.C., on September 11, 2001, and the subsequent anthrax cases in Florida. The Secretary also declared a public health emergency in a number of states due to Hurricanes Katrina, Rita, and Wilma in September 2005.³⁸

³³ *Id.*

³⁴ *Id.*

³⁵ Centers for Disease Control & Prev., *Emergency Use Authorization (EUA) of Medical Products and Devices*, <http://www.cdc.gov/H1N1flu/eua/> (last updated Oct. 23, 2009).

³⁶ *Public Readiness and Emergency Preparedness Act Questions and Answers*, *supra* note 24.

³⁷ *Id.*

³⁸ *Id.*

Conclusion

While no funds have yet been appropriated by Congress under the PREP Act, any resulting claims for compensation due to adverse events experienced from any of the named countermeasures must be filed within one year of administration or use of the countermeasure. Requests will go to the Health Resources and Services Administration's Countermeasures Injury Compensation Program.³⁹

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³⁹ See U.S. Dep't of Health & Human Servs., Health Resources and Servs. Admin., *Countermeasures Injury Compensation Program*, <http://www.hrsa.gov/countermeasurescomp/> (last accessed Oct. 27, 2009).