



# Pandemic Flu and Medical Biodefense Countermeasure Liability Limitation

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## Summary

Division C of P.L. 109-148 (2005), 42 U.S.C. §§ 247d-6d, 247d-6e, also known as the Public Readiness and Emergency Preparedness Act (PREP Act), limits liability with respect to pandemic flu and other public health countermeasures. Specifically, upon a declaration by the Secretary of Health and Human Services of a public health emergency or the credible risk of such emergency, Division C would, with respect to a “covered countermeasure,” eliminate liability, with one exception, for the United States, and for manufacturers, distributors, program planners, persons who prescribe, administer or dispense the countermeasure, and employees of any of the above. The exception to immunity from liability is that a defendant who engaged in willful misconduct would be subject to liability under a new federal cause of action, though not under state tort law, if death or serious injury results. Division C’s limitation on liability is a more extensive restriction on victims’ ability to recover than exists in most federal tort reform statutes. However, victims could, in lieu of suing, accept payment under a new “Covered Countermeasure Process Fund,” if Congress appropriates money for this fund.

The first PREP Act declaration was issued on January 26, 2007, to limit liability for the administration of the H5N1 influenza vaccine. Since then, declarations have been issued covering countermeasures against other strains of influenza (including H1N1), anthrax, botulism, small pox, and acute radiation syndrome.

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This report analyzes Division C of the Department of Defense Emergency Supplemental Appropriations, P.L. 109-148, which was signed into law on December 30, 2005, and which limits liability with respect to pandemic flu and other public health countermeasures. Division C, which is titled the “Public Readiness and Emergency Preparedness Act,” (PREP Act) created § 319F-3 of the Public Health Service Act, which provides that, except in one circumstance (discussed below under “New Federal Cause of Action”), a “covered person” would be immune from suit and liability for “all claims 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.” The declaration referred to is a declaration by the Secretary of Health and Human Services (HHS) of a public health emergency or the credible risk of such emergency.

## **Immunity from Liability**

Division C defines a “covered person” to include the United States and a (i) manufacturer, (ii) distributor, (iii) program planner, (iv) qualified person who prescribed, administered, or dispensed a covered countermeasure, or (v) official, agent, or employee of (i) through (iv). Under the Federal Tort Claims Act (FTCA), officials, agents, and employees of the United States are already immune from tort liability.<sup>1</sup>

Immunity is granted “to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, or use of such countermeasure.”

A “covered countermeasure” includes (A) “a qualified pandemic or epidemic product,” (B) “a security countermeasure,” or (C) a drug, biological product, or device that is authorized for emergency use in accordance with section 564 of the Federal, Food, Drug, and Cosmetic Act (FDCA). Each of the terms in (A), (B), and (C) is itself defined in Division C as follows:

- A. “Qualified pandemic or epidemic product” is defined as a drug, biological product, or device, as these three terms are defined in the FDCA, with the additional limitation that all three terms apply only to “a product manufactured, used, designed, developed, modified, licensed, or procured ... to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic,” or “a serious or life-threatening disease or condition caused by [such] a product”—but only if such a product meets one of three other qualifications under the FDCA.
- B. “Security countermeasure” is defined in Division C as it is defined in § 319F-2(c)(1)(B) of the Public Health Service Act,<sup>2</sup> as a drug, biological product, or device (as those terms are defined in the FDCA) that the Secretary of HHS approves as necessary to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent.<sup>3</sup>

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<sup>1</sup> 28 U.S.C. §§ 2679(b)(1), 2671.

<sup>2</sup> Section 319F-2 was enacted by the Project Bioshield Act of 2004, P.L. 108-276, § 3, and is codified at 42 U.S.C. § 247d-6b.

<sup>3</sup> This is a summary of a more complex definition.

C. “Drug,” “biological product,” and “device” are all defined by the FDCA.

On January 26, 2007, Secretary Michael O. Leavitt made the first such declaration “to provide targeted liability protections for pandemic countermeasures based on a credible risk that an avian influenza virus spreads and evolves into a strain capable of causing a pandemic of human influenza.”<sup>4</sup> Since then, the Secretary of HHS has issued additional declarations covering various countermeasures against anthrax, botulism, acute radiation syndrome, smallpox, and various strains of influenza.<sup>5</sup> Most recently, in response to the H1N1 influenza pandemic, Secretary Kathleen Sebelius issued declarations limiting liability for harm arising from the use of certain influenza antivirals<sup>6</sup> and vaccines.<sup>7</sup>

## **New Federal Cause of Action**

The single circumstance in which Division C allows a covered person to be held liable is when a “death or serious physical injury” was caused by the “willful misconduct” of a covered person. Division C defines “willful misconduct” as an act or omission that is taken “(i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; and (iii) 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.” In addition, the Secretary of HHS, in consultation with the Attorney General, “shall promulgate regulations ... that further restrict the scope of actions or omissions by a covered person that may qualify as ‘willful misconduct.’” Furthermore, “the plaintiff shall have the burden of proving by clear and convincing evidence willful misconduct by each covered person sued and that such willful misconduct caused the death or serious physical injury.” The “clear and convincing” standard is higher than the usual burden of proof in civil cases, which is proof by a “preponderance of the evidence.” Finally, if an act or omission by a manufacturer or distributor is subject to regulation by Division C or by the FDCA, then such act or omission shall not constitute willful misconduct if neither the Secretary of HHS nor the Attorney General has initiated an enforcement action with respect to the act or omission, or if such an enforcement action has been initiated and the enforcement action has been terminated or finally resolved without a specified penalty imposed on the covered person.

The proceeding in which an injured party may seek to prove that a covered person had engaged in willful misconduct is a new federal cause of action that Division C created; suits under state tort law are prohibited. Subsection (d) of the new § 319F-3 provides: “For purposes of section 2679(b)(2)(B) of title 28, United States Code, such a cause of action is not an action brought for violation of a statute of the United States under which an action against an individual is otherwise

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<sup>4</sup> Pandemic Countermeasures; Declaration Under the Public Readiness and Emergency Preparedness Act, 72 Fed. Reg. 4710 (Feb. 1, 2007).

<sup>5</sup> See HHS, *Public Readiness and Emergency Preparedness (PREP) Act*, available at <http://www.hhs.gov/disasters/discussion/planners/prepact/index.html>. All declarations thus far have been issued without geographic limitation and, with the exception of the influenza declarations, cover any vaccine, drug, diagnostic test, or device to identify, prevent or treat the respective disease. The countermeasures covered by the influenza declarations are generally limited to particular vaccines or antivirals.

<sup>6</sup> HHS, Office of the Secretary, “Pandemic Influenza Antivirals—Amendment,” 74 Fed. Reg. 29213-29214 (June 19, 2009); HHS, Office of the Secretary, “Declaration Under the Public Readiness and Emergency Preparedness Act,” 74 Fed. Reg. 50968-50970 (Oct. 2, 2009).

<sup>7</sup> HHS, Office of the Secretary, “Pandemic Influenza Vaccines—Amendment,” 74 Fed. Reg. 30294-30297 (June 25, 2009).

authorized.” This apparently means that the new federal cause of action may not be brought against a federal employee.<sup>8</sup>

Division C provides that suits under the new federal cause of action may be brought only in the U.S. District Court for the District of Columbia, and that such court, with exceptions noted below, shall apply the substantive law, including choice of law principles, of the state in which the alleged willful misconduct occurred. The reference to “choice of law principles” means that the court will apply the law of the state in which the alleged willful misconduct occurred, but, if that state’s law provides that a different state’s law should apply, then the court will apply the other state’s law.<sup>9</sup>

Although federal district court cases are usually heard by a single judge, cases under Division C’s new federal cause of action will be “assigned initially to a panel of three judges. Such panel shall have jurisdiction over such action for purposes of considering motions to dismiss, motions for summary judgment, and matters related thereto. If such panel has denied such motions, or if the time for filing such motions has expired, such panel shall refer the action to the chief judge for assignment for further proceedings, including any trial.” This suggests that the panel’s jurisdiction is limited to pretrial motions, and that a single judge will run the trial, including ruling on motions to dismiss and motions for summary judgment that were made after the trial began.

Under the new federal cause of action, certain matters are not governed by state law. Damage awards will be reduced by the amount of collateral source benefits, with “collateral source benefits” defined to include amounts the plaintiff is entitled to receive from any governmental program, workers’ compensation law, health or disability insurance, and the like. Collateral sources will have no right of subrogation, which means that they could not recover, out of the damages the plaintiff recovers in a lawsuit brought under the new federal cause of action, benefits that they had paid the plaintiff.

Under the new federal cause of action, noneconomic damages, which are damages for pain and suffering and other non-monetary losses, “may be awarded only in an amount directly proportional to the percentage of responsibility of a defendant for harm to the plaintiff.” This means that, if two defendants are found liable for willful misconduct, then they will not be jointly and severally liable for noneconomic damages, which means that they will not each be liable for the full amount of the plaintiff’s noneconomic damages. If, for example, one of the two defendants was 25% responsible for the harm and the other was 75% responsible for the harm, then the plaintiff may recover no more than 25% of his noneconomic damages from the first, even if the second is insolvent. With respect to economic damages, however, the plaintiff may recover up to 100% from either liable party, if the relevant state law provides for joint and several liability.

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<sup>8</sup> Strictly speaking, § 2679(b)(2)(B) does not authorize actions against federal employees, but provides that § 2679(b)(1), which gives federal employees immunity from suits under state tort law, shall not apply to actions brought under federal statutes. It is such federal statutes, not § 2679(b)(2)(B), that authorize actions against federal employees.

<sup>9</sup> The reason that Division C created a federal cause of action and has federal courts apply state law, rather than simply requiring state causes of action to be brought in federal court, may be that it might have been unconstitutional to allow state causes of action between plaintiffs and defendants from the same state to be brought in federal court. *See, In re TMI Litigation Cases Consol. II*, 940 F.2d 832, 848-851 (3d Cir. 1991).

Under the new federal cause of action, Rule 11 sanctions against attorneys, law firms, or parties, for filing frivolous claims or defenses or filing papers for improper purposes, are mandatory. Rule 11 currently makes sanctions discretionary on the part of the court.

## **Covered Countermeasure Process Fund**

Division C also created a new section 319F-4 of the Public Health Service Act which, upon issuance by the Secretary of the declaration referred to in the first paragraph of this report, would establish in the Treasury the “Covered Countermeasure Process Fund.” “[T]he Secretary shall, after amounts have by law been provided for the Fund under subsection (a)<sup>10</sup> provide compensation to an eligible individual for a covered injury [i.e., serious physical injury or death] directly caused by the administration or use of a covered countermeasure pursuant to such declaration.”<sup>11</sup> Despite the “shall” quoted in the previous sentence, an eligible “individual has an election to accept the compensation or to bring an action under” the new federal cause of action, but may not do both. Compensation under this fund would be in the same amount as is prescribed by sections 264, 265, and 266 of the Public Service Health Act for persons injured as a result of the administration of certain countermeasures against smallpox.<sup>12</sup> These three sections provide, respectively, medical benefits, compensation for lost employment income, and death benefits, but do not provide damages for pain and suffering.

## **Comparison with Existing Federal Tort Reform Statutes**

Congress has enacted other tort reform statutes to limit liability under state law.<sup>13</sup> The rest of this report describes the broad categories into which these statutes may be placed, so that Division C can be compared with them. Some federal statutes have eliminated tort liability with no exceptions, and without providing an alternative means of compensation. Other federal statutes have eliminated tort liability for ordinary negligence but not for gross negligence or willful misconduct. Division C eliminated tort liability except for willful misconduct, and therefore falls in between these two categories. In addition, Division C would allow injured persons to recover compensation from the Covered Countermeasure Process Fund, if Congress appropriates money for it.

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<sup>10</sup> The reference to subsection (a) seems unclear because subsection (a) provides for the establishment of the fund, not for its funding. Perhaps the reference was meant to be “for the Fund [established] under subsection (a).” The Supplemental Appropriations Act of 2009 provided authority for the Secretary of HHS to transfer amounts not specifically designated for other purposes to the Covered Countermeasure Process Fund. P.L. 111-32, 123 Stat. 1859, 1885.

<sup>11</sup> Thus, the Covered Countermeasure Process Fund will not provide compensation unless Congress enacts a separate statute that appropriates money for it.

<sup>12</sup> Sections 264, 265, and 266 were enacted by the Smallpox Emergency Personnel Protection Act of 2003, P.L. 108-20 (2003), and are codified, respectively, at 42 U.S.C. § 239c, 239d, and 239e.

<sup>13</sup> These statutes are listed in, and briefly summarized in the appendix to, CRS Report 95-797, *Federal Tort Reform Legislation: Constitutionality and Summaries of Selected Statutes*, by Henry Cohen and Vanessa K. Burrows.

More than 50 federal statutes provide total immunity to particular private parties, but make the U.S. government liable, under the Federal Tort Claims Act, in their stead.<sup>14</sup> There are situations, however, in which the U.S. government may not be held liable under the FTCA, and, in those situations, victims may be left without a remedy.<sup>15</sup> Even when the United States may be held liable under the FTCA, it may never be held liable for punitive damages, even in states that authorize punitive damages awards.

Occasionally Congress immunizes private parties but establishes a federal compensation program. Examples include the Radiation Exposure Compensation Act, which immunizes government contractors who carried out atomic weapons testing programs from 1946 to 1962, as well as the National Childhood Vaccine Injury Compensation Act of 1986 and the September 11<sup>th</sup> Victims Compensation Fund of 2001.

Finally, some federal tort reform statutes do not eliminate the right to sue and do not establish alternative compensation mechanisms. Rather, they cap noneconomic and punitive damages, limit each defendant's share of the total liability to its share of responsibility for the plaintiff's injuries, or take other steps to limit recovery. Division C substitutes a federal cause of action for state causes of action, but continues to apply state law.

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<sup>14</sup> These statutes make private parties immune from suit by declaring them federal employees for liability purposes, as the Federal Tort Claims Act makes federal employees immune from liability for torts they commit in the course of employment. For additional information, see CRS Report 97-579, *Making Private Entities and Individuals Immune from Tort Liability by Declaring Them Federal Employees*, by Henry Cohen.

<sup>15</sup> Federal employees, civilian or military, may not sue under the FTCA, but may receive federal benefits if injured on the job. Plaintiffs who may sue under the FTCA nevertheless may not recover, and be left without a remedy, if one of the FTCA's exceptions applies. These include the discretionary function exception and the exception for claims arising in a foreign country. For additional information, see CRS Report 95-717, *Federal Tort Claims Act*, by Henry Cohen and Vanessa K. Burrows.