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Pandemic Flu Liability Limitation Legislation

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Summary

S. 1873, 109th Congress, the Biodefense and Pandemic Vaccine and Drug Development Act of 2005, as reported, would eliminate liability, with one exception, for manufacturers, distributors, administrators, and health care providers, of a security countermeasure or a qualified pandemic and epidemic product. The exception would be when the defendant violated the Federal Food, Drug, and Cosmetic Act and, in doing so, engaged in willful misconduct. This would be a more severe restriction on victims' ability to recover than exists in most federal tort reform statutes.

Pending Legislation

This report analyzes the pandemic flu liability limitation legislation pending in the 109th Congress, and compares it with existing federal tort reform statutes. At present, only the Senate has been actively considering a bill on this issue. Section 6 of S. 1873, the Biodefense and Pandemic Vaccine and Drug Development Act of 2005, as reported on October 24, 2005, by the Committee on Health, Education, Labor, and Pensions, would create § 319F-3 of the Public Health Service Act, which would provide that, except in one circumstance, "a manufacturer, distributor, or administrator of a security countermeasure, or a qualified pandemic and epidemic product . . . or a health care provider shall be immune from suit or liability caused by or arising out of the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescribing, administration, or use of a security countermeasure pandemic and epidemic product . . . ."[1]

The bill defines or amends existing definitions of some of the terms used in the above quotation. A "security countermeasure" is defined in § 319-F-2(c)(1) of the Public Health Service Act,[2] as it would be amended by § 4(b) of S. 1873, as a drug, biological

[1] All references in this report to S. 1873 are to the reported version.

[2] 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.

product, or device (as those terms are defined in the Federal Food, Drug, and Cosmetic Act) that the Secretary of Health and Human Services approves as necessary to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent.[3]

A "qualified pandemic or epidemic product" is defined in § 319L of the Public Health Service Act, which would be created by § 4 of S. 1873, as having "the meaning given the term in section 319F-3(c)(5)." This should say "319F-3(d)(5)," as that provision defines a "qualified pandemic or epidemic product" as a drug, biological product, or device (as those terms are defined in the Federal Food, Drug, and Cosmetic Act) designed, developed, modified, or procured to diagnose, mitigate, prevent, or treat or cure a pandemic or epidemic that the Secretary approves.[4]

The immunity from suit or liability that S. 1873 would provide with respect to security countermeasures and qualified pandemic and epidemic products would not apply in one circumstance, which would be when an HHS administrative law judge finds clear and convincing evidence that the defendant violated a provision of the Federal Food, Drug, and Cosmetic Act and in doing so "acted with willful misconduct," and that such willful misconduct "caused the product to present a significant or unreasonable risk to human health; and . . . proximately caused the injury alleged by the party."[5] If an administrative law judge makes this finding, then the defendant would have a right to judicial review by the U.S. District Court for the District of Columbia.[6] If the administrative law judge's finding stands, then the defendant would be liable under relevant state law; i.e., there would be no caps on non-economic or punitive damages, for example, except as provided by state law.

In sum, S. 1873 would provide total immunity from liability, except in cases of willful misconduct that violates the Federal Food, Drug, and Cosmetic Act, for certain manufacturers, distributors, administrators, and health care providers. Congress has enacted other tort reform statutes to limit liability under state law, and these are briefly summarized in the appendix to CRS Report 95-797, *Federal Tort Reform Legislation: Constitutionality and Summaries of Selected Statutes*, by Henry Cohen.[7] The rest of this report will describe the broad categories into which these statutes may be placed, so that S. 1873 can be compared with them.

Comparison with Existing Federal Tort Reform Statutes

S. 1873 is most similar to federal statutes that eliminate liability (usually with exceptions) and do not provide for an alternate means of recovery by victims. The General Aviation Revitalization Act, enacted in 1994, for example, bars, without exception, products liability suits against manufacturers of small planes more than 18

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[3] This is a summary of a more complex definition.

[4] This is a summary of a more complex definition.

[5] Section 319F-3(b)(1)(C) and (D), as added by S. 1873, § 6.

[6] Section 319F-3(b)(1)(D)(4), as added by S. 1873, § 6.

[7] Includes citations to all statutes mentioned in this report.

years old. The Protection of Lawful Commerce in Arms Act, enacted in October 2005, bars, with exceptions, suits against manufacturers and sellers of firearms or ammunition, and trade associations, for damages resulting from the criminal or unlawful misuse of a firearm or ammunition. The exceptions in the Protection of Lawful Commerce in Arms Act, include, but are not limited to, violations of law.

With some statutes, Congress has eliminated the right to sue for ordinary negligence, but not eliminated it for gross negligence or for intentional or willful misconduct. Examples include the Bill Emerson Good Samaritan Food Donation Act, the Volunteer Protection Act, the Aviation Medical Assistance Act of 1998, the Cardiac Arrest Survival Act of 2000, and the Paul D. Coverdell Teacher Protection Act of 2001. S. 1873, by eliminating liability for gross negligence and retaining it only for willful misconduct that violates a federal law, would go further in preempting state law than the statutes cited in this paragraph do.

More than fifty 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.[8] An example of such a statute is section 304 of the Homeland Security Act of 2002, which immunizes from liability manufacturers and administrators of smallpox vaccine.[9] 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.[10] Even when the United States may be held liable under the FTCA, it may never be held liable for punitive damages.

Occasionally Congress immunizes private parties but establishes a federal compensation program. Examples include the Radiation Exposure Compensation Act, which immunized government contractors who carried out atomic weapons testing

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[8] 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.

[9] The Project BioShield Act of 2004, P.L. 108-276, which enacted § 319F-1(d)(2) of the Public Service Health Act, 42 U.S.C. § 247d-6a(d)(2), provides that a person carrying out a personal service contract under the statute, "and an officer, employee, or governing board member of such person shall, subject to a determination by the Secretary, be deemed to be an employee of the Department of Health and Human Services for purposes of [the FTCA]." The section, however, contains exceptions to the immunity from liability that the FTCA otherwise grants to federal employees: "Should payment be made by the United States to any claimant . . . , the United States shall have . . . the right to recover against [the person deemed a federal employee] for that portion of the damages so awarded or paid, as well as interest and any costs of litigation, resulting from the failure . . . to carry out any obligation or responsibility . . . under a contract with the United States or from any grossly negligent or reckless conduct or intentional or willful misconduct. . . ."

[10] 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: Current Legislative and Judicial Issues*, by Henry Cohen.

programs from 1946 to 1962, as well as the National Childhood Vaccine Injury Compensation Act of 1986 and the September 11th Victims Compensation Fund of 2001. These three programs differ in various ways. Only the radiation law precludes lawsuits. The vaccine law requires that victims first apply for no-fault, limited compensation under the National Vaccine Injury Compensation Program (which is funded by a manufacturers' excise tax on certain vaccines). Claimants, however, may reject what they are offered under the program and sue under state law, though with some limitations on their rights under state law. The September 11th fund did not limit the right to sue unless one chose to file for compensation under the fund, but, with respect to lawsuits, it capped airlines' liability at the limits of their liability insurance coverage.

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. Examples include the Y2K Act, which limited liability for Y2K failures, and the SAFETY Act, which limits the liability of sellers of anti-terrorism technologies. The SAFETY Act substitutes a federal cause of action for state causes of action, but continues to apply state law.[11] Capping damages and otherwise limiting liability while retaining the right to sue is also the approach taken by pending medical malpractice legislation, such as H.R. 5, 109th Congress, which the House passed on July 28, 2005.

[11] For additional information on the SAFETY Act, see CRS Report RL31649, *Homeland Security Act of 2002: Tort Liability Provisions*, by Henry Cohen.