

CRS Report for Congress

Homeland Security Act of 2002: Tort Liability Provisions

Updated May 9, 2008

Henry Cohen
Legislative Attorney
American Law Division



Prepared for Members and
Committees of Congress

Homeland Security Act of 2002: Tort Liability Provisions

Summary

The Homeland Security Act of 2002, P.L. 107-296 (H.R. 5005), contains the following provisions that limit tort liability, and this report examines each of them.

- Section 304 immunizes manufacturers and administrators of smallpox vaccines from tort liability. It makes the United States liable, but not strictly liable, as manufacturers and administrators would be under state law. Rather, the United States will be liable only for the negligence of vaccine manufacturers and administrators.
- Section 863 limits the tort liability of sellers of anti-terrorism technologies. It prohibits punitive damages, joint and several liability for noneconomic damages, and application of the collateral source rule; in addition, it permits the government contractor defense. Section 864 limits the tort liability of sellers of anti-terrorism technologies to the amount of liability insurance required by the Secretary of Homeland Security.
- Section 890 limits the tort liability of air transportation security companies and their affiliates for claims arising from the September 11, 2001 air crashes. It limits it to the amount of their liability insurance coverage on that date.
- Section 1201 limits the tort liability of air carriers for acts of terrorism committed on or to an air carrier. If the Secretary of Homeland Security certifies that an act of terrorism occurred, then air carriers shall not be liable for losses that exceed \$100 million for all claims, but the government shall be liable for losses above that amount.
- Section 1402 immunizes air carriers from liability arising out of a Federal flight deck officer's use or failure to use a firearm, and immunizes Federal flight deck officers from liability, except for gross negligence or willful misconduct, for acts or omissions in defending the flight deck of an aircraft.
- Sections 1714-1717 limit the tort liability of manufacturers and administrators of the components and ingredients of various vaccines. They require victims to file a petition for limited no-fault recovery under the National Vaccine Injury Compensation Program before they may sue. These sections reportedly were designed to benefit pharmaceutical manufacturer Eli Lilly in suits against it concerning Thimerosal. Sections 1714-1717 were repealed by P.L. 108-7 (2003), Division L, § 102.

Contents

Introduction	1
Smallpox Vaccine Manufacturers and Administrators	2
No strict liability	2
Some Other Features of Section 304	3
Sellers of Anti-Terrorism Technologies: the SAFETY Act	3
Exceptions to the Application of State Law	5
Liability Insurance	7
Air Transportation Security Companies	7
Air Carriers	8
Federal Flight Deck Officers	9
Vaccine Components and Ingredients Manufacturers and Administrators	9
National Childhood Vaccine Injury Act of 1986	9
Homeland Security Act Amendments	10

Homeland Security Act of 2002: Tort Liability Provisions

Introduction

Tort liability is traditionally governed by state law, but Congress has the power to regulate it when it affects interstate commerce. Past instances in which Congress has limited tort liability include the National Childhood Vaccine Injury Act of 1986, which is discussed below, and the September 11th Victim Compensation Fund of 2001.¹ The Homeland Security Act of 2002, P.L. 107-296, contains the following provisions that limit tort liability, and this report examines each of them.

- Section 304 immunizes manufacturers and administrators of smallpox vaccines from tort liability.
- Sections 863 and 864 limit the tort liability of sellers of anti-terrorism technologies.
- Section 890 limits the tort liability of air transportation security companies and their affiliates for claims arising from the September 11, 2001 air crashes.
- Section 1201 limits the tort liability of air carriers for acts of terrorism committed on or to an air carrier.
- Section 1402 immunizes air carriers from liability arising out of a Federal flight deck officer's use or failure to use a firearm, and immunizes Federal flight deck officers from liability, except for gross negligence or willful misconduct, for acts or omissions in defending the flight deck of an aircraft.
- Sections 1714-1717 limit the tort liability of manufacturers and administrators of the components and ingredients of various vaccines; these sections reportedly were designed to benefit pharmaceutical manufacturer Eli Lilly in suits against it concerning Thimerosal. These sections were repealed by P.L. 108-7 (2003).

¹ Others are listed in CRS Report 95-797, *Federal Tort Reform Legislation: Constitutionality and Summaries of Selected Statutes*.

Smallpox Vaccine Manufacturers and Administrators

Section 304(c) of the Homeland Security Act of 2002 amended the Public Health Service Act by adding 42 U.S.C. § 233(p), which provides that “a covered person shall be deemed to be an employee of the Public Health Service with respect to liability arising out of administration of a covered countermeasure [e.g., a vaccine] against smallpox to an individual during the effective period of a declaration [of a public health emergency] by the Secretary” This language immunizes from tort liability any “covered person,” which the statute defines to include manufacturers and distributors of a smallpox vaccine, health care entities under whose auspices a smallpox vaccine is administered, and licensed health professionals or other individuals who are authorized to administer the vaccine. The Secretary of Health and Human Services issued the specified declaration, making it effective as of January 24, 2003.²

The reason that the provision just quoted immunizes covered persons from tort liability is that it deems such persons to be employees of the Public Health Service for tort liability purposes. The Public Health Service is a federal agency, and the Federal Tort Claims Act (FTCA) makes all federal employees immune from liability for torts they commit within the scope of their employment.³ They are immune, that is, from liability under state tort law; they may be held liable for violating the U.S. Constitution or a federal statute that authorizes them to be sued.

At the same time that the FTCA immunizes federal employees (and those deemed federal employees for liability purposes) from liability for torts they commit within the scope of their employment, it makes the United States government liable for such torts, under the law of the state where the tort occurred, in the same manner that private employers are generally liable for the torts of their employees.⁴ The FTCA, however, does not permit awards of punitive damages, and does not allow jury trials. It also contains exceptions under which the United States may not be held liable even though a private employer in the same situation could be held liable under state law. Even when one of these exceptions precludes the United States from being held liable, the FTCA continues to immunize federal employees from liability for torts they commit within the scope of their employment.⁵

No strict liability. The exceptions under which the United States may not be held liable include suits by military personnel for injuries sustained incident to service (the *Feres* doctrine), suits based on the performance of a discretionary

² 68 Fed. Reg. 2121 (January 28, 2003).

³ 28 U.S.C. § 2679(b). See CRS Report 97-579, *Making Private Entities and Individuals Immune From Tort Liability by Declaring Them Federal Employees*.

⁴ 28 U.S.C. §§ 1346(b), 2674. Because the United States is liable under the law of the state where the tort occurred, state tort reform statutes, such as those imposing caps on noneconomic damages, apply in suits under the FTCA. For general information on the FTCA, see CRS Report 95-717, *Federal Tort Claims Act: Current Legislative and Judicial Issues*.

⁵ *United States v. Smith*, 499 U.S. 160 (1991).

function (i.e., a policy judgment), suits for assault or battery or specified other intentional torts, claims arising out of combatant activities, claims arising in foreign countries, and others.

For present purposes, however, the FTCA's most significant exception to federal government liability is that the United States may not be held liable in accordance with state law imposing strict liability.⁶ Strict liability means liability regardless of negligence, and manufacturers and sellers of defective products, including vaccines, may be held strictly liable under state law.⁷ A product may be found defective under state law not only when it was defectively manufactured, but when it was defectively designed in the sense that it feasibly could have been designed to be safer, or when a warning that might have prevented injury was not provided. The fact that the FTCA does not permit strict liability apparently means that, under the Homeland Security Act of 2002, the government will not be liable for injuries caused by a smallpox vaccine unless the plaintiff proves that the vaccine manufacturer or other "covered person" had been negligent, in which case the government may be held liable, if no other exceptions in the FTCA preclude liability.

Some Other Features of Section 304. Section 304 also provides that the United States may be held liable for injuries caused by a smallpox vaccine only if the vaccine was administered by a "qualified person" (a person authorized by state law to administer the vaccine) during the effective period of a declaration of a public health emergency by the Secretary of Homeland Security, and only if the person receiving the vaccine "was within the category of individuals covered by the declaration" or the person administering the vaccine "had reasonable grounds to believe" he was.

If a person who did not receive the vaccine contracts vaccinia (the smallpox virus), and resides with an individual who did receive the vaccine, then he shall be "rebuttably presumed" to have contracted vaccinia from the individual who received the vaccine. This means that, unless the government proves that the person who did not receive the vaccine contracted vaccinia from a source other than the individual who did receive the vaccine, the person who contracted vaccinia may sue the government as if he had contracted vaccinia from the vaccine.

Sellers of Anti-Terrorism Technologies: the SAFETY Act

Section 863 of the Homeland Security Act of 2002, titled "Litigation Management" is part of the Support Anti-terrorism by Fostering Effective

⁶ Under 28 U.S.C. § 1346(b), liability must be based on a "negligent or wrongful act or omission," and the Supreme Court has construed this to preclude strict liability. *See, Dalehite v. United States*, 346 U.S. 15, 44-45 (1953).

⁷ In the case of some vaccines, not including smallpox, one may not file a civil action for damages in an amount greater than \$1,000 against a vaccine or administrator until one first files a petition for compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-11(a)(2), and the United States Court of Federal Claims issues a judgment on the petition. This statute is discussed below, under "Vaccine Components and Ingredients."

Technologies Act of 2002, or the SAFETY Act.⁸ Section 863 created a federal cause of action against sellers of anti-terrorism technologies for claims arising out of “an act of terrorism when qualified anti-terrorism technologies have been deployed in defense against or response or recovery from such an act” Prior to enactment of this section, suits against sellers of qualified anti-terrorism technology would have been brought under state law, but the new federal cause of action apparently precludes suits from being brought under state law.⁹ Under the new federal cause of action, liability against qualified sellers of anti-terrorism technologies is more limited than it generally is under state law. The Secretary of Homeland Security shall determine whether an anti-terrorism technology qualifies for liability protection, and shall place each technology that does on an “Approved Product List for Homeland Security” and issue it a “certificate of conformance.” The Department of Homeland Security issued a proposed rule to implement the SAFETY Act,¹⁰ then an interim rule, which took effect on October 16, 2003,¹¹ and then a final rule, which took effect July 10, 2006.¹²

Under the new federal cause of action, the substantive (as opposed to procedural) law that governs liability is the law of the state in which the acts of terrorism occur, except for the federal liability limitations discussed below.¹³ The significance of creating a federal cause of action is that suits may be brought in federal court regardless of the domicile of the parties and regardless of the amount of damages that the plaintiff seeks.¹⁴ In fact, section 863 requires that suits be brought in federal court; though federal causes of action generally may also be brought in state court, this particular cause of action may not be, as section 863 provides that the “appropriate federal district court” shall have “exclusive jurisdiction.”¹⁵

⁸ For additional information, see [<http://www.safetyact.gov>].

⁹ The SAFETY Act does not explicitly preempt state causes of action, but appears to do so implicitly. Section 863(a)(2) gives federal district courts exclusive jurisdiction, but the statute does not state that the federal cause of action is exclusive. It would not seem reasonable, however, to construe the statute not to preempt state causes of action because, if it did not preempt them, then, because state causes of action in some states do not include liability limitations similar to those in the SAFETY Act, plaintiffs in those states would bring state causes of action (albeit in federal court) and the SAFETY Act would have no effect in those states.

¹⁰ 68 Fed. Reg. 41419-41432 (July 11, 2003), 6 C.F.R. Part 25.

¹¹ 68 Fed. Reg. 59684-59704 (October 16, 2003), 6 C.F.R. Part 25.

¹² 71 Fed. Reg. 33147-33168 (June 8, 2006), 6 C.F.R. Part. 25.

¹³ This includes “choice of law principles,” which means that, under section 863, if a state’s law calls for the application of another state’s law, then the first state may apply the second state’s law.

¹⁴ 28 U.S.C. § 1332 allows state causes of action to be brought in federal court only if the plaintiffs and defendants are from different states and the amount in controversy exceeds \$75,000.

¹⁵ The reason that the statute created a federal cause of action, 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
(continued...)

Exceptions to the Application of State Law. Although the substantive law of the state in which the acts of terrorism occur governs the new federal cause of action, section 863 prescribes some rules that preempt state law.

- Section 863 prohibits awards of punitive damages and of interest prior to judgment.
- Section 863 prohibits joint and several liability for noneconomic damages. Noneconomic damages are damages for pain and suffering and other losses that do not constitute monetary expenses, such as medical bills and lost wages. Joint and several liability is the rule that, if more than one defendant is found liable for a plaintiff's injuries, then each defendant may be held 100 percent liable. (The plaintiff may not recover more than once, but he may recover all his damages from one defendant, with that defendant then entitled to seek contribution from other liable defendants.) The reason for joint and several liability is that the common law viewed it as preferable for a wrongdoer to pay more than his share of the damages than for an injured plaintiff to recover less than the full compensation to which he is entitled. Under section 863, in lieu of joint and several liability for noneconomic damages, "[n]oneconomic damages may be awarded against a defendant only in an amount directly proportional to the percentage of responsibility for the harm to the plaintiff." Joint and several liability will continue to apply to economic damages, except when state law provides otherwise.
- Section 863 eliminates the collateral source rule. This is the rule that allows an injured party to recover damages from the defendant even if he is also entitled to receive them from a third party (a "collateral source"), such as a health insurance company or an employer. The collateral source rule may allow double recovery for the plaintiff, but the common law viewed it as better for the victim than for the wrongdoer to profit from the victim's prudence (as in buying health insurance) or good fortune (in having some other collateral source available). Section 863 provides: "Any recovery by a plaintiff . . . shall be reduced by the amount of collateral source compensation, if any, that the plaintiff has received or is entitled to receive. . . ."
- Section 863 permits the government contractor defense. This is a defense, created by the Supreme Court pursuant to "federal common law," that product manufacturers may use in products liability cases that allege a design defect or a failure to warn.¹⁶ These are cases,

¹⁵ (...continued)

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).

¹⁶ *Boyle v. United Technologies Corp.*, 487 U.S. 500, 504 (1988) (design defect); *Densberger v. United Technologies Corp.*, 297 F.3d 66, 75 n.11 (2d Cir. 2002) (failure to (continued...))

brought under state law, in which the plaintiff alleges that his injuries were caused by a product that was defective in that the manufacturer failed to use the safest feasible design for the product or failed to provide adequate warnings of a product hazard that could not be eliminated by a feasible safer design. In its defense, the manufacturer may assert that it manufactured the product pursuant to a government contract and that the design or warning it used was required by contract specifications. When it successfully asserts this defense, it may not be held liable. Under section 863, however, as interpreted by the Department of Homeland Security, “[s]ellers of qualified anti-terrorism technologies need not design their technologies to federal government specifications in order to obtain the government contractor defense under the SAFETY Act. Instead, the Act sets forth criteria for the Department’s Certification of technologies [that are eligible for the defense].”¹⁷

Under section 863, that is, the government contractor defense would be available “when qualified anti-terrorism technologies approved by the Secretary” have been deployed, and “[t]he Secretary will be exclusively responsible for the review and approval of anti-terrorism technology for purposes of establishing a government contractor defense” This indicates that the Secretary’s approval of anti-terrorism technology for purposes of establishing a government contractor defense is separate from his determination that anti-terrorism technology qualifies to be subject to suit under section 863 instead of under state law.

Section 863(d) provides:

Should a product liability or other lawsuit be filed . . . relating to . . . qualified anti-terrorism technologies approved by the Secretary . . . there shall be a rebuttable presumption that the government contractor defense applies in such a lawsuit. This presumption shall only be overcome by evidence showing that the Seller acted fraudulently or with willful misconduct in submitting information to the Secretary This presumption of the government contractor defense shall apply regardless of whether the claim against the Seller arises from a sale of the product to Federal Government or non-Federal Government customers.”

On its face, this language seems to immunize government contractors from liability for injuries caused by defects that were not necessarily required by contract specifications, including defects that were not even design defects but that occurred in the manufacturing process. In other words, it appears to provide immunity to sellers in all cases in which the seller did not engage in the specified fraud or misconduct. One might argue, however, that, when section 863 says that “the government contractor defense applies,” it means only that it applies in the general circumstance in which it ordinarily applies, namely in design defect cases in which the defendant followed government contract specifications. The Department of Homeland

¹⁶ (...continued)
warn).

¹⁷ 71 Fed. Reg. 33149.

Security apparently takes this position when it states that, except when the presumption in favor of the government contract is rebutted, it is “clear that any Seller of an ‘approved’ technology cannot be held liable under the Act for design defects or failure to warn claims. . . . The Department believes that Congress incorporated the Supreme Court’s *Boyle* line of cases as it existed on the date of enactment of the SAFETY Act, rather than incorporating future developments of the government contractor defense in the courts.”¹⁸

Liability Insurance. Section 864(a) of the Homeland Security Act of 2002 provides that sellers of anti-terrorism technology to federal and non-federal government customers must obtain liability insurance in such amounts as the Secretary shall require, and such insurance shall protect, in addition to the seller, “contractors, subcontractors, suppliers, vendors and customers of the Seller,” and “contractors, subcontractors, suppliers, and vendors of the customer.” Section 864(b) provides that “[t]he Seller shall enter into a reciprocal waiver of claims with its contractors, subcontractors, suppliers, vendors and customers, and contractors and subcontractors of the customers . . . under which each party to the waiver agrees to be responsible for the losses . . . that it sustains” Section 864(c) provides that a seller’s liability shall be limited to the amount of liability insurance coverage that it is required to maintain under section 864(a).

Air Transportation Security Companies

Section 890 of the Homeland Security Act of 2002 limits the liability of air transportation security companies and their affiliates for claims arising from the September 11, 2001 air crashes. It limits their liability to the amount of liability insurance they had on that date.

Section 890, more precisely, limits the liability of “persons engaged in the business of providing air transportation security and their affiliates,” if they are employees or agents of “a citizen of the United States undertaking . . . to provide air transportation” and, if agents, “have contracted directly with the Federal Aviation Administration on or after and commenced services no later than February 17, 2002, to provide such security and have not been or are not debarred for any period within six months from that date.” Section 890 limits the liability of such persons (i.e., air transportation security companies and their affiliates) only for claims “arising from the terrorist-related crashes of September 11, 2001,” and it limits it to the “amount of liability insurance coverage maintained by that . . . person.”¹⁹

¹⁸ *Id.*

¹⁹ It is not apparent the circumstances in which an air transportation security company would both be an agent of a citizen of the United States who provides air transportation and have contracted directly with the FAA. It is also not apparent why companies who provided air transportation security on September 11, 2001 are required to have contracted with the FAA by February 17, 2002 in order to benefit from the liability limitation.

The September 11th Victim Compensation Fund of 2001²⁰ already provides this liability limitation for air carriers. What section 890 of the Homeland Security Act of 2002 does is to redefine “air carrier” to include the persons referred to in the preceding paragraph.

Air Carriers

Section 1201 of the Homeland Security Act of 2002, 49 U.S.C. § 44303(b), limited the liability of air carriers “[f]or acts of terrorism committed on or to an air carrier” through 2003, and it has been extended through 2008. This section, in effect, reenacted section 201(b)(2) of the Air Transportation Safety and System Stabilization Act, P.L. 107-42, which was enacted on September 22, 2001. (Title IV of this act created the September 11th Victim Compensation Fund of 2001.)

Section 201(b)(2) of P.L. 107-42 conferred a liability limitation on air carriers for terrorist attacks that might have occurred after September 11, 2001. It provides that,

[f]or acts of terrorism committed on or to an air carrier during the 180-day period following the date of enactment of this Act, the Secretary of Transportation may certify that the air carrier was a victim of an act of terrorism and . . . shall not be responsible for losses suffered by third parties (as referred to in section 205.5(b)(1) of title 14, Code of Federal Regulations) that exceed \$100,000,000, in the aggregate, for all claims by such parties arising out of such act.

If the Secretary so certifies, making the air carrier not liable for an amount that exceeds \$100 million, then “the Government shall be responsible for any liability above such amount. No punitive damages may be awarded against an air carrier (or the Government taking responsibility for an air carrier under this paragraph) under a cause of action arising out of such act.”

The section in the Code of Federal Regulations that section 201(b) mentions refers to “persons, including non-employee cargo attendants, other than passengers”; these are apparently the “third parties” to whom section 201(b) refers, for whose losses above \$100 million the government, but not an air carrier, would be responsible. P.L. 107-42, as noted, was enacted on September 22, 2001, which means that it sunset on March 21, 2002.

Section 1201 of the Homeland Security Act of 2002 extended the period during which section 201(b) would apply to December 31, 2003. It also gave certifying authority for operation of the liability limitation to the Secretary of Homeland Security instead of the Secretary of Transportation, and it codified the section in 49 U.S.C. § 44303(b). P.L. 110-161, § 114(b) extended the liability limitation to December 31, 2008.²¹

²⁰ 49 U.S.C. § 40101 note; P.L. 107-42, title IV, as amended by P.L. 107-71, title II. See CRS Report RL31179, *The September 11th Victim Compensation Fund of 2001*.

²¹ For prior extensions, see P.L. 110-116, §§ 101 and 102 (specifically, the new § 156 of P.L. (continued...))

Federal Flight Deck Officers

Section 1402 of the Homeland Security Act of 2002 created 49 U.S.C. § 44921 to “establish a program to deputize volunteer pilots of air carriers providing passenger air transportation or intrastate passenger air transportation as Federal law enforcement officers to defend the flight decks of aircraft of such air carriers against of criminal violence or air piracy. Such officers shall be known as ‘Federal flight deck officers.’” Subsection (h) of section 44921 provides: “(1) An air carrier shall not be liable for damages in any action . . . arising out of a Federal flight deck officer’s use of or failure to use a firearm,” and “(2) A Federal flight deck officer shall not be liable for . . . acts or omissions . . . in defending the flight deck of an aircraft unless the officer is guilty of gross negligence or willful misconduct.”

Subsection (h)(3) provides: “For purposes of an action against the United States with respect to acts or omissions of a Federal flight deck officer in defending the flight deck of an aircraft, the officer shall be treated as an of the Federal Government.” This means (as explained above under “Smallpox Vaccines”) that the federal government may be sued under the Federal Tort Claims Act. This is apparently the case even when a Federal flight deck officer is guilty of gross negligence or willful misconduct, except that, among the FTCA’s exceptions to government liability is that the government may not be held liable for claims based on assault or battery.

Note that, ordinarily, when a person is treated as a federal employee for liability purposes, he becomes totally immune from tort liability. Section 1402 makes Federal flight deck officers an exception, as it leaves them liable for gross negligence or willful misconduct. Subsection (h)(3) recognizes this by treating Federal flight deck officers’ as federal employees only “[f]or purposes of an action against the United States”; it does not treat them as federal employees for purposes of an action against themselves.

Vaccine Components and Ingredients Manufacturers and Administrators

Sections 1714-1717 of the Homeland Security Act of 2002 amended the National Childhood Vaccine Injury Act of 1986,²² which is part of the Public Health Service Act. We first explain the 1986 act and then the Homeland Security Act’s amendments to it. **Note:** *sections 1714-1717 were repealed by P.L. 108-7 (2003), Division L, § 102; see the end of this report for details.*

National Childhood Vaccine Injury Act of 1986. This statute created the National Vaccine Injury Compensation Program and provides that one may not sue a vaccine manufacturer or administrator for more than \$1,000, for death or injury caused by vaccines set forth in the statute’s Vaccine Injury Table, unless one first files a petition for compensation under the Program, and the United States Court of Federal

²¹ (...continued)
110-92 added by § 102 of P.L. 110-116).

²² 42 U.S.C. §§ 300aa-1 — 300aa-34.

Claims issues a judgment on the petition. The Program, which is funded by a tax on vaccines, provides more limited recovery than is generally allowed under state tort law, but provides relatively fast, no-fault compensation. It was hoped that “the relative certainty and generosity of the system’s awards will divert a significant number of potential plaintiffs from litigation.”²³

Recovery under the Program is limited to actual unreimbursable expenses, up to \$250,000 for pain and suffering and emotional distress, \$250,000 in the event of a vaccine-related death, actual and anticipated loss of earnings, and attorneys’ fees and other costs, but no punitive damages. A petitioner dissatisfied with his recovery under the Program may sue a vaccine manufacturer or administrator under state tort law, with some limitations. Manufacturers are not liable for failure to provide warnings directly to the injured party, as a warning to the vaccine administrator is deemed sufficient. There are rebuttable presumptions that manufacturers who comply with federal regulations are not subject to suit for failure to warn or to punitive damages.

Petitions for compensation under the Program are filed for “a vaccine-related injury or death,” and that “term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such vaccine.”²⁴

Homeland Security Act Amendments. Sections 1714-1716 of the Homeland Security Act of 2002 made the Program applicable not only to vaccines in the Vaccine Injury Table, but to “any component or ingredient of any such vaccine.” Section 1717 made sections 1714-1716 applicable “to all actions or proceedings pending on or after the date of enactment of this Act,” which was November 25, 2002. An action or proceeding is no longer pending when a court has entered a judgment that entirely disposes of it, regardless of whether the time for appeal has expired.

Section 1715 added a sentence to the section quoted above that provides that the Program does not cover “an adulterate or contaminant.” The new sentence provides that the term “adulterate or contaminant shall not include any component or ingredient.”

The statute does not state whether a claim that was pending on November 25, 2002 may be pursued if the statute of limitations in the National Childhood Vaccine Injury Act of 1986 had already run on that date.²⁵

Although sections 1714-1717 apply to the components and ingredients of every vaccine listed in the Vaccine Injury Table, press reports indicate that this provision was intended to benefit pharmaceutical manufacturer Eli Lilly, which has been “a

²³ H.Rept. 99-908, Part I, 99th Cong., 2d Sess. 13 (1986); *reprinted in* 1986 U.S.C.C.A.N. 6354.

²⁴ 42 U.S.C. § 300aa-33(5).

²⁵ The statute of limitations is three years from “the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury,” except that if a death occurred as a result of the vaccine, then the statute of limitations is two years from the date of death and four years from “the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of the injury from which the death resulted.” 42 U.S.C. § 300aa-16(a)(2),(3).

major target in a spate of lawsuits filed since 2000” concerning Thimerosal, which is a preservative used in some childhood vaccines. Thimerosal contains mercury, which allegedly has caused autism in some vaccinated children.²⁶

Courts, however, have held that Thimerosal is not an “adulterant” or “contaminant” as used in the statute (as quoted above), but is a vaccine “component”²⁷ and therefore was covered by the Program before enactment of the Homeland Security Act of 2002. A case decided in September 2002 stated:

It appears that every federal court to have ruled on the issue has held that injuries resulting from Thimerosal contained in vaccines are vaccine-related under the meaning of the Act. *See Liu v. Aventis Pasteur*, No. A-02-CA-395-SS, 2002 WL 31007709 (W.D.Tex. August 23, 2002) (holding the injuries were vaccine related in a motion to dismiss); *Owens v. Am. Home Prods. Corp.* 203 F. Supp.2d 748 (S.D. Tex. 2002); *see also McDonald v. Abbott Labs*, 02-77 (S.D. Miss. Aug. 1, 2002); *Collins v. Am. Home Prods. Corp.*, 01-979 (S.D.Miss. Aug. 1, 2002); *Stewart v. Am. Home Prods. Corp.*, 02-427 (S.D. Miss. Aug. 1, 2002)(denying motion to remand and granting motion to dismiss); *Strauss v. American Home Prod. Corp.*, 208 F. Supp.2d 711 (S.D. Tex., 2002) (finding injuries from Thimerosal are “vaccine-related” under the Vaccine Act); *Blackmon v. American Home Prod. Corp.*, Cause No. G-02-179 (S.D. Tex. May 8, 2002) (same); *Owens v. American Home Prod. Corp.*, 203 F. Supp.2d 748 (S.D. Tex. 2002)(same). Additionally, the Department of Health and Human Services has taken the position that Thimerosal is not an adulterant or contaminant of vaccines.²⁸

It appears, therefore, that, with respect to Thimerosal, sections 1714-1717 would have made a difference only to the extent that they would have precluded future court decisions that disagree with these.

P.L. 108-7 (2003), Division L, § 102, repealed sections 1714-1717, and provided that the Vaccine Program “shall be applied and administered as if the sections . . . had never been enacted. . . . No inference shall be drawn from enactment of sections 1714 through 1717 . . . or from this repeal, regarding the law prior to enactment of sections 1714 through 1717. . . . Further, no inference shall be drawn that [this repeal] affects [sic] any change in that prior law, or that *Leroy v. Secretary of Health and Human Services* [*supra*, note 22] was incorrectly decided.”

P.L. 108-7 (2003), Division L, § 102, also provides that it is the sense of Congress that, not later than six months after the date of its enactment, which was February 20, 2003, the Senate Committee on Health, Education, Labor, and Pensions; and the House Committee on Energy and Commerce, “should report a bill addressing the issues” of ensuring an adequate supply of vaccines, developing new vaccines, and liability for vaccine-related injuries.

²⁶ “Homeland Bill Rider Aids Drugmakers,” *Washington Post*, November 15, 2002, p. A7.

²⁷ *Leroy v. Secretary of the Department of Health and Human Services*, No. 02-392, 2002 U.S. Claims LEXIS 284 (October 11, 2002).

²⁸ *Bertrand v. Aventis Pasteur Laboratories, Inc.*, 226 F. Supp.2d 1206, 1213 (D. Ariz. 2002). This quotation names eight cases, and the cases cited in this footnote and the previous footnote make a total of ten that have ruled the same way.