LEGISLATIVE MODIFICATIONS TO TORT LIABILITY: THE UNINTENDED CONSEQUENCE OF PUBLIC HEALTH AND BIOTERRORISM THREATS

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I. INTRODUCTION

Public health concerns, bioterrorism, and limited vaccine availability have prompted the enactment of laws that modify causes of action ordinarily available to litigants. Vaccine manufacturers, producers of qualified anti-terrorist technologies, and manufacturers of other products deemed necessary to address public health threats, including entities in the line of distribution, have benefitted from these revised tort remedies. The U.S. Congress continues to use legislation as a tool to assist the federal government in protecting the public health and well-being of U.S. citizens.

The rationale for such legislative modifications to traditional tort law remedies is simple: to encourage manufacturers to produce products deemed essential by the federal government to protect citizens against public-health and other threats without undue risk of liability. This Article discusses the diverse legislative enactments, whether and how they have achieved their stated goals, the impact of such legislation on principles of traditional tort law in the United States, and the methods available for achieving legislative protection.

II. ORIGINS OF TORT LAW MODIFICATION: THE 1976 SWINE FLU PROGRAM

Legislative tort modification is a concept that was initially considered in response to what was believed to be an exigent health crisis. When faced with the possibility of a flu pandemic, the federal govern-

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ment, acting through both the executive and legislative branches, believed creative solutions were necessary to provide the government with tools to protect U.S. citizens. In particular, tort liability regimes in both state and federal judicial systems were modified.

A. HISTORY AND BACKGROUND

The genesis of the Swine Flu Program was the apparent isolation of the swine flu virus from a small number of soldiers at the Fort Dix U.S. Army Base in New Jersey in January 1976.¹ Throat cultures taken from sick soldiers grew what scientists at the Centers for Disease Control and Prevention ("CDC") identified as a "swine-like flu virus which was believed to have been inactive in the human population since 1930 with the exception of a handful of cases of swine-toperson transmission."² Fearful that the isolation of this virus meant that the country was on the verge of a large-scale influenza pandemic, government scientists promptly responded.³

In the days and weeks that followed, a flurry of meetings were held involving representatives of various federal agencies, including the CDC, the United States Food and Drug Administration ("FDA"), Bureau of Biologics ("BoB"), the National Institute of Allergies and Infectious Diseases ("NIAID"), and the World Health Organization ("WHO"). The representatives from these agencies extensively debated numerous alternatives on how to respond to the outbreak, including stock-piling vaccine, delaying administration pending a second outbreak, or doing nothing.

On March 18, 1976, Dr. Theodore Cooper, the Assistant Secretary for the United States Department of Health, Education, and Welfare ("HEW"), issued a memorandum—which was drafted by CDC Director Dr. David Sencer—addressed to David Mathews, Secretary of HEW, bearing the heading "Swine Influenza: ACTION," which contained seven facts. The second fact stated: "The virus [isolated at Fort Dix] is antigenically related to the influenza virus . . . implicated as the cause

^{1.} RICHARD E. NEUSTADT & HARVEY V. FINEBERG, THE SWINE FLU AFFAIR: DECI-SION-MAKING ON A SLIPPERY DISEASE 4 (1978); Walter R. Dowdle, *The 1976 Experience*, 176 J. INFECTIOUS DISEASES 69, 69 (1976).

^{2.} Memorandum from the Assistant Sec'y of Health to the Sec'y of Health, Educ., & Welfare (Mar. 18, 1976), *reprinted in* NEUSTADT & FINEBERG, *supra* note 1, app. D at 127.

^{3.} In the 1918-19 influenza pandemic, twenty million people worldwide died of influenza, and two billion people contracted the disease. Arnold W. Reitze, Jr., Federal Compensation for Vaccination Induced Injuries, 13 B.C. ENVTL. AFF. L. REV. 169, 170 (1986). In the United States alone, 500,000 people died. Id. Between one-quarter and one-third of all Americans were infected. Douglas Almond, Is the 1918 Influenza Pandemic Over? Long-Term Effects of In-Utero Influenza Exposure in the Post-1940 U.S. Population 8 (June 15, 2006) (unpublished dissertation, Columbia University), available at http://www.nber.org/-almond/jmp3/pdf.

of the 1918-1919 pandemic which killed 450,000 people—more than 400 out of every 100,000 Americans."⁴ With this, Dr. Cooper stated that the following factors were "the ingredients for a pandemic": "person-to-person spread had been proven[,] . . . additional outbreaks [could] not be ruled out[, then-p]resent evidence and past experience indicate[d] a strong possibility that this country [would] experience widespread Influenza A/swine influenza in 1976-77[,] . . . and the population under 50 was almost universally susceptible."⁵

Following further discussions, and in accordance with the unanimous views of his professional and scientific advisors (including Drs. Jonas Salk and Albert Sabin), President Gerald Ford announced on March 24, 1976, that he would seek supplemental funds from Congress for the purpose of organizing and conducting an influenza mass immunization program.⁶ That same date, President Ford announced on national television his recommendation for a nationwide influenza vaccination program to include "every man, woman and child in the United States."⁷ Indeed, he committed to giving the swine flu program his direct and continuous attention "[b]ecause the health of our nation is at stake"⁸

Congressional hearings promptly followed President Ford's public pronouncement.⁹ On April 12, 1976, Congress passed the supplemental appropriation legislation President Ford had requested. President Ford signed the bill into law on April 15, 1976.¹⁰

B. The Role of Vaccine Manufacturers and Their Insurers in the Swine Flu Program

Legislation alone, however, was not enough to implement a mass immunization program. To actually proceed with such a program, a suitable vaccine needed to be developed and tested, which required difficult decisions on the scope and extent of the program. Even assuming a suitable vaccine could be developed, a major stumbling block

^{4.} Memorandum from the Assistant Sec'y of Health, supra note 2, at 127.

^{5.} Id. at 127-28.

^{6.} NEUSTADT & FINEBERG, supra note 1, at 24-25.

^{7.} Id. at 25.

^{8.} Memorandum on a National Swine Flu Immunization Program from President Gerald Ford to the Heads of Dep'ts & Agencies (Mar. 31 1976), *available at* http://www.presidency.ucsb.edu/ws/index.php?pid=5778#axz1ZXtjDdEO.

^{9.} See Proposed National Swine Flu Vaccination Program: Hearing on H.R. 13012 Before the Subcomm. on Health & the Envit of the H. Comm. on Interstate & Foreign Commerce, 94th Cong. (1976); Emergency Supplemental Appropriations Bill: Hearing on H.R.J. Res. 890 Before the Subcomm. on the Dep'ts of Labor and Health, Educ., & Welfare of the H. Comm. on Appropriations, 94th Cong. (1976); see also Sharon L. Begley, The Failure of the 1976 Swine Flu Program, 50 YALE J. BIOLOGY & MED. 645, 650-51 (1977).

^{10.} NEUSTADT & FINEBERG, supra note 1, at 109.

remained: liability protection for the vaccine manufacturers from the very viable threat of litigation following the contemplated mass immunization program, even if such anticipated claims lacked merit.¹¹

Manufacturers raised their concern early on regarding liability exposure. The issue became more pronounced after insurers for the four major vaccine manufacturers, one by one, advised that they would exclude manufacturers from products liability coverage for all indemnity and defense costs associated with claims arising out of the swine flu program.¹² The Pharmaceutical Research and Manufacturers of America also cautioned that the government should indemnify the manufacturers for claims regarding the "quality of the vaccine, since it was being produced according to strict government specifications."¹³

Insurers drew a bold line in the sand, clarifying that coverage for all indemnity and defense costs associated with claims arising out of the swine flu program would be excluded.¹⁴ Just months before the program was to begin, the manufacturers and their insurers firmly stated their refusal to participate in the program, unless they were assured of complete governmental indemnification.¹⁵ On June 25, 1976, the chief of the Washington branch of the American Insurance Association, Leslie Cheek, advised government representatives that the insurance industry would not provide insurance to vaccine manufacturers because the liability potential was "enormous and worse, uncertain."16 Perhaps smarting from earlier vaccine-related injury claims stemming from polio immunizations, the insurers asserted that there was no experience from which they could draw to assess the costs associated with such a massive vaccination program, and they bristled about the overhead and management costs associated with defending litigation that might arise from the administration of 200 million doses of vaccine.¹⁷

Even before the swine flu event at Fort Dix, a lawyer on the HEW staff questioned whether federal indemnification, wherever there was federal sponsorship of immunization, had potential ramifications far beyond the indemnification of vaccine manufacturers for vaccine-associated disability, which would create an undesirable precedent almost across the board.¹⁸

^{11.} Begley, supra note 9, at 653.

^{12.} See NEUSTADT & FINEBERG, supra note 1, at 108-14; Begley, supra note 9, at 653.

^{13.} Begley, supra note 9, at 651.

^{14.} See NEUSTADT & FINEBERG, supra note 1, at 108-14.

^{15.} Begley, supra note 9, at 653-54.

^{16.} NEUSTADT & FINEBERG, supra note 1, at 41.

^{17.} Id. at 41, 45-46; Begley, supra note 9, at 653.

^{18.} NEUSTADT & FINEBERG, supra note 1, at 42-43.

In response to industry concerns, the government initially proposed that it would assume the duty to warn all vaccine recipients.¹⁹ The manufacturers would accept responsibility for simple negligence, and no more.²⁰ The response to this proposal was lukewarm, and as the president of one vaccine manufacturer stated in hindsight, "If the public was really endangered, the government should take the risk; it certainly could, we couldn't."²¹ With the benefit of hindsight, the large number of lawsuits filed after the cessation of the Swine Flu Program proved that insurers' and manufacturers' concerns were ultimately justified.

On Capitol Hill, hearings on vaccine manufacturer indemnification drew a harsh response. Some members of the House Health Subcommittee could "not understand why insurers were reluctant to insure a vaccine whose medical risks appeared minimal."²² Despite this objection on the Hill, and the accompanying risk of derailing the Swine Flu Program, President Ford remained resolute. When advised about the continuing risk of a pandemic, he stated, "[W]e are going to find a way, either with or without the help of Congress, to carry out this program that is absolutely essential"²³

C. CONGRESSIONAL ACTION

On August 12, 1976, after much discussion and debate, Congress enacted the National Swine Flu Immunization Program Act of 1976²⁴ ("Swine Flu Act") "to amend the Public Health Service Act to authorize the establishment and implementation of an emergency national swine flu immunization program and to provide an exclusive remedy for personal injury or death arising out of the manufacture, distribution, or administration of the swine flu vaccine under such program."²⁵ The liability provisions of the legislation warrant careful consideration.

The Swine Flu Act was the government's first real attempt at protecting the vaccine production industry from liability in order to "achieve the participation in the swine flu program of . . . the manufac-

^{19.} See id. at 108 (referencing Letter from Dr. Theodore Cooper, Assistant Sec'y for Health of the U.S. Dep't of Health, Educ., and Welfare to the Pharm. Mfrs. Ass'n (Apr. 5, 1976) ("Cooper says that the manufacturers' concern over liability should be alleviated by the Federal Government's assuming the duty to warn.")). See generally Begley, supra note 9, at 645-53.

^{20.} NEUSTADT & FINEBERG, supra note 1, at 44 (internal quotation marks omitted).

^{21.} Id. at 46.

^{22.} Id. at 49.

^{23.} Id. at 50.

^{24.} Pub. L. No. 94-380, 90 Stat. 1113 (codified at 42 U.S.C. § 274b (2006)).

^{25.} National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380, 90 Stat. 1113 (codified at 42 U.S.C. § 247b).

turers and distributors of the swine flu vaccine."²⁶ Termed "revolutionary" by one commentator, the Swine Flu Act constituted the first time that the federal government abandoned its traditional sovereign immunity to ensure that an adequate flu vaccine stockpile existed.²⁷

Specifically, the Swine Flu Act amended the Public Health Service Act²⁸ by inserting several new subsections, including provisions deemed necessary to assure the availability of vaccine to meet the potential emergency of a swine flu epidemic. Furthermore, to ensure participation by the manufacturers and distributors of the vaccine, the Swine Flu Act included sweeping language, which provided,

The United States shall be liable with respect to claims submitted after September 30, 1976 for personal injury or death arising out of the administration of swine flu vaccine under the swine flu program and based upon the act or omission of a program participant in the same manner and to the same extent as the United States would be liable in any other action brought against it under such section 1346(b) and chapter 171 [The Federal Tort Claims Act] except that . . . the liability of the United States arising out of the act or omission of a program participant may be based on any theory of liability that would govern an action against such program participant under the law of the place where the act or omission occurred, including negligence, strict liability in tort, and breach of warranty²⁹

To further protect the manufacturers and other program participants, the Swine Flu Act established a statutory claims protocol. The liability limitations were drafted to "protect" vaccine manufacturers, distributors, and others though a process which provided for "an exclusive remedy... against the United States"³⁰ Under the Swine Flu Act, claimants and litigants were required to pursue the well-established process for seeking remedies against the United States under the Federal Tort Claims Act,³¹ with modifications to extend the liability in particular instances (e.g., strict liability claims and narrowing of jurisdictional defenses otherwise available to the United States). The United States in turn was entitled to recover the portion of damages it paid to the extent that the payment resulted

30. Id. § 247b(k)(1)(A).

^{26.} Id.; B. Kurt Copper, Note and Comment, "High and Dry?" The Public Readiness and Emergency Preparedness Act and Liability Protection for Pharmaceutical Manufacturers, 40 J. HEALTH L. 65, 71 (2007).

^{27.} Copper, supra note 26, at 71-72.

^{28. 42} U.S.C. §§ 201-300.

^{29.} Id. § 247b(k)(2)(A).

^{31. 28} U.S.C. §§ 1346(b), 2401(b), 2402, 2671-2680 (1976).

from the failure of any program participant to carry out any obligation or responsibility assumed by it under a contract with the United States in connection with the program or from any negligent conduct on the part of any program participant in carrying [sic] out any obligation or responsibility in connection with the swine flu program.³²

This legislation set forth liability limitations that have, consciously and subconsciously, served as a template for subsequent tort liability limitation legislation, related to both health and non-health tort liability concerns.³³

D. THE AFTERMATH

The Swine Flu Immunization Program ended just ten months after it started. Approximately one-quarter of the United States population, roughly forty-five million people, was vaccinated during the twoand-one-half-month course of the program.³⁴ No pandemic ever occurred. As of January 3, 1991, 1,604 civil actions had been filed and 4,179 claims had been presented administratively, resulting in payouts through judgments and settlements totaling \$92,833.02; as of that date, seven suits and one claim remained pending.³⁵

E. RISK ASSESSMENT V. RISK MANAGEMENT

After the Fort Dix influenza outbreak, scientists were called in from far and wide to assess the risk of a pandemic. Concerns regarding a possible repeat of the 1918 pandemic and the dire ramifications were palpable. The scientific task of "risk assessment" required gathering data relevant to the public health risk through surveys, epidemiologic investigations, research, vitals statistics, and surveillance programs, which were performed by a myriad of public health agencies and private research institutions.³⁶

In contrast, "risk management" involved "action taken in response to the scientific findings of risk assessment . . . includ[ing] prevention and control programs for communicable diseases[,] . . . the provision of public health clinics and prevention messages on health

^{32. 42} U.S.C. § 247b(k)(7).

^{33.} See Begley, supra note 9, at 653-54.

^{34.} Dowdle, supra note 1, at 69, 71; Carol Singer, The Swine Flu Scare of 1976, Docs PRESCRIPTIONS, Spring 2006, at 16-17, available at http://www3.wooster.edu/library/gov/ohgodort/docsrx/issue63.pdf.

^{35.} Torts Branch, Civil Division, Department of Justice, Swine Flu Statistics, (Jan. 3, 1991) (unpublished fact sheet) (on file with author). Of the cases resolved, liability was stipulated in 53 cases, judgments were entered for plaintiffs in 56 contested cases, actions were dismissed in 813 cases, and judgments were entered in favor of the United States in 282 cases. *Id.*

^{36.} Dowdle, supra note 1, at 71.

issues[,]... [and] consensus building among public health workers, the medical community, and the public."³⁷ In addition, risk management called for the support of elected and appointed officials and funding by legislative bodies.³⁸ In sum, risk management is a political process, which, in a democratic society with elected officials, entails determinations about "what risks [society] is willing to take and for just how much management they are willing to pay."³⁹

Ultimately, the decision to enact the Swine Flu Act and proceed with the goal of immunizing every man, woman, and child was a political one. Congressional leaders concluded that the risk of a pandemic, however small, justified the program.

F. Constitutional Challenges to Manufacturers' Immunity Under the Swine Flu Act

Congressional enactment of an exclusive remedy against the United States under the Swine Flu Act meant that plaintiffs were permitted to file claims for vaccine-related injury and damages pursuant to the Swine Flu Act. The Swine Flu Act, however, precluded individuals from obtaining pre-judgment interest, punitive damages, or jury trials or from otherwise seeking remedies that might have been available to them absent enactment of the legislation. Furthermore, claimants and plaintiffs seeking recovery for injuries or damages were required to comply with the procedural conditions and limitations for filing and proceeding with lawsuits, as stated under the Federal Tort Claims Act. In a number of lawsuits, plaintiffs challenged the constitutionality of this statutory scheme by suing program participants, particularly vaccine manufacturers. Courts that addressed these challenges uniformly rejected the plaintiffs' constitutional arguments in terms broad enough to provide a strong precedent for future congressional limitations on tort actions where there is a federal interest in limiting liability.⁴⁰

^{37.} Id.

^{38.} Id.

^{39.} Id. at 71-72.

^{40.} See Jones v. Wyeth Labs., Inc., 583 F.2d 1070 (8th Cir. 1978) (dismissing action for failure to exhaust administrative remedies pursuant to the Federal Tort Claims Act and claim of unconstitutionality in a similar fashion without analysis); Ducharme v. Merrill-National Labs., 574 F.2d 1307 (5th Cir. 1978) (upholding Swine Flu Program immunity against constitutional challenges under due process and trial by jury clauses and finding exclusive cause of action against the United States (versus program participants) rationally related to achieving goal of assuring interstate distribution of swine flu vaccine, in view of the fact that commercial insurers refused to insure drug manufacturers for interstate distribution of the vaccine but would provide insurance for limited risk for which the government could seek indemnity); Sparks v. Wyeth Labs., Inc., 431 F. Supp. 411 (D. Okla. 1977) (opining "the Swine Flu Act comports with due process

III. LESSONS LEARNED: INCORPORATION OF MODIFIED TORT LIABILITY IN SUBSEQUENT CONGRESSIONAL ACTS INVOLVING HEALTH AND SAFETY

CHILDHOOD VACCINE ACT Α.

In the 1980s, the volume of lawsuits filed against pharmaceutical companies for vaccine-related injuries increased substantially, and the number of manufacturers willing to manufacture diphtheria, pertussis, and tetanus ("DPT") vaccinations dropped from eight to two. Partially in response to these facts, Congress passed the National Childhood Vaccine Injury Act of 1986⁴¹ ("Childhood Vaccine Act").⁴²

The childhood vaccine program is no-fault in concept, as it allows claimants to obtain a monetary award from a special master. The Childhood Vaccine Act includes a Vaccine Injury Table of covered vaccines, along with the "injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines," and, inter alia, a time period for symptom manifestation.⁴³ The key issue in the recovery determination for all claims is causation. Claims are submitted to the United States Department of Health and Human Services ("HHS"), which then makes a determination on whether the petition seeking compensation satisfies the symptoms and periods of onset delineated in the Childhood Vaccine Act or contests the claim. Where HHS determines that the petition meets the requirements of the Act, the petition is granted, resulting in compensation. Significantly, HHS is authorized under the Childhood Vaccine Act to promulgate regulations to modify the Vaccine Injury Table, and individuals may petition the HHS Secretary to amend the Table.⁴⁴ The statute of limitation for filing a petition, based on occurrence of the first symptom or manifestation of the injury for which relief is sought, is two years from injury or three years from death.45

Liability protections for vaccine manufacturers are included in this legislation, along with a no-fault compensation system for individuals who demonstrate injuries associated with the administration of

43. 42 U.S.C. § 300aa-14.
44. Id. § 300aa-14(c).

clause of Fifth Amendment" because it abolished cause of action against program participants prospectively and substantial and efficient remedy is provided).

^{41.} Pub. L. No. 99-660, § 301, 100 Stat. 3743 (codified at 42 U.S.C. §§ 300aa-1 to 300aa-34 (2006)).

^{42.} See generally National Childhood Vaccine Injury Compensation Act of 1985: Hearing on S. 827 Before the S. Comm. on Labor & Human Res., 99th Cong. (1985); Vaccine Injury Compensation: Hearings on H.R. 5810 Before the Subcomm. on Health and the Env't of the H. Comm. on Energy & Commerce, 98th Cong. (1984); National Childhood Vaccine-Injury Compensation Act: Hearings on S. 2117 Before the S. Comm. on Labor & Human Res., 98th Cong. (1984); H.R. REP. No. 99-908 (1986).

^{45.} See Cloer v. Sec'y of Health & Human Servs., 654 F.3d 1322 (Fed. Cir. 2011).

vaccinations.⁴⁶ Under the Childhood Vaccine Act, no person can file an action in any state or federal court for more than \$1,000 or for an unspecified amount, claiming vaccine-related injury from a vaccine that HHS has determined to be covered, without first following the claims procedures set forth in the Act. In essence, the procedures ordinarily require a proceeding, which is semi-adversarial in nature, before a United States Court of Federal Claims special master, whose decision is subject to review by a Court of Federal Claims judge. Appeals from the judgment may thereafter be pursued in the United States Court of Appeals for the Federal Circuit. Notably, courts have imposed limits on the seemingly broad scope of the Childhood Vaccine Act. In Moss v. Merck & Co.,47 the United States Court of Appeals for the Fifth Circuit held that the Act did not bar a suit against a manufacturer of thimerosal even though thimerosal had been used as a preservative component in vaccines.⁴⁸ In a separate case involving a loss of consortium claim brought by the non-affected parents of a child who sustained polio from contact with the polio vaccine, the United States Court of Appeals for the First Circuit determined that such a claim fell outside of the Childhood Vaccine Act, even though the affected child had accepted a Court of Federal Claims award. Then-judge, now United States Supreme Court Justice, Breyer rendered this decision.49

The United States Supreme Court recently decided a significant case, *Bruesewitz v. Wyeth, Inc.*,⁵⁰ in which the Court determined that a preemption provision of the Childhood Vaccine Act bars plaintiffs from relying on state law based design defect claims for United States Food and Drug Administration ("FDA") approved vaccines, which are subject to the Childhood Vaccine Act. Justice Breyer's concurring opinion explicitly follows the approach the amicus brief of the United States suggested. That brief succinctly describes the question presented:

The National Childhood Vaccine Injury Act of 1986 provides that "[n]o vaccine manufacturer shall be liable in a civil action" for any injury that "resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. 300aa-22(b)(1). The question presented is whether that provision preempts state law claims against a vaccine

^{46.} See generally 42 U.S.C. §§ 300aa-1 to 300aa-34.

^{47. 381} F.3d 501 (5th Cir. 2004).

^{48.} Moss v. Merck & Co., 381 F.3d 501, 503-04 (5th Cir. 2004).

^{49.} Schafer v. Am. Cyanamid Co., 20 F.3d 1, 1, 3 (1st Cir. 1994).

^{50. 131} S. Ct. 1068 (2011).

manufacturer based on alleged defects in the design of a vaccine subject to the $\rm Act.^{51}$

As this Article has stated, Justice Scalia's opinion for the Court and Justice Breyer's concurring opinion answer this question affirmatively.

B. BIOSHIELD ACT

The September 11, 2001, attacks forced the United States to reassess the real risk of a mass-casualty bioterrorist event. In the 2001 Third Annual Report to the President and to Congress, the Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction concluded that "[1]imited research, development, and production capability for certain vaccines is one of the largest hurdles currently facing military and civilian responders as they prepare for biological threats." Perhaps for this reason, Mark B. McClellan, then-commissioner of the FDA, called counterterrorism the FDA's "biggest new challenge."⁵²

On July 21, 2004, Congress enacted the Project BioShield Act of 2004⁵³ ("BioShield Act") as part of a broader strategy to defend the United States against threats to public health, particularly those posed by terrorists. With this enactment, President George W. Bush declared:

Project BioShield will transform our ability to defend the nation in three essential ways. First, Project BioShield authorizes \$5.6 billion over 10 years for the government to purchase and stockpile vaccines and drugs to fight anthrax, smallpox and other potential agents of bioterror. The Department of Health and Human Services has already taken steps to purchase 75 million doses of an improved anthrax vaccine for the Strategic National Stockpile. Under Project BioShield, HHS is moving forward with plans to acquire a safer, second generation smallpox vaccine, an antidote to botulinum toxin, and better treatments for exposure to chemical and radiological weapons.⁵⁴

The purpose of Project BioShield was to accelerate the research, development, purchase, and availability of effective medical counter-

^{51.} Brief for the United States as Amicus Curiae Supporting Respondent at 1, Bruesewitz v. Wyeth, Inc., 131 S. Ct. 1068 (2011) (No. 09-152), 2010 WL 3017753.

^{52.} Mark B. McClellan, Speech before FDLI (Apr. 1 2003), available at http://www.fda.gov/NewsEvents/Speeches/ucm053719.htm.

^{53.} Pub. L. No. 108-276, 118 Stat. 835 (codified as amended in scattered sections of 42 U.S.C.).

^{54.} Press Release, White House, President Bush Signs Project BioShield Act of 2004 (July 21, 2004), available at http://georgewbush-whitehouse.archives.gov/news/re-leases/2004/07/20040721-2.html.

measures against chemical, biological, radiological, and nuclear ("CBRN") agents.⁵⁵ The BioShield Act's inclusion of funding for the purchase of vaccines was intended to protect the public in the event of a bioterrorist attack.⁵⁶

Like the National Swine Flu Immunization Program Act of 1976⁵⁷ ("Swine Flu Act"), the BioShield Act provided targeted liability protection for manufacturers and others involved in providing medical countermeasures under defined emergency circumstances.⁵⁸ Specifically, it provided that "a covered person shall be immune from suit and liability under Federal and State law with respect to 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....⁷⁵⁹ This immunity broadly applies to any claim for loss that has a causal relationship with the covered countermeasure, including "design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure."⁶⁰

C. THE HOMELAND SECURITY ACT OF 2002 AND THE SAFETY ACT

Consider the following scenario: A bioterrorist attack occurs using a substance that causes a wave of morbidity and mortality. A vaccine could have prevented the devastation if it had been timely administered. This vaccine, however, was negligently manufactured or otherwise "defective" in the product-liability sense of the term. Would this scenario provide the factual predicate for filing common law tort claims? Federal legislation provides a decisive response: not necessarily.

The Support Anti-terrorism by Fostering Effective Technologies Act of 2002⁶¹ ("SAFETY Act"), enacted in response to the events of

^{55.} Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications, 67 Fed. Reg. 1980 (Jan. 15, 2002); *Public Health Emergency*, U.S. DEP'T HEALTH & HUMAN SERVS., http://www.phe.gov/preparedness/ pages/default.aspx (last reviewed Dec. 21, 2011).

^{56.} See U.S. DEP'T OF HEALTH & HUMAN SERVS., PROJECT BIOSHIELD ANNUAL RE-PORT FOR AUGUST 2006-JULY 2007 (2007), available at https://www.medicalcountermeasures.gov/BARDA/documents/bioshieldannualreport2006.pdf.

^{57.} Pub. L. No. 94-380, 90 Stat. 1113 (codified at 42 U.S.C. § 274b (2006)).

^{58.} Pandemic Countermeasures; Declaration Under the Public Readiness and Emergency Preparedness Act, 72 Fed. Reg. 4710 (Feb. 1, 2007).

^{59. 42} U.S.C. § 247d-6d(a)(1).

^{60.} Id. § 247d-6d(a)(2)(B).

^{61.} Pub. L. No. 107-296, § 861, 116 Stat. 1235 (codified at 6 U.S.C. §§ 441-444 (2006)).

September 11, 2001, changed long-standing products liability laws.⁶² As explained by Under Secretary Cohen of the United States Department of Homeland Security ("DHS"), "The mission of the SAFETY Act [was] to facilitate the development and deployment of qualified antiterrorism technologies by creating a system of risk and litigation management."⁶³ The ultimate goal of this legislation was to ensure that "the threat of liability does not deter potential manufacturers or sellers of anti-terrorism technologies from creating or providing products and services that could save lives."⁶⁴ As Representative Thomas Davis, then-Chairman of the House Committee on Oversight and Government Reform stated, by passing the SAFETY Act, "Congress acted quickly to resolve uncertainly over liability concerns so that the full power of the American technology could be unleashed in the war on terrorism."⁶⁵

As with the earlier vaccine legislation, the SAFETY Act constitutes a change in traditional tort reform by recognizing that potential legal exposure would discourage the development, production, and deployment of new technologies needed to protect the United States from "acts of terrorism."⁶⁶ As defined under the SAFETY Act, an "act of terrorism" is a term of art that includes any unlawful act "designed or intended to cause mass destruction, injury or other loss to citizens or institutions of the United States."⁶⁷ Given the vast uncertainties about the adverse impact that future acts of terrorism would have in the United States, Congress decided to remove impediments to the development and use of essential counterterrorism technologies. The goal was to stimulate private industry to create products and services by providing companies legislative protections to limit liability exposure.⁶⁸ While the SAFETY Act does not eliminate liability for the pro-

64. Harter, supra note 63, ¶ 2 n.5.

65. Id. (quoting Advancing New Technologies for Homeland Security: Hearing Before the H. Comm. on Government Reform, 108th Cong. 2 (2003)).

66. See Regulations Implementing the Support Anti-terrorism by Fostering Effective Technologies Act of 2002, 71 Fed. Reg. 33,147, 33,158 (June 8, 2006) (codified at 6 C.F.R. pt. 25 (2011)).

^{62.} The SAFETY Act was part of the Homeland Security Act of 2002, Pub. L. No. 107-296, § 1, 116 Stat. 1235.

^{63.} Ava A. Harter, Encouraging Corporate Innovation During for Our Homeland During the Best of Times for the Worst of Times: Extending SAFETY Act Protections to Natural Disasters, 2007 DUKE L. & TECH. REV. 7, ¶ 2 n.4 (citing Testimony Before the Subcomm. on Mgmt., Integration & Oversight of the H. Comm. on Homeland Sec., 109th Cong. (2006) (statement of Jay M. Cohen, Under Sec'y, Sci. & Tech. Directorate, U.S. Dep't of Homeland Sec.)). See generally Wendy Howe, Getting Anti-Terrorism Technologies Out for Homeland Use—That's Why It's Called the SAFETY Act, J. HOMELAND SE-CURITY, May 2004, available at http://www.homelandsecurity.org/journal/Default.aspx? oid=132&ocat=1.

^{67. 6} C.F.R. § 25.2.

^{68.} See Harter, supra note 63, at ¶ 3.

duction of anti-terrorism products and services, it "provides incentives for the development and deployment of anti-terrorism technologies by creating a system of 'risk management' and 'litigation management,'" thus encouraging manufacturers and sellers of such technologies to "develop and commercialize technologies that may significantly reduce the risks or mitigate the effects of large-scale terrorist events."⁶⁹

Pursuant to the SAFETY Act, if a "qualified technology" has been deployed in defense of a terrorist attack, the appropriate federal district court would have exclusive jurisdiction over any civil action arising from the terrorist acts, except actions against the terrorists.⁷⁰ Moreover, the qualified technology seller cannot be liable for more than the amount of reasonably available insurance coverage.⁷¹ The Secretary of DHS determines the amount of insurance that the statute requires the seller to obtain; the liability insurance must protect contractors, subcontractors, and suppliers as well as the technology seller.⁷²

The limit of liability to reasonably available insurance, however, is not the only significant liability limitation in the SAFETY Act. In a pronounced effort to protect the health and safety of Americans, Congress included provisions in the SAFETY Act, which like the Swine Flu Act, alter the traditional tort law remedies otherwise available to the public. In any action covered by the exclusive remedy provision of the SAFETY Act, no punitive damages may be awarded;⁷³ noneconomic damages may not be awarded unless the plaintiff suffered actual physical harm⁷⁴; noneconomic damages may be awarded against a defendant only in an amount directly proportional to the percentage of responsibility of such defendant for the harm to the plaintiff⁷⁵; and collateral source compensation may be used to reduce the plaintiff's recovery.⁷⁶

If a technology is "approved" by DHS—in addition to being designated as a "qualified" technology—another key barrier exists, which can potentially bar recovery altogether. Specifically, the barrier to any recovery in an action arising out of or relating to a DHS-qualified and approved technology is the "government contractor defense" incorporated in, and modified by, the SAFETY Act. The SAFETY Act cre-

^{69.} U.S. Dep't of Homeland Sec., Step-By-Step User Guide (slideshow), available at https://www.safetyact.gov/ (last visited Jan. 13, 2012).

^{70. 6} U.S.C. §§ 442(a), 442(e).

^{71.} Id. § 443(c).

^{72.} Id. §§ 443(a)(1), 443(a)(3).

^{73.} Id. § 442(b)(1).

^{74.} Id. § 442(b)(2)(A).

^{75.} Id. § 442(b)(2)(A).

^{76.} Id. § 442(c).

ates a presumption that the "government contractor defense" applies in any such action. $^{77}\,$

In Boyle v. United Technologies Corp.,⁷⁸ the seminal case defining the contours of this defense to tort claims, the United States Supreme Court looked to the discretionary function exception⁷⁹ in the Federal Tort Claims Act⁸⁰ as a starting point because this exception raises potential "significant conflict" between federal interests and state law.⁸¹ Based on this premise, the Boyle Court enunciated a three-part test for displacing state tort liability for design defects in military equipment. Under Boyle, state law is displaced where (1) the federal government "approved reasonably precise specifications"; (2) the equipment "conformed to those specifications"; and (3) the supplier gave a warning to the government "about dangers in the use of the equipment known to the supplier but not to the [government]."⁸²

In SAFETY Act suits—unlike proceedings in ordinary tort suits the government contractor defense presumptively applies, regardless of whether the sale is to government or non-government customers, and "shall only be overcome by evidence showing that the Seller acted fraudulently or with willful misconduct in submitting information to the Secretary" during the design-approval process.⁸³

1. Department of Homeland Security Regulations

DHS promulgated regulations to implement the SAFETY Act.⁸⁴ These regulations, along with the supplementary information and comments DHS included at the time it issued the interim final regulations, constitute logical initial steps to establish procedures for how manufacturers can seek certification and approval of anti-terrorist technologies from DHS.⁸⁵ The regulations and explanatory guidelines highlight issues related to tort immunity, which may equally apply to other products and future legislation.

Consistent with Congress's clear intent in enacting this legislation, DHS recognized that "the current development of anti-terrorism technologies has been slowed due to the potential liability risks associ-

^{77.} Id. § 442(d).

^{78. 487} U.S. 500 (1988).

^{79. 28} U.S.C. § 2680(a) (1976).

^{80.} Id. §§ 1346(b), 2401(b), 2402, 2671-2680.

^{81.} Boyle v. United Techs. Corp., 487 U.S. 500, 501 (1988).

^{82.} Boyle, 487 U.S. at 512.

^{83. 6} U.S.C. § 442(d)(1).

^{84. 6} C.F.R. pt. 25 (2011).

^{85.} Regulations Implementing the Support Anti-Terrorism by Fostering Effective Technologies Act of 2002, 71 Fed. Reg. 33,147 (June 8, 2006) (codified at 6 C.F.R. pt. 25); Regulations Implementing the Support Anti-Terrorism by Fostering Effective Technologies Act of 2002, 68 Fed. Reg. 59,684 (Oct. 16, 2003) (codified at 6 C.F.R. pt. 25).

ated with their development and eventual deployment."⁸⁶ While some might maintain that tort liability strikes a fair balance between innovation and incentives to develop reasonably safe technologies thereby obviating the need for legislative modification to traditional tort liability—companies would likely be reticent to mass-produce innovative products used to defend and protect citizens from harm associated with heinous and potentially large-scale terrorist acts without having legislative protection from liability.⁸⁷

Since the enactment of the SAFETY Act, a broad range of antiterrorism products, services, software, and other forms of intellectual property have been designated and certified for use in addressing terrorism. Furthermore, DHS now includes detailed information on its website to explain the nature and purpose of the SAFETY Act and provides detailed step-by-step guidelines for submitting applications for "designated technologies" and certification, which allow sellers of anti-terrorism technology to use the government contractor defense.

DHS regulations also highlight many less philosophical but equally important issues that may have bearing on other existing and future legislative provisions which serve to limit the liability of manufacturers who produce products used to protect the health and safety of American citizens. These issues include:

- (1) DHS's regulations apply to services as well as products.⁸⁸
- (2) The SAFETY Act includes seven criteria that DHS "shall include" in determining whether to designate a technology as "qualified," thereby entitling it to the Act's coverage.⁸⁹ Even if a technology fails to meet a criterion, it can still be designated as an anti-terrorist technology.⁹⁰
- (3) DHS says that even if fraud or willful misconduct on the part of a person obtaining DHS approval and certification is proven in court, the technology's seller will still retain other substantive liability limitations obtained through DHS certification.⁹¹

91. 6 U.S.C. § 442(d)(1); 6 C.F.R. § 25.8.

^{86.} Regulations Implementing the Support Anti-Terrorism by Fostering Effective Technologies Act of 2002, 71 Fed. Reg. at 33,157.

^{87.} See generally Greta Wodele, Aviation-screening Firms May Get Some Liability Protection, Gov'T EXECUTIVE (Mar. 7, 2005), http://www.govexec.com/story_page.cfm? filepath=/dailyfed/0305/030705tdpm1.htm&oref=search.Interestingly, the regulations have been subject to congressional criticism as too bureaucratic and limited.

^{88. 6} C.F.R. § 25.2.

^{89. 6} U.S.C. § 441(b) (2006).

^{90.} Regulations Implementing the Support Anti-Terrorism by Fostering Effective Technologies Act of 2002, 71 Fed. Reg. at 33,149.

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(4) DHS exegesis of the statutory scheme includes discussion of the scope of the SAFETY Act's exclusive remedy provision.⁹²

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2. Impact of the SAFETY Act

The SAFETY Act exemplifies Congress's willingness to modify traditional tort law remedies to achieve an important federal goal: protecting the health of all Americans. Described as a "vital tool for our government to remove barriers to full industry participation in finding new and unique technologies to combat an evolving enemy,"⁹³ it is also an opportunity that industry can use to partner with the government, by developing innovative technologies without undue liability exposure. Furthermore, proponents of tort reform can point to the SAFETY Act's federally imposed ban on state court jurisdiction, substantive limitations on both liability and damages, and other provisions as legislative precedent for future modifications of tort liability.⁹⁴

IV. DECISIVE CONGRESSIONAL ACTION: THE H1N1 VACCINATION PROGRAM

A. THE PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT

The Public Readiness and Emergency Preparedness Act⁹⁵ ("PREP Act"), enacted by Congress as Division C of the Defense Appropriations Act for fiscal year 2006, added new provisions under the Public Health Service Act⁹⁶ "to alleviate concerns about liability related to the manufacture, testing, development, distribution, administration and use of countermeasures against chemical, biological, radiological and nuclear agents of terrorism, epidemics, and pandemics."⁹⁷

^{92. 6} U.S.C. § 442(d)(1); 6 C.F.R. § 25.8. Query whether the courts will give deference to DHS's construction of the scope of the exclusive remedy, in that DHS is charged with administration of the Act and its construction of the statute was contemporaneous with its enactment, or whether the courts will independently determine the bounds of their subject-matter jurisdiction without DHS's "guidance."

^{93.} Testimony Before the Subcomm. on Mgmt., Integration & Oversight of the H. Comm. on Homeland Sec., supra note 63.

^{94.} The Homeland Security Act of 2002 also added a smallpox program, which similarly immunized "covered persons" from most liability. This serves as another illustration of the use of immunization programs, such as the Swine Flu enactment, to modify tort liability. See Homeland Security Act of 2002, Pub. L. No. 107-296, § 304(c), 116 Stat. 2135, 2165-68 (codified at 42 U.S.C. § 233(p) (2006)).

^{95.} Pub. L. No. 109-148, 119 Stat. 2818 (2005) (codified at 42 U.S.C. § 247d-6d (2006)).

^{96.} Ch. 373, 58 Stat. 682 (1944) (codified as amended at 42 U.S.C. §§ 201-300).
97. Public Readiness and Emergency Preparedness Act Questions and Answers,

^{97.} Public Readiness and Emergency Preparedness Act Questions and Answers, U.S. DEP'T HEALTH & HUMAN SERVS., http://www.phe.gov/preparedness/legal/prepact/pages/prepqa.aspx (last reviewed Aug. 12, 2010).

Senator Bill Frist, then-Senate Majority Leader and co-sponsor of the Emergency Supplemental Appropriations Bill, summarized the purpose of the PREP Act succinctly:

The real and imminent dangers posed by diseases like Avian influenza underscore the serious need to bolster Americans' preparedness by enacting meaningful liability reform. These sensible and measured reforms will encourage manufacturers, distributors, and first responders to keep Americans safe once disaster strikes. The bill 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.⁹⁸

Congress wanted to provide targeted liability protection against biologic emergencies, whether in the form of a biologic attack or an avian influenza pandemic.⁹⁹ The purpose of the Act was "to encourage the design, development, clinical testing or investigation, manufacturing and product formulation, labeling, distribution, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of medical countermeasures . . . to provide immunity from liability for covered persons, as that term is defined . . . [in] the Act "100 The Act serves to preempt state tort law by granting "covered persons" immunity from suit and liability under both federal and state law 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 the Secretary of United States Department of Health and Human Services ("HHS") makes the requisite declaration to trigger liability protection.¹⁰¹ Only a showing of willful misconduct can circumvent this immunity.¹⁰²

Pursuant to the PREP Act, the HHS Secretary is authorized to issue a declaration which provides immunity from tort liability for claims of loss caused, arising out of, relating to or resulting from administration or use of countermeasures to diseases, threats, and conditions that the Secretary determines constitute a risk of future public health emergency.¹⁰³ Where such declarations are issued, individuals engaged in the development, manufacture, testing, distribution, ad-

^{98.} Copper, *supra* note 26, at 67-68.

^{99.} See id. at 86. See generally 42 U.S.C. §§ 247d-6d.

^{100.} Pandemic Influenza Vaccines—Amendment, 74 Fed. Reg. 30,294, 30,295 (June 25, 2009).

^{101. 42} U.S.C. § 247d-6d(a)(1).

^{102. 42} U.S.C. § 247d-6d(c)(3).

^{103.} See generally Public Readiness and Emergency Preparedness Act, U.S. DEP'T OF HEALTH & HUMAN SERVS., http://www.phe.gov/preparedness/legal/prepact/Pages/default.aspx (last reviewed Feb. 8, 2011); Frequently Asked Questions About Federal Public Health Emergency Law, CTRS. FOR DISEASE CONTROL & PREVENTION (Sept. 2009), http://www2.cdc.gov/phlp/docs/FAQs%20Fed%20PHE%20laws%20101409.pdf.

ministration, and use of such countermeasures are deemed immune from tort liability, as long as there is no willful misconduct. The breadth of tort immunity is expansive, is not dependent on other emergency declarations, and covers all claims premised on either federal or state law.¹⁰⁴ From a pharmaceutical manufacturer's standpoint, the PREP Act provided necessary liability protection, thereby encouraging the manufacture and stockpiling of countermeasures.¹⁰⁵

On April 26, 2009, Acting HHS Secretary Charles E. Johnson determined that a national public emergency existed involving the 2009 H1N1 influenza virus "that affects or has significant potential to affect the national security."106 In order to protect the public, the Act provided immunity to governmental program planners for "covered countermeasures."107

"Covered Countermeasures" Defined Under the PREP Act 1.

Under the PREP Act, covered countermeasures are broadly defined to include (1) a qualified pandemic or epidemic product; (2) a drug, biological product or device that is authorized for emergency in accordance with the federal Food, Drug, and Cosmetic Act¹⁰⁸; and (3) a security countermeasure.¹⁰⁹

2. Compensation Program for Covered Countermeasures

Like the National Swine Flu Immunization Program Act of 1976,¹¹⁰ but unlike the Project BioShield Act of 2004,¹¹¹ the PREP Act provides a compensation scheme for injuries that arise from administration of covered countermeasures.¹¹² With a declaration by the HHS Secretary of a public health emergency, a "Covered Countermeasure Process Fund" may be established to compensate "eligible individuals for covered injuries directly caused by the administration or

 Pub. L. No. 94-380, 90 Stat. 1113 (codified at 42 U.S.C. § 274b (2006)).
 Pub. L. No. 108-276, 118 Stat. 835 (codified as amended in scattered sections of 42 U.S.C.).

^{104.} Public Readiness and Emergency Preparedness Act (PREP Act) for Pandemic Influenza Medical Countermeasures Utilization Protocol & Decision Tools, FLU.GOV, http://www.flu.gov/professional/federal/prep_act.html (last visited Dec. 28, 2011).

^{105.} Copper, supra note 26, at 86.

^{106.} Pandemic Influenza Vaccines-Amendment, 74 Fed. Reg. at 30,294.

^{107.} Id. at 30,296.

^{108. 21} U.S.C. § 360bbb-3 (2006).

^{109. 42} U.S.C. § 247d-6d(i)(1).

^{112.} It is important to note that the Act does not actually allocate money for this fund but rather declares that the fund will "consist of such amounts designated as emergency appropriations." 42 U.S.C. §§247d-6e. Because of this, the effectiveness of the PREP Act was contingent on funding the compensation fund, as commercial enterprises will be reticent to participate in countermeasure programs, even if personal health and safety is at risk, if no funded compensation fund exists to pay for any resulting injuries.

use of a covered countermeasure pursuant to such declaration."¹¹³ Once such declaration is issued, and funds are appropriated, requests for compensation may be filed with the Covered Countermeasure Process Fund within one year of administration or use of the countermeasure.¹¹⁴ Any compensation ultimately paid will be reduced by public or private insurance or workers' compensation available to the injured individual.¹¹⁵

B. H1N1

1. History and Background

H1N1 was first reported internationally in early 2009, and by late May 2009, had spread to forty countries.¹¹⁶ On April 26, 2009, Acting Secretary Charles Johnson issued a declaration under section 319 of the Public Health Service Act, that a national public health emergency existed involving the H1N1 flu virus "that affects or has significant potential to affect the national security."¹¹⁷

On April 30, 2009, the United States Food and Drug Administration ("FDA") Acting Commissioner issued an emergency use authorization pursuant to section 564(b)(1) of the federal Food, Drug, and Cosmetic Act¹¹⁸ ("FD&C Act"), paving the way for the use of unapproved products—or approved products for unapproved uses—based on the determination that the totality of the available scientific evidence showed certain products to be effective against H1N1.¹¹⁹ Accordingly, two FDA-approved drugs, Relenza and Tamiflu, were authorized for the treatment and prevention of the 2009-10 H1N1 flu virus. Additionally, the FDA authorized an RT-PCR test used to diagnose infection with the virus and certain personal respiratory protection devices known as N95 respirators.¹²⁰

^{113. 42} U.S.C. § 247d-6e(a).

^{114.} Countermeasures Injury Compensation Program, 75 Fed. Reg. 63,656, 63,666 (Oct. 15, 2010) (codified at 42 C.F.R. pt. 110 (2011)).

^{115.} Id. at 63,658.

^{116.} Influenza A(H1N1)—Update 33, WORLD HEALTH ORG. (May 19, 2009), http://www.who.int/csr/don/2009_05_19/en/index.html.

^{117.} Pandemic Influenza Vaccines—Amendment, 74 Fed. Reg. 51,153, 51,154 (Oct. 5, 2009).

^{118.} Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified at 21 U.S.C. § 301 (2006)).

^{119.} Pandemic Influenza Vaccines—Amendment, 74 Fed. Reg. 30,294, 30,295 (June 25, 2009).

^{120.} Interim Guidance for Influenza Surveillance: Prioritizing RT-PCR Testing in Laboratories, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 9, 2009), http://www.cdc. gov/h1n1flu/screening.htm.

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2. Declaration of Public Health Threat Associated with H1N1

On June 11, 2009, the World Health Organization ("WHO") declared a global pandemic.¹²¹ Thereafter, on June 25, 2009, pursuant to the Public Health Service Act, the HHS Secretary issued a declaration to expand coverage of the PREP Act to H1N1 vaccines.¹²² This declaration provided targeted liability protections for pandemic countermeasures related to 2009 H1N1 swine influenza A based on the Secretary's determination that H1N1 constituted a public health emergency.¹²³

3. Immunity for H1N1 Manufacture, Distribution, and Related Activities Under the PREP Act

The April 26, 2009, declaration, which acknowledged the existence of a public health emergency regarding the ability of H1N1 to affect national security, was intended to encourage the production of effective vaccines.¹²⁴ Specifically, it advocated, inter alia, the design, development, clinical testing, manufacture and product formulation, labeling, distribution, packaging, marketing, promotion, sale, administration, and use of vaccines.¹²⁵

As a result of this declaration, persons and entities involved in the broad scope of administration of the H1N1 vaccine were covered by the immunity protections set forth in the PREP Act. Specifically, limited immunity under the Act applies to manufacturers, distributors, qualified persons who prescribe, administer, or dispense countermeasures (such as healthcare and other providers), the government, and program planners. The term "manufacturer" is broadly defined as

(1) a contractor or subcontractor of a manufacturer; (2) a supplier . . . of any product, intellectual property, service, research tool, or component or other article used in the design, development, clinical testing, investigation or manufacturing of a covered countermeasure and (3) any or all of the parents, subsidiaries, affiliates, successors and assigns of a manufacturer.¹²⁶

^{121.} World Now at the Start of 2009 Influenza Pandemic, WORLD HEALTH ORG. (June 11, 2009), http://www.who.int/mediacentre/news/statements/2009/h1n1_pandemic_phase6_20090611/en/index.html.

^{122.} See Pandemic Influenza Vaccines—Amendment, 74 Fed. Reg. 30,294, 30,294-97 (June 25, 2009).

^{123.} Id.

^{124.} Id. at 30,294; Determination that a Public Health Emergency Exists, U.S. DEP'T HEALTH & HUMAN SERVS. (Apr. 26, 2009), www.hhs.gov/secretary/phe_swh1n1_april_2009.html.

^{125.} Pandemic Influenza Vaccines-Amendment, 74 Fed. Reg. at 30,295.

^{126. 42} U.S.C. § 247d-6d (2006).

The term "person" is similarly defined in a broad manner as "an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local government agency or department."¹²⁷

V. COMPARISON BETWEEN CONGRESSIONAL ACTS DIRECTED TO THE PROTECTION OF PUBLIC HEALTH AND SAFETY

All of the legislative exceptions to sovereign immunity delineated in the acts of Congress described in this Article have the same bases, including the following:

- (1) Protecting the health and public safety of Americans;
- (2) Recognizing the legitimate reluctance of manufacturers to mass-produce vaccinations and other products used to safeguard the public without governmental indemnification;
- (3) Providing statutory vehicles for compensation programs similar to the Federal Tort Claims Act¹²⁸ and similar provisions; and
- (4) Promoting commercial innovation of new products for use in the fight against terrorism and the treatment of Americans impacted in this endeavor.

VI. LESSONS LEARNED; PREPARING FOR THE FUTURE

A. LIMITING LIABILITY EXPOSURE THROUGH THE DEVELOPMENT OF New Products Used to Combat Against or Protect Americans from Acts of Terrorism

Precedent has paved the way for developing innovative new products that will protect and safeguard the U.S. public from terrorist acts. Engaging in research and development of new products to be used to defend individuals from bioterrorist and other aggressive acts will likely allow companies to grow and profit while simultaneously limiting liability exposure that would otherwise be associated with product manufacture and distribution of such products.

Under the Support Anti-terrorism by Fostering Effective Technologies Act of 2002¹²⁹ ("SAFETY Act"), the development of "qualified technology" products should afford manufacturers exclusive jurisdiction in federal district courts for any civil action arising from acts of terrorism (except actions against the terrorists); rule out any award of

^{127.} Id.

^{128. 28} U.S.C. §§ 1346(b), 2401(b), 2402, 2671–2680 (1976).

^{129.} Pub. L. No. 107-296, § 861, 116 Stat. 1235 (codified at 6 U.S.C. §§ 441-444 (2006)).

damages against the qualified technology seller beyond the amount of reasonably available insurance coverage; and preclude awards of punitive and other damages. Furthermore, if a technology is approved by United States Department of Homeland Security and is also designated as a qualified technology, an important barrier may potentially block recovery.

B. Avoiding the "Willful Misconduct" Label

Under the Public Readiness and Emergency Preparedness Act¹³⁰ ("PREP Act"), entities involved in the manufacture, use, design, development, licensure, or procurement of covered countermeasures are immune from suit, unless "willful misconduct" is shown.¹³¹ Willful misconduct is likely to be difficult for claimants to establish, as it requires a showing by clear and convincing evidence.

For example, manufacturers and distributors cannot be found to have engaged in willful misconduct for acts or omissions related to the Food, Drug, and Cosmetics Act^{132} ("FD&C Act") if no enforcement action is taken or, if such action is taken, it is terminated or resolved without the imposition of criminal, civil, or administrative remedies. Additionally, program planners or qualified persons who act in accordance with guidelines declared by the United States Department of Health and Human Services Secretary cannot be found to have engaged in willful misconduct, as long as they notify the Secretary, state, or local health authority about the serious injury or death within seven days of the discovery. In sum, the term "willful misconduct" as used in the PREP Act "is beyond any standard of negligence or recklessness."¹³³

Other exceptions under the PREP Act include claims for negligence in providing medical care unrelated to vaccine administration and use, claims brought under foreign law, and claims for civil rights or labor law violations. Immunity is not available for claims of loss that do not assert an alleged causal relationship between the administration or use of a countermeasure and the injury.

Immunity from liability under the PREP Act is limited to tort claims and is not available for claims filed under foreign law in courts outside of the United States. It is important to note, however, that immunity may be available for claims filed under U.S. law in U.S.

^{130.} Pub. L. No. 109-148, 119 Stat. 2818 (2005) (codified at 42 U.S.C. § 247d-6d (2006)).

^{131. 42} U.S.C. § 247d-6d(d).

^{132. 21} U.S.C. § 360bbb-3.

^{133.} Coverage Under the PREP Act for H1N1 Vaccination, FLU.Gov, http://www.pandemicflu.gov/professional/federal/vaccineliability.html (last visited Oct. 4, 2011).

courts, even when they are based on acts or omissions that took place outside of the United States.

C. ANTICIPATING CONSTITUTIONAL CHALLENGES

While the purposes for modifications to traditional principles of tort liability are well documented in the acts described above, if history is a guide, constitutional challenges are likely to be brought to circumvent the immunity these legislative provisions provide to qualified persons and entities who manufacture and produce products to protect against acts of terrorism. The rationale for such anticipated challenges is simple: claimants want to benefit from a whole panoply of redress, rather than be limited to a structured protocol that potentially limits monetary recovery. This issue was analyzed in the context of the National Swine Flu Immunization Program Act of 1976¹³⁴ at both the district court and circuit court levels.¹³⁵

VII. CONCLUSION

Congress, in its wisdom, has recognized the need to enact legislative immunity for the pharmaceutical and other industries to preserve the health and safety of all Americans. In light of the enormous costs associated with the development and manufacture of vaccines and other countermeasures, the risk-management determination of extending statutory immunity appears reasonable and necessary to ensure that innovative products are developed, litigation risks to such industries are minimized, and adequate supplies of these products are stockpiled as necessary to respond to bioterrorist acts. If recent history is taken into account, ongoing and emerging public health and safety risks will likely cause policy drafters to consider and revise historic liability models and templates used to craft effective and timesensitive responses.

^{134.} Pub. L. No. 94-380, 90 Stat. 1113 (codified at 42 U.S.C. §274b (2006)).

^{135.} See Jones v. Wyeth Labs., Inc., 583 F.2d 1070 (8th Cir. 1978) (dismissing action for failure to exhaust administrative remedies pursuant to the Federal Tort Claims Act and claim of unconstitutionality in a similar fashion without analysis); Ducharme v. Merrill-National Labs., 574 F.2d 1307 (5th Cir. 1978) (upholding Swine Flu Program immunity against constitutional challenges under due process and trial by jury clauses and finding exclusive cause of action against the United States (versus program participants) rationally related to achieving goal of assuring interstate distribution of swine flu vaccine, in view of the fact that commercial insurers refused to insure drug manufacturers for interstate distribution of the vaccine but would provide insurance for limited risk for which the government could seek indemnity); Sparks v. Wyeth Labs., Inc., 431 F. Supp. 411 (D. Okla. 1977) (opining "the Swine Flu Act comports with due process clause of Fifth Amendment" because it abolished cause of action against program participants prospectively and substantial and efficient remedy is provided).