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Rethinking Liability for Vaccine Injury

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ARTICLE

RETHINKING LIABILITY FOR VACCINE INJURY

*Joanna B. Apolinsky** and *Jeffrey A. Van Detta***

In April 2009, the first cases of the novel influenza A (H1N1) virus were detected in humans in the United States. As of June 2009, there had been 27,717 confirmed or probable cases of H1N1 infection and 127 deaths in the United States alone. By the end of August 2009, the number of deaths had risen to 593. More than seventy countries have now confirmed human infection with novel H1N1 flu. On June 11, 2009, the World Health Organization (WHO) raised the worldwide pandemic alert level to Phase Six. At this time, since H1N1 is a new virus, there is little human immunity to it. And while the government has been encouraging the public to be vaccinated, fear of vaccine injury persists.

Congress has created a variety of statutory systems for adjudicating vaccine injury claims. These systems are undoubtedly flawed, however, because they provide virtual immunity for vaccine manufacturers and arguably modest, if any, compensation to injured vaccine recipients. Yet, they provide at least a potential method for acknowledging and providing some compensation to those injured by vaccines. Notwithstanding such administrative adjudication, plaintiffs in some instances rely on state-law tort claims against vaccine manufacturers. Yet state law tort suits are an expensive, inefficient, and inconsistent means of compensating vaccine injuries or regulating vaccine manufacturers. Moreover, lawyers for pharmaceutical manufacturers have lobbed an assault against the availability of tort recovery by arguing that state law tort claims are preempted by approval by the Food and Drug Administration.

Therefore, the time is ripe for a re-examination of the distribution of tort liability for vaccine-related injuries. Our rethinking comes at a time when diseases that were supposedly eradicated by twentieth century vaccines—such as smallpox and polio—are rearing their heads again, the former as a terroristic weapon and the latter as the product of an anti-vaccine movement in the United States and continuing socio-economic problems abroad. Moreover, twenty-first century society is confronting new, continually changing, and potentially devastating strains of pandemic flu virus threatening not only the public health but also the very

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fabric of our economic system and social order. Thus, the legal questions surrounding vaccines and injury compensation have left the realm of academic speculation and been thrust into the spotlight of an imminent, looming crisis. When should there be liability for vaccine-related injuries? What kind of liability should there be? How should liability be allocated for vaccine-related injuries? And might that inquiry be made more meaningful by considering the liability-compensation question within a holistic framework of strategic planning and policy for vaccination as a cornerstone of societal stability and progress, rather than as an isolated pocket of tort or administrative law?

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INTRODUCTION

“A Pandemic is Declared”¹

In April 2009, the first cases of the novel influenza A (H1N1) virus (earlier called “swine flu”) were detected in humans in the United States.² As of June 2009, there were 27,717 confirmed or probable cases

¹ Ctrs. for Disease Control & Prevention, Novel H1N1 Flu: Background on the Situation, <http://www.cdc.gov/h1n1flu/background.htm> [hereinafter Novel H1N1 Flu: Background on the Situation] (last visited Mar. 28, 2010).

² *Id.* The virus originated in Mexico. *Id.* It has genes similar to those found in swine flu viruses in Europe and Asia, as well as avian genes and human genes. See Ctrs. for Disease Control & Prevention, 2009 H1N1 Flu (“Swine Flu”) and You, <http://www.cdc.gov/h1n1flu/>

of H1N1 infection and 127 deaths in the United States alone.³ By the end of August 2009, the number of deaths rose to 593.⁴ More than seventy countries have now confirmed human infection with the novel H1N1 flu.⁵ On June 11, 2009, the World Health Organization (WHO) raised the worldwide pandemic alert level to Phase Six.⁶ The alert level is based on the spread of the virus, as opposed to the severity of the illness.⁷ However, at this time, since H1N1 is a new virus, there is little

[qa.htm](#) (last visited Mar. 28, 2010). Scientists refer to this as a “quadruple reassortant” virus. *Id.*

³ See Ctrs. for Disease Control & Prevention, Novel H1N1 Flu Situation Update, <http://www.cdc.gov/h1n1flu/updates/062609.htm> (last visited Mar. 28, 2010).

⁴ See Ctrs. for Disease Control & Prevention, Novel H1N1 Flu Situation Update, <http://www.cdc.gov/h1n1flu/updates/090409.htm> [hereinafter Novel H1N1 Flu Situation Update] (last visited Mar. 28, 2010). On July 24, 2009, the CDC ceased tracking and reporting confirmed and probable H1N1 flu cases. See Ctrs. for Disease Control & Prevention, Monitoring Influenza Activity, Including 2009 H1N1, <http://www.cdc.gov/h1n1flu/reportingqa.htm> (last visited Mar. 28, 2010). As the outbreak expanded, case counts became increasingly more difficult because only a small number of those with respiratory illnesses were being tested for H1N1. *Id.* Moreover, case counting was extremely resource intensive. *Id.* Instead, the CDC has been reporting hospitalizations and deaths (either confirmed or probable) resulting from all types of influenza, including H1N1. *Id.* The CDC estimates that as of January 16, 2010, the number of cases of H1N1 in the United States to range between 41 million and 84 million; the number of hospitalizations in the United States from H1N1 to range between 183,000 and 378,000; and the number of deaths in the United States from H1N1 to range between 8,330 and 17,160. Ctrs. for Disease Control & Prevention, CDC Estimates of 2009 H1N1 Influenza Cases, Hospitalizations and Deaths in the United States, April 2009 to January 16, 2010, Mar. 12, 2010, http://www.cdc.gov/h1n1flu/estimates_2009_h1n1.htm (last visited Mar. 28, 2010).

⁵ See Ctrs. for Disease Control & Prevention, Novel H1N1 Flu Situation Update, June 12, 2009, <http://www.cdc.gov/h1n1flu/updates/061209.htm> (last visited Mar. 28, 2010).

⁶ See *id.*

In nature, influenza viruses circulate continuously among animals, especially birds. Even though such viruses might theoretically develop into pandemic viruses, in Phase 1 no viruses circulating among animals have been reported to cause infections in humans. In Phase 2 an animal influenza virus circulating among domesticated or wild animals is known to have caused infection in humans, and is therefore considered a potential pandemic threat. In Phase 3, an animal or human-animal influenza reassortant virus has caused sporadic cases or small clusters of disease in people, but has not resulted in human-to-human transmission sufficient to sustain community-level outbreaks. . . . Phase 4 is characterized by verified human-to-human transmission of an animal or human-animal influenza reassortant virus able to cause ‘community-level outbreaks.’ . . . Phase 5 is characterized by human-to-human spread of the virus into at least two countries in one WHO region. While most countries will not be affected at this stage, the declaration of Phase 5 is a strong signal that a pandemic is imminent and that the time to finalize the organization, communication, and implementation of the planned mitigation measures is short. Phase 6, the pandemic phase, is characterized by community level outbreaks in at least one other country in a different WHO region in addition to the criteria defined in Phase 5. Designation of this phase will indicate that a global pandemic is under way.

Current WHO phase of pandemic alert, http://www.who.int/csr/disease/avian_influenza/phase/en (last visited Feb. 10, 2010).

⁷ See Novel H1N1 Flu: Background on the Situation, *supra* note 1.

human immunity to it.⁸ The Centers for Disease Control's (CDC) earlier warnings that the virus could cause significant illness and death during the 2009–2010 flu season were correct.⁹

The government is working aggressively to continue manufacturing the H1N1 vaccine.¹⁰ The vaccine undoubtedly helped millions ward off a potential threat of significant illness due to the virus. But what of others who suffer significant adverse consequences from a vaccine? The safety and efficacy of the H1N1 vaccine is at the center of a growing debate. Many are skeptical of the vaccine's safety and have criticized the way in which it has been produced, as well as its rushed distribution.¹¹ The uncertainty is not merely being channeled from the usual "anti-vaccinators."¹² Rather, many who have historically supported vaccination are wary of the H1N1 vaccine.¹³ This skepticism has even resulted in a lawsuit against the State of New York filed by three nurses who claim the State has violated their civil rights by requiring that all state health employees be vaccinated against the H1N1 virus by November 30, 2009 or face fines.¹⁴

Currently, atypical, but possible, side effects from the "generic" flu vaccine include severe allergic reactions or Guillain-Barré syndrome, a rare and occasionally fatal paralytic condition.¹⁵ All too often, significantly debilitating and sometimes deadly side effects result from other

⁸ See Ctrs. for Disease Control & Prevention, Interim Guidance on Infection Control Measures for 2009 H1N1 Influenza, http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm (last visited Mar. 28, 2010).

⁹ See Novel H1N1 Flu Situation Update, *supra* note 4. See also Richard P. Wenzel, Op-Ed., *What We Learned from H1N1's First Year*, N.Y. TIMES, Apr. 13, 2010, at A25, available at <http://www.nytimes.com/2010/04/13/opinion/13wenzel.html> (positing that although the 2009–2010 H1N1 epidemic was not as deadly as initially feared, it was more serious than many have suggested).

¹⁰ See Ctrs. for Disease Control & Prevention, Key Facts About 2009 H1N1 Flu Vaccine, http://www.cdc.gov/h1n1flu/vaccination/vaccine_keyfacts.htm (last visited Mar. 28, 2010).

¹¹ See Jennifer Steinhauer, *Swine Flu Shots Revive a Debate About Vaccines*, N.Y. TIMES, Oct. 16, 2009, at A1.

¹² See *id.* at A19; Sewell Chan & Anemona Hartocollis, *Judge Halts Mandatory Flu Vaccines for Health Care Workers*, NYTIMES.COM, <http://cityroom.blogs.nytimes.com/2009/10/16/judge-halts-mandatory-flu-vaccines-for-health-care-workers>, (Oct. 16, 2009, 12:58 PM).

¹³ See Steinhauer, *supra* note 11, at A19.

¹⁴ See Chan & Hartocollis, *supra* note 12. The mandate was subsequently dropped, with the State citing a shortage in availability of the vaccine as the reason. See Rick Karlin & Scott Waldman, *New York Drops Mandatory Swine Flu Shots for Health Workers After Lawsuit Filed*, THE FLU CASE, Oct. 23, 2009, http://www.theflucase.com/index.php?option=com_content&view=article&id=1339%3Anew-york-drops-mandatory-swine-flu-shots-for-health-workers-after-lawsuit-filed&catid=41%3Ahighlighted-news&Itemid=105&lang=en.

¹⁵ See James M. Wood et al., *Product Liability Protection for Stem Cell Research and Therapies – A Proposal*, 18 HEALTH LAWYER 1, 8 (2005); Ctrs. for Disease Control & Prevention, General Questions and Answers on 2009 H1N1 Influenza Vaccine Safety, http://www.cdc.gov/h1n1flu/vaccination/vaccine_safety_qa.htm (last visited Mar. 28, 2010).

vaccines that are routinely administered to the population.¹⁶ In an effort to prevent an avalanche of state law tort claims against manufacturers of those vaccines, Congress has created a variety of statutory systems in an attempt to protect manufacturers, while sometimes also providing for a compensation model for victims of vaccine-related injury. Most notable of these is the National Childhood Vaccine Injury Act (NCVIA) and its attendant Vaccine Injury Compensation Trust Fund.¹⁷ As discussed below, these types of systems undeniably are flawed. Yet, they at least provide a potential method for acknowledging and providing some compensation to those injured by vaccines.

In other contexts when victims are injured by drugs and medical devices, no statutory compensation scheme exists; rather, plaintiffs must rely on state law tort claims against manufacturers of such products.¹⁸ The “unavoidably unsafe” product concept makes state law products liability claims against manufacturers a very tough road for the injured; and even when the injured can find another state law theory (such as inadequate patient warnings), state law tort suits are an expensive, inefficient, and inconsistent means of compensating vaccine injuries or regulating vaccine manufacturers.¹⁹

Not surprisingly, the pharmaceutical industry—and their shareholder investors—would prefer no transactional costs for litigation. Yet with NCVIA-style programs allowing claimants to opt for a regular tort lawsuit after prior vaccine court adjudication, state tort lawsuits remain a potential problem. In pursuit of a régime in which pharmaceutical companies would enjoy virtually absolute immunity from legal claims, lawyers for pharmaceutical manufacturers have lobbed an assault against the availability of tort recovery by arguing that state law tort claims are preempted by approval of the drug or device in question by the Food and Drug Administration (FDA).²⁰ Now that an H1N1 vaccine exists, the federal government could attempt to protect manufacturers of the vaccine by statutorily preempting any tort claims which otherwise could be brought by an injured recipient of the vaccine.²¹ Even if Congress did

¹⁶ See Ctrs. for Disease Control & Prevention, Possible Side-effects from Vaccines, <http://www.cdc.gov/vaccines/vac-gen/side-effects.htm> (last visited Feb. 24, 2010).

¹⁷ See *infra* I.B.

¹⁸ See, e.g., *Wyeth v. Levine*, 129 S. Ct. 1187 (2009); *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008); *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

¹⁹ See Okianer Christian Dark, *Is the National Childhood Vaccine Injury Act of 1986 the Solution for the DTP Controversy?*, 19 U. TOL. L. REV. 799, 817–34 (1988); Mary Beth Neraas, *The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis?*, 63 WASH. L. REV. 149, 151–56, 159 (1988).

²⁰ See generally Lawrence O. Gostin, *Regulating the Safety of Pharmaceuticals: The FDA, Preemption and the Public’s Health*, 301 JAMA 2036–37 (2009).

²¹ Currently, the H1N1 vaccine is considered a “covered countermeasure” under the Countermeasures Injury Compensation Program which administers the compensation fund uti-

not act, preemption due to FDA approval of the vaccine, undoubtedly, would be argued aggressively in defense of the claim. If preemption was found to exist, the vast majority of those injured by the vaccine over time would have little to no compensation for injuries that may be disabling for life. The time is ripe, therefore, for a re-examination of the distribution of tort liability for vaccine-related injuries. This Article proposes in the first instance that FDA preemption of state law tort claims against manufacturers of vaccines is inappropriate, for it would leave vaccine injury victims who fall outside the NCVIA or other statutory program with no compensation at all. It then proposes a more appropriate compensation model for injured victims that borrows from the NCVIA that takes into consideration the unique role of vaccines within the pharmaceutical industry, medicine, and society as a whole. We propose that Congress re-examine vaccine liability, not in isolation, but as part of a broader review of vaccines as a holistic social phenomenon—i.e., programmatic planning for vaccine research, development, testing, distribution, monitoring, and injury compensation. Various elements of programmatic planning currently exist in isolation. Congress has the opportunity to take this foundation of modern public health out of the partisan arena where it is treated as a manufacturer's liability problem and pits the perceived self-interests of "trial lawyers" against the pro-industry lobby of "tort reformists." Congress could develop comprehensive legislation to shift the paradigm to one of holistic strategic planning that assures the maintenance of current vaccines and the development of new vaccines, incentivizes the expensive research required for vaccine development and renewal, and protects the public which undertakes substantial risks yet reaps unprecedented benefits from no longer having to suffer the costs, casualties, and catastrophic calamities that infectious disease wrought for thousands of years.

Our rethinking of vaccine-injury liability comes at a time when diseases, like smallpox and polio, that were supposedly eradicated by twentieth century vaccines, are rearing their heads again, the former as a terroristic weapon²² and the latter as the product of an anti-vaccine movement in the United States,²³ and continuing socio-economic

lized by the Prep Act. See U.S. Dept. of Health and Human Services Health Resources and Services Administration, Countermeasures Injury Compensation Program, <http://www.hrsa.gov/countermeasurescomp/default.htm> (last visited Feb. 24, 2010). For more information on the Prep Act, see *infra* Part I.D.

²² See Remarks Announcing the Smallpox Vaccination Plan, 1 PUB. PAPERS 2191 (Dec. 13, 2002) (discussing the possibility of smallpox as a bioterrorist weapon); see also Alan W. Dove & Vincent R. Racaniello, *The Polio Eradication Effort: Should Vaccine Eradication Be Next?*, 277 SCI. 779–80, Aug. 8, 1997.

²³ The anti-vaccine movement consists both of those parents who oppose compulsory vaccination on grounds of personal autonomy as well as fear of injury and parents who do not vaccinate children because they are home schooled and therefore the state school-registration

problems abroad.²⁴ Moreover, twenty-first century society has been confronted with new, continually changing, and potentially devastating strains of pandemic flu viruses, threatening not only the public health, but also the very fabric of our economic system and social order. Thus, the legal questions surrounding vaccines and injury compensation have left the realm of academic speculation and been thrust into the spotlight of an imminent, looming crisis. When should there be liability for vaccine-related injuries? What kind of liability should there be? How should liability be allocated for vaccine-related injuries? And might that inquiry be made more meaningful by considering the liability-compensation question within a holistic framework of strategic planning and policy for vaccination, rather than as an isolated pocket of tort or administrative law? These are the fundamental questions that drive our rethinking of vaccine-injury liability.

The time has come for such an examination, not only practically, as noted in this introduction, but also legally. Between 1976 and the present, Congress has enacted several vaccine-injury liability control programs.²⁵ Current world events have changed the potential role and scope of mandatory vaccine programs in America. Since September 11, 2001, the world has been recognized as a far more dangerous place than most had realized in the 1990s, due to the threat of bio-terrorism.²⁶ Similarly, globalization has increased the opportunities for global pandemics—with H1N1 virus the most serious recent and continuing concern—against which some governments and pharmaceutical companies are racing to develop a new generation of rapidly manufactured and widely distributed vaccines.²⁷ Moreover, conditions in some countries have led to the resurgence of disease, such as polio, against which existing vaccines and

system for enforcing vaccinations is not engaged. *See, e.g.*, Donya Khalili & Arthur Caplan, *Off the Grid: Vaccinations Among Homeschooled Children*, 35 J.L. MED. & ETHICS 471, 471 (2007). *See also* Jacobson v. Commonwealth of Massachusetts 197 U.S. 11, 31 n.1 (1905) (reciting the history of compulsory vaccination around the world since creation of England's National Vaccine Establishment in 1808).

²⁴ *See, e.g.*, LEAH EISENSTEIN ET AL., FLA. DEPT. OF HEALTH, EPIDEMIOLOGY OF VACCINE-PREVENTABLE DISEASES PART 4: SMALLPOX, POLIO AND VARICELLA (July 2009), available at http://www.doh.state.fl.us/disease_ctrl/epi/epi_updates/2009/July2009EpiUpdate.pdf (stating that at least in the Polio context vaccination refusal as well as socio-economic factors, including displaced populations, migration, act as barriers complete irradiation of the virus).

²⁵ *See infra* Part I.

²⁶ *See* U.S. Food & Drug Admin., Emergency Preparedness and Response, Counterterrorism-Related Legislation, www.fda.gov/emergencypreparedness/counterterrorism/bioterrorismact/default.htm (last visited Jan. 26, 2010).

²⁷ *See, e.g.*, Donald G. McNeil, Jr., *Clinical Trials for Flu Vaccine Are to Begin Soon*, N.Y. TIMES, July 23, 2009, at A4. The tenor of this news story should make any member of the public nervous about corner-cutting and risk-imposition in the scramble for roll-out with only limited field testing. *Id.* (quoting leading federal vaccine official stating that because the trials are so small—2,400 participants—“researchers will be able to pick up only obvious problems”).

vaccination programs in America may be vulnerable.²⁸ Thus, public health authorities are confronted with calls for new and broad vaccination programs, some using new vaccines. And with these efforts to meet new—and renewed—biological threats to the public comes the age-old question of the risks posed by vaccines and how the risks ought to be distributed among the public, individuals, manufacturers, and governments.

Part I of this Article describes the congressional vaccination programs to date and highlights the major differences among them. In Part II, we explore various criticisms of these congressional programs and analyze how the goals associated with each of these programs, although born of arguably well-placed intentions, may be better served in the context of fairness, without an oversimplified emphasis on a risk-utility analysis or the overall benefit to society as a whole. Part II opens with a close look at the more aggressive program of “tort reform” through pre-emption: that federal regulation, especially federal approval and labeling processes promulgated by the FDA, “preempts” any claims by injured persons, thereby effectively eliminating remedies and compensation for injuries that arise during post-approval actual experience. In Part III, we suggest that the time has come for Congress to review vaccine liability. We provide a paradigm in which future congressional consideration of legislation regulating vaccine liability can proceed from a principled, rather than purely instrumentalist, basis. Building upon Professor George Fletcher’s nonreciprocal risk theory of corrective justice,²⁹ as further refined by Professor Gregory C. Keating in what we call “the distribution of nonreciprocal harms,”³⁰ we set out a new perspective from which Congress can perceive the intersecting legal principles implicated by the competing interests along a vast spectrum. The interests implicated by vaccine injury range from strict liability, as argued successfully by attorney Melvin Belli fifty years ago in *Gottsdanker v. Cutter Laboratories*³¹ (that the process of vaccine manufacture “should and

²⁸ See, e.g., Donald G. McNeil, Jr., *Polio: New Outbreak of Polio in Africa Prompts Appeal for Vaccine Financing*, N.Y. TIMES, Apr. 21, 2009, at D6.

²⁹ See George P. Fletcher, *Fairness and Utility in Tort Theory*, 85 HARV. L. REV. 537 (1972).

³⁰ See Gregory C. Keating, *Distributive and Corrective Justice in the Tort Law of Accidents*, 74 S. CAL. L. REV. 193, 195 (2000).

³¹ 6 Cal. Rptr. 320 (Cal. Ct. App. 1960); see PAUL A. OFFIT, M.D., THE CUTTER INCIDENT: HOW AMERICA’S FIRST POLIO VACCINE LED TO THE GROWING VACCINE CRISIS 132–53 (2005). This case involved one of the seven laboratories that had made the original issue of the Salk killed-virus polio vaccine, Cutter Laboratories, and its failure to ensure that all live polio viruses had been killed in the vaccine, resulting in Cutter-produced lots of the vaccine causing the very disease in children it was supposed to prevent. *Id.* at 3, 133. In the worlds of vaccinology and law, this event quickly acquired the moniker, “The Cutter Incident.” *Id.* at 3; see, e.g., Neal Nathanson & Alexander D. Langmuir, *The Cutter Incident: Poliomyelitis Following Formaldehyde-inactivated Poliovirus Vaccination in the United States During the Spring of 1955, II: Relationship of Poliomyelitis to Cutter Vaccine*, 78 AM. J. OF HYGIENE 29–60 (1963).

could be perfect"),³² to government immunity from tort liability, the responsibility of the public in preventing preventable disease, the role of the pharmaceutical industry in modern life, and the social responsibilities that must attend the profits³³ reaped for shareholders. These substantial profits pharmaceutical companies enjoy include those acquired from necessary vaccines, "designer" or convenience pharmaceuticals such as Viagra, "me-too" drugs that are but prosaic variations of currently marketed drugs, and drugs that are the product of "promot[ing] diseases to fit their drugs" rather than "promot[ing] drugs to treat diseases."³⁴

I. CONGRESSIONAL VACCINATION PROGRAMS

A. *The National Swine Flu Immunization Program of 1976*

When four cases of swine flu were discovered at Fort Dix, New Jersey in January 1976, fear of a flu pandemic prompted the federal government to pass the Swine Flu Act.³⁵ The swine flu virus was the same virus that caused the 1918–1919 flu pandemic, which reportedly infected

³² OFFIT, THE CUTTER INCIDENT, *supra* note 31, at 141–42. Dr. Offit quotes attorney Belli in his closing argument from the Gottsdanker trial transcript:

Belli concluded that if medicine was a process of evolution, Anne Gottsdanker shouldn't have to pay for the process. '[T]here is, as a matter of law [the notion] that you cannot assume a risk in a case like this. Maybe only a few got [paralyzed]. Maybe science advanced. Maybe science must advance over the bodies of the young and old and the twisted and the lame, [but] there is no doubt in my mind—and there should be none in yours—that the process could and should be perfect.'

Id. at 142 (quoting the reporter's transcript, Gottsdadanker v. Cutter Labs, 6 Cal. Rptr. 320 (Cal. Ct. App. 1960) (Civ. 18413-14)).

³³ For example, Congressman Waxman complied a table of leading drug company profit increases from 2005 to 2006 that showed, among other things:

The ten largest pharmaceutical companies enjoyed substantial profit increases in the first six months of the new Medicare drug program. In the first half of 2006, profits for these companies increased by over \$8 billion, a 27% increase.

Overall, profits have increased for eight of the world's ten largest pharmaceutical companies. Pfizer, the largest pharmaceutical company, had the largest increase in profits. The company's profits over this six-month period increased by \$2.7 billion, a 73% increase. Merck's profits have increased by almost \$1 billion (44%); Sanofi-Aventis's profits have increased by more than \$1.3 billion (35%); and AstraZeneca's profits have increased by more than \$750 million (33%).

See REP. HENRY A. WAXMAN, ANALYSIS: PHARMACEUTICAL INDUSTRY PROFITS INCREASE BY OVER \$8 BILLION AFTER MEDICARE DRUG PLAN GOES INTO EFFECT 2 (Sept. 2006), available at <http://oversight.house.gov/images/stories/documents/20060919115623-70677.pdf>.

³⁴ MARCIA ANGEL, THE TRUTH ABOUT DRUG COMPANIES xv–xvi, 12, 74–85, 86, 87–94 (2004). Angel notes that drug companies are spending 2.5 times as much on "marketing and administration" as they are on "research and development." *Id.* at 12. She also notes that a common pharmaceutical business strategy is "treat[ing] the normal accompaniments of aging . . . as diseases" for which drugs must be developed. *Id.* at 86.

³⁵ See Michael Greenberger, *The 800 Pound Gorilla Sleeps: The Federal Government's Lackadaisical Liability and Compensation Policies in the Context of Pre-Event Vaccine Immunization Programs*, 8 J. HEALTH CARE L. & POL'Y 7, 11 (2005); Charles F. Hagan, *Vaccine Compensation Schemes*, 45 FOOD DRUG COSM. L.J. 477, 477 (1990).

two billion people and killed twenty million worldwide.³⁶ In an attempt to avoid a similar pandemic, the administration of President Gerald Ford requested that Congress appropriate emergency funds to support a nationwide vaccination initiative.³⁷ The need for liability protection in the Act for vaccine manufacturers was not a concern until insurance companies declined to provide liability coverage for vaccine manufacturers for any liability this particular vaccine allegedly caused.³⁸ This refusal was largely because of the 5th Circuit's decision in *Reyes v. Wyeth Laboratories*,³⁹ holding polio vaccine manufacturers liable for failing to provide adequate product warnings directly to vaccinees even if they had provided them in package inserts.⁴⁰ The *Reyes* court recognized the practical problems of vaccine-injury liability; pediatricians and epidemiologists, for example, argued that "the holding [the court] reached is 'dangerous' to the nation's preventive medicine programs and contravenes a strong public policy favoring large-scale participation in immunization efforts to combat infectious disease."⁴¹ Moreover, these problems raise "public health policy questions [that] cut across the law"⁴² and:

[u]ntil Americans have a comprehensive scheme of social insurance, courts must resolve by a balancing process the head-on collision between the need for adequate recovery and viable enterprises This balancing task should be approached with a realization that the basic consideration involves a determination of the most just allocation of the risk of loss between the members of the marketing chain.

Statistically predictable as are these rare cases of vaccine-induced polio, a strong argument can be advanced that the loss ought not lie where it falls (on the victim),

³⁶ See Hagan, *supra* note 35, at 477.

³⁷ *Id.*

³⁸ *Id.*; Greenberger, *supra* note 35, at 11.

³⁹ 498 F.2d 1264 (5th Cir. 1974)

⁴⁰ See *id.* at 1295; see also Greenberger, *supra* note 35, at 11. *Reyes* dealt with the manufacturer's failure to provide a direct warning of the risks associated with the vaccine directly to the vaccine recipient. See *Reyes*, 498 F.2d at 1270. The manufacturer, Wyeth Laboratories, argued that it had provided an adequate warning in a package insert to the nurse who administered the vaccine, *id.* at 1275, claiming that the nurse was a "learned intermediary." *Id.* The learned intermediary doctrine allows a manufacturer to rely on the warnings provided to the prescribing physician, as the physician is in a better position than the manufacturer to balance the risks posed by the vaccine against its utility. *Id.* at 1277–78. The Fifth Circuit rejected this argument, however, largely because the vaccine was administered in a county health clinic, as opposed to by a private physician. *Id.* at 1277.

⁴¹ *Id.* at 1295.

⁴² *Id.* at 1293.

but should be borne by the manufacturer as a foreseeable cost of doing business, and passed on to the public in the form of price increases to his customers.⁴³

Thus, a bill was introduced in Congress in June 1976, providing for government indemnification for swine flu vaccine manufacturers.⁴⁴ Congress did not act on the bill immediately, however, because the federal government did not want to accept financial responsibility on behalf of the manufacturers.⁴⁵ As a result, manufacturers ceased producing the swine flu vaccine.⁴⁶ Had a pandemic actually occurred (which ultimately did not happen), there would have been no vaccine for the potentially millions of Americans who would have contracted this flu.⁴⁷ Yet later that summer, the fear created by an outbreak of Legionnaire's disease, another infectious disease which is a type of pneumonia,⁴⁸ prompted Congress to finally pass the Swine Flu Act.⁴⁹ To encourage the development of the vaccine without any resulting liability, the Act provided protection for manufacturers against liability for other than their own negligence and thus provided plaintiffs a cause of action exclusively under the Federal Tort Claims Act (FTCA).⁵⁰

The Swine Flu Act provided that the exclusive remedy against the United States was necessary due to the government's "unique role in the initiation, planning, and administration of the swine flu program."⁵¹ Thus, the Act provided protection for not only manufacturers, but also distributors and administrators of the vaccine (collectively, defined in the Act as "program participants").⁵² The plaintiff would sue the United States instead of the actual program participant under any theory of liability the plaintiff could have otherwise brought against the participant, "including negligence, strict liability in tort, and breach of warranty."⁵³ The courts interpreted the language allowing such a suit to effectively create a no-fault compensation system, whereby the United States would be liable to any plaintiff who could show that his injuries were caused by

⁴³ *Id.* at 1293–94 & n.57 (citations & footnotes omitted). Judge Wisdom also observed that "[i]t can also be argued, of course, that since all society benefits from universal immunization against infectious disease, the loss should be borne by the local, state or federal government." *Id.* (emphasis added).

⁴⁴ See Greenberger, *supra* note 35, at 11.

⁴⁵ See *id.* at 11–12.

⁴⁶ See *id.* at 12.

⁴⁷ See *id.*

⁴⁸ See Ctrs. for Disease Control & Prevention, Patient Facts: Learn More About Legionnaires' Disease, http://www.cdc.gov/legionella/patient_facts.htm (last visited Feb. 10, 2010).

⁴⁹ See Greenberg, *supra* note 35, at 12.

⁵⁰ 42 U.S.C. § 274b(k)(1)(A)(i)–(ii) (1976); see also Greenberger, *supra* note 35, at 12.

⁵¹ § 274b(k)(1)(A)(ii).

⁵² § 274b(k)(2).

⁵³ § 274b(k)(2)(A)(i).

the vaccine.⁵⁴ However, if the United States was held liable due to a program participant's negligence or failure to carry out any obligation under the program, it could seek indemnification from that participant because of that negligence or failure.⁵⁵ Further, the Act did not place any limits on the amount of compensation that could be awarded to any particular plaintiff.⁵⁶

Under the program, roughly forty million Americans were vaccinated in a two-month period.⁵⁷ And although the program achieved the goals of broad manufacturer and doctor participation,⁵⁸ and high vaccination levels around the country, it has been criticized for being too hasty a reaction to a pandemic that never transpired.⁵⁹ Further, the government abruptly halted the program because the vaccine itself increased the risk to those who had been vaccinated from developing Guillain-Barré syndrome, a rare and occasionally fatal paralytic condition.⁶⁰ Research showed that those who received the swine flu vaccination developed Guillain-Barré at seven times the rate of those who had not been vaccinated.⁶¹ Vaccine recipients filed suit after contracting Guillain-Barré, which was ultimately attributed to the vaccine.⁶² By 1985, the federal government had paid over \$90 million in damages to these injured plaintiffs who had contracted Guillain-Barré.⁶³

B. *National Childhood Vaccine Injury Act*

Vaccines administered in childhood have been the most pervasive vaccine programs, originating with childhood vaccines against smallpox in colonial times,⁶⁴ and currently encompassing diphtheria, tetanus, pertussis, haemophilus influenzae type b, hepatitis A, hepatitis B, human papillomavirus, seasonal influenza, measles, mumps, rubella, meningococcal, polio, pneumococcal conjugate, rotavirus, varicella, and “[a]ny

⁵⁴ See Greenberger, *supra* note 35, at 12.

⁵⁵ § 274b(k)(5)(C)(ii).

⁵⁶ 42 U.S.C. § 274b (1976).

⁵⁷ See Greenberger, *supra* note 35, at 13.

⁵⁸ See Michael H. LeRoy, *Pox Americana? Vaccinating More Emergency Doctors for Smallpox: A Law and Economics Approach to Work Conditions*, 54 EMORY L.J. 597, 626 (2005).

⁵⁹ See, e.g., Sharon L. Begley, *The Failure of the 1976 Swine Influenza Immunization Program*, 50 YALE J. BIOLOGY & MED. 645, 645, 655 (1977).

⁶⁰ See Wood et al., *supra* note 15, at 8.

⁶¹ See *id.*

⁶² See Greenberger, *supra* note 35, at 13.

⁶³ See *id.*

⁶⁴ See Alvin Powell, *The Beginning of the End of Smallpox*, HARV. UNIV. GAZETTE, May 20, 1999, available at <http://www.news.harvard.edu/gazette/1999/05.20/waterhouse.html>.

combination of the vaccines above.”⁶⁵ Sales of such vaccines generated \$16.3 billion for pharmaceutical companies in 2007.⁶⁶ Yet manufacturers of childhood vaccines have also incurred liability for injuries and death allegedly caused by vaccines that were administered to a previously healthy child.⁶⁷ In the preceding twenty years, a number of childhood vaccine manufacturers left the market for a complex set of reasons relating primarily to the labor-intensive production process and lower profitability of vaccines than pharmaceuticals that are less challenging to manufacture. The departure also related, in some measure, to litigation costs experienced and even more so to the perception of the potentially high costs of future litigation as well as the lack of liability insurance coverage due to the unpredictability of tort liability.⁶⁸ This decline in available manufacturers affected the country’s ability to maintain acceptable vaccine supply and vaccination levels.⁶⁹ In addition, as the occurrence of many historically common and very serious childhood diseases had seemingly been all but eradicated,⁷⁰ many people became less concerned with these diseases themselves and more concerned with the risk of potential side effects from the vaccinations.⁷¹ Further, there was great

⁶⁵ See U.S. Dep’t Health & Human Services, Health Resources & Services Administration, National Vaccine Injury Compensation Program—Covered Vaccines, http://www.hrsa.gov/vaccinecompensation/covered_vaccines.htm (last visited Feb. 10, 2010).

⁶⁶ Andrea Hiller, *Gardasil, Other New Products Spur Strong Vaccine Sales in 2007*, REUTERS, Apr. 7, 2008, <http://www.reuters.com/article/pressRelease/idUS184052+07-Apr-2008+PRN20080407> (noting that this “represents an increase of 38% over 2006 sales of \$11.7 billion” among the “five major players—Merck & Co., GlaxoSmithKline, Sanofi Pasteur, Wyeth and Novartis—which “dominate vaccine sales” expected to “more than double in five years”). Full, worldwide market reports on vaccines and their pharmaceutical manufacturers are proprietary and available only from research firms such as Kalorama, at a price-tag of \$4,000.00 —beyond our budget but well within Congress’s in considering our recommendations in Part III, *infra*. See generally Kalorama Information, <http://www.kaloramainformation.com> (last visited Feb. 24, 2010).

⁶⁷ See H.R. REP. No. 99-908, at 4–6 (1986). The pertussis component of the DPT vaccine (diphtheria, pertussis and tetanus) has been one of the most controversial of the childhood vaccines because of the pertussis component of the vaccine. See Keith E. Abbott, *The National Vaccine Injury Compensation Program*, 20 COLO. L. 1825, 1825 (1991). See generally Susan G. Clark, Commentary, *The National Childhood Vaccine Injury Act—The National Vaccine Injury Compensation Program*, 94 EDUC. L. REP. 671, 674 (1994) (addressing the issues raised by manufacturer liability for vaccine-related injuries and the resulting enactment of the National Vaccine Injury Compensation Program).

⁶⁸ See, e.g., H.R. REP. No. 99-908, at 4–5; Hagan, *supra* note 35, at 479. The Centers for Disease Control website also claims that liability was imposed on manufacturers for alleged vaccine-related injuries when there was little or no scientific evidence to establish causation. Ctrs. for Disease Control & Prevention, History of Vaccine Safety, http://www.cdc.gov/vaccinesafety/Vaccine_Monitoring/history.html (last visited Feb. 10, 2010).

⁶⁹ See H.R. REP. No. 99-908, at 7.

⁷⁰ See U.S. FOOD & DRUG ADMIN., A PARENT’S GUIDE TO KIDS’ VACCINES, 1 (2007), <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/ucm048771.pdf>.

⁷¹ See Ctrs. for Disease Control & Prevention, History of Vaccine Safety, http://www.cdc.gov/vaccinesafety/Vaccine_Monitoring/history.html (last visited Feb. 24, 2010).

uncertainty as to whether victims injured by vaccines would be able to obtain compensation.⁷² This concern was due in large part to the many different theories of liability a plaintiff could bring against a manufacturer and the inconsistencies among the jurisdictions in how these various theories were applied.⁷³

In response to the concerns of both manufacturers and vaccine recipients, Congress passed the National Childhood Vaccine Injury Act of 1986 (NCVIA).⁷⁴ The NCVIA, through the National Childhood Vaccine Compensation Program (the Program), created a no-fault compensation system, allowing claimants to proceed with their claim without having to prove fault on the part of the manufacturer.⁷⁵ The Program is designed to be a two-tiered system, whereby a claimant must first fully adjudicate her claims under the NCVIA.⁷⁶ If the claimant is dissatisfied with the result under the Program, he is then allowed to file a civil action against the manufacturer.⁷⁷ This system is intended to be a more efficient alternative to a civil action against a manufacturer with more consistent results for claimants.⁷⁸ Further, claimants are diverted away from the tort system, thereby limiting the potential financial exposure risked by the manufacturers.⁷⁹

Claimants file their petitions with the United States Court of Federal Claims.⁸⁰ The Secretary of the Department of Health and Human Services (HHS Secretary) is the named respondent in the petition, rather than the manufacturer of the vaccine alleged to have caused the injury.⁸¹ The claims are heard initially by a Special Master, who decides whether and to what extent compensation should be awarded.⁸² The judges of the Federal Court of Claims have sole discretion in determining the qualifications of, and appointments to, these Special Master positions, and no medical or scientific background has been mandated as a prerequisite to appointment as a Special Master.⁸³ Moreover, once a Special Master is

⁷² See Hagan, *supra* note 35, at 479.

⁷³ See Dark, *supra* note 19, at 817; Neraas, *supra* note 19, at 153–56, 159.

⁷⁴ 42 U.S.C. § 300aa-1 (1994); see Elizabeth A. Breen, *One Shot Deal: The National Childhood Vaccine Injury Act*, 41 WM. & MARY L. REV. 309, 316, 319–20 (1999) (explaining the two concerns of the act, while also indicating that the Act has not adequately met the concerns of vaccine recipients).

⁷⁵ See § 300aa-11(c).

⁷⁶ See Neraas, *supra* note 19, at 162.

⁷⁷ See *id.*

⁷⁸ See H.R. REP. No. 99–908, at 5–7 (1986); Neraas, *supra* note 19, at 164, 165; see also Breen, *supra* note 74, at 317.

⁷⁹ See Neraas, *supra* note 19, at 162.

⁸⁰ 42 U.S.C. § 300aa-11(a)(1) (1994).

⁸¹ See *id.*

⁸² *Id.* § 300aa-12(d)(3)(A).

⁸³ See, e.g., Craig A. Conway, *Federal Court Reverses Denial of Vaccination Compensation Claim*, HEALTH L. PERSPECTIVES (2009), available at <http://www.law.uh.edu/health>

appointed, he may be removed during his four-year term only for “incompetence, misconduct, neglect of duty, or physical or mental disability.”⁸⁴ Criticism has been leveled at the selection process, qualifications, and jurisdictional purview of these vaccine court Special Masters for creating arguably improper “unbridled discretion.”⁸⁵

Generally, in order to succeed with their claims, claimants must establish, by a preponderance of the evidence, the following four elements: [1] that they received a vaccine set forth on a “Vaccine Injury Table,”⁸⁶ [2] they sustained injury, aggravation of an illness, disability, injury or condition listed on the Table, or died as a result of administration of the vaccine,⁸⁷ [3] that the first symptoms or onset of injury, aggravation of an injury, or condition, or death, occurred within the period of time specified in the Table,⁸⁸ and [4] that the injury or death was not caused by factors unrelated to the administration of the vaccine.⁸⁹ The parties shall have the right for the Special Master’s decision to be reviewed by the Court of Federal Claims, and then may obtain review of the Claims Court’s judgment by the Federal Circuit Court of Appeals.⁹⁰

Any compensation paid to a claimant is based on the Vaccine Injury Table.⁹¹ This Table includes all routinely recommended childhood vaccines, the potential adverse side effects a particular vaccine might cause, and the time frame within which a side effect might occur.⁹² To the extent the claimant can establish these requirements, he is entitled to a presumption of causation.⁹³ If, however, a claimant’s injury is not on the Table, or a manifestation of symptoms did not occur within the period of time specified in the Table, then the claimant must establish, by a preponderance of the evidence, that the vaccine was a cause-in-fact of his

law/perspectives/2009/(CC)%20Vaccine.pdf. Surprisingly, “[t]here is no requirement that a special master has any formal medical training, and none of the current special masters have an extensive scientific background. The special masters have two primary functions: collection of relevant information in a timely manner, and rendering a final, enforceable decision.” *Id.* at 3 (quoting Bruce Patsner, *Childhood Vaccines and Autism, Special Courts and Torts*, HEALTH L. PERSP., Feb. 18, 2008, [http://www.law.uh.edu/healthlaw/perspectives/2008/\(BP\)%20autism.pdf](http://www.law.uh.edu/healthlaw/perspectives/2008/(BP)%20autism.pdf)).

⁸⁴ Breen, *supra* note 74, at 321 (footnotes omitted).

⁸⁵ *Id.*

⁸⁶ 42 U.S.C. § 300aa-14 (2006) (listing the table); § 300aa-11(c)(1)(A) (indicating that the vaccinated individual must have “received a vaccine set forth in the Vaccine Injury Table”).

⁸⁷ *Id.* § 300aa-11(c)(1)(C)(i).

⁸⁸ *Id.*

⁸⁹ *Id.* § 300aa-13(a)(1).

⁹⁰ *Id.* §§ 300aa-12(e)(1), (f).

⁹¹ See H.R. Rep. No. 99-908 at 15 (1986).

⁹² See *id.* at 19.

⁹³ See *id.* at 18.

injury by providing some scientific study or expert medical testimony.⁹⁴ This Table is periodically updated based on the most up to date data in an attempt to more justly compensate those with “good” claims, while weeding out the “bad” claims.⁹⁵

Compensation under the Program includes expenses that have been or will be incurred for diagnosis and medical or other remedial care, “rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.”⁹⁶ Determining these damages is a complicated process that requires the use of an expert who should be experienced in preparing a comprehensive “life care plan” that details the types of care the claimant will need over the course of his lifetime.⁹⁷ However, compensation under the Program is secondary to other sources of compensation, including state compensation programs or insurance policies.⁹⁸ Thus, a claimant must first exhaust those sources of payment before receipt of funds under the Program.⁹⁹

Unlike the Swine Flu Act which did not place caps on any awards, the NCVIA caps compensation at \$250,000 for the estate of the deceased, as well as for pain and suffering and emotional distress.¹⁰⁰ Claimants are entitled to compensation for actual and anticipated loss of earnings, and reasonable attorney’s fees and other costs.¹⁰¹ Punitive or exemplary damages, however, are not allowed.¹⁰² Damage awards are paid from the Vaccine Injury Compensation Trust Fund,¹⁰³ which is funded by an excise tax charged on all childhood vaccines.¹⁰⁴

If the claimant chooses to receive the compensation awarded under the Program, he is prohibited from bringing a civil suit against the vaccine manufacturer.¹⁰⁵ However, if he is unsatisfied with the administra-

⁹⁴ See *id.* at 15; Lisa J. Steel, *National Childhood Vaccine Injury Compensation Program: Is This the Best We Can Do for Our Children?*, 63 GEO. WASH. L. REV. 144, 156–57 (1994–1995).

⁹⁵ See 42 U.S.C. § 300aa-14(c) (2006); Breen, *supra* note 74, at 326 (describing the authorities that bring the table up to date).

⁹⁶ § 300aa-15(a)(1)(A).

⁹⁷ See Abbott, *supra* note 67, at 1827.

⁹⁸ See § 300aaa-15(g).

⁹⁹ See *id.*

¹⁰⁰ See *id.* § 300aa-15(a)(2), (4).

¹⁰¹ See *id.* § 300aa-15(a)(3)(A), (B).

¹⁰² *Id.* § 300aa-15(d)(1), (e)(1).

¹⁰³ See *id.* § 300aa-15(i)(2); Hagan, *supra* note 35, at 482.

¹⁰⁴ See 26 U.S.C. §§ 4131, 9510 (2006); Hagan, *supra* note 35, at 482.

¹⁰⁵ See 42 U.S.C. § 300aa-21(a); see also *id.* § 300aa-11(a)(2) (specifying the limitations on bringing a civil action after October 1, 1988).

tive award, he can file a civil tort action against the manufacturer.¹⁰⁶ As this route is not the “desired” one in the NCVIA’s two-tiered structure,¹⁰⁷ Congress amended certain aspects of traditional tort law in an effort to maintain protections for manufacturers.¹⁰⁸ For example, no vaccine manufacturer shall be liable in a civil action for damages if the injury or death resulting from administration of the vaccine resulted from “unavoidable” side effects that are inherent in the vaccine, “even though the vaccine was properly prepared and was accompanied by proper directions and warnings.”¹⁰⁹ Further, a vaccine is presumed to be accompanied by proper instructions and warnings if the manufacturer shows it complied with the federal Food, Drug and Cosmetic Act and the Public Health Service Act, unless the plaintiff can show fraudulent or intentional and wrongful withholding of information when submitting information for the vaccine’s approval, or other criminal or illegal activity relating to the vaccine’s safety.¹¹⁰

Congress also legislatively amended the rule from *Reyes* by providing that no manufacturer shall be liable for any injury or death due to the manufacturer’s failure to provide warnings about the risks associated with the vaccines directly to the vaccinee.¹¹¹ Recall that it was precisely the holding from that case that led insurance companies to drop liability insurance for vaccine manufacturers in connection with liability associated with the swine flu vaccine.¹¹²

Thus, due to the government’s increasing unwillingness to accept full financial responsibility for vaccine manufacturers,¹¹³ the NCVIA did many things to change what the Swine Flu Act had provided.¹¹⁴ First, the Swine Flu Act created an exclusive civil tort remedy against the federal government, rather than the two-step program mandated by the NCVIA, which requires the preliminary step of administrative adjudication of claims.¹¹⁵ And to the extent a claimant chooses to pursue civil tort liability, manufacturers are exposed to liability to which they were not otherwise exposed under the Swine Flu Act,¹¹⁶ but yet certain tenets

¹⁰⁶ See § 300aa-21(a); see also *id.* § 300aa-11(a)(2) (specifying the limitations on bringing a civil action after October 1, 1988).

¹⁰⁷ See Greenberger, *supra* note 35, at 15.

¹⁰⁸ See § 300aa-22; Greenberger, *supra* note 35, at 15.

¹⁰⁹ § 300aa-22(b)(1).

¹¹⁰ *Id.* § 300aa-22(b)(2).

¹¹¹ *Id.* § 300aa-22(c).

¹¹² See *supra* notes 38–46 and accompanying text.

¹¹³ See Greenberger, *supra* note 35, at 14.

¹¹⁴ See *id.* at 11.

¹¹⁵ See *id.* at 14.

¹¹⁶ See *id.* at 16 (“NCVIA’s litigation stage potentially exposed vaccine manufacturers and others to liability, if claimants were not satisfied with their administrative awards.”).

of tort law have been statutorily amended to the claimant's detriment.¹¹⁷ Further, the NCVIA capped certain damages awards that the Swine Flu Act did not.¹¹⁸ Thus, "NCVIA's limitations clearly demonstrate that Congress 'learned a lesson' from the 'open-ended' liability of the Swine Flu Act and wanted to limit expenditures for injuries and deaths resulting from childhood vaccines under NCVIA."¹¹⁹

C. Smallpox Vaccination Program

More recently, the government has dictated vaccination liability and compensation policy in the context of this country's war on terror. In December 2002, President Bush announced a plan to vaccinate roughly 500,000 civilian health care workers and emergency personnel against smallpox in anticipation of the potential for terrorists to use smallpox as a weapon against the United States.¹²⁰ Although the White House stressed that there was no imminent threat of smallpox, the terrorist attacks of September and October 2001 created heightened concern that terrorists may have access to and use smallpox in another terrorist attack against this country.¹²¹ Thus, the President requested that health care workers and emergency personnel, or "first responders," volunteer to receive the smallpox vaccination, allowing them to mobilize quickly and without risk of infection in the event of a smallpox attack.¹²² Even though the WHO declared in 1980 that smallpox had been eradicated worldwide, the virus still exists in laboratories, and the President expressed concern that terrorist régimes may possess it.¹²³

Unfortunately, Bush's vaccination plan was an incredible failure.¹²⁴ Section 304 of the Homeland Security Act (HSA),¹²⁵ which authorized the civilian smallpox countermeasures, specifically protected vaccine manufacturers and those who administer the vaccine (collectively, "covered persons" under the HSA) from liability, except in the case of negligence.¹²⁶ These covered persons are made federal employees under the

¹¹⁷ See *id.* at 15 ("Congress made certain alterations to traditional tort law to protect vaccine manufacturers, as the government would not pay awards that arose out of litigation.").

¹¹⁸ *Id.* at 14.

¹¹⁹ *Id.* at 16.

¹²⁰ See Remarks Announcing the Smallpox Vaccination Plan, *supra* note 22, at 2191; Greenberger, *supra* note 35, at 16.

¹²¹ See Remarks Announcing the Smallpox Vaccination Plan, *supra* note 22.

¹²² See *id.*

¹²³ See *id.*

¹²⁴ See Marcia Coyle, *Congress Tackles Vaccine Liability*, FULTON COUNTY DAILY REP., Dec. 14, 2005, at 5 (quoting Michael Greenberger).

¹²⁵ Homeland Security Act of 2002, Pub. L. No. 107-296, 116 Stat. 2135, 2165 (codified as amended at 42 U.S.C. § 233(p) (2003)).

¹²⁶ *Id.*

HSA.¹²⁷ Thus, any cause of action for injuries would have to be brought against the federal government under the Federal Tort Claims Act (FTCA).¹²⁸ However, commentators have suggested that it would be very difficult for a plaintiff to claim negligence, as there would be no reason to believe anyone would negligently administer (or presumably, manufacture) the vaccine.¹²⁹ This liability scheme was in stark contrast to the “no-fault” compensation schemes of the Swine Flu Act and NCVIA, where injured victims need only establish that their injuries were caused by administration of the vaccine, rather than prove fault.¹³⁰ Further, under the FTCA, the federal government is immune from liability for any discretionary policy decision.¹³¹ Thus, while it may be a poor public policy decision to vaccinate health care workers against smallpox, it is not necessarily a negligent decision.¹³²

More importantly, the HSA provided no sufficient mechanism for compensation for those injured due to their inoculation.¹³³ Rather than provide for a no-fault compensation system like the Swine Flu Act and NCVIA, the HSA simply provided that those injured by the administration of a vaccine had an exclusive remedy against the United States.¹³⁴ However, the United States would only assume liability for negligence or any other wrongful act or omission by a covered person,¹³⁵ which, as stated above, would be very difficult to establish. Thus, those injured had either their own health insurance plans or state workers’ compensation laws as their only remedy.¹³⁶ However, one commentator has suggested that securing private insurance coverage for this kind of injury is virtually impossible.¹³⁷ Further, it was not certain that all state workers’

¹²⁷ *Id.*

¹²⁸ See Susan J. Landers, *Compensation Plan Needed to Offset Smallpox Vaccine Risks*, AM. MED. NEWS, Jan. 13, 2003, <http://www.ama-assn.org/amednews/2003/01/13/hlsa0113.htm>

¹²⁹ *See id.*

¹³⁰ See Greenberger, *supra* note 35, at 18.

¹³¹ Federal Tort Claims Act, 28 U.S.C. §§ 2671, 2680(a) (1948).

¹³² Robert Pear, *Legal Risks; For Victims of Vaccine, Winning Case Will Be Hard*, N.Y. TIMES, Dec. 13, 2002, at A13; see also Wood, *supra* note 15, at 12 (stating that under the Swine Flu Act, the federal government could not avail itself of the discretionary function exception).

¹³³ The CDC reports complications of the smallpox vaccine to include that “[a]bout 1 out of 10,000 people vaccinated for the first time will experience an inflamed heart (can be mild to life-threatening); about 1 out of 83,000 people vaccinated will experience encephalitis, which can lead to permanent brain damage or death; and about 1 out of 667,000 people vaccinated will experience skin and tissue destruction which can lead to scarring or death.” Ctrs. for Disease Control & Prevention, Smallpox Vaccine: What You Need to Know, <http://www.bt.cdc.gov/agent/smallpox/vaccination/needtoknow.asp> (last visited Feb. 11, 2010).

¹³⁴ See 42 U.S.C. § 233(a) (2006).

¹³⁵ *See id.*

¹³⁶ See AFL-CIO, State and Federal Smallpox Compensation, <http://www.aflcio.org/issues/safety/smallpoxcomp.cfm#smact> (last visited Feb. 11, 2010).

¹³⁷ See Greenberger, *supra* note 35, at 19.

compensation laws would accept claims for sickness caused by the smallpox vaccine.¹³⁸

Bush's plan was ambitious: beginning January 24, 2003 and continuing for the next month, 500,000 first responders would be vaccinated.¹³⁹ However, only 5,000 first responders were vaccinated, due in large part to the lack of compensation in the HSA.¹⁴⁰ In response to the low success rate of the vaccination plan, Congress passed the Smallpox Emergency Personnel Protection Act (SEPPA) on April 30, 2003.¹⁴¹

SEPPA created a no-fault compensation system, similar to an extent in structure to the NCVIA, for first responders who are injured as the result of the administration of smallpox countermeasures.¹⁴² Unfortunately (as under the NCVIA), state workers' compensation and health insurance plans are still the primary source of recovery for smallpox-related injuries.¹⁴³ Claimants may request benefits from the HHS Secretary who will determine whether payment of benefits is appropriate based on a vaccine injury table.¹⁴⁴ Benefits include: all reasonable and necessary medical expenses to treat the injury, loss of employment income benefits at the rate of 66 2/3 percent of wages (increased by 8 1/3 percent if there are dependents) with total compensation per year not to exceed \$50,000 and capped for life at \$262,100 for those with only partial disability, as opposed to permanent disability; and a lump sum death benefit payment of \$262,100, to be reduced by any lost employment income benefits previously paid.¹⁴⁵ These benefits seemingly cover significantly fewer medical expenses than those provided for in the NCVIA,

¹³⁸ See AFL-CIO, *supra* note 136. According to the AFL-CIO website:

First Responders who have health insurance have the same cost-sharing now required by all health insurance plans. Less fortunate First Responders, who figure among the forty-one million uninsured Americans, have nothing at all to cover the medical care required to treat smallpox reactions. As for state workers' compensation, an AFL-CIO survey reveals that only fourteen states clearly guarantee coverage of smallpox injuries as of April 2, 2003.

Id.

¹³⁹ Donald G. McNeil, Jr., *Smallpox Inoculations Begin with Four Connecticut Doctors*, N.Y. TIMES, Jan. 25, 2003, at A11; AFL-CIO, *supra* note 136.

¹⁴⁰ AFL-CIO, *supra* note 136.

¹⁴¹ See Greenberger, *supra* note 35, at 19. SEPPA is codified at 42 U.S.C. §§ 233, 239, 239a–239h (2006).

¹⁴² 42 U.S.C. § 239a(c) (2006).

¹⁴³ *Id.* § 239c(b); see Greenberger, *supra* note 35, at 20.

¹⁴⁴ *Id.* §§ 239a, 239b. The vaccine injury table component is similar to that under the NCVIA. *See id.* In other words, if an injury or other adverse effect is specified on the table and occurs within the time period specified in the table, such injury or side effect shall be presumed to have been caused by administration of the vaccine. *Id.* § 239b.

¹⁴⁵ *Id.* §§ 239c, 239d, 239e. For the purpose of providing benefits under these subsections, Congress authorized appropriations in such sums as may be necessary for each of the fiscal years 2003 through 2007. *Id.* § 239g. The Secretary's payment of any benefits is subject to the availability of such appropriations. *Id.* *See also* Greenberger, *supra* note 35, at 20 (discussing SEPPA benefit scheme).

which includes things like special education, counseling, special equipment, and the like.¹⁴⁶ SEPPA, on the other hand, provides only expenses necessary to “treat” the injury.¹⁴⁷ Assuming SEPPA’s benefits would not cover such future expenses, many injured by the smallpox vaccination may not receive full compensation for all of their injuries.

Unlike the NCVIA, there is no judicial review by any court of the HHS Secretary’s determination of appropriate compensation.¹⁴⁸ Moreover, SEPPA’s caps on these awards are more stringent than those imposed in prior federal vaccine compensation programs: the Swine Flu Act did not cap any awards, and the NCVIA’s awards are generally more generous than those in SEPPA.¹⁴⁹ For example, NCVIA’s lost income benefit is equivalent to the “actual and anticipated loss of earnings,” as opposed to the \$50,000 per year and life total of \$262,100 (in the absence of a permanent and total disability) under SEPPA.¹⁵⁰ Notwithstanding the government’s attempt to reinvigorate the Program by passing SEPPA, as of October 31, 2005, only 39,608 individuals have been vaccinated.¹⁵¹

D. Public Readiness and Emergency Preparedness Act

Another recent congressional vaccine-related initiative is the Public Readiness and Emergency Response Act, or “Prep Act.”¹⁵² Reports of bird flu and the possibility of a worldwide flu pandemic recently flooded the news media.¹⁵³ The bird flu, or avian influenza, known as A (H5N1), has been in existence for the past ten years in Southeast Asia.¹⁵⁴ The cause of the more recent concern about the spread of bird flu, however, is the fact that a few years ago, it moved out of Southeast Asia to Europe, Africa and India.¹⁵⁵ Many scientists believe it is only a matter of time before the bird flu reaches North America.¹⁵⁶ Not only has the bird flu migrated across the globe, it has also infected other animals, such as

¹⁴⁶ See 42 U.S.C. § 300aa-15(a)(1)(A)(iii)(II) (2006).

¹⁴⁷ See 42 U.S.C. § 239c(a) (2006).

¹⁴⁸ *Id.* § 239a(f)(2).

¹⁴⁹ See Greenberger, *supra* note 35, at 14–16, 20.

¹⁵⁰ *Id.* at 14, 16, 20.

¹⁵¹ See Ctrs. for Disease Control & Prevention, Smallpox Vaccination Programs by State, Oct. 31, 2005, <http://www.cdc.gov/media/pressrel/smallpox/spvaccin.htm> (last visited Feb. 11, 2010).

¹⁵² See Public Readiness and Emergency Response Act, 42 U.S.C. § 247d-6d (2006).

¹⁵³ Donald G. McNeil, Jr., *Avian Flu: The Worrier; At the U.N.: This Virus Has an Expert ‘Quite Scared’*, N.Y. TIMES, Mar. 28, 2006, at F1.

¹⁵⁴ *Id.*

¹⁵⁵ *Id.* at F1–F2.

¹⁵⁶ Erin Aigner & David Constantine, *Avian Flu: Calibrating the Message; The Spread: In 3 Years, 3 Continents*, N.Y. TIMES, Mar. 28, 2006, at F5.

ferrets and cats.¹⁵⁷ Further, influenza generally is a virus that can quickly mutate;¹⁵⁸ thus, the H5N1 virus could combine with a human flu strain and create a new virus that could cause a pandemic.¹⁵⁹ All of these factors combine to create a real concern around the globe that the virus will infect more humans, and that human to human transmission of the virus will also begin to occur.¹⁶⁰ To date, the virus has killed millions of birds and approximately 200 people.¹⁶¹ However, this flu is still largely an avian disease, and the humans who have contracted the disease have mostly been exposed to infected birds.¹⁶² And although there are people on both sides of the debate who believe a pandemic either is or is not likely, there is no doubt that the disease can be quite deadly when contracted by a human.¹⁶³

In December of 2005, Congress passed bio-defense legislation as part of a Department of Defense appropriations bill.¹⁶⁴ The appropriations provisions in the bill provided funds “to prepare for and respond to an influenza pandemic, including the development and purchase of vaccines, antivirals, and necessary medical supplies, and for planning activities[.]”¹⁶⁵ These appropriations allowed the federal government to procure and stockpile vaccines in the event of a bird flu pandemic.¹⁶⁶ However, provisions were later added to the bill after a House-Senate conference committee, which offered drug manufacturers “targeted liability protection,”¹⁶⁷ even though House Republicans had earlier prom-

¹⁵⁷ Elisabeth Rosenthal, *On the Front: A Pandemic is Worrisome but ‘Unlikely’*, N.Y. TIMES, Mar. 28, 2006, at F1.

¹⁵⁸ See McNeil, *supra* note 153.

¹⁵⁹ See Lawrence K. Altman, M.D., *With Every Epidemic, Health Officials Face Tough Choices*, N.Y. TIMES, Mar. 28, 2006, at F5.

¹⁶⁰ See Denise Grady & Gina Kolata, *How Avian Flu: The Uncertain Threat*, N.Y. TIMES, Mar. 28, 2006, at F1.

¹⁶¹ See *id.*

¹⁶² *Id.* The *New York Times* reports an example of bird-to-human transmission, where a 13-year old boy died within nine days of being hospitalized with flu symptoms. *From Birds to Humans*, N.Y. TIMES, Mar. 28, 2006, at F4. He lived near a live-poultry market and handled birds at cockfights. *Id.* An example of possible human-to-human contact occurred where a mother sat at her 11-year old daughter’s hospital bedside for 16 hours, wiping and kissing the girl’s mouth. *Id.* Although the girl played and slept where chickens were kept, the mother lived in Bangkok and had no exposure to birds. *Id.* The mother died 12 days after her daughter. *Id.*

¹⁶³ See Grady & Kolata, *supra* note 160. In the few human autopsies that have been done, it appears that the virus can attack the lungs, the brain and possibly the intestines. *See id.* And of the 186 people in the world who have contracted the virus, 105 have died. *See Altman, supra* note 159.

¹⁶⁴ See Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act, 2006, Pub. L.109-148, 119 Stat. 2818 (2005).

¹⁶⁵ *Id.* 119 Stat. at 1786.

¹⁶⁶ *Id.*

¹⁶⁷ See Public Readiness and Emergency Response Act, 42 U.S.C. § 247d-6d (2006).

ised that there would be no liability protections included in the legislation.¹⁶⁸ Leading Senate Democrats alleged that then-Senate Majority Leader Bill Frist and others “cut a back room deal” at the last minute to give massive liability protections to drug companies.¹⁶⁹

These immunity provisions, collectively called the Prep Act,¹⁷⁰ provide immunity from lawsuits for any manufacturer, distributor or administrator of a “covered countermeasure”—drugs, vaccines or other medical devices—used to protect Americans in the event of a pandemic, epidemic, or biological attack.¹⁷¹ The sole exception to immunity “shall be” for injury caused by willful misconduct.¹⁷² The immunity is qualified in that it is afforded only to the extent the countermeasure was administered during the period of a declaration issued by the HHS Secretary.¹⁷³

Although effectively immunizing drug manufacturers from virtually all liability, the Prep Act does allow compensation from a fund to victims injured by a vaccine administered pursuant to the HHS Secretary’s declaration.¹⁷⁴ However, the fund is contingent—Congress will appropriate funds only after the issuance of a declaration.¹⁷⁵ The compensation amounts provided in the Prep Act are the same as those provided by SEPPA to victims injured by smallpox vaccinations.¹⁷⁶ Further, like SEPPA and the NCVIA, injuries eligible for compensation are only those that fall on a vaccine injury table, which are presumed to be caused by the vaccine, assuming the symptoms or manifestation or onset of adverse side effects occur within a specified period of time.¹⁷⁷ Moreover, no

¹⁶⁸ See Sheryl Gay Stolberg, *Legal Shield for Vaccine Makers Is Inserted into Military Bill*, N.Y. TIMES, Dec. 20, 2005, at A26; *Democrats Blast ‘Midnight Rider’ Adding Rx Liability Shield to DOD Bill*, FDA WEEK, Dec. 23, 2005.

¹⁶⁹ Stolberg, *supra* note 168.

¹⁷⁰ See § 247d-6d.

¹⁷¹ See *id.* § 247d-6d(a)(1).

¹⁷² *Id.* § 247d-6d(d)(1). Most significantly, if an act or omission by a manufacturer is alleged to constitute willful misconduct, and that act or omission is subject to FDA regulation, the act or omission shall not constitute willful misconduct unless the HHS Secretary or Attorney General has initiated an enforcement action with respect thereto, establishing the willful misconduct. *Id.* § 247d-6d(c)(5).

¹⁷³ 42 U.S.C. § 247d-6d(a)(3) (2006).

[I]f the Secretary makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency, the Secretary may make a declaration . . . recommending . . . the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures.

Id. § 247d-6d(b)(1).

¹⁷⁴ See *id.* § 247d-6e.

¹⁷⁵ See *id.*

¹⁷⁶ See *id.* § 247d-6e(b)(2).

¹⁷⁷ See *id.* § 247d-6e(b)(5).

court may review any action of the HHS Secretary taken under the Prep Act,¹⁷⁸ nor may one eligible for compensation bring a civil tort action without first exhausting his remedies available under these provisions.¹⁷⁹

According to critics, the Prep Act falls short of its goal on a variety of fronts. Not only was manufacturer immunity inserted allegedly “behind closed doors,”¹⁸⁰ and “without Congressional debate or public scrutiny,”¹⁸¹ critics have condemned the compensation provided in the Act as a “fig leaf”—a compensation fund that has not been funded ahead of time.¹⁸² According to a statement by Senator Edward Kennedy, “[t]here is no guarantee that any victim of a faulty or negligently made drug or vaccine will receive any compensation whatsoever.”¹⁸³ Finally, critics argue that the language of the Prep Act is too broad.¹⁸⁴ A determination by the HHS Secretary that a public health emergency exists (and thus, immunity for manufacturers would attach) is not specifically limited in the Prep Act to a pandemic, epidemic, or bio-terror attack “emergency”; rather, the HHS Secretary’s declaration could be used to include any “epidemic” such as obesity, diabetes, or arthritis.¹⁸⁵ Thus, the provisions could allow the manufacturers of Vioxx, for example, to escape liability for any act other than the manufacturer’s willful misconduct.¹⁸⁶ The HHS Secretary has not exercised any declaratory power as yet, so the effect this law will have is unclear.¹⁸⁷

Many Democrats joined with Senator Kennedy in proposing what they call the Responsible Public Readiness and Emergency Preparedness Act of 2006.¹⁸⁸ This Act would repeal the Prep Act and replace it with limited liability protection (rather than effectively full immunity) for a specified set of countermeasures.¹⁸⁹ It would also include a fully-funded

¹⁷⁸ See *id.* § 247d-6e(b)(5)(C).

¹⁷⁹ 42 U.S.C. § 247d-6e(d) (2006).

¹⁸⁰ Senator Kennedy, *Colleagues Call on Majority Leader Frist, Speaker Hastert to Repeal ‘Dead of Night’ Vaccine Liability Provision, Enact Real Protections*, U.S. FED. NEWS, Feb. 16, 2006, at 2, available at 2006 WLNR 2705752 (Westlaw) [hereinafter Senator Kennedy, *Colleagues*].

¹⁸¹ *Id.*

¹⁸² Stolberg, *supra* note 168, at 1.

¹⁸³ See *id.* The Republican response to this criticism is that it is impossible to know how much money to set aside in a fund, and to allocate money to the fund right now could make the bill too expensive to pass. *Id.* at 2. Rather, the compensation fund would be funded after an emergency has been declared. *Id.*

¹⁸⁴ See Senator Kennedy, *Colleagues*, *supra* note 180, at 3.

¹⁸⁵ See *id.*

¹⁸⁶ See *id.*

¹⁸⁷ See THOMAS O. MCGARITY, THE PREEMPTION WAR: WHEN FEDERAL BUREAUCRACIES TRUMP LOCAL JURIES 127 (2008).

¹⁸⁸ Responsible Public Readiness and Emergency Preparedness Act, S. 2291, 109th Cong. (2006).

¹⁸⁹ S. 2291, § 3(a).

compensation plan, modeled after the NCVIA.¹⁹⁰ Further, the federal government would indemnify manufacturers, distributors, and administrators of certain countermeasures.¹⁹¹ Thus, victims may choose to sue the federal government under any theory of liability.¹⁹² However, the government would indemnify manufacturers only where [1] the product has not undergone full FDA testing, and [2] the product is recommended by the HHS Secretary in a declaration for use to protect the American people.¹⁹³ Thus, manufacturers of drugs and vaccines that must be used in an emergency situation for this specific set of countermeasures (rather than any public health “epidemic”), but have not undergone full FDA testing, would be protected.¹⁹⁴ Finally, the government would be able to sue a manufacturer or administrator who was grossly negligent or reckless to recover payments made by the government to an injured victim.¹⁹⁵ Supporters of the Prep Act, on the other hand, maintain that the liability protections are in fact targeted only for pandemic, epidemic and biodefense products, and that such protections are necessary to better protect American citizens, as not doing so would expose the United States to threats such as avian influenza.¹⁹⁶

II. NONRECIPROCAL RISK THEORY AS APPLIED TO VACCINE-RELATED INJURIES AND THE APPROPRIATE LIABILITY AND COMPENSATION SCHEME

Other commentators have reviewed the positive and negative aspects of these congressional programs from the confines of a purely instrumentalist or “goal-oriented” perspective by suggesting a variety of ways to “fix” the problems of manufacturer immunity or victim compensation inherent in these programs.¹⁹⁷ Yet their suggestions disregard the fact that vaccine liability and compensation should be driven by principle, rather than instrument. Principles implicated by vaccine injury include corrective justice (that the tort system should fully compensate victims of torts) and nonreciprocal risks (that liability for injury-causing conduct should not be determined by the reasonableness—or social utility—of such conduct, but rather on the disproportionality of the risks the conduct imposes on its victims). Professor Fletcher’s nonreciprocal risk

¹⁹⁰ *Id.*

¹⁹¹ S. 2291, § 4(5)(D).

¹⁹² *Id.*

¹⁹³ S. 2291, § 4(6)(A).

¹⁹⁴ *Id.*

¹⁹⁵ Senator Kennedy, *Colleagues*, *supra* note 180.

¹⁹⁶ See John Clerici & Dana Perkins, *From BioShield to the Prep Act and Beyond: Developing a Market for Infectious Disease and Bioterror Countermeasures*, 14 METRO CORP. COUNS. 18 (2006).

¹⁹⁷ See *infra* Part II.B. (discussing the various criticisms of these congressional programs).

theory of corrective justice challenged the historical development of tort doctrine along instrumentalist lines.¹⁹⁸ His theory focuses on the fairness of recovery, measured not by fault, social costs, or utility of the risk-creating activity, but by injuries resulting from nonreciprocal risks: risks imposed on the plaintiff that are greater in degree than those the plaintiff imposes on the defendant.¹⁹⁹

We apply Fletcher's theory of nonreciprocal risk as a starting point for rethinking what kind of liability various stakeholders should have for vaccine injury and how that liability ought to be distributed among the stakeholders. At its most intuitive level, vaccine liability seems to present a conflict of objectives that appear difficult to reconcile without doing violence to the interests of objectives that are preferred over other objectives. Certainly, it is a socially desirable goal for our society to be vaccinated against a variety of contagious diseases. But if that instrumentalist objective dictates the result that one injured by a vaccine should receive no compensation, this Article concludes otherwise. Drawing coherence between such objectives requires us to examine the principles at work behind any régime of compensation and regulation, and to recognize the limits of the reciprocity paradigm to permit a fully coherent resolution of the tension among those principles, as well as between those principles and the various outcomes that may be seen to serve them. Those are the complex tasks we undertake in this Part and Part III.

A. *The Preemption Debate: FDA Preemption in Light of the Nonreciprocal Risk Theory of Corrective Justice*

Notwithstanding the current statutory régimes pursuant to which many vaccine injuries are adjudicated, the tort system still exists for injuries which fall outside of those programs and for exceptions to immunity provided therein. Yet tort liability is threatened by a new argument which defendants have thrust before the courts in the last few years in the context of other prescription drugs and medical devices: preemption. Preemption offers a certain superficial appeal, but poses serious problems and, if applied to vaccines, would transgress fundamental aspects of corrective justice and enterprise regulation principles. FDA preemption of private tort claims is a widely debated issue.²⁰⁰ The debate

¹⁹⁸ See Fletcher, *supra* note 29.

¹⁹⁹ See *id.*

²⁰⁰ On March 8, 2010, the United States Supreme Court granted review in *Bruecewitz v. Wyeth*, No. 09-152, to determine whether section 22(b)(1) of the NCVIA preempts all vaccine design defect claims, whether based on negligence or strict liability. See *Wyeth v. Levine*, 129 S. Ct. 1187 (2009); *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008); *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996); Richard A. Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda*, 1 J. TORT LAW 5 (2007);

lies at the intersection of the advisability of tort recovery against a manufacturer who, theoretically, has complied with all FDA regulations regarding its medical product, and the disquiet accompanying a failure to provide a remedy for victims injured by a FDA-approved product. The Supreme Court jurisprudence in this area has been inconsistent, stoking the fires of this dispute.²⁰¹ In addition, the FDA's own position as to preemption has changed, from one in which FDA regulatory action and tort liability "maintained a relatively tranquil coexistence"²⁰² to one in which tort liability must yield to the administrative state.²⁰³ Much scholarly commentary has been devoted to this debate, and the sometimes widely divergent views are dramatic in their breadth and depth.²⁰⁴ Yet the recognition of corrective justice principles in any of these contexts is largely absent.²⁰⁵ And the extent to which tort claims for injuries caused by vaccines would be preempted due to FDA approval of those vaccines is unclear.

One of the first Supreme Court cases to take up the FDA preemption debate was *Medtronic, Inc. v. Lohr*.²⁰⁶ In *Lohr*, the Court held that the plaintiff's design defect claim against the manufacturer of a pacemaker was not preempted by § 360k of the Medical Device Amendments (MDA)²⁰⁷ to the Food, Drug, and Cosmetic Act of 1938 (FDCA).²⁰⁸ The

David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461 (2008); Richard A. Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. TORT LAW 4 (2007); Catherine M. Sharkey, *Federalism in Action: FDA Regulatory Preemption in Pharmaceutical Cases in State Versus Federal Courts*, 15 J. L. & POL'Y, 1013 (2007) [hereinafter Sharkey, *Federalism in Action*]; Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449 (2008) [hereinafter Sharkey, *Products Liability Preemption*]. See also, Tara Guffrey, Note, *Does the National Childhood Vaccine Injury Compensation Act Really Prohibit Design Defect Claims?: Examining Federal Preemption in Light of American Home Products Corp. v. Ferrari*, 26 GA. ST. U. L. REV. 617 (2010).

²⁰¹ Compare *Lohr*, 518 U.S. 470, and *Wyeth*, 129 S.Ct. 1187 (finding no preemption of state law tort claims), with *Riegel*, 128 S.Ct. 999 (finding preemption of state law tort claims to exist). The question of FDA preemption appears to turn on "the nature of the claim and the degree of prior FDA scrutiny of the product." Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 YALE J. HEALTH POL'Y, L. & ETHICS 587, 610 (2005).

²⁰² Nagareda, *supra* note 200, at 1.

²⁰³ See *Wyeth*, 129 S. Ct. at 1201–03; Epstein, *supra* note 200, at 4–7; Nagareda, *supra* note 200, at 37–40; Jonathan V. O'Steen, *The FDA Defense: Vioxx and the Argument Against Federal Preemption of State Claims for Injuries Resulting from Defective Drugs*, 48 ARIZ. L. REV. 67, 77 (2006); Sharkey, *Products Liability Preemption*, *supra* note 200, at 472–76.

²⁰⁴ See *supra* note 200.

²⁰⁵ But see McGARITY, *supra* note 187, at 183, 185, 195, 210, 232, 237, 253. Professor McGarity notes that if preemption of tort claims is to be found to exist, the regulatory agencies must perform their functions close to perfectly for corrective justice principles not to be thwarted. *Id.*

²⁰⁶ 518 U.S. 470 (1996).

²⁰⁷ 21 U.S.C. § 360c (2006).

²⁰⁸ 21 U.S.C. § 301 (2006); *Lohr*, 518 U.S. at 487–89.

pacemaker at issue in *Lohr* was designated a “Class III” medical device.²⁰⁹ Class III medical devices must receive premarket approval from the FDA before being introduced to the market, unless it can be shown that the device is “substantially equivalent” to a Class III device that is already on the market.²¹⁰ In that instance, the device can avoid the rigorous premarket approval process and be introduced to the market pursuant to a “premarket notification” process, a more rapid process pursuant to § 360e of the MDA.²¹¹ Section 360k of the MDA provides that subject to limited exceptions:

no State or political subdivision of a State may establish or continue in effect with respect to a device . . . any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.²¹²

The manufacturer in *Lohr* argued that by the language in this section, Congress meant to preempt all common law tort claims, insofar as tort liability would amount to a “requirement” that is different from or in addition to the requirements imposed by the FDA approval process.²¹³ The Court held otherwise; none of the legislative history with regard to the MDA suggested a comprehensive preemption of traditional common law remedies.²¹⁴ Moreover, had Congress intended such a result, it chose a very odd word with which to achieve it.²¹⁵ When it used the word *requirement*, Congress was primarily concerned with conflicting

²⁰⁹ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476–77 (1996). A Class III device is one which either “presents a potential unreasonable risk of illness or injury,” or which is “purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health.” 21 U.S.C. § 360c(a)(1)(C)(ii) (2006).

²¹⁰ See *Id.* § 360c(f)(1)(A).

²¹¹ See 21 U.S.C. § 360e(b)(1); *Lohr*, 518 U.S. at 477–79. As the Court explains in *Lohr*, this process of limited review by the FDA for devices which are substantially equivalent to previously approved devices is known as the “premarket notification process” or the “510(k) process,” after the number of the section in the original MDA. *Id.* at 478. The Court in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), noted that in 2005 the “FDA authorized the marketing of 3,148 devices under § 510(k) and granted premarket approval to just 32 devices.” 128 S.Ct. 999, 1004 (citing P. Hutt, R. Merrill, & L. Grossman, *FOOD AND DRUG LAW* 992 (3d ed. 2007)).

²¹² 21 U.S.C. § 360k(a) (2006).

²¹³ See *Lohr*, 518 U.S. at 486.

²¹⁴ *Id.* at 491. The portion of the opinion rejecting the argument that common law tort claims are preempted by § 360k was joined by only three other justices, in addition to Justice Stevens, who delivered the opinion. *Id.* at 474.

²¹⁵ *Lohr*, 518 U.S. at 487.

state statutes and regulations, not state common law duties and remedies.²¹⁶ With specific regard to the design defect claim, the manufacturer argued that since the pacemaker was deemed “substantially equivalent” to an earlier-approved device, that determination amounted to a specific, federal requirement that could not be affected by tort liability.²¹⁷ The Court rejected this argument. As the premarket notification process is concerned with “equivalence” to another device, as opposed to safety of the current device, the Court reasoned that the process could not be deemed to impose requirements on the manufacturer.²¹⁸

The Court changed course in *Riegel v. Medtronic, Inc.* when it again considered the preemptive effect of § 360k.²¹⁹ In *Riegel*, however, the device at issue—a balloon catheter used for a coronary angioplasty—had undergone the rigorous premarket approval process.²²⁰ The Court reasoned that the premarket approval process does impose “requirements,” as it relates specifically to the “safety and efficacy” of a particular device.²²¹ Moreover, the Court held that a tort judgment also imposes a requirement, insofar as it “establishes that the defendant has violated a state law obligation.”²²² Thus, a tort judgment that requires the manufacturer’s device to be safer than what was prescribed by the FDA approval process would “disrupt[] the federal scheme no less than state regulatory law to the same effect.”²²³

The most recent Supreme Court case to address the tension between FDA preemption and common law tort claims is *Wyeth v. Levine*.²²⁴ *Wyeth* involved a failure to warn claim against Wyeth, the manufacturer of Phenergan, an anti-nausea drug.²²⁵ The plaintiff’s right forearm had to be amputated after she developed gangrene caused by injection of the drug by the “IV-push method,”²²⁶ whereby the drug entered plaintiff’s

²¹⁶ *Id.* at 489.

²¹⁷ *Id.* at 492.

²¹⁸ *Id.* at 492–94. Even though the Court held that the premarket notification process did not impose requirements sufficient to satisfy the preemptive effect of § 360k, five Justices concluded that, in a different context, tort liability could be a requirement that is different from, or in addition to, a federal requirement. *Id.* at 503–05 (Breyer, J., concurring), 512 (O’Connor, J., concurring in part and dissenting in part) (joined by Rehnquist, C.J., Scalia, J., and Thomas, J.).

²¹⁹ See *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999, 1011 (2008).

²²⁰ *Id.* at 1005.

²²¹ *Id.* at 1007.

²²² *Id.* at 1008 (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 522 (1992)).

²²³ *Id.* Justice Scalia, writing for the Court, reasoned that tort judgments should yield to FDA regulation because a jury does not engage in the same cost-benefit analysis that the FDA does in determining whether a device is safe. *Id.* The jury only sees the harm done to this one plaintiff before it; it does not see the patients who have benefited greatly from the device. *Id.*

²²⁴ 129 S.Ct. 1187 (2009).

²²⁵ *Id.* at 1191.

²²⁶ Phenergan can be administered either directly into a muscle or intravenously, by either an IV drip (where the drug is introduced into a saline solution and then dripped into the patient

artery.²²⁷ The plaintiff alleged that Phenergan's label was "defective because it failed to instruct physicians to use the IV-drip method of intravenous administration instead of the higher-risk IV-push method."²²⁸ Moreover, she alleged that intravenous administration of the drug was not reasonably safe because the risk of gangrene and amputation outweigh the drug's benefits.²²⁹

The FDA's drug labeling regulations include no preemption provision similar to that found in § 360k in the medical device context. Thus, Wyeth's preemption arguments focused on the FDA approval of Phenergan's label generally.²³⁰ As FDA approval of a drug includes approval of the drug's label, Wyeth claimed it could not have changed the Phenergan label without violating FDA regulations.²³¹ In other words, it could not comply with both the FDA labeling requirements and the tort liability against it that would require it to change its label.²³² The Court rejected this argument; the FDA regulations allow a manufacturer to "add [to] or strengthen" a drug's label without prior FDA approval.²³³ Thus, Wyeth could have changed Phenergan's label to contraindicate the IV-push method of administration without violating federal law.²³⁴ Wyeth also contended that the plaintiff's tort claims were preempted because the FDA's preamble to its regulation governing labeling requirements declared that FDA approval of drug labels establishes "'both a 'floor' and a 'ceiling,'" so that 'FDA approval of labeling . . . preempts conflicting or contrary [s]tate law.'"²³⁵ The Court rejected this assertion, reasoning that Congress had not enacted an express preemption provision for drugs in the FDCA, nor would it accord deference to the FDA's contention.²³⁶

from a hanging bag) or a direct injection into the vein. *Id.* This direct injection into the vein is called the IV-push method. *Id.* The drug causes irreversible gangrene if it enters a patient's artery. *Id.* At trial, evidence was introduced that the risks associated with the IV-push method could be almost entirely eliminated using the IV-drip, and that even an experienced and careful clinician using the IV-push method will sometimes expose an artery to Phenergan. *Id.* at 1192.

²²⁷ *Id.* at 1191.

²²⁸ *Id.* at 1192.

²²⁹ *Id.*

²³⁰ *Wyeth v. Levine*, 129 S.Ct. 1187, 1193–94 (2009).

²³¹ *Id.* at 1193.

²³² *Id.* at 1196.

²³³ *Id.*

²³⁴ *Id.*

²³⁵ *Id.* at 1200 (citing Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed.Reg. 3922, 3934–35 (Jan. 24, 2006) (to be codified at 21 C.F.R. pt. 201, 314, 601)).

²³⁶ *Wyeth v. Levine*, 129 S.Ct. 1187, 1200–02 (2009). The Court reasoned that in prior cases where deference was given to an agency's views of the preemptive effect on tort law of its own regulations, that deference was based on the agency's explanation of how state law affects the regulatory framework, not on a conclusory statement that state law is preempted. *Id.* at 1201.

These cases are troubling in light of the fact that the FDA preemption battle could next be fought in the context of vaccine injury. Imagine the next vaccine created to stave off the latest pandemic illness. Imagine, perhaps, that the HHS Secretary announces to a group of governmental leaders in July that a vaccine for the H1N1 virus will be ready by mid-October of that same year.²³⁷ The vaccine receives FDA approval prior to its use, and perhaps receives “fast track approval”²³⁸ due to timing concerns as flu season approaches. Notwithstanding FDA approval, it causes many to suffer adverse—and perhaps, life-threatening—effects. To what extent would those injured by the vaccine be able to recover against the manufacturers for their injuries in the face of a preemption argument? Since the Prep Act immunizes manufacturers for any injury absent willful misconduct upon the HHS Secretary’s declaration of a pandemic, victims injured by certain vaccines may receive nothing. At this point, it is unclear whether or to what extent FDA approval of a vaccine would be considered as having imposed federal requirements on a manufacturer, and the current jurisprudential landscape yields little in the way of consistently preserving corrective justice principles in this context, particularly when the nonreciprocal risks created are so blatant. The approval process in a given context is far too open to conflicting interpretations, particularly in light of the deference a court might give to the FDA’s own views on the matter.²³⁹ And, assuming a court determined federal requirements did exist, the Supreme Court’s current stance on tort liability as a conflicting requirement would compel preemption of the claim. Certainly, if preemption was found to exist, any victims’ injuries would go uncompensated, thwarting corrective justice principles.

If the current conventional wisdom would yield preemption as the appropriate result, the FDA approval process deserves attention, particularly since the process has been criticized as having serious deficiencies that should counter-balance any preemptive effect FDA approval would have.²⁴⁰ To obtain FDA approval for a new vaccine, the manufacturer must submit a “new drug application” (NDA) to the FDA’s Center for Drug Evaluation and Research (CDER) for review.²⁴¹ The NDA must contain reports of investigations which demonstrate the vaccine’s safety

²³⁷ States Told to Prepare for Worst-case Swine Flu Scenario, CNN.com, <http://www.cnn.com/2009/HEALTH/07/09/obama.swine.flu/index.html> (last visited Feb. 24, 2010).

²³⁸ See *infra* notes 248–54 and accompanying text.

²³⁹ See Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227, 233–49 (2007).

²⁴⁰ See *infra* notes 273–76 and accompanying text.

²⁴¹ 21 U.S.C. § 355(b) (2006); see FDA, Development and Approval Process (Drugs), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm> [hereinafter FDA, Development and Approval Process] (last visited Feb. 24, 2010) (describing the approval process for new drugs).

and effectiveness.²⁴² These investigations include such things as laboratory testing of the drug, as well as clinical trials on human subjects.²⁴³ A team of CDER physicians, statisticians, chemists, pharmacologists, and other scientists reviews the NDA.²⁴⁴ The CDER may deny approval to the NDA upon a finding that, *inter alia*, [1] the investigations do not include adequate tests to show whether or not a drug is safe for its intended use; [2] the results of such tests show the drug is unsafe or do not show the drug is safe for its intended use; [3] there is insufficient information to determine whether the drug is safe for its intended use; or [4] there is a lack of substantial evidence that the drug will have the effect it purports.²⁴⁵

Approval of a drug is a lengthy process, yet an accelerated “fast track” approval process exists for a drug “if it is intended for the treatment of a serious or life-threatening condition and . . . demonstrates the potential to address unmet medical needs for such a condition.”²⁴⁶ These drugs have shorter review periods²⁴⁷ and may require less in the way of safety and efficacy information prior to approval.²⁴⁸ The drug may also receive accelerated approval.²⁴⁹ Drugs which might receive fast track approval include those the HHS Secretary designates a “priority countermeasure,” which may occur prior to any request for such a designation

²⁴² § 355(b).

²⁴³ See FDA, Development and Approval Process, *supra* note 241.

²⁴⁴ See *id.*

²⁴⁵ § 355(d).

²⁴⁶ § 356(a)(1).

²⁴⁷ § 356(a)(3). The FDA designates certain fast-tracked drugs for Priority Review. See FDA, Fast Track, Accelerated Approval and Priority Review, <http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/SpeedingAccessstoImportantNewTherapies/ucm128291.htm>. (last visited Mar. 8, 2010). The goal for completing a Priority Review is six months, as opposed to ten months for a drug receiving Standard Review. *Id.*

²⁴⁸ See Kessler & Vladeck, *supra* note 200, at 470 (citing U.S. GOV’T ACCOUNTABILITY OFFICE, DRUG SAFETY: IMPROVEMENT NEEDED IN FDA’S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS 10, available at <http://www.gao.gov/new.items/d06402.pdf>).

²⁴⁹ See FDA, Fast Track, Accelerated Approval and Priority Review, *supra* note 247 (last visited Feb. 24, 2010).

When studying a drug, it can take a long time—sometimes many years—to learn whether a drug actually provides real improvement for patients—such as living longer or feeling better. This real improvement is known as a “clinical outcome.” Mindful of the fact that obtaining data on clinical outcomes can take a long time, in 1992 FDA instituted the *Accelerated Approval* regulation, allowing earlier approval of drugs . . . based on a surrogate endpoint. A surrogate endpoint is a marker—a laboratory measurement, or physical sign—that is used in clinical trials as an indirect or substitute measurement that represents a clinically meaningful outcome, such as survival or symptom improvement. The use of a surrogate endpoint can considerably shorten the time required prior to receiving FDA approval. Approval of a drug based on such endpoints is given on the condition that post marketing clinical trials verify the anticipated clinical benefit.

by the manufacturer.²⁵⁰ A priority countermeasure includes any vaccine that the HHS Secretary determines to be “a priority to treat, identify, or prevent infection” by a biological agent or toxin, or to “prevent conditions that may result in adverse health consequences or death.”²⁵¹ In other words, the H1N1 vaccine would be designated a priority countermeasure. Presumably in response to the fast track approval process and the nature of the expedited approval process, a fast tracked drug may be subject to post-approval studies conducted by the manufacturer.²⁵²

While the FDA approval process is lengthy and detailed, many criticisms have been leveled against it, particularly as the process relates to the FDA’s pro-preemption stance.²⁵³ First, the process focuses on the safety and efficacy of a drug or vaccine *prior* to its use by the general public.²⁵⁴ Yet, as clinical trials involve generally only a few thousand people, many adverse effects from a drug occur only after it is on the market;²⁵⁵ generally, clinical testing pre-approval would not reveal adverse effects which “occur infrequently, have long latency periods, or affect subpopulations not included or adequately represented in the studies.”²⁵⁶ Thus, the FDA’s approval of a drug is premised on, arguably, modest information as to the drug’s potential side effects.²⁵⁷ Moreover,

²⁵⁰ 21 U.S.C. § 356-1(c) (2006).

²⁵¹ 42 U.S.C. § 247d-6(e)(4) (2006).

²⁵² § 356(b)(2).

²⁵³ See Kessler & Vladeck, *supra* note 200, at 481–90; see also Struve, *supra* note 201, at 598–606 (discussing why post-marketing surveillance is critical to the FDA’s process).

²⁵⁴ See Kessler & Vladeck, *supra* note 200, at 483–84 (arguing that premarket approval is generally incapable of detecting certain adverse effects). According to Kessler and Vladeck:

[M]ost clinical studies ‘can detect drug-related injuries that occur at a rate of between one in 500 and one in 1,000. Yet, if the drug is used by 200,000 people . . . a serious adverse event appearing in as few as one in 10,000 people is very significant, since it would occur 20 times. These rare reactions can be identified only after the drug has been widely used.’

Id. at 471 (quoting William B. Schultz, *How to Improve Drug Safety*, WASH. POST, Dec. 2, 2004, at A35). See also Struve, *supra* note 201, at 595–606 (arguing that even though the premarket approval process may be rigorously conducted, it will inevitably fail to reveal all of the risks associated with a medical product).

²⁵⁵ See Kessler & Vladeck, *supra* note 200, at 466, 470.

[T]he FDA’s knowledge-base of the risks posed by a new drug is far from static. At the time of approval, the FDA’s knowledge-base may be close to perfect, but it is also highly limited because, at that point, the drug has been tested on a relatively small population of patients. Once the drug enters the marketplace, risks that are relatively rare, that manifest themselves only after an extended period of time, or that affect vulnerable subpopulations, begin to emerge.

Id. at 466 (citing INST. OF MED. OF THE NAT’L ACADS., THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 36 (Alina Baciu, Kathleen Stratton & Sheila P. Burke eds., 2006) [hereinafter IOM Report]).

²⁵⁶ *Id.* at 471; see Struve, *supra* note 201, at 598–99.

²⁵⁷ A different kind of risk created by vaccines is the extent to which they may lack potency to ward off the very disease they are meant to protect against. Recently, pharmaceutical company Sanofi Pasteur recalled 800,000 doses of the H1N1 vaccine due to a 12% loss in

in determining whether to approve a drug, the FDA relies on advisory committees composed of “independent” experts in the field.²⁵⁸ Yet a *Journal of the American Medical Association* study details financial conflicts of interest between advisory committee members and the pharmaceutical companies seeking approval for their drugs.²⁵⁹ A new report finds that the CDC’s advisory committee members evaluating flu vaccines also had unresolved potential conflicts with drug companies.²⁶⁰ The danger in such conflicts existing, of course, is the potential that advisory committees are recommending potentially unsafe drugs in part because manufacturers are paying them.²⁶¹

In addition, once a drug has been approved and distributed in the market, significant deficiencies exist regarding the FDA’s post-market surveillance process. First, the FDA has limited resources that prevent it from adequately monitoring a drug’s safety post-approval and taking prompt corrective measures.²⁶² Congress recently enacted the Food and Drug Administration Amendments Act (FDAAA),²⁶³ which provides the FDA with new resources to monitor a drug’s safety once it has been approved.²⁶⁴ Although the FDAAA is a step in the right direction, the extent to which these new resources will improve the post-market surveillance process is unknown at this time. Moreover, it has been suggested that the infusion of resources by Congress suggests that Congress

potency. See Sheila M. Poole & Craig Schneider, *Ga. Got 43,000 Doses of Recalled Swine Flu Vaccine*, THE ATL. J. CONST., <http://www.ajc.com/health/ga-got-43-000-242141.html> (last visited Dec. 15, 2009). Although this relatively small decrease in potency did not create any safety concerns, one could envision a scenario where a vaccine has lost all or most of its potency, and thus cannot provide necessary protection.

²⁵⁸ See FDA, Advisory Committees, <http://www.fda.gov/AdvisoryCommittees/default.htm> (last visited Feb. 24, 2010).

²⁵⁹ See Peter Lurie et al., *Financial Conflict of Interest Disclosure and Voting Patterns at Food and Drug Administration Drug Advisory Committee Meetings*, 295 JAMA 1921–28 (Apr. 26, 2006).

²⁶⁰ See Gardiner Harris, *Advisors on Vaccines Often Have Conflicts, Report Says*, N.Y.TIMES, Dec. 18, 2009, at A28.

²⁶¹ See *id.*

²⁶² See Kessler & Vladeck, *supra* note 200, at 465, 467–68. The FDA’s post-market surveillance of approved drugs is chronically underfunded and has not functioned appropriately. *Id.* at 472. And although the FDA has an adverse reaction reporting system in place, only a small number of adverse reactions are reported. *Id.*

The Institute of Medicine (IOM) reported in 2006 that the FDA “lacks the resources needed to accomplish its large and complex mission today, let alone position itself for an increasingly challenging future.” FDA doctors and scientists share this view; 70% believe that the FDA lacks sufficient resources to protect the public health, and two-thirds worry that the FDA is not adequately monitoring the safety of drugs once they are on the market.

Id. at 485 (quoting the IOM Report, *supra* note 255). See Struve, *supra* note 201, at 601.

²⁶³ Food & Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007) [hereinafter FDAAA].

²⁶⁴ FDAAA, tit. I, sec. 103(b)(4), § 736(b), 121 Stat. 823, 828 (2007).

does not agree with the FDA's view that it is able adequately to monitor drug safety.²⁶⁵ In addition, Congress did not include any preemption language in the FDAAA, much to the pharmaceutical companies' disappointment.²⁶⁶

Other criticisms include the lack of data the FDA can demand drug companies produce post-approval, as well as the FDA's laxity in oversight of companies that it requires to perform post-marketing studies.²⁶⁷ These critical assessments of the FDA approval process demonstrate that the process itself, while certainly essential to the public welfare, should not provide the basis for preemption of tort claims. Even if the safety and effectiveness of a drug or vaccine can conclusively be determined at the time of approval, at most that determination should be relevant to that period of time only. To the extent adverse reactions occur over time that could not have been established at the moment of approval, tort liability—or some other form of compensation—should continue to fill in the gaps. Allowing the two systems to parallel one another will best serve corrective justice principles.

These criticisms highlight well that aspect of the preemption debate which focuses on whether the FDA regulates for "minimal" versus "optimal" safety.²⁶⁸ In other words, does FDA regulation create a "floor" with regard to a drug's safety over which tort liability can comfortably exist? Or does it create a "ceiling," thereby effectively ensuring a drug's safety, with which tort liability would be inherently inconsistent? If the FDA approval process for vaccines creates a floor, the preemption of tort claims has effectively endorsed a structure whereby the standard for vaccine safety is less than that which would be imposed in the tort system, yet recovery is eradicated at the same time. On the other hand, if the FDA regulates for optimal safety, the argument for preemption may be stronger, but it still ignores the fact that even exceptionally safe vaccines can cause injury to some, particularly as additional risks become known over time. Yet the nonreciprocal risk theory of corrective justice would

²⁶⁵ See Kessler & Vladeck, *supra* note 200, at 468.

²⁶⁶ See FDAAA, tit. IX, sec. 901(a), § 505(o)(4)(I), 121 Stat. 823, 925-26 (2007); Kessler & Vladeck, *supra* note 200, at 468-69. The Rule of Construction in the FDAAA clarifies the FDA's authority regarding labeling, and reiterates that manufacturers have an obligation to provide up-to-date safety information without first securing FDA approval. See Kessler & Vladeck, *supra* note 200, at 468-69. "The codification of this obligation undercuts the key pro-preemption argument the FDA and manufacturers make—namely, that the FDA alone decides the content of drug labels." *Id.* at 468-69.

²⁶⁷ See Kessler & Vladeck, *supra* note 200, at 486, 488-89, 491.

²⁶⁸ See Peter H. Schuck, *FDA Preemption of State Tort Law in Drug Regulation: Finding the Sweet Spot*, 13 ROGER WILLIAMS U. L. REV. 73, 77-78 (2008). Professor Schuck describes optimal safety standards as those which have "the socially best balance between safety, effectiveness, cost, and other relevant factors, taking into account that some individual users may be harmed even under such a standard." *Id.*

deem the distinction irrelevant and demand that all injured plaintiffs be compensated for their losses. As the preceding discussion illuminates, the approval process is flawed in many respects. Thus, using the process as the basis for preemption is inappropriate, particularly in light of the corrective justice principles upon which the tort system is founded.

Despite the criticisms that accompany the FDA approval process, preemption nonetheless offers a certain attractiveness. After all, notwithstanding the flaws in the FDA's process, the manufacturer has theoretically complied with the FDA's conditions for approval. Thus, as the preemption debate continues to advance, tort liability may be usurped, leaving injured plaintiffs with no remedy. Yet corrective justice does not necessarily require tort liability; it merely requires that a plaintiff be compensated—monetarily or otherwise—for his injuries.²⁶⁹ Thus, as explained in greater detail in Part III below, corrective justice can still be achieved, notwithstanding the perceived effect tort liability might have on a defendant who must also comply with federal regulation.²⁷⁰

B. *Criticisms of Current Congressional Vaccine Programs*

Even if traditional tort claims for vaccine injury are not deemed preempted, recovery for a particular vaccine injury may ultimately be prescribed pursuant to a statutory program. This section explores the shortcomings of the existing statutory programs for vaccine compensation upon which a future vaccine program could be based, particularly in light of the nonreciprocal risk theory of corrective justice. These inadequacies inform our determination of a more appropriate paradigm for determining liability and compensation in Part III below.

Congress has created the current statutory vaccine programs with an eye toward purely instrumentalist goals like widespread vaccination levels and protection of vaccine manufacturers that facilitate continued production of vaccines. One goal of the NCVIA does appear to be ensuring compensation to certain victims as well.²⁷¹ But the other more recent vaccine programs appear to eschew such a goal, with the sole objective being manufacturer immunity.²⁷² Those programs have substantially diminished claimants' ability to recover for vaccine-related injuries, while manufacturer liability has all but disappeared.²⁷³ Although the federal government's programs have most assuredly solved the concern regarding manufacturer liability, with the subsequent consequence of limited vaccine resources and vaccination levels, injured victims increasingly ap-

²⁶⁹ See Nagareda, *supra* note 200, at 15.

²⁷⁰ See *id.*; Sharkey, *Products Liability Preemption*, *supra* note 200, at 459–66.

²⁷¹ See Clark, *supra* note 67, at 674.

²⁷² See Coyle, *supra* note 124 at 5.

²⁷³ See, e.g., Steel, *supra* note 94, at 160; see also *supra* Part I.B.

pear to get the short end of the stick. Benefits received have been reduced from the unlimited awards procured by virtue of a civil tort action under the Swine Flu Act (not to mention the right of the United States to seek indemnification from manufacturers in certain instances), to capped awards, no judicial review of administrative decisions, and virtual immunity for manufacturers under SEPPA and the Prep Act.

Although it is important to keep this nation's vaccine supply at safe working levels by shielding manufacturers from liability, this goal is purely instrumental in nature. It focuses on what result would benefit society at large, as opposed to whether it is fair to allow injured victims to recover. "Targeted liability protection"²⁷⁴ for manufacturers has become a code word for instrumentalist thinking. However, Fletcher's theory may be a more appropriate and principled starting place for establishing rules of liability and compensation. In other words, the focus in vaccination liability and compensation should reflect what result is fair as among the parties involved, rather than allowing compensation and liability to be directed by the most powerful lobby groups in Washington. When principles of corrective justice fail to underlie a particular vaccine program, the program fails, as in the case of SEPPA. If the possibility exists that a victim of a vaccine injury may not receive any damages for that injury, then that person may choose not to be vaccinated. This result may be tolerated when the threat of infection is not imminent, as in the case of a terrorist smallpox attack when SEPPA was enacted. But what about those injured by vaccines when the threat of infection is real and imminent, as perhaps the H1N1 virus? Or those infected because they declined vaccination due to fear of injury and lack of compensatory mechanisms? Or those the infected subsequently infect? Increasingly, the existing statutory framework is failing these parties.

It is useful to keep in mind that these congressional programs were born from certain specific problems. Enactment of the NCVIA was driven by the problems inherent in the civil tort system: inconsistent judgments for plaintiffs on the one hand,²⁷⁵ and potentially crippling conditional liability for pharmaceutical companies on the other.²⁷⁶

²⁷⁴ See Public Readiness and Emergency Response Act, 42 U.S.C. § 247d-6d (2006).

²⁷⁵ See, e.g., *Givens v. Lederle*, 556 F.2d 1341, 1345 (5th Cir. 1977); *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1295 (5th Cir. 1974); *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 128 (9th Cir. 1968). But see, e.g., *Johnson v. American Cyanamid Co.*, 718 P.2d 1318, 1325–26 (Kan. 1986); *Wyeth Labs., Inc. v. Fortenberry*, 530 So. 2d 688, 691–93 (Miss. 1999). See also Steel, *supra* note 94, at 152.

²⁷⁶ At least one commentator is skeptical of the vaccine industry's claims that the product liability system is responsible for deterring research and development of products. See *Teresa Moran Schwartz, Prescription Drugs and the Proposed Restatement (Third)*, 61 TENN. L. REV. 1357, 1361 (1994). As Schwartz points out, little data exists to provide a causal link between liability costs and the development or availability of prescription products, as the pharmaceutical companies are the best ones to provide that data, but they have been reluctant to do so. See

SEPPA and the Prep Act were created due to governmental, and perhaps, societal, fear of a pandemic—borne either naturally, or by terroristic means. The geneses of these programs, in conjunction with the criticisms and shortcomings thereof, are significant in light of corrective justice principles and provide the basis for our construction of a more comprehensive compensation and liability model, focused on the intersection of a variety of risks implicated by vaccine injury. As discussed below, they each provide a “band-aid” for a perceived problem. Moreover, they serve to further the purely instrumentalist goals of widespread vaccination and some degree of manufacturer immunity.

Both SEPPA and the Prep Act, either effectively or directly, provide immunity for vaccine manufacturers. Thus, any compensation would be paid from funds appropriated by Congress. In this era of insurance companies refusing to cover liability costs for vaccine-related injuries, manufacturers must be protected so as not to threaten the nation’s vaccine supply.²⁷⁷ Governmental payment of claims may be appropriate here considering the government is mandating the manufacture, distribution and administration of an H1N1 vaccine, for example, in case of a pandemic. Yet the decision to vaccinate oneself is purely voluntary. This decision furthers the government’s goal of public health;²⁷⁸ each person who voluntarily receives a vaccination is effectively a “foot soldier” for the United States fighting the war on terror or the war on disease.²⁷⁹ In case of a flu pandemic or bioterrorist attack, the American public must be immunized at a high rate and on a large scale to prevent the spread of disease.²⁸⁰

Further, the extent to which a vaccine’s risks are relatively unknown at the time the government mandates its manufacture and administration to the public may very well dictate government responsibility for injuries.²⁸¹ This reasoning reflects the language in the Responsible Public Readiness and Emergency Preparedness Act of 2006²⁸² that indemnification should be available only to the extent the HHS Secretary has issued a declaration *and* the vaccine or other countermeasure has not received

id. at 1399; *see also* Kelley E. Cash, *The New Restatement (Third) of Torts: Is it the Cure for the AIDS Vaccine Ailment?*, 16 REV. LITIG. 413, 418–19 (1997); H. William Smith III, *Vaccinating AIDS Vaccine Manufacturers Against Product Liability*, 42 CASE W. RES. L. REV. 207, 238–39 (1992).

²⁷⁷ See Greenberger, *supra* note 35, at 27, 31–32.

²⁷⁸ See Derry Ridgway, *No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program*, 24 J. HEALTH POL. POL'Y & L. 59, 79 (1999).

²⁷⁹ Steel, *supra* note 94, at 145.

²⁸⁰ See Robert M. McKenna, *The Impact of Product Liability Law on the Development of a Vaccine Against the AIDS Virus*, 55 U. CHI. L. REV. 943, 945–46 (1988).

²⁸¹ See *id.*; Greenberger, *supra* note 35, at 31–32.

²⁸² Responsible Public Readiness and Emergency Preparedness Act, S. 2291, 109th Cong. (2006).

full FDA testing. In other words, the fact that the government has effectively required immediate manufacture, testing, and administration of a vaccine, without knowing the full extent of the risks involved, suggests, if not requires, that the government be the one to pay any claims.²⁸³

Yet the immunity for manufacturers under SEPPA and the Prep Act, in addition to the dim prospect of just compensation for victims under these programs, is inconsistent with corrective justice principles. Not only do corrective justice principles favor compensating victims, they do so from the standpoint of forcing the wrongdoer—here theoretically, the manufacturer, not the government—to pay a victim's damages.²⁸⁴ Thus, some specter of liability should remain to maintain vaccine manufacturers' consistent production of safe, effective vaccines.²⁸⁵ Moreover, the compensation provided under these Acts has been criticized as being illusory.²⁸⁶ If a claimant has no realistic possibility for compensation, corrective justice principles are assuredly thwarted. That does not mean, however, that the manufacturer's liability must be expressed as a judicial judgment or special-court award directly against the manufacturer. Rather, there may be other ways, through a comprehensive regulatory system and mandated contributions from all manufacturers in the pharmaceutical industry. Notions of this kind of approach are sometimes referred to as "enterprise liability"—and we will take those up in more depth in Part III.

The NCVIA, on the other hand, was the product of the compulsory system for vaccine administration to children in this country. Each state and the District of Columbia requires a child be vaccinated if the child is enrolled at a day care or is in a public school.²⁸⁷ The decision whether to vaccinate one's child has been made for every parent who chooses either of these paths. NCVIA is arguably the most successful of these congressional programs, in terms of claimant numbers under the program and the extent to which damages are paid to those claimants.²⁸⁸ Yet the NCVIA is still not an adequate model upon which to formulate a future program

²⁸³ The FDA also states that, notwithstanding a rigorous licensure system for vaccines, all potential risks and side effects cannot be anticipated until the vaccine is administered to the general public and may need to undergo further studies. FDA, Vaccines, <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/default.htm> (last visited Feb. 12, 2010).

²⁸⁴ See McGARITY, *supra* note 187, at 232.

²⁸⁵ See Victor E. Schwartz & Liberty Mahshigian, *National Childhood Vaccine Injury Act of 1986: An Ad Hoc Remedy or a Window for the Future?*, 48 OHIO ST. L.J. 387, 395 (1987).

²⁸⁶ See Breen, *supra* note 74, at 319–20.

²⁸⁷ See Hagan, *supra* note 35, at 479. Although compulsory vaccination laws are a product of state law, the funding of state's vaccination programs is made possible by a grant from the federal government. *Id.* "These federal grants require compliance with national objectives, such as 'the rigorous enforcement of school immunization laws.'" *Id.*

²⁸⁸ See U.S. Dep't of Health & Human Services, Health Resources and Services Admin., National Vaccine Injury Compensation Program Statistics Report, Jan. 20, 2009, http://www.hrsa.gov/vaccinecompensation/statistics_report.htm.

for injuries due to other vaccines. First, although the government mandates administration of childhood vaccines, the manufacturer should bear some responsibility for any injuries suffered. As suggested by the vaccine table, there are a number of well-known side effects, as well as well-known rates of such side effects occurring.²⁸⁹ Thus, insurance companies may be able, and perhaps should be willing, to insure manufacturers to the extent there is predictable liability. Currently, manufacturers feel no sting of liability under the NCVIA, as the compensation fund from which claimants are paid is funded by excise taxes paid by the purchasers of the vaccines.²⁹⁰

Moreover, as the NCVIA involves the use of a vaccine table, it may be “easier” to withhold compensation under the NCVIA in situations where the injury falls outside the table. Even the NCVIA’s “fail-safe” vaccine table, however, is prone to unreliability, as revealed by the FDA’s inability or unwillingness to conduct post-marketing surveillance.²⁹¹ In fact, all vaccine tables under each of these programs become increasingly suspect for that reason. This problem is exacerbated by the fact that side effects of future vaccines, particularly those that are manufactured hastily to respond to a growing threat of pandemic, may not be known for many years. To the extent a vaccine table is created to weed out good claims from bad in this context, claimants would face the almost insurmountable task of proving causation, and many victims of vaccine injury may be left with no recompense.²⁹² A choice must be made to either [a] get vaccinated and face potential injury with perhaps little chance of recovery, or [b] decide against receiving a vaccination. This choice implicates a variety of risks, which extend well beyond the risks that underlie Fletcher’s theory. As discussed in more detail in Part III, a liability and compensation scheme must take these other risks into con-

²⁸⁹ See, e.g., LESTER M. CRAWFORD, ACTING COMMISSIONER OF FOOD AND DRUGS, ENSURING THE SAFETY, EFFECTIVENESS, AND AVAILABILITY OF INFLUENZA AND OTHER VACCINES, TESTIMONY BEFORE THE SENATE COMMITTEE ON ENERGY AND COMMERCE (Nov. 18, 2004), available at <http://www.fda.gov/NewsEvents/Testimony/ucm113231.htm> (“[The Center for Biologics Evaluation and Research (CBER)] and the [CDC] jointly manage the Vaccine Adverse Event Reporting System (VAERS), a cooperative program for vaccine safety. VAERS is a post-marketing safety surveillance program, collecting information about adverse events (side effects) that occur after the administration of U.S. licensed vaccines.”); FDA, Vaccine Adverse Events, <http://www.fda.gov/cber/vaers/vaers.htm> (last visited Feb. 24, 2010) (“The purpose of VAERS is to detect possible signals of adverse events associated with vaccines. VAERS collects and analyzes information from reports of adverse events (possible side effects) that occur after the administration of US licensed vaccines.”); see generally 42 U.S.C. § 300aa(1)-(5) (2006) (describing the purposes, structure, and risks of the National Vaccine Program).

²⁹⁰ See Steel, *supra* note 94, at 158.

²⁹¹ See *id.* at 169.

²⁹² See *id.* at 170–71.

sideration if it is to encompass the spectrum of risks created in this context.

Although NCVIA's vaccine table may streamline the proceedings for certain claimants because causation is presumed, others have significant difficulties proving their case. Certainly, a plaintiff who brings a tort claim against a vaccine manufacturer may encounter difficulty establishing that a particular vaccine caused her injury. However, the mechanisms in the NCVIA make proving causation considerably more difficult. While having proven successful at reducing the amount of lawsuits brought against vaccine manufacturers, the Special Masters' discretion in making compensation determinations, as well as the Act's causation requirements, have resulted in the denial of compensation to the majority of persons seeking it.²⁹³

As discussed earlier,²⁹⁴ Special Masters gain their expertise on the job—in the rough and tumble of handling actual NCVIA cases; they are not scientific or medical experts. Yet, anomalously, the NCVIA treats them as though they were. Each Special Master is chosen by a majority of the judges on the U.S. Federal Claims Court²⁹⁵ and has total jurisdiction over the initial proceedings.²⁹⁶ Although a petitioner may seek review of the Special Master's determination of compensation, and even appeal that review to the U.S. Court of Appeals for the Federal Circuit, the standard of review of these courts is highly deferential to the Special Master's decision.²⁹⁷ The U.S. Federal Claims Court will only set aside the Special Master's decision if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."²⁹⁸ And although the NCVIA imposes no standard of review upon the federal courts of appeal for the Federal Claims Court's review of the Special Master's decision, one such court has determined that the standard should be the same as that of the Federal Claims Court.²⁹⁹ This highly deferential standard of review of the Special Masters effectively ensures that a Special Master's determination will not be overturned.³⁰⁰

Not only has the authority of the Special Masters been called into question, the entire goal of the NCVIA of fair and efficient adjudication

²⁹³ Breen, *supra* note 74, at 320. Despite the fact that between 1988 and 1999 Special Masters have awarded over \$1 billion in damages and attorneys' fees, "more than two-thirds of all claims filed by petitioners ultimately are dismissed." *See id.*; Ridgway, *supra* note 278, at 59; Steel, *supra* note 94, at 146, 168–71.

²⁹⁴ *See supra* Introduction.B.

²⁹⁵ 42 U.S.C. § 300aa-12(c)(1) (2006).

²⁹⁶ *Id.* § 300aa-12(a).

²⁹⁷ *See* Breen, *supra* note 74, at 322–23.

²⁹⁸ § 300aa-12(e)(2)(B); *see* Breen, *supra* note 74, at 322.

²⁹⁹ *See* Breen, *supra* note 74, at 323.

³⁰⁰ *See id.*

of claims has also been criticized.³⁰¹ The system has become increasingly adversarial, and the government has taken to arguing “aggressive and technical” defenses, comparable to a trial.³⁰² Similarly, other than for very clear-cut injuries that fall within the Table injuries and time periods, expert testimony is routinely provided to support causation.³⁰³ As one commentator has stated:

After repeated exposure [to certain experts’ testimony], Special Masters have developed preferences for or against the testimony of certain experts. In the published opinions, claimants are warned off some experts as being unsuitable for [National Vaccine Injury Compensation Program (VICP)] cases. At the other extreme, preferred experts receive rich praise in the Special Masters’ decisions, and one was singled out to receive hourly consultation fees of \$250 instead of the \$200 HHS rate Criticism of the tort system often focuses on the arbitrary and irrelevant factors that determine outcomes. The VICP contains no provision to deflect accusations of the same sort brought against the no-fault claims process.³⁰⁴

This process, therefore, pits experts against one another, and the Special Master—“special” only in the sense that they are an administrative judge employed to hear a single category of controversies—has total discretion to determine whether a compensable injury occurred.³⁰⁵

NCVIA’s promise of reasonable attorney’s fees has also suffered from this heightened adversarialness. The NCVIA allows the Special Master to determine “reasonable attorneys’ fees,” regardless of whether the claim was decided in favor of the claimant, “if the Special Master determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.”³⁰⁶ The attorney is thus required to prove that the fee requested was reasonable.³⁰⁷ However, as these claims have become more adversarial in nature, attorneys have spent many more hours on them than was initially anticipated.³⁰⁸ As such, Special Masters have determined in some cases

³⁰¹ See *id.* at 320; see also H.R. REP. NO. 99-908, at 12 (1986) (describing congressional goals in passing the NCVIA).

³⁰² See Steel, *supra* note 94, at 159–60.

³⁰³ Ridgway, *supra* note 278, at 68.

³⁰⁴ *Id.* at 69.

³⁰⁵ See Steel *supra* note 94, at 169.

³⁰⁶ 42 U.S.C. § 300aa-15(e) (2006).

³⁰⁷ Steel *supra* note 94, at 161.

³⁰⁸ See *id.* at 162.

that the attorney's fee was not reasonable.³⁰⁹ Moreover, if a claimant wants the Special Master's decision reviewed, and then appeals that review, the attorney will not be compensated until a final decision has been reached.³¹⁰ As a result, many attorneys are now reluctant to take NCVIA cases.³¹¹

Similarly, attorneys pay for the expert witness testimony, which is necessary to establish causation in many cases; thus, the expert cannot get paid until all of the subsequent judicial reviews have been exhausted.³¹² And since the Special Master has discretion to determine that the fee paid to an expert was not reasonable, and thus, decide not to compensate the attorney for having paid the fee, an attorney takes a very large risk in securing expert testimony.³¹³ Some attorneys have chosen to hire a less qualified, and therefore, less expensive expert, which can prove to be risky to the claimant's case.³¹⁴ Finally, an attorney is only paid under the program by the HHS if the claimant chooses the Special Master's award; if the claimant rejects this award and files a civil tort action, the attorney can only recover if the claimant is successful at trial.³¹⁵ This system effectively places the attorney's interests at odds with the claimant's interests.³¹⁶

Finally, although the NCVIA may adequately compensate claimants in that it provides recovery for all incurred and future expenses, as well as actual and anticipated loss of earnings, it also provides for certain caps on awards, such as death benefits and pain and suffering³¹⁷—and it covers no injuries that are suffered *in vitro* when an expectant mother receives a vaccine.³¹⁸ Arguably, the caps on those awards should be increased from what was established twenty years ago,³¹⁹ death benefits should be significantly enhanced, the scope of covered vaccines should be expanded, and the vaccination of expectant mothers encompassed.

³⁰⁹ See *id.*

³¹⁰ See *id.* at 160–61.

³¹¹ Cf. *id.* at 161 (“The prospect of postponed attorney fees may make some attorneys wary of pursuing a long and expensive appeals process.”).

³¹² See *id.* at 166.

³¹³ See *id.*

³¹⁴ See *id.* at 166–67.

³¹⁵ See *id.* at 165.

³¹⁶ See *id.*

³¹⁷ 42 U.S.C. § 300aa–15 (2006).

³¹⁸ Compare *Rooks v. Sec'y of Dep't of Health & Human Servs.*, 35 Fed. Cl. 1, 12 (1996) (finding that Congress intended to provide compensation for injuries stemming from *in utero* receipt of vaccines), with Steven L. Schooner, *The Future: Scrutinizing the Empirical Case for the Court of Federal Claims*, 71 GEO. WASH. L. REV. 714, 734 (2003) (quoting special master who followed *Rooks* as a matter of preference but noted that decisions of U.S. Court of Federal Claims are not binding on special masters).

³¹⁹ See Jaclyn Shoshana Levine, *The National Vaccine Injury Compensation Program: Can It Still Protect an Essential Technology?*, 4 B.U. J. SCI. & TECH. L. 9 ¶ 77 (1998).

This certainly seems possible, as the fund from which these benefits are paid currently has a balance of over \$2 billion.³²⁰ Moreover, a renewed profitability of vaccines to the pharmaceutical industry, such as Gardasil and DNA-based vaccines under current development, augur a more than adequate industry source from which a compensation fund—or even more usefully, a comprehensive vaccine policy implementation fund—may be maintained. These ideas are further developed in Part III.

In sum, while these programs arguably serve laudable goals, they are exactly that: goal oriented. They serve to further instrumentalist interests, rather than taking a more principled approach. They also were targeted on a fairly narrow aspect of vaccine policy—the protestations of pharmaceutical companies that they would get out of the vaccine business entirely unless Congress immunized their vaccine products from products liability claims. As such, the statutory programs are not destinations, but rather, milestones on the road travelled since the introduction of vaccination in colonial America towards a coherent national vaccine policy that achieves the optimal balance of stakeholder interests in congruence with the overarching legal principles in this area that must be accounted for if vaccine injury in particular and vaccine policy in general is to be reasoned and effective. Outlining the parameters of such a holistic vaccine policy, and exploring the principles that must undergird it, are what we now take up in Part III.

III. RETHINKING THE MODEL FOR VACCINE-INJURY REGULATION: A PARADIGM FOR CONGRESSIONAL ACTION

A. *Introduction*

As Professor Thomas O. McGarity recently observed in his book *The Preemption War*, “Congress is the only institution that can bring an end to the preemption war”—and, as we contend here, prevent that war from making the twenty-first century world of vaccination its latest front—for the simple reason that Congress is the only institution with the power to preempt.”³²¹ Congress should, therefore, take up the question of FDA preemption generally—and the related question of the current statutory preemption by the NCVIA and similar laws specifically—and do so with special regard to vaccines. The time for rethinking vaccine liability has come, given the confluence of legal, medical, and historical developments of the last decade. It is our concern in this section to suggest a thought-paradigm for Congress.

³²⁰ See U.S. DEP’T OF TREASURY, BUREAU OF PUB. DEBT, VACCINE INJURY COMPENSATION REPORTS 7–8 (Jan. 2010), <ftp://ftp.publicdebt.treas.gov/dfi/tfmb/dfivi0110.pdf>.

³²¹ McGARITY, *supra* note 187, at 247.

B. *Using Principles and a Dépeçage Approach to Begin the Rethinking of Approaches to Vaccine-Injury Liability*

1. Principles

The nonreciprocal risk theory calls into question some aspects of the current congressional schemes in use or proposed to deal with vaccine-caused injuries.³²² Each of these schemes distorts the nature of the risks—both reciprocal and nonreciprocal—in favor of vaccine manufacturers and the federal government.³²³ These bills strike a balance at various points along a risk continuum in favor of a governmental interest in widespread vaccination by incentivizing the pharmaceutical industry with liability sieves—and in some of the legislation—outright shields.³²⁴

The nonreciprocal risk theory also calls into question the “tort-reform” effort du jour—the activist wielding of federal preemption.³²⁵ The balance is struck, of course, at the expense of each individual member of the public that is subjected to vaccine-associated risks; and the subset of individuals that actually suffer when the risks eventuate in their case. This is fairly typical of the tort-reform movement.³²⁶

However, in the vaccine cases, we are not speaking merely of the risks posed to individuals by the vaccines created by manufacturers and mandated by legislatures and public health administrative agencies. The picture is more complex. Unlike the typical case of consumer products, vaccines are not simply disposal goods, luxury items, or commodities of convenience. The risk analysis must take into account a larger set of risk-causers and risk-exposed because of the very fact that we have more than binary relationships between, for example, manufacturers and consumers. Reciprocity must be viewed not in the monochromatic, illustrative risk-creating pairs analysis that characterized the examples Fletcher used in his iconic article³²⁷—i.e., the risk that the manufacturers of vaccines pose to the vaccinated consumer versus the risk that the vaccinated consumer poses to the manufacturer. Rather, the risk must be viewed in a much more complex—and confusing—confluence of risks.

For example, vaccines reduce the risk that each of us, as individuals, poses to every other individual in our community³²⁸ and, on a more attenuated yet palpable level due to modern car and air travel, to our state

³²² See Fletcher, *supra* note 29, at 572 (discussing nonreciprocal risks); Kathleen E. Payne, *Linking Tort Reform to Fairness and Moral Values*, 1995 DET. C. L. REV. 1207, 1228 (1995) (discussing nonreciprocal risks in medical malpractice cases).

³²³ See Payne, *supra* note 322, at 1224, 1228.

³²⁴ See *supra* Part II.B.

³²⁵ See Payne, *supra* note 322, at 1227–33.

³²⁶ See, e.g., *id.* at 1224–36.

³²⁷ Fletcher, *supra* note 29, at 572.

³²⁸ See Ctrs. for Disease Control & Prevention, Vaccines: How Vaccines Prevent Disease, <http://www.cdc.gov/vaccines/vac-gen/howvpd.htm#why> (last visited Feb. 24, 2010); Nat'l

and the nation as extended communities.³²⁹ The risk calculus here is particularly challenging, because it requires a zero-sum arrangement: either we are all vaccinated, to protect us from being carriers or victims of disease, or we are not, subjecting ourselves to the risk of being a carrier or victim, and all others, potentially, of being infected by us and becoming carriers and victims. This confluence of risk also includes the risk that an unvaccinated person, or groups of persons, pose to society as a whole (and, in some cases, the risk that the vaccinated pose to unvaccinated or not recently vaccinated persons because of the “shedding” effects of some live-virus vaccines³³⁰), versus the risk society poses to that unvaccinated individual or group. To that extent, the risks might appear reciprocal.³³¹

Such appearances are misleading. While binary pairs of risks may suggest that the problem is susceptible to characterization as reciprocal risks, closer scrutiny reveals the fallacy of such comforting simplicity. The risks are far more complex than that. They are linked not by pure reciprocity pairs, but rather, in a polycentrism that weaves interconnections. For example, the entity creating the vaccine-injury risk to individuals is not merely another person in the victim’s space-time. Instead, that entity is composed of a collection of entities, in addition to the phar-

Inst. of Allergy & Infectious Diseases, Vaccines: Vaccine Benefits, <http://www3.nih.gov/topics/vaccines/understanding/vaccineBenefits.htm> (last visited Feb. 24, 2010).

³²⁹ The notorious instance in 2007 of an individual suffering from drug-resistant tuberculosis who engaged in inter-continental and trans-national travel while infected and contagious brought the globalization of infectious disease into sharp relief. See, e.g., Felice Batlan, *Law in the Time of Cholera: Disease, State Power, and Quarantines Past and Future*, 80 TEMP. L. REV. 53, 58 n.22 (2007); David P. Fidler et al., *Through the Quarantine Looking Glass: Drug-Resistant Tuberculosis and Public Health Governance, Law, and Ethics*, 35 J.L. MED. & ETHICS 616, 617–18 (2007); L. Masae Kawamura, Op-Ed., *Have Germs Will Travel*, N.Y. TIMES, June 2, 2007, at A13.

³³⁰ See Minn. Dep’t of Health, Infectious Disease Epidemiology, Live Attenuated Influenza Vaccine (LAIV): A Safe and Effective Choice, <http://health.minnesota.gov/divs/idepc/diseases/flu/hcp/vaccine/laiv.html#shed> (discussing the risks of virus shedding after vaccination).

³³¹ On the other hand, with some illnesses, there are subpopulations of individuals who are much more likely to come in contact with the disease in their work and life. See Ctrs. for Disease Control & Prevention, Disease Listing: Anthrax General Information, http://www.cdc.gov/nczved/dfbmd/disease_listing/anthrax_gi.html#common (last visited Feb. 24, 2010). Such subpopulations pose greater risks of spreading disease than others in the population present of spreading it to them. *Id.* Anthrax is a paradigm example:

Anthrax is most common in agricultural regions where it occurs in animals. These include South and Central America, Southern and Eastern Europe, Asia, Africa, the Caribbean, and the Middle East. When anthrax affects humans, it is usually due to an occupational exposure to infected animals or their products. Workers who are exposed to dead animals and animal products from other countries where anthrax is more common may become infected with *B. anthracis* (industrial anthrax). Anthrax outbreaks occur in the United States on an annual basis in livestock and wild game animals such as deer.

maceutical entities which design, manufacture, and/or distribute the vaccine. This collection of entities includes representatives of the military-industrial complex, research laboratories, public health agencies and officials, government officials, administering medical professionals, and the medical profession generally. These players engage in disparate, yet integrally interconnected activities, the sum total of which is to require individuals to confront the risk of taking the vaccine. The interaction of these players varies by such circumstances as [a] the specific disease to be prevented, [b] the specific variety and functionality of the vaccine at issue (live-virus, killed-virus, culture medium (e.g. kidney cells of monkeys, as Salk's vaccine was, or chicken egg embryos, the common method for the last 40 years), and the addition of adjuvants), as well as the circumstances of the vaccine's marketing, field testing, approval process, governmental adoption or mandate, and systematic distribution. Furthermore, the risks of infection and contagion posed by the individual and posed by the societal group are different than the risks created by the vaccine work of developers, manufacturers, distributors, physicians, and public health authorities who mandate particular vaccines or approve particular vaccines.

It is evident, therefore, upon closer examination that the relationships are too heterogeneous, and their intersections too polycentric, to admit of fine distinction and categorization of real-world vaccine-to-injury encounters. Because of the peculiar, multi-layered nature of the risk-reciprocity analysis, we must work with an approximation of the typical risk reciprocities created in the aggregate by the operation and interplay of these forces. Recognizing, then, that we are dealing at best with a proxy for the existence of risks and the constituencies affected by them is critical to the construction of a tenable assessment model.

But there is more here to consider. As noted above, the risk-calculus when various systems of liability allocation and dispute resolution are at play—as they have been, historically, in the vaccine products liability area since the 1980s—the adjudicatory process itself becomes an extension of the tort injury and the limitations that the régime imposes operate as an extension of the risk to person. The relationship among the principles underlying such procedural régimes is worth fleshing out.

Scholars typically view corrective justice as a principle underlying the substantive aims of tort law.³³² That principle intersects with the

³³² See, e.g., Jules L. Coleman, *The Practice of Corrective Justice*, in *PHILOSOPHICAL FOUNDATIONS OF TORT LAW* 53 (David G. Owen ed., 1995); Jules L. Coleman, *RISKS AND WRONGS* 361–85 (1992); DAN B. DOBBS, *THE LAW OF TORTS* 13–16 (2000); ERNEST J. WEINRIB, *THE IDEA OF PRIVATE LAW* 84–113 (1995); Fletcher, *supra* note 29, at 538; Keating, *supra* note 30, at 195 (“Tort scholarship on the law of negligence has long been torn between two competing conceptions. One of these conceptions—the corrective justice conception—holds that negligence law is (and should be) an articulation of our ordinary moral conceptions

broader principle of what is called enterprise regulation.³³³ What we typically describe as tort law are substantive rules that emanate from one or both of those principles. The rules of law we choose to apply should reify the corrective justice and enterprise regulation principles in a Dworkinian model.³³⁴ Those principles justify the rules for framing and pursuing a tort cause of action.

To use Dworkin's lexicon, the enterprise regulation principle delineates those situations in which it is appropriate for the state to apply its coercive rules to shape corporate activity and to provide remedies for the effects of non-conforming corporate activity.³³⁵ The enterprise regulation principle defines the categories of cases in which a state may legitimately impose its positive rules of law. This is particularly so when an alleged tortfeasor—such as a vaccine maker—is licensed by the government to manufacture and distribute a particular product.

There is a third principle that must be recognized for vaccine liability: the "Social Compact or Society Principle,"³³⁶ which embodies the

of agency and responsibility, carelessness and wrongdoing, harm and reparation."); Richard A. Posner, *The Concept of Corrective Justice in Recent Theories of Tort Law*, 10 J. LEGAL STUD. 187, 188 (1981); Susan Randall, *Corrective Justice And The Torts Process*, 27 IND. L. REV. 1 (1993) ("Corrective justice stands in direct opposition to instrumental views of tort law, positing a moral foundation of and rationale for the present system of tort law."); Alan Schwartz, *Responsibility and Tort Liability*, 97 ETHICS 270, 270 (1986); Gary T. Schwartz, *Mixed Theories of Tort Law: Affirming Both Deterrence and Corrective Justice*, 75 TEX. L. REV. 1801, 1801 (1997); Catharine Pierce Wells, *Corrective Justice and Corporate Tort Liability*, 69 S. CAL. L. REV. 1769, 1769 (1996); Catharine Pierce Wells, *Tort Law as Corrective Justice: A Pragmatic Justification for Jury Adjudication*, 88 MICH. L. REV. 2348, 2348 (1990).

³³³ See Jeffrey A. Van Detta, *Dialogue with a Neurosurgeon: Toward a Dépeçage Approach to Achieve Tort Reform and Preserve Corrective Justice in Medical Malpractice Cases*, 71 U. PITTS. L. REV. 1, 27 diag.1 (2009) [hereinafter Van Detta, *Dialogue with a Neurosurgeon*]; see also Jeffrey A. Van Detta, *Justice Restored: Using a Preservation-of-Court-Access Approach to Replace Forum Non Conveniens in Five International Product-Injury Cases*, 28 NW. J. INT'L L. & BUS. 53 (2003) [hereinafter Van Detta, *Justice Restored*]; Jeffrey A. Van Detta, *The Irony of Instrumentalism: Using Dworkin's Principle-Rule Distinction to Reconceptualize Metaphorically a Substance-Procedure Dissonance Exemplified by Forum Non Conveniens Dismissals in International Product Injury Cases*, 87 MARQ. L. REV. 425, 441–45 (2004) [hereinafter Van Detta, *The Irony of Instrumentalism*].

³³⁴ See Ronald M. Dworkin, *Model of Rules*, in *TAKING RIGHTS SERIOUSLY* 14 (1978); RONALD DWORKIN, *A MATTER OF PRINCIPLE* 147 (1978); Kenneth J. Kress, *Legal Reasoning and Coherence Theories: Dworkin's Rights Thesis, Retroactivity, and the Linear Order of Decisions*, 72 CAL. L. REV. 369, 373 (1984) ("Dworkin's objections [to an entirely rule-bound view of law] are motivated by the need to provide principled justification for the State's use of coercion and force in enforcing judgments."); Eric Dorkin, Note, *Debunking Integrity's "Equality Advantage": The Absence of Coordination in Ronald Dworkin's Law's Empire*, 83 IOWA L. REV. 1071, 1080 (1997–1998) ("Within Dworkin's jurisprudence, principles have a descriptive and a normative function. Principles simultaneously explain (descriptive) and justify (normative) the legal practice within a particular community").

³³⁵ See Ronald M. Dworkin, *The Model of Rules*, 35 U. CHI. L. REV. 14 (1967–1968).

³³⁶ See THOMAS HOBBES, *LEVIATHAN: PARTS ONE AND TWO* (Herbert W. Scheider ed., Liberal Arts Press, 1958) (1651); JOHN LOCKE, *THE SECOND TREATISE OF GOVERNMENT* (Thomas P. Peardon ed., Liberal Arts Press, 1952) (1689); JEAN-JACQUES ROUSSEAU, *THE*

post-Enlightenment philosophical view that civil society is organized to create the security needed to enjoy life, liberty, property, and the pursuit of happiness. In such a system of reciprocal benefits, social theory extracts from the individual certain sacrifices of life, liberty, and property in the benefit both of the individual and the common good. Such sacrifices include paying taxes, military service, jury service, and public health measures—such as vaccination—in which an individual is asked to sacrifice some of his or her liberty and health in a group enterprise to preserve the health and liberty of all members of society as a whole, including that individual.³³⁷ The inherent duality in the nation of benefits and obligations—including the obligation to incur risks to the individual in pursuit of societal goals—makes the evaluation of scenarios of individual sacrifice for what is perceived as the social good potentially complex as an equation of polycentric decisions.³³⁸

We may get a better understanding of the intersection of these three principles in vaccine-injury cases by resorting to the following visual metaphors. The first diagram is a visual metaphor illustrating the polycentric nature of the relationships among communicable disease, vaccination, and vaccine-related injuries. Decisions made in one domain may have effects that produce significant results in another. Because the cause-and-effect relationship of disease, vaccination, and injury is not necessarily linear, but may produce differing but overlapping results as demonstrated in Diagram No. 1, the great flaw in a one-size-fits-all approach to vaccine injuries is that it tends to obscure the polycentric nature of these decisions, producing results that are incoherent and dissonant when considered in light of the three over-arching legal principles implicated by vaccines.

The second diagram is a visual metaphor useful in elucidating the polycentric relationships from the perspective of the three relevant legal principles themselves. Diagram No. 2 presents the zones of isolation and intersection among the three principles as they are invoked in scenarios—i.e., “litigation events”—combining four risk-related variables of

SOCIAL CONTRACT, OR PRINCIPLES OF POLITICAL RIGHT (Henry J. Tozer trans., Swan Sonnen-schein & Co., 1905) (1762); Joseph H. Kary, *Contract Law and the Social Contract: What Legal History Can Teach Us About the Political Theory of Hobbes and Locke*, 31 OTTAWA L. REV. 73 (2000).

³³⁷ See, e.g., CHRISTOPHER G. TIEDEMAN, TREATISE ON STATE AND FEDERAL CONTROL OF PERSONS AND PROPERTY IN THE UNITED STATES CONSIDERED FROM BOTH A CIVIL AND CRIMINAL STANDPOINT 39 (1900); see generally Jeffrey A. Van Detta, Comment, *Compelling Governmental Interest Jurisprudence of the Burger Court: A New Perspective on Roe v. Wade*, 50 ALB. L. REV. 675 (1986).

³³⁸ See, e.g., RANDY BARNETT, RESTORING THE LOST CONSTITUTION: THE PRESUMPTION OF LIBERTY 44–45, 336–38 (Princeton, 2004); see also GEORGE WILLIAM WINTERBURN, THE VALUE OF VACCINATION: A NON-PARTISAN REVIEW OF ITS HISTORY AND RESULTS 145–50 (expressing contrarian view, suggestive of polycentrism).

knowledge and prospective exercise of care, in which vaccine risks are classified as unknown, or unknown and preventable, or unpreventable with the exercise of reasonable care. Together, these diagrams provide a snapshot of the theoretical and intellectual bases for the more subtle evaluation of liability rules and public policy choices undertaken in Part III.B.2, below, and the model we develop in Part III.B.3 below for classifying vaccine injuries and considering alternatives for resolving those injuries, as well as for preventing them in the first place.

DIAGRAM No. 1

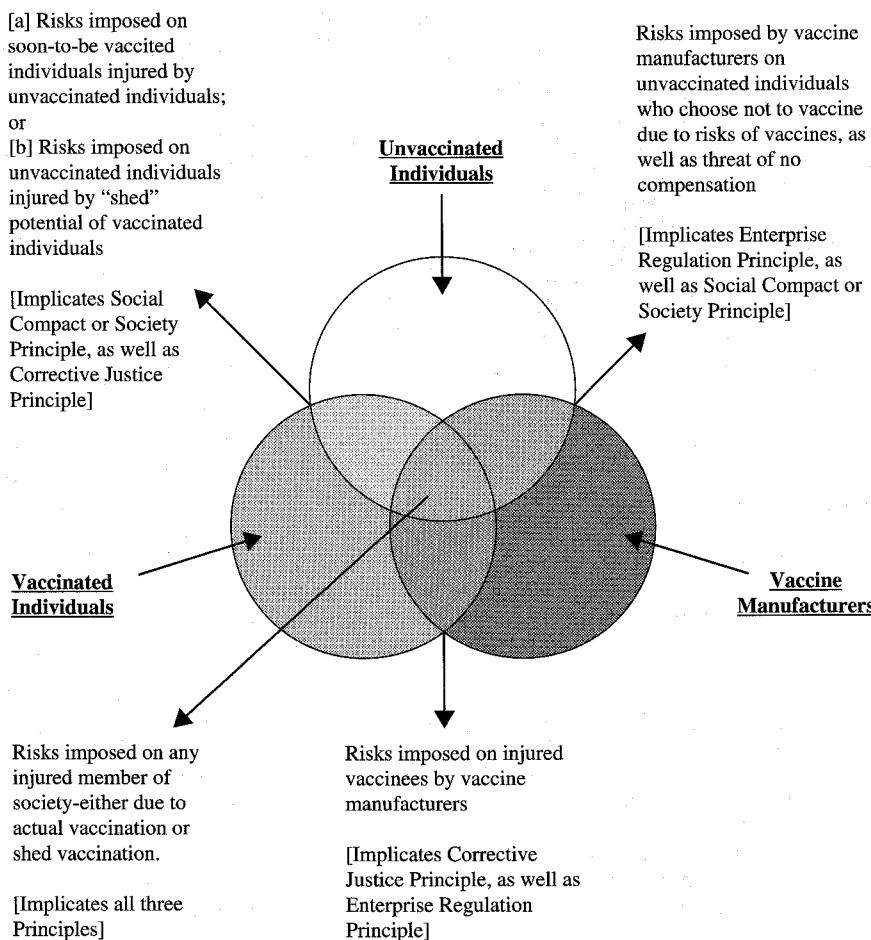
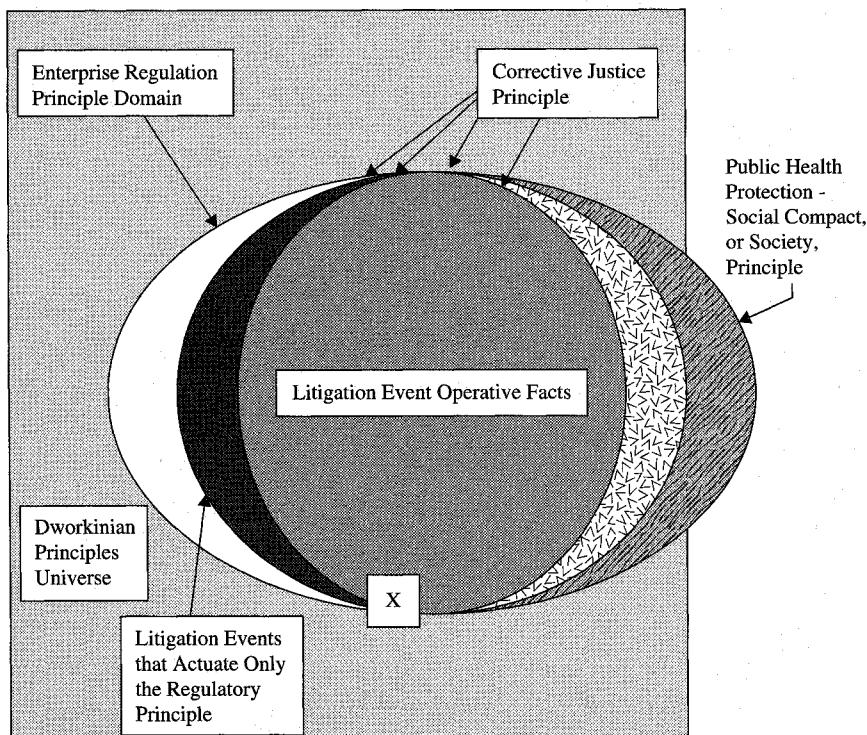


DIAGRAM No. 2
DWORKINIAN PRINCIPLES AND VACCINE-INJURY LIABILITY:
A METAPHORIC VENN DIAGRAM



Operative facts of litigation events fall within the domains of the Corrective Justice principle and the Social Compact principle but outside domain of Enterprise Regulation principle corresponds to known vaccine risks that cannot be prevented with the exercise of reasonable care and, at the limb of the Enterprise Regulations Principle domain, corresponds to unknown vaccine risks that cannot be eliminated with the exercise of reasonable care.



Operative facts of litigation events fall within domain of Corrective Justice, Social Compact, (and Enterprise Regulation principles)—corresponds to known vaccine risks preventable by exercise of reasonable care.



Operative facts of litigation fall within corrective Justice and Social Compact domains but on limb of intersection with domains of Enterprise Regulation principles—corresponds to unknown vaccine risks that cannot be discovered with reasonable care.



Operative facts of the litigation event fall within common domain of Enterprise Regulation and Corrective Justice principles, but outside of Social Compact principle's domain. Corresponds with no class of risks created by vaccines, because all vaccine matters implicate the Social Compact principle.

2. Choices

Two critical factors separate consideration of vaccine liability from other kinds of drugs, devices, or pharmaceuticals asserted to be therapeutic but attended with harmful risks. First, vaccine injuries are unique. Vaccines are used not to treat those sick, those portending signs of illness, or even those having necessarily been exposed to illness under identifiable circumstances, and thus at a cognizable risk. Vaccines, to the contrary, are given to those who are presumably healthy—risking making them sick now as a prophylaxis to more serious illness later.

Second, unlike other therapeutic pharmaceuticals, many vaccines are mandated as a function of public policy, and administered in blanket vaccination programs that cover entire groups of similarly situated individuals—e.g., school age children or persons entering military service. There is in such programmatic administration little to no individualized assessment, and next to no element of patient choice.

Thus analysis of vaccine liability involves layers of policy, politics, and status that differentiate it from most product liability issues. And to the extent vaccines are mandated, it invokes the very political powerlessness of groups—e.g., children, immigrants, and rank-and-file soldiers—as paradigmatically represented by the immigrant Mary O'Brien, who although forced to endure a painful smallpox vaccine to which she did not actually consent, was held to consent merely by her presence and by her politically powerless immigrant social status.³³⁹

The public policy choices that have confronted Congress and the courts in dealing with vaccine-related injuries have generally not been discussed in terms of principle or in terms of the two critical factors discussed above that separate vaccine liability issues from other tort and products-liability issues. Typically, the analysis begins—and ends—with an instrumentalist view of outcomes, rather than the foundations for those outcomes. The outcomes of a vaccine policy analysis—whether based on instrumentalism or upon overarching principles of law—can be reduced to six rule outcomes:

- 1) immunity of vaccine manufacturers and suppliers;
- 2) partial immunity of vaccine manufacturers and suppliers;
- 3) defining liability of vaccine manufacturers and suppliers as limited to instances in which their acts or omissions do not meet the low standard of “ordinary” or “reasonable” care;
- 4) defining liability of vaccine manufacturers and suppliers as limited to instances in which their acts or omissions do not meet

³³⁹ See, e.g., Jody Amour, *Just Deserts: Narrative, Perspective, Choice, and Blame*, 57 U. PITTS. L. REV. 525, 530–35 (1996) (discussing the teaching of *O'Brien v. Cunard S.S. Lines*, 154 Mass. 272, 28 N.E. 266 (1891)).

some heightened standard of care—a standard of care higher than reasonable care but lower than “the highest possible degree of care”;

- 5) defining liability of vaccine manufacturers and suppliers as encompassing any instance in which their acts or omissions do not meet “the highest possible degree of care”;
- 6) imposing strict liability on vaccine manufacturers and suppliers for any injury causally connected to administration of a vaccine.

This sixth rule outcome eliminates any evaluation of the acts or omissions of vaccine manufacturers and suppliers; the care they did, or did not, exercise becomes legally irrelevant. The inquiry shifts entirely to causation, and the strict liability rule will have a scope of operation directly circumscribed by the causation rule adopted as the standard:

- a) liability only when the vaccine is proven to be the “but for” cause of an injury;
- b) liability if the vaccine is proven to be a “substantial factor” in the cause of the injury. Causation can be proven under this rule even if other contributing, non-vaccine causes exist;
- c) liability if the vaccine is proven to be “a factor” in the cause of the injury. Causation can be proven under this standard by simply proving that the vaccine was a factor—among possibly many known, or unknown, factors—contributing to a vaccine injury.

Of course, these three basic, competing causation standards admit of further variations by the assignment of burdens of proof, the adoption of presumptions (either for or against causation), and the standard of proof imposed (e.g., preponderance of the evidence, or clear and convincing evidence).

In addition to the choices to be made among these six rule outcomes, there are also choices to be made about both the adjudicatory forum and the adjudicatory form in which the chosen rule outcomes will be applied. The adjudicatory fora include courts of general jurisdiction, courts of special jurisdiction, government-facilitated arbitration, privately facilitated arbitration, administrative agency adjudication, or administrative agency preemption. The forms of adjudication include trial by jury, trial by judge, trial by administrative law judge, determination by a panel of scientific experts, arbitration, or no adjudication because of prior administrative agency determinations that are given preemptive effect.

The problem of how to adjudicate and compensate vaccine injuries involves the tension between, and overlapping considerations of, the three relevant principles. The complexity of this interaction multiplies because of the tangle between the societal interest and the interest of the vaccine injury recipient, with simultaneous identities as [1] autonomous persons meriting protection from both [a] the target disease as well as [b]

vaccine injury; as well as [2] members of the group to be protected from the disease by the vaccine. The contours and boundaries of these principles, and their applicability, when considered from the varied perspectives of the simultaneous identities are so difficult to isolate in a neat and clean pattern that it seems clear that we have on our hands a polycentric decisional paradigm that does not admit of easy answers—but is nonetheless vulnerable to the excess of overemphasis that comes from focusing on a particular identity perspective or underlying principle to the diminution, or even exclusion, of others. Thus, [it] focuses too much on enterprise regulation, corrective justice, and the injured individual's autonomy to argue that the process of vaccine manufacture “should and could be perfect”³⁴⁰—i.e., that both the public expects, and the law should demand, perfection in vaccination. Similarly, the societal principle would be unfairly ascendant over the corrective justice and enterprise regulation principles and group identities to immunize the vaccine industry from liability and the obligation of compensation for vaccine injury.

Between these extremes lie two sets of complicating factors. First, there is the peculiar and multi-layered nature of the risk-reciprocity analysis identified above when applying Fletcher’s theory. Second, there is a problem that already troubles many vaccine-injury claimants under present régimes: causation. The elusive problem of causation dominates all but the most well-documented and directly discernible vaccine-injuries.³⁴¹ The experience under the NCVIA is emblematic of what the experience is like generally in the realm of state and federal tort litigation as well. Recently, a student attorney who volunteered in representing vaccine claimants before the vaccine court under the NCVIA noted a number of serious problems faced by claimants who must prove cause-in-fact—even under the somewhat more generous “substantial factor” standard—to make out a vaccine injury claim.³⁴² The difficulties come in six principle areas: [1] availability to claimants of the kind of evidence to prove causation that either has not been developed by the government or industry, or is within their hands and not available to claimants; [2] nature of the evidence needed, since “vaccines generally do not leave ‘footprints,’ or pathological markers, on the body that prove causation;” [3] failure of the government or industry to regularly conduct epidemiological studies, which would be “the next-best form of evidence”; [4]

³⁴⁰ OFFIT, THE CUTTER INCIDENT, *supra* note 31, at 141–42.

³⁴¹ See, e.g., Kathleen A. Strong, Note, *Proving Causation Under the Vaccine Injury Act: A New Approach for a New Day*, 75 GEO. WASH. L. REV. 426, 445–48 (noting that claimants under the NCVIA who must establish causation succeed only in only 13% of cases; and, due to changes in the vaccine injury table made under the auspices of HHS, 90% of claims filed under NCVIA now fall into the category of cases in which cause is not presumed, but rather, claimants must bear the burden of proving cause in fact).

³⁴² See *id.*

clinical, rather than epidemiological, nature of the evidence that typically is available; [5] disagreement by judges over “whether circumstantial evidence alone can satisfy a petitioner’s preponderance of the evidence burden, or whether some direct evidence is required”; [6] the much heightened transactional costs of making causation a duel to the death in the great majority of vaccine claims—which has resulted in “[t]he intent of the program [being] lost because the government lawyers want to defeat every claim at all costs and for any reason. . . . [so that] [t]here is now no difference in the level of litigation than if the case were in state or federal court.”³⁴³

The next step in our process of rethinking vaccine liability, therefore, is to discern more carefully and delineate more precisely how these two unique characteristics should be addressed. The first step we take in that direction is to rethink whether all vaccine injuries should be treated alike for purposes of this analysis—or whether, at least initially, we ought to consider whether the interplay of corrective justice, enterprise regulation, and social compact principles require a more categorical approach that refines the injuries that vaccines may cause into classes based on attendant risks and their degree of foreseeability.

3. *Dépeçage* Classification: The Method of Sorting Choices by Scenarios and the Implications of the Relevant Principles

To begin evaluating these issues, it will assist us to look more deeply at the kinds—or, as we prefer to call them, “classes”—of injuries that vaccines may cause. The classes at which we look are not defined symptomatically, anatomically, or systemically. Rather, the classes of vaccine injury we examine are based on the following combination of variables—characteristics relating to the risk(s) they present to the vaccinated—that are more pertinent to a legal analysis, rather than a strictly medical one:

1. The state of knowledge regarding the injury—i.e., is it known or unknown?
2. The probability with which the injury occurs—i.e., is it significant or remote?
3. The avoidability of the injury—i.e., can it be eliminated at all, and if so, by what level of care?

Few commentators—or legislators, for that matter—have approached the question of tort liability generally, or vaccine-related injury liability specifically, from the perspective of what the principles animating tort law rules may counsel. Rather, commentators tend to espouse a single approach as “the” answer, typically looking at the ends rather than

³⁴³ See *id.* (citations omitted).

the means. This variety of reasoning, however, has not led to coherent results; rather, it has produced prodigious debate and analytic dissonance. There is, however, an approach available to Congress to make reasoned, well-informed choices in this area—and to aspire to more innovative approaches better adapted both to the unique context of vaccine injury and of the governmental compulsion behind many vaccines. The liability schemes and compensation offered for vaccine-related injuries calls for a subtler and more finely-tuned analytic approach: one that the co-author has called a “dépeçage approach.”³⁴⁴

The dépeçage approach to rethinking tort liability is particularly well-suited for decisional processes that are polycentric in nature. One of us demonstrated this process with respect to classifying and evaluating medical malpractice in complex neurosurgery by various classes of injuries and how relevant legal principles counsel rule-making (for liability and remedy) individualized to the particular interests and their balance inherent in each separate class of injury.³⁴⁵ The following is a chart summary of one dépeçage model that legislators may use in considering how to allocate risks, burdens, and costs among the individuals and groups who comprise the stakeholders in vaccine liability issues:

³⁴⁴ Dépeçage refers to interstate or international cases in which choice-of-law questions have arisen with respect to more than one issue. See Willis L. M. Reese, *Dépeçage: A Common Phenomenon in Choice of Law*, 73 COLUM. L. REV. 58, 58 (1973). Rather than simply apply one state’s or nation’s law as a one-size-fits-all answer, dépeçage indicates more subtlety and concern for competing state interests by separately analyzing, under the relevant choice-of-law rules, the appropriate choice of law on an issue-by-issue approach. See SYMEON C. SYMEONIDES ET AL., *CONFLICT OF LAWS: AMERICAN, COMPARATIVE, INTERNATIONAL* 128 & n.1 (1998); Van Detta, *Dialogue with a Neurosurgeon*, *supra* note 333, at 3–4.

³⁴⁵ See Van Detta, *Dialogue with a Neurosurgeon*, *supra* note 333, at 42–50.

Dépeçage Model for Classification of Vaccine Injuries and Resolution Issues for Vaccine Claims Arising from Each Injury Principles and Resolution Issues

	Enterprise Regulation	Corrective Justice	Social Compact, or Societal Principle
Class 1 Injury risk known, probability significant, and cannot be eliminated with all reasonable care.	Most effectively accomplished by administrative oversight (FDA) and voluntary industry competence with adequate labeling and warning. Safety of individual must be balanced against tailoring of regulation so that vaccine manufacture and further refinement does not become untenable from investor viewpoint.	Persons harmed by the vaccine have palpable injuries that merit compensation. The question remains how to establish the entitlement? Proof of causation is most significant hurdle.	Is vaccine necessary to protect the public at large? Is the risk of vaccination to each recipient outweighed by the risk to the group if the vaccine is not mandatory, or at least widespread?
Class 2 Injury risk known, probability remote, and cannot be eliminated with all reasonable care.	Controlling for remote risks involves tracking to determine [a] if they are really so remote-experience may fall differently and [b] developing profile of bio-sociological factors of those most susceptible to eventuation of risk. Global data gathering, analysis, strategic modeling, and disseminating of paradigms in field.	Persons harmed by the vaccine have palpable injuries that merit compensation. The question remains how to establish the entitlement? Proof of causation is most significant hurdle. Causation of proofs is even more problematic in this class of cases.	The balance in Class 2 may differ from Class 1. If the imminence of the risk of the illness, either to individual or to group is substantial, then that may often outweigh the more remote risk of vaccine injury. Although the calibration is always in question because the causation of vaccine injury may later become evident (if or) when relevant epidemiological data is collected and properly evaluated.

Class 3

Injury risk known, probability significant, and can be eliminated by exercise of at least reasonable care.

Business must be encouraged to bear the expense of eliminating known risks that are not remote and can feasibly be eliminated.

Persons harmed by the vaccine have palpable injuries that merit compensation. The compensation interest is particularly strong where the risk they expect to encounter in vaccine administration [a] eventuates in actual injury because the manufacturer fails to exercise the degree of reasonable care likely to eliminate the known risk and [b] is nonreciprocal—i.e., absent the manufacturer's reasonable care, the risk to the vaccine recipient consented to undertake is magnified substantially. Causation is less problematic in this class of cases because there is sufficient, pre-injury data establishing the causal linkage.

The balance in Class 3 is typically the closest between society's interest in disease control and prevention and the individual's welfare (which is protected by the enterprise regulation and corrective justice principles). When a potential injury is both known and avoidable through the exercise of reasonable care, or a higher, yet attainable, level of vigilance, the ratio between the individual and group risks is diminished. Depending on the severity of the target illness and its communicability, the societal risk may not so far outweigh the individual compensation for injury can justifiably be limited by the social benefits of the vaccine *in toto*.

Class 4

Injury risk known, probability remote, and can be eliminated by exercise of at least reasonable care.

Cases at the margin push the economics of the enterprise regulation to the edge. Relevance of the enterprise principle could be measured by the *U.S. v. Carroll Towing* formula—is the burden of exercising reasonable care to avoid a remote injury justified by its proportionality to the remote probability of the injury considered and the gravity of the harm in those instances where the remote risk actually eventuates in harm? Regulation becomes more relevant as the particular injury in question poses a lower burden to avoid and/or an increased gravity of harm.

Even in cases of the economic margin of the enterprise principle, the corrective justice principle still applies that persons harmed by a vaccine have palpable injuries that merit compensation. As with Class 3 injuries, the compensation interest is particularly strong where the risk they expect to encounter in vaccine administration [a] eventuates in actual injury because the manufacturer fails to exercise the degree of reasonable care likely to eliminate the known risk and [b] is nonreciprocal—i.e., absent the manufacturer's reasonable care, the risk to the vaccine recipient consented to undertake is magnified substan-

The balance in Class 4 cases between society's interest in disease control and prevention, and the enterprise regulation and corrective justice principles' protection of individual welfare is not as close as the balance in Class 3 cases. Although the risk of injury in Class 4 cases is more remote, it is both foreseeable and preventable by the exercise of the same level of care as we require of motorists and amusement park operators. When a potential risk is both known and avoidable, even if remote in probability, there must be some obligation to exercise at least reasonable care to avoid the risk. While the societal

Class 5

Injury risk unknown, but could be discovered by exercise of at least reasonable care.

The starting point of this class of risks as unknown shifts the regulatory paradigm from the issue of the vaccine industry to take reasonable care to discover risks that are as yet unknown, but will eventuate in the future. The relevant principle is recognized in the famous case, *The T.J. Hooper*, that an industry will not be allowed to rest upon the laurels of the states' good state of knowledge, and must maintain reasonable care in efforts to find and recognize tangible improvements to safety. Regulation in this class of cases is particularly important because the risk of continuing to administer a vaccine without exercising reasonable care to identify new risks during its post-approval period creates a substantial nonreciprocal risk in vaccine recipients.

tially. Causation is less problematic in this class of cases because there is sufficient, pre-injury data establishing the causal linkage.

Persons injured by palpable injuries that were not reasonably foreseeable normally have not been afforded compensation in this tort system. However, where the exercise of reasonable care to discover unknown risks more likely than not would have unearthed information that might reasonably have been used in time to prevent a particular victim's injury, compensation for that victim is appropriate.

interest in preventing the disease outweighs the imposing legal liability to an extent that makes the production and distribution of the vaccine untenable, that interest is not so strong as to displace the victims' compensation interest which can be maintained without disadvantaging the public vaccine program—particularly were the injury's remoteness suggest a low number of claims. The possibility of unknown complications exists for every kind of drug or vaccine. Only time over the course of distribution in the field will reveal the full set of risks presented by any product. In almost any conceivable case, the interest of society as a whole, and the health interest of individuals, strongly outweighs the risk of any vaccine recipient enduring an unforeseen risk. However, the risk to society of having unvaccinated members or an inconsistent vaccine program does not so far outweigh the individual risk that compensation for injury should be denied because of the societal benefits of the vaccine *in toto*—particularly where reasonable care would have led to the identification of the unknown risk. This factor also raises the societal interest from the perspective of creating and funding the programs needed to identify such risks as early as possible in the post-approval, field use of the vaccine.

Class 6

Injury risk unknown, but could have not have been discovered even by exercise of reasonable care.

This class of cases presents a *sui generis* issue for applying the enterprise regulation principle. The other classes involve measures of manufacturers' reasonableness—i.e., in knowledge of risk, or prediction of risk. In Class 6, reasonable care—indeed, care of any level—plays no role whatsoever. The risks in this class are unknown and unknowable until they eventuate in actual harm. Thus, traditional notions of regulating an enterprise to compel more responsible conduct do not figure into the equation. The question here is whether the enterprise should bear the harm caused by its product—basically a choice between a negligence régime (and thus no liability) versus a strict liability régime (always liability). Considerations here most clearly and markedly make the nonreciprocal risk model, by itself, inadequate to reach a model of fair distribution of harm among those who benefit from the relevant risks.³⁴⁶

Persons injured by palpable injuries whose risk is both unknown and unknowable *ex ante* have traditionally not been afforded compensation in the tort system. This is particularly so when no amount of vigilance on the part of the tortfeasor would result in detection and prevention of the harm. However, persons harmed by vaccines continue to have palpable injuries that merit compensation. It is arguable that the individual assumes a greater risk in submitting to vaccination than does the vaccine's progenitors. However, the risk to society averted by vaccination complicates the equation. Given the severity and life-long nature of many vaccine-related injuries, corrective justice may, like the enterprise principle, require here an analysis based on fair distribution of risks.³⁴⁷

The possibility of unknown complications exists for every kind of drug or vaccine. Only time over the course of distribution in the field will reveal the full set of risks presented by any product. In almost any conceivable case, the interest of society as a whole, and the health interest of individuals, strongly outweighs the risk of any vaccine recipient enduring an unforeseen risk. However, the risk to society of having unvaccinated members or an inconsistent vaccine program does not so far outweigh the individual risk that compensation for injury should be denied because of the societal benefits of the vaccine *in toto*. This is arguable the case even where no amount of care would protect the vaccinated from risk, because the group health interest still outweighs the individual health interest when viewed in the aggregate. In that sense, application of this principle, just as with the other two principles, militates not for a régime of no liability, but rather for one based on fairly distributing burdens of harm among those who benefit from the risk-creating activity.³⁴⁸

³⁴⁶ See Gregory C. Keating, *Rawlsian Fairness and Regime Choice in the Law of Accidents*, 72 FORDHAM L. REV. 1857, 1860–62, 1870–80 (2004).

³⁴⁷ See *id.*

³⁴⁸ See *id.*

Having set out in this schematic form the classes of risk and considerations they raise under each of three relevant tort-law principles, it will be helpful to comment further on each class with the objective of determining a methodology for transcending the simple two-risk nonreciprocal risk model—risks shared exclusively between tort victim and tortfeasor—and establishing a new realm to accommodate the additional problems posed by multi-risk, multi-player, polycentric decision-making processes—a realm in which we may cogently rethink vaccine-injury liability.

a. Class One Risks—In Which the Injury Risk is Known, Its Probability Significant, and It *Cannot Be* Eliminated with All Reasonable Care

The Pasteur rabies vaccine is the classic example involving Class One risks. It is cited in the commentary to the Restatement (Second) of Torts Section 402A as an example of a vaccine that is “unavoidably unsafe” because of its inherent, serious side effects,³⁴⁹ yet persons bitten by rabid animals submitted to it because the disease was still worse (100%

³⁴⁹ RESTATEMENT (SECOND) OF TORTS, § 402A cmt. k (1965).

The Pasteur rabies vaccine, administered without any means to confirm that the patient exposed to rabies actually has rabies (since that can only be confirmed in post-mortem dissection), can both cause rabies as well as encephalomyelitis. See, e.g., G. K. Schlenska, *Neurological Complications Following Rabies Duck Embryo Vaccination*, 214 J. NEUROL. 71, 71–74 (1976). Medical scientists began recording data in the 1880s that suggested that the actual number of deaths from rabies increased after the introduction of the prophylactic vaccine—deaths from rabies or encephalomyelitis occurred at a higher rate among the exposed and vaccinated than previously among the exposed and unvaccinated. See, e.g., Scientific Anti-Vivisectionism, Rabies Vaccine, http://www.freewebs.com/scientific_anti_vivisectionism16/rabiesvaccine.htm (last visited Feb. 13, 2010); see generally GERALD L. GEISON, THE PRIVATE SCIENCE OF LOUIS PASTEUR (1995) (discussing Pasteur’s development of the rabies vaccine). The Pasteur vaccine was developed before the rabies virus had even been identified and isolated, making contamination or insufficient inactivation, impossible to detect; and later, even after further refinement, problems adhered because of “the presence of the myelin component in nervous tissue [in which the vaccine was cultured] . . . has resulted in severe neuroparalytic adverse reactions and even death.” Deborah J. Briggs et al., *Vaccines*, in RABIES 371, 372, 380 (Alan C. Jackson & William H. Wunner eds. 2002). Along with a far more precise understanding of the rabies virus itself, new generations of rabies vaccines have significantly reduced these risks. See *id.* at 380–394.

A more modern example is the Sabin live-virus polio vaccine, of which a federal court observed:

[T]he vaccine was unavoidably unsafe because the live poliomyelitis virus, which is the essence of the vaccine, always presented the danger of causing poliomyelitis. It also found that Wyeth had enclosed a circular warning of the danger with the vaccine. Using its two-step analysis, the court held that the vaccine’s usefulness prevention of paralysis far outweighs the statistically minuscule risk that the vaccine may cause poliomyelitis. Thus, it is not unreasonably dangerous per se.

Needham v. White Labs., 639 F.2d 394, 401 (7th Cir. 1981) (describing the holding in Reyes v. Wyeth Labs., 498 F.2d 1264 (5th Cir. 1974), *cert. denied*, 419 U.S. 1096 (1974)).

fatal) than the cure.³⁵⁰ According to the Restatement, such products, provided that they are properly prepared, are effective, yet present “a reasonable risk,” and accompanied by warnings of that risk, expose their makers and distributors to no liability.³⁵¹ Deciding to make such products available, which have terrible risks along with important benefits, is ultimately a mixed question of science and policy that inevitably must be made in the administrative sphere (FDA), and cannot be effectively regulated by post-injury lawsuits. All three principles—enterprise, corrective justice, and societal—are in play to be balanced after consideration of many factors by administrators. The agency must consider whether its mandates (such as for labeling and warning) suffice to vindicate the enterprise regulation principle, while calibrating the right balance between safety of potential recipients with tailoring of regulation so that vaccine manufacture and further refinement does not become untenable from investor viewpoint. Yet, despite the often “life-and-death” conundrum presented by unavoidably unsafe products, the corrective justice principle instructs us that persons harmed by the vaccine have palpable injuries that merit compensation. Thus, a policy tension arises between the corrective justice and societal principles expressed in the questions: Is the vaccine necessary to protect the public at large? Is the risk of vaccination to each recipient outweighed by the risk to the group if the vaccine is not mandatory, or at least widespread?

If we view this Class from the perspective of the risks posed between manufacturer and recipient, it is clear that the risk is nonreciprocal and that the recipient is put at a greater risk—particularly because that risk is significant and cannot be eliminated. However, if we view this Class in light of additional risks—the risk posed to the non-recipient by the disease, the risk the disease poses to other members of society, the risk that the non-recipient poses of communicating the disease to other members of society, the risks between a government that mandates vaccination and the risk of vaccination to unvaccinated, the risks between government that does not mandate the vaccination and the risk of disease posed to society—the picture becomes too polycentric to permit coherent resolution under Fletcher’s theory alone.

³⁵⁰ See RESTatement (SECOND) OF TORTS, § 402A cmt. k (1965); see, e.g., *Allison v. Merck & Co., Inc.*, 878 P.2d 948, 953 (Nev. 1994).

³⁵¹ See RESTatement (SECOND) OF TORTS, § 402A cmt. k (1965). However, theories of liability have been recognized when the warnings are not communicated to the vaccine recipient. See, e.g., *Reyes*, 498 F.2d at 1273.

b. Class Two Risks—In Which the Injury Risk is Known, Its Probability Remote, and *Cannot Be Eliminated* with All Reasonable Care

Oral polio vaccine (OPV) presents the textbook example of the Class Two risk. As originally conceived by Dr. Albert Sabin, the bitter rival of Jonas Salk, OPV uses weakened (i.e., “attenuated” in vaccine terminology) but live polio virus to stimulate immunity.³⁵² OPV offered greater ease in large-scale polio eradication campaigns, afforded a long-lasting immunity, and more rapidly stamps out the virus in newly-vaccinated communities by a process called “shedding,” in which live, but attenuated, virus excreted by the vaccinated exposes the unvaccinated to polio and triggers their immune systems to develop antibodies, producing what is called “herd” immunity.³⁵³ When properly manufactured according to industry standards, OPV still carried a one in 2.4 million risk of causing Vaccine-Associated Paralytic Polio (VAPP) in recipients.³⁵⁴ “Because Sabin strains contain the live polio virus, there is a risk that either a recipient or a contact could develop polio.”³⁵⁵ The risk rate of a non-vaccinated person contracting VAPP from live virus shed by a vaccine is discernible but even more remote than the risk of VAPP developing in recipients—approximately one in six million.³⁵⁶

When applied to Class Two risk scenarios, the principles strike a balance that favors vaccination and compensation, with warnings of the risks—particularly where there are vaccination choices, as there are in the case of the safer, but more expensive and complicated, Salk killed-virus injected polio vaccine versus the Sabin live-virus oral polio vaccine. Enterprise regulation here commands controlling for remote risks by tracking actual results in the field and continuously recalibrating the risk assessments with two definite goals in mind. First, risks at one time found to be remote may, as field use of the vaccine generates more epidemiological data, be found much more probable across a broad population than scientists had at first thought. Second, that additional

³⁵² See, e.g., MARTIN G. MYERS, M.D. & DIEGO PINEDA, DO VACCINES CAUSE THAT?: A GUIDE FOR EVALUATING VACCINE SAFETY CONCERN 26 (2008).

³⁵³ See *id.* at 26–28.

³⁵⁴ See *id.* at 27. In the 1970s, the CDC apparently was estimating this number as 1 in 20 million. See *Plummer v. Lederle Labs.*, 819 F.2d 349, 352 (2d Cir. 1987). Subsequent data apparently shows that VAPP is a greater risk than the CDC thought it to be in the early 1970s. See *id.* at 26–27 (stating that “about 1 out of 2.4 million doses of OPV distributed in the United States cause vaccine-associated paralytic polio (VAPP)”).

³⁵⁵ *Loge v. United States*, 662 F.2d 1268, 1270 (8th Cir. 1981). As the Court of Appeals for the Eighth Circuit noted, “Mrs. Loge was exposed to the shed virus in 1976 after a doctor inoculated her infant son Todd with Orimune. Within one month after her son’s inoculation, Mrs. Loge was stricken with a vaccine-associated case of poliomyelitis, Type 2. As a result, she is now a paraplegic.” *Id.*

³⁵⁶ See *Plummer*, 819 F.2d at 352.

information will also allow the development and refinement of a bio-sociological factor profile of those most susceptible to eventuation of risk, which should serve to identify those most in need of risk warnings and for whom the vaccine development community should develop alternatives.³⁵⁷ Global data gathering, analysis, strategic modeling, and disseminating of paradigms in field are critical components. The essence of addressing Class Two risks is, as reflected in numerous vaccine-injury cases of the 1970s and 1980s, creating and disseminating proper warnings of the remote risks.³⁵⁸

As in the other Classes of injury, the corrective justice principle compels us to recognize that persons harmed by the vaccine have palpable injuries that merit compensation. The societal principle more strongly compels the public policy decision to expose large groups of people to the remote risk of harm over a large number of vaccine administrations to ensure the health of many more persons who, without the vaccine, would be at a statistically greater risk of harm from the disease in the absence of programmatic vaccination. The equipoise between the principles favoring compensation for victims and broad reach of vaccination can be delicate—as those who emphasize the severe compression of

³⁵⁷ The concept of “adequate warning” is a murky one in the area of vaccines. A serious question arises whether a layperson—or even a non-specialist physician—can truly make an intelligent choice to receive, or to forego if permitted by law, a vaccine, especially where the risks of harm have probabilities in the ranges of uncommon to remote to unknown—i.e., “Do I know too little about the unknown risks to take the risk?” Lawyers have used patient consent as a convenient legal dodge around the tougher issues of both science, as well as morality. Questions of whether a vaccinee’s consent is genuinely [1] informed and [2] voluntary indeed present issues to manufacturers, physicians, and public health care agencies that are of a moral dimension, closely allied to legal notions of duress, unconscionability, and innocent/negligent misrepresentation. Such issues require an extended treatment drawing on sources outside of law. *See, e.g.*, KENT GREENAWALT, CONFLICTS OF LAW AND MORALITY, 207–25 (1989). They are beyond the scope of our mission in this Article. Therefore, we will treat the question of patient consent to receive a vaccine as a non-relevant factor in the classification of risk or application of enterprise regulation, corrective justice, and social compact principles to the scenarios in those various classifications. Suffice it to say that since many of the vaccines are compulsory since they are required either for admittance to the country or for school attendance, with itself is required, consent would not figure much in the kind of analysis we undertake here. For a general and informative aspect of the historical, moral, and legal considerations surrounding the question of consent and balancing of risks to individuals in the trials of vaccines and other biological products during the twentieth century, see generally SYDNEY A. HALPERN, LESSER HARM: THE MORALITY OF RISK IN MEDICAL RESEARCH (2004).

³⁵⁸ See, e.g., *Graham v. American Cyanamid Co.*, 350 F.3d 496 (6th Cir. 2003); *MYERS & PINEDA*, *supra* note 352, at 19 & n.1; *Plummer*, 819 F.2 at 349; *Reyes v. Wyeth Labs.*, 498 F.2d 1264 (5th Cir. 1980). *See also* ARTHUR ALLEN, VACCINE: THE CONTROVERSIAL STORY OF MEDICINE’S GREATEST LIFE SAVER 264–65 (2008). Of course, meaningful warnings of remote risks are difficult for non-statisticians to interpret and contextualize. *See generally* JOHN ALLEN PAULOS, INNUMERACY: MATHEMATICAL ILLITERACY AND ITS CONSEQUENCES (1988).

players in the vaccine industry since the 1950s consistently point out.³⁵⁹ The question remains how to establish the entitlement? Proof of causation is the most significant hurdle.³⁶⁰ Causation proof is even more problematic in this class of cases precisely because statistically remote risks will not appear until many vaccine doses are administered for a period of years—or even decades—and even then, it may take even more vaccinations and adverse events to establish the statistical significance to overcome objections that the causal link is equally as well explained by coincidence.³⁶¹

The balance in Class Two may differ from Class One. If the imminence of the risk of the illness, either to individual or to group, is substantial, that may often outweigh the more remote risk of vaccine injury—although the calibration is always in question because the causation of vaccine injury may later become evident when—and if—relevant epidemiological data is collected and properly evaluated.

If we view this Class from the perspective of the risks posed between manufacturer and recipient, it is clear that the risk is nonreciprocal and that the recipient is put at a greater risk—particularly since the risks at issue in Class Two cannot be eliminated—but the small possibility of the risk eventuating into actual harm pushes the notion of nonreciprocity to its conceptual limits. The risk may even be so minute as to lack statistical significance for comparison purposes. In addition, as with the risks in the other Classes, we must view Class Two risks in light of additional risks—the risk posed to the non-recipient by the disease, the risk the disease poses to other members of society, the risk that the non-recipient poses of communicating the disease to other members of society, the risks between a government that mandates vaccination and the risk of vaccination to unvaccinated, and the risks between no mandated vaccination and the risk of disease posed to society. The remote risk of harm to

³⁵⁹ See OFFIT, THE CUTTER INCIDENT, *supra* note 31, at 181–83. Others reject Offit's attribution of blame to facts—or fears—of products liability, and cite other economic issues—i.e., limited profitability from providing a product that most consumers use only once, that is complicated to develop, test, and manufacture, and that cannot be sold at a premium price like “designer” pharmaceuticals. See ALLEN, *supra* note 358, at 426–35.

³⁶⁰ See MYERS & PENADA, *supra* note 352, at 48–74. Under a protocol developed by the Institute of Medicine (IOM) within the National Academy of Sciences (NAS), both non-profit, non-government, private associations, causation categories were developed. *Id.* These causation categories are: [1] No Evidence (complee absence of clinical or epidemiological evidence); [2] Evidence Is Inadequate To Accept Or Reject A Causal Relationship (i.e., sparse, conflicting, at best merely suggestive); [3] Evidence Favors Rejection Of A Causal Relationship; [4] Evidence Favors Acceptance Of A Causal Relationship (i.e., evidence is strong and generally convincing—but not to a degree sufficient to characterize the link as unequivocal or established); [5] Evidence Establishes A Causal Relationship (i.e., evidence unequivocally shows causal link between a vaccine and an injury). *Id.* at 72–73. Compare the discussion of the options for the legal approach to causation at Part III.B.2 *supra*.

³⁶¹ See ALLEN, *supra* note 358, at 325.

the vaccinee seems least compelling when compared to other risks, such as the risk of the illness to the vaccinee, the risk to society if the vaccine is not used. Pure reciprocity alone, between manufacturer and vaccinee, is hardly sufficient as the sole basis on which to predicate questions of liability and compensation for Class Two risks. When the additional risks are factored into the picture, we once again have a portrait of polycentrism that will not admit of resolution under Fletcher's theory alone.

c. Class Three Risks—In Which the Injury Risk is Known, Its Probability Significant, and *Can Be Eliminated by Exercise of at Least Reasonable Care*

The paradigmatic Class Three risk is exemplified by the manufacturer process and quality-control errors in what has become known as "the Cutter Incident."³⁶² Cutter Laboratories was one of six companies licensed by the federal government to make the first production run of the Salk killed-virus polio vaccine.³⁶³ The risk of some viruses not being killed in the production process (and thus capable of actually causing polio in vaccinated persons) was well-known to researchers and pharmaceutical companies.³⁶⁴ The protocols developed for manufacturing of the vaccine called both for a filtration process designed to capture and remove live viruses from the vaccine and a testing process to ascertain whether that in fact happened.³⁶⁵ In production, Cutter Laboratories made errors at both critical stages of the process.³⁶⁶ These errors resulted in the production of 120,000 doses of polio vaccine that contained live polio virus.³⁶⁷ Of the children who received the vaccine, 40,000 developed abortive poliomyelitis (a form of the disease that does not involve the central nervous system), fifty-six developed paralytic poliomyelitis, and five children died as a result of polio infection.³⁶⁸ The live virus that the Cutter vaccine carried was more potent than the naturally occurring polio virus, and it also was shed in the excretions of the vaccinated.³⁶⁹ That resulted in a considerable secondary exposure to parents, other adults, and children.³⁷⁰ As one writer summarized the widening ripple from the Cutter Laboratories error:

³⁶² See Nathanson & Langmuir, *supra* note 31, at 29–30; see generally OFFIT, THE CUTTER INCIDENT, *supra* note 31.

³⁶³ OFFIT, THE CUTTER INCIDENT, *supra* note 31, at 62.

³⁶⁴ See *id.* at 48–51.

³⁶⁵ *Id.* at 47–48.

³⁶⁶ *Id.* at 62–65.

³⁶⁷ *Id.* at 87.

³⁶⁸ *Id.* at 86–87 (citing Nathanson & Langmuir, *supra* note 31).

³⁶⁹ OFFIT, THE CUTTER INCIDENT, *supra* note 31, at 85–89.

³⁷⁰ *Id.*

[I]t is likely that the Mahoney virus present in Cutter's vaccine infected at least 100,000 family and community contacts. In the end, at least 220,000 people were infected with live polio virus contained in Cutter's vaccine; 70,000 developed muscle weakness, 164 were severely paralyzed, and 10 were killed. Seventy-five percent of Cutter's victims were paralyzed for the rest of their lives.³⁷¹

Production problems had plagued Cutter's manufacture—one-third of the vaccine lots of the original production failed tests that looked for rogue active virus, and for some of these failed lots, Cutter repeated the formaldehyde process that was supposed to kill any live polio virus and re-submitted it for approval and distribution.³⁷² The risk here was well-known—previous live-virus and killed-virus vaccines had been developed and tested independently by the researchers Kolmer and Brodie in 1934, and both vaccines appeared to cause polio in an alarming number of otherwise healthy children.³⁷³ Jonas Salk, the killed-vaccine's developer, was quite aware of this, and developed an elaborate protocol for production to insure that this very kind of thing did not recur.³⁷⁴ As Dr. Paul Offit, a former vaccine research scientist and current, prolific author on vaccine-related issues who closely studied the Cutter Incident with information from a variety of perspectives, noted, "Cutter did many things wrong, and it didn't have the internal expertise that was available to other companies [like Eli Lilly and Parke-Davis]. . . . [I]t made a vaccine that was far more dangerous than any other polio vaccine made in the United States or in the world."³⁷⁵

Class Three scenarios involve recognized risks that can be eliminated. As the Cutter Incident suggests, the specifics of such cases may not necessarily be simple or cut and dry. There may be complications—such as a significant one in the Cutter Incident that the federal government shared responsibility by signing off on a vaccine-batch testing methodology that was not sufficient to detect all batches of vaccine that

³⁷¹ *Id.* at 89.

³⁷² *Id.* at 90.

³⁷³ *Id.* at 14–18. As Offit notes, "[t]he vaccine trials of John Kolmer and Maurice Brodie had a chilling effect on polio vaccine research. Twenty years passed before anyone dared to try again." *Id.* at 18.

³⁷⁴ *Id.* at 59–61.

³⁷⁵ OFFIT, THE CUTTER INCIDENT, *supra* note 31, at 114. Offit attributes many errors to Cutter's production process, including: [1] failing to use the appropriate filters during the formaldehyde treatment process; *id.* at 106; [2] "let[ting] filtered virus sit in the refrigerator for long periods before inactivating it with formaldehyde . . . caus[ing] fine clumps of monkey kidney cell debris to form on the bottoms of the flasks[;]" *id.* at 110; [3] failing to determine how long to treat the virus with formaldehyde so as to ensure elimination of the live virus; *id.* at 111–13.

might have live virus, by not recognizing the challenges of taking Salk's techniques for limited, trial vaccine production and rapidly implementing them into much larger scale production, and by not proceeding more carefully and slowly until a margin of reliable safety had been established.

In these circumstances, however, both business and government, when it partners with business, must be encouraged to bear the expense of eliminating known risks that are not remote and can feasibly be eliminated. As the jury's verdict in the *Gottsdanker* case reflects,³⁷⁶ the corrective justice principle supports the idea that persons harmed by a vaccine have palpable injuries that merit compensation. The compensation interest is particularly strong where the risk they expect to encounter in vaccine administration [a] eventuates in actual injury because the manufacturer fails to exercise the degree of reasonable care likely to eliminate the known risk and [b] is nonreciprocal—i.e., absent the manufacturer's reasonable care, the risk the vaccine recipient consented to undertake is magnified substantially. Causation is less problematic in this class of cases because there is sufficient, pre-injury data establishing the causal linkage—there was ultimately little doubt in the Cutter vaccine-injury cases what had caused the victims' polio, despite Cutter's unconvincing efforts to argue otherwise.³⁷⁷

The somewhat simpler picture when looking at the scenario only though the lens of enterprise regulation and corrective justice becomes more complicated when we add the perspective of the societal principle. The balance in Class Three is typically the closest between society's interest in disease control and prevention and the individual's welfare (which is protected by the enterprise regulation and corrective justice principles). When a potential injury is both known and avoidable through the exercise of reasonable care, or a higher, yet attainable, level of vigilance, the ratio between the individual and group risks is diminished. Depending on the severity of the target illness and its communicability, the societal risk may not so far outweigh the individual compensation for injury which may otherwise justifiably be limited by the social benefits of the vaccine *in toto*. That surely was the case for the polio vaccine; for though it received great publicity due to President Roosevelt, his former law partner Basil O'Connor, and the organization he founded, The March of Dimes, polio was not nearly as common or communicable as many other diseases of childhood at the time.³⁷⁸

If we view this Class from the perspective of the risks posed between manufacturer and recipient, it is clear that the risk is nonreciprocal

³⁷⁶ *Id.* at 150.

³⁷⁷ *Id.* at 142–47.

³⁷⁸ See DAVID M. OSHINSKY, POLIO: AN AMERICAN STORY 45, 53–91 (2005).

and that the recipient is put at a greater risk—particularly because that risk is significant and cannot be eliminated. However, just as in the case of Class One and Class Two risks, if we view this Class in light of additional risks—the risk posed to the non-recipient by the disease, the risk the disease poses to other members of society, the risk that the non-recipient poses of communicating the disease to other members of society, the risks between a government that mandates vaccination and the risk of vaccination to unvaccinated, the risks between government that does not mandate the vaccination and the risk of disease posed to society, the picture, once again, becomes too polycentric to permit coherent resolution under Fletcher's theory alone.

d. **Class Four Risks—In Which Injury Risk is Known, Its Probability Remote, and *Can Be Eliminated by Exercise of at Least Reasonable Care***

The question of whether an expectant mother can safely—both for herself and her in vitro child—take a vaccine provides a ready example of Class Four risks. The Advisory Committee on Immunization Practices (ACIP) states that “the risk of a developing fetus being harmed by vaccination of the mother during pregnancy is only theoretical.”³⁷⁹ Of this heady realm of remote risks, the current medical consensus is that risk from inactivated viral or bacterial vaccine is less than that from vaccines, such as the Mumps-Measles-Rubella (MMR) or varicella, which are made from live attenuated viruses.³⁸⁰ The injury is readily preventable—pregnant women should not get the vaccine while pregnant.³⁸¹ Of course, this raises the possibility that an unvaccinated woman could contract mumps, measles, rubella, or varicella (i.e., “chickenpox”—three of which demonstrably pose a real risk to the development and post-partum health of the child.³⁸² Similarly, though no link has yet to be scientifically established, the elimination of thimerisol (a mercury compound) as a preservative in vaccines after 2001 addressed and eliminated the risk

³⁷⁹ MYERS & PINEDA, *supra* note 352, at 210–11.

³⁸⁰ See *id.* at 211; see also ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES WORK-GROUP ON THE USE OF VACCINES DURING PREGNANCY AND BREASTFEEDING, GUIDING PRINCIPLES FOR DEVELOPMENT OF ACIP RECOMMENDATIONS FOR VACCINATION DURING PREGNANCY AND BREASTFEEDING 1 (2008), available at <http://www.cdc.gov/vaccines/recs/ACIP/downloads/preg-principles05-01-08.pdf> (noting paucity of data, theoretical concerns, and FDA classification of risks to pregnant women). The Secretary of the U.S. Department of Health and Human Services selects a panel of 15 members, based on perceived vaccine expertise, to advise the government on vaccine policy. See Ctrs. for Disease Control & Prevention, Advisory Committee on Immunization Practices (ACIP), <http://www.cdc.gov/vaccines/recs/ACIP/default.htm> (last visited Feb. 24, 2010).

³⁸¹ See MYERS & PINEDA, *supra* note 352, at 212.

³⁸² See *id.* at 212–14.

that vaccination could cause the condition of autism.³⁸³ Yet that move did create a cost for a leading vaccine maker, Wyeth, which closed its Diphtheria-Tetanus-Pertussis (DPT) vaccine manufacturing plant and withdrew from DPT vaccine production rather than retrofit the existing production facility to a thimerisol-free production process.³⁸⁴

Cases at this margin push the economics of enterprise regulation to the edge. How much precaution is required and at what price to the benefit and efficacy of the activity or product? This is at the heart of the so-called “Learned Hand” formula, a metaphor for cost-benefit analysis that he suggested in *United States v. Carroll Towing*.³⁸⁵ Relevance of the enterprise principle could be measured by the Hand formula, expressing it in the form of the following question—is the burden of exercising reasonable care to avoid a remote injury justified by its proportionality to the remote probability of the injury considered and the gravity of the harm in those instances where the remote risk actually eventuates in harm?

Regulation becomes more relevant as the particular injury in question poses a lower burden of avoidance, an increased gravity of harm, or both. Even in cases at the economic margin of the enterprise principle, the corrective justice principle still demands for persons harmed by a vaccine that their palpable injuries be compensated. As with Class Three injuries, the compensation interest is particularly strong where the risk they expect to encounter in vaccine administration [a] eventuates in actual injury because the manufacturer fails to exercise the degree of reasonable care likely to eliminate the known risk and [b] is nonreciprocal—i.e., absent the manufacturer’s reasonable care, the risk the vaccine recipient consented to undertake is magnified substantially. Causation, however, is more problematic in this class of cases because the rarity of the injury may make it difficult, if not sometimes impossible, to have pre-injury data sufficient to satisfy the statistical and scientific demands for causation evidence.

The balance in Class Four cases between society’s interest in disease control and prevention, and the enterprise regulation and corrective justice principles’ protection of individual welfare is not as close as the balance in Class Three cases. Although the risk of injury in Class Four cases is more remote, it is both foreseeable and preventable by the exer-

³⁸³ See *id.* at 148–74; see generally PAUL A. OFFIT, M.D., AUTISM’S FALSE PROPHETS: BAD SCIENCE, RISKY MEDICINE, AND THE SEARCH FOR A CURE 71–73, 102 (2008).

³⁸⁴ ALLEN, *supra* note 358, at 412, 425. As Allen notes, a significant factor in Wyeth’s decision was that Aventis and GlaxoSmithKline “were coming out with products that combined DPT with hepatitis B or Hib in a single convenient shot, and Wyeth wasn’t interested in regearing to make thimerosal-free shots in a factory that it believed was obsolete,” to produce a DPT-only vaccine that was on the way to being redundant. *Id.* at 412.

³⁸⁵ 159 F.2d 169 (2d. Cir. 1947).

cise of the same level of care as we require of motorists and amusement park operators. When a potential risk is both known and avoidable, even if remote in probability, there must be some obligation to exercise at least reasonable care to avoid the risk. While the societal interest in preventing the disease outweighs imposing legal liability to an extent that makes the production and distribution of the vaccine untenable, that interest is not so strong as to displace the victims' compensation interest, which can be maintained without disadvantaging the public vaccine program—particularly where the injury's remoteness suggests a low number of claims. Yet, the precise resolution of these competing principles into concrete policies and rules once again involves a substantial set of polycentric decisions—and once again, while the nonreciprocal risk theory can guide our thinking, the polycentric nature of the problem is not entirely resolvable on nonreciprocal risk grounds alone.

e. Class Five Risks—In Which the Injury Risk is
Unknown, but Could Be Discovered by Exercise of at Least Reasonable Care

The line between Class Five and Class Six risks is a very fine one—it involves classic "Monday morning quarterbacking." It is very difficult in many cases to determine whether something that was not discovered was foreseeable—or not—and at what point in the past to stake the determination. Deciding in the present what should have been foreseen in the past is always a tricky business, even if judges and juries are asked to do this every day in garden-variety negligence cases. But vaccine injuries, particularly those not foreseen at the time a vaccine was designed, approved, and administered, are much more complex factually and causally than ordinary negligence cases. Vaccines are not developed in a vacuum as just another pharmaceutical product. They most often are developed in response to a felt and urgent societal need.³⁸⁶ The decisions that go into the scope of research and risk-planning when vaccines are made—i.e., how far afield we look for potential complications and side effects—will vary depending on the state of medical and other scientific knowledge at the time the vaccine is developed.³⁸⁷ Since that is an ever-

³⁸⁶ See ALLEN, *supra* note 358, at 14–17.

³⁸⁷ A good example of this comes from the history of polio vaccine research. In the early 1900s, medical science had not isolated the microorganism that causes polio. In 1908, the famous blood-type discoverer, Karl Landsteiner, identified the virus. Rockefeller Medical Institute researcher Simon Flexner then set about designing a vaccine. His efforts were hampered, however, because he could not foresee that there might be other strains of the polio virus, not just the one Landsteiner had identified, and therefore, anything he developed would be insufficient to provide adequate protection to vaccinees. See OSHINSKY, *supra* note 378, at 12–19. Flexner also could not foresee that his research subject—the rhesus monkey "is one of the rare primates that cannot contract polio through oral feeding" and "the only sure way to infect this species is to shoot poliovirus directly to its brain or spinal cord, as Flexner had

evolving body of context, the point in time when foreseeability can be assigned is critical to determining whether an unknown risk could have been discovered sufficiently in advance of a vaccination injury that it would have been predicted and prevented.³⁸⁸

An example that demonstrates the fineness of the line separating Class Five and Six risks comes, once again, from the paradigm of polio vaccine research. Polio research scientists at the major pharmaceutical companies and the National Institutes for Health (NIH) realized that by cultivating polio viruses in the kidney tissue of monkeys, a theoretical risk was created that one or more simian viruses might make their way into the vaccine and, thus, into human populations.³⁸⁹ In 1954, Eli Lilly's researchers commenced work to classify the simian viruses they found in monkey kidney tissues.³⁹⁰ The number escalated to forty such monkey-specific viruses when in 1959 a NIH researcher identified SV40 (i.e., Simian Virus number 40), which she found strongly correlated with fatal cancerous tumors in newborn hamsters injected with kidney tissue extract containing SV40.³⁹¹ Researchers erroneously concluded that SV40 was a risk for transmission only through the Sabin vaccine; in fact, it was also transmitted by the Salk vaccine (since it was resistant to the formaldehyde that had been designed to kill the polio virus—not the unknown SV40).³⁹² “This meant that close to 100 million American children had been inadvertently exposed to SV40 in the years between 1954 and 1963, when the government began to carefully screen all new lots of polio vaccine for simian virus.”³⁹³

Of course, it would hardly seem foreseeable that SV40, hitherto unknown, would be imparted by polio vaccines into human populations, at

done”—would lead him to make a series of incorrect “discoveries” about the nature and behavior of polio that would dominate polio studies over the next forty years and seriously hamper the effort to create a vaccine. *Id.* at 18–19.

³⁸⁸ See, e.g., MYERS & PINEDA, *supra* note 352, at 56–60 (discussing the adverse effects caused by the rotavirus vaccine).

³⁸⁹ See DEBBIE BOOKCHIN & JIM SCHUMACHER, THE VIRUS AND THE VACCINE: THE TRUE STORY OF A CANCER-CAUSING MONKEY VIRUS, CONTAMINATED POLIO VACCINE, AND THE MILLIONS OF AMERICANS EXPOSED 72 (2004).

³⁹⁰ See *id.* at 40–42.

³⁹¹ There is still considerable debate about whether SV40, which unquestionably causes fatal cancerous tumors in a variety of laboratory animals, is a cause of human cancer. See ALLEN, *supra* note 358, at 209–13 (noting the continuing controversy and that “[p]olymerase chain reaction, a sensitive molecular detection test, has found SV-40 in many types of cancerous cells”); compare OSHINSKY, *supra* note 378, at 281–82 (noting NIH’s position in 2003 before Congress that “numerous” epidemiological studies “found no correlation between human cancers, including mesothelioma, and exposure to SV40” and that “[a]t this time,” NIH’s view “is that the body of evidence is inconclusive as to the role of SV40 in the development of [human] cancer”) with BOOKCHIN & SCHUMACHER, *supra* note 389 (marshalling contrary information and argument that SV40 is a human carcinogen).

³⁹² See OSHINSKY, *supra* note 378, at 281.

³⁹³ *Id.*

least at the time the first polio vaccines were introduced. But researchers were concerned about “unintended consequences” of the polio vaccine—and the possibility of transferring viruses from monkeys to humans—even before the Salk vaccine’s FDA approval.³⁹⁴ Still, the vaccines continued to be administered—even after SV40 was isolated and suggested as a cause of cancer.³⁹⁵ Further research was not undertaken at the time, in part because both Salk and Sabin deemed SV40 as “harmless.”³⁹⁶ Thus, there is ground in this scenario to find a point in time during the polio vaccination campaign when the government and pharmaceutical manufacturers made the conscious decision to risk exposing vaccinees to unknown—and as time passed, known—simian viruses, and, after 1959, to the specific risk that SV40 may be a human carcinogen.

How can this kind of risk be assessed under the dictating principles and in light of nonreciprocal risk theory? The starting point of this class of risks—as unknown—shifts the regulatory paradigm from the issue of the vaccine industry to take reasonable measures to eliminate known risks, to using reasonable care to discover risks that are as yet unknown, but will eventuate in the future. The relevant principle is recognized in the famous case, *The T.J. Hooper*,³⁹⁷ that an industry will not be allowed to rest upon the laurels of the status quo state of knowledge. Rather, it must maintain reasonable care in efforts to find and recognize tangible improvements to safety.³⁹⁸ Regulation in this class of cases is particularly important because the risk of continuing to administer a vaccine without exercising reasonable care to identify new risks during its post-approval period creates a substantial nonreciprocal risk in vaccine recipients.³⁹⁹

The corrective justice principle continues to have the same compelling role in this class of cases as in the others. Persons harmed by palpable injuries that were not reasonably foreseeable have normally not been

³⁹⁴ See ALLEN, *supra* note 358, at 209 (“[T]he measures designed to protect the world from polio may, in their turn, for all we know, lead to some other quite unexpected consequence which may be to man’s disadvantage, a contemporary of the vaccine trials wrote.”).

³⁹⁵ See OSHINSKY, *supra* note 378, at 281.

³⁹⁶ See *id.*

³⁹⁷ 60 F.2d 737 (2d Cir. 1932).

³⁹⁸ See *id.* at 740.

³⁹⁹ See, e.g., MYERS & PINEDA, *supra* note 352, at 57.

In July 1999, after approximately 1 million children had been immunized with the vaccine, the Centers for Disease Control and Prevention (CDC) recommended that people temporarily stop immunizing infants with RotaShield. The CDC was concerned that the vaccine might be causing a serious bowel disease called intussusception, because an unexpected number of cases of this condition (15) had been reported in children who had received the vaccine.

afforded compensation in the tort system.⁴⁰⁰ However, where the exercise of reasonable care to discover unknown risks would have unearthed, more likely than not, information that might reasonably have been used in time to prevent a particular victim's injury, compensation for that victim is appropriate.⁴⁰¹

The possibility of unknown complications exists for every kind of drug or vaccine. Only time over the course of distribution in the field will reveal the full set of risks presented by any product, particularly vaccines.⁴⁰² In almost any conceivable case, the interest of society as a whole, and the health interest of individuals, strongly outweighs the risk of any vaccine recipient enduring an unforeseen risk. However, the risk to society of having unvaccinated members or an inconsistent vaccine program does not so far outweigh the individual risk that compensation for injury should be denied because of the societal benefits of the vaccine *in toto*—particularly where reasonable care would have led to the identification of the unknown risk. This factor also raises the societal interest from the perspective of creating and funding the programs needed to identify such risks as early as possible in the post-approval, field use of the vaccine.

Once again, the precise resolution of these competing principles into concrete policies and rules involves a substantial set of polycentric decisions—and once again, while the nonreciprocal risk theory can guide our thinking, the polycentric nature of the problem is not entirely resolvable on nonreciprocal risk grounds alone.

⁴⁰⁰ Cf. *Weirum v. RKO General, Inc.*, 539 P.2d 36 (Cal. 1975) (finding liability precisely because the injury was foreseeable).

⁴⁰¹ See *The T.J. Hooper*, 50 F.2d 737 (2d. Cir. 1932).

⁴⁰² The breadth and depth of clinical trials and controlled field testing is one of the key factors in determining the learning curve on any new vaccine introduced. See ALLEN, *supra* note 358, at 429–31; JULIE MILSTIEN & BRENDA CANDRIES, THE ECONOMICS OF VACCINE DEVELOPMENT AND IMPLEMENTATION: CHANGES OVER THE PAST 20 YEARS, (2001), at 6–9, available at http://www.who.int/immunization_supply/introduction/economics_vaccineproduction.pdf. Trials must not only be large enough (some, for example, over 100,000 persons) to demonstrate a vaccine's efficacy; to adequately put the developers on a course to uncover the unknown risks, they must also be large enough to detect statistically significant increases in harms. See *id.* at 6–7. For illustration, Milstien describes how even after a 10,000-person clinical trial, RotaShield, “a tetravalent rhesus-based recombinant rotavirus vaccine licensed by the FDA,” was linked to “increased reports of intussusception in recipients of the vaccine” after 1.8 million doses, an “event could not have been picked up in any reasonably-sized clinical trial.” *Id.* at 7–8. Today's vaccines demand far more comprehensive clinical and field trials than the polio vaccine developers undertook—12 to 15 years of development at a cost to the developer approaching \$1 billion. See *The Vaccine Industry: An Overview*, VACCINEETHICS.ORG, http://www.vaccineethics.org/issue_briefs/industry.php (last visited Feb. 13, 2010).

f. Class Six Risks—In Which the Injury Risk is *Unknown*,
but Could *Not* Have Been Discovered Even by
Exercise of Reasonable Care

This Class of cases presents a *sui generis* issue for applying the enterprise regulation principle. The other classes involve measures of manufacturers' reasonableness—in knowledge of a risk, precaution against a risk, or prediction of a risk. In Class Six, reasonable care—indeed, care of any level—plays no role whatsoever. The risks in this Class are unknown and unknowable until they eventuate in actual harm. Thus, traditional notions of regulating an enterprise to compel more responsible conduct do not figure into the equation. The question here is whether the enterprise should bear the harm caused by its product—basically a choice between a negligence régime (and thus no liability) versus a strict liability régime (always liability). Considerations here most clearly and markedly make the nonreciprocal risk model, by itself, inadequate to reach a model of fair distribution of harm among those who benefit from the relevant risks.⁴⁰³

Persons injured by palpable injuries whose risk is both unknown and unknowable *ex ante* have traditionally not been afforded compensation in the tort system. This is particularly so when no amount of vigilance on the part of the tortfeasor would result in detection and prevention of the harm. However, persons harmed by vaccines continue to have palpable injuries that merit compensation under principles of corrective justice.

From the nonreciprocal risk perspective, it is arguable that the individual assumes a greater risk in submitting to vaccination than does the vaccine's progenitors. Yet the risk to society averted by vaccination—and thereby effectuating the societal principle—complicates the equation. Focusing on reciprocity of risk may in this Class, as in the others, lead us into a Gordian knot of polycentric decisions. That does, however, end our effort to rethink vaccine liability in a stalemate among worthy principles of tort law or with resort only to an end-run instrumentalist solution. Recently, Professor Gregory Keating proposed a rethinking of Fletcher's theory itself to create a practical paradigm for making principled decisions about how the law should deal with injury.⁴⁰⁴ As Professor Keating succinctly states, his approach “argue[s] against Fletcher's identification of fairness in the choice between negligence and strict liability with the presence or absence of reciprocity of risk, and in favor of focusing on the fair distribution of” harms—or “the costs of accidental injury among those who benefit from the imposition of the underlying

⁴⁰³ See Keating, *supra* note 346, at 1860.

⁴⁰⁴ *Id.* at 1858.

risks.”⁴⁰⁵ In so doing, Professor Keating’s approach, which we shall call “distribution of the costs of nonreciprocal harms” based on notions of “reciprocity of harms,”⁴⁰⁶ gives us a more philosophically sophisticated approach to grapple with injuries that result from the polycentric nature inherent in complex public policy and science decisions.

Given the severity and life-long nature of many vaccine-related injuries, corrective justice may, like the enterprise principle, require here an analysis based on fair distribution of harms among those who benefit from the risky activities that created them.⁴⁰⁷ The possibility of unknown complications exists for every kind of drug or vaccine. Only time over the course of distribution in the field will reveal the full set of risks presented by any product. In almost any conceivable case, the interest of society as a whole, and the health interest of individuals, strongly outweighs the risk of any vaccine recipient enduring an unforeseen risk. However, the risk to society of having unvaccinated members or an inconsistent vaccine program does not so far outweigh the individual risk that compensation for injury should be denied because of the societal benefits of the vaccine *in toto*. This is arguably the case even where no amount of care would protect the vaccinated from risk, because the group health interest still outweighs the individual health interest when viewed in the aggregate. In that sense, application of this principle, just as with the other two principles, militates not for a régime of no-liability, but rather, for one based on fairly distributing burdens of harm among those who benefit from the risk-creating activity.⁴⁰⁸

In the following subsection, we discuss how Congress might use the perspective afforded by Professor Keating’s transformation of nonreciprocal risk theory into the “distribution of the costs of harms” approach to identify parameters of a comprehensive policy—not just for vaccine liability—but for vaccine research, development, approval, distribution, and injury compensation as an integrated program.

C. *Implications of a “Distribution of the Costs of Nonreciprocal Harms” Approach to Rethinking Vaccine-Injury Liability*

1. Beyond Nonreciprocal Risks to Nonreciprocal Harms

The basis for Professor Keating’s approach is explained extensively in his article,⁴⁰⁹ and will not be repeated here. Instead, we will explain how his approach extends—and supersedes—basic nonreciprocal risk theory for the context of polycentric problems. We will then, in the spirit

⁴⁰⁵ *Id.*

⁴⁰⁶ *Id.* at 1859.

⁴⁰⁷ *See id.*

⁴⁰⁸ *See id.*

⁴⁰⁹ *See id.*

of that approach, suggest generally that the vaccine area be re-thought by Congress holistically, and state specifically a number of features that we believe should be adopted consistent with the theory of “distribution of the costs of nonreciprocal harms.”

In his critique of Fletcher, Keating notes that starting and ending with Fletcher’s emphasis on risk reciprocity advances the ultimate solution of the cost of injuries little beyond “a common law régime which resembles the common law of accidents at the turn of the twentieth century”⁴¹⁰—trapping us within a framework that, as “a kind of nostalgia,” shuts us off from exploring solutions “both within and beyond the tort law of accidents” and from “seeing a wide variety of administrative schemes” as part of “an agenda for progress and reform.”⁴¹¹

This is particularly the case where “[t]he diverse aims of a plurality of persons” are involved—as they are in the Six Classes of vaccine-injury risk we have developed—because those aims “cannot be converted into a single scale, so that we may make collectively the same kinds of judgments that we each make individually.”⁴¹² While “[t]he reasonableness of risk impositions . . . turns on the way that the impositions reconcile the competing claims of liberty and security,”⁴¹³ risk impositions in polycentric policy matters like vaccination “arise against a background of mutually beneficial cooperative conduct among”⁴¹⁴ persons who inhabit simultaneously “‘communities of risk’” (wherein “potential injurers are also potential victims”—i.e., infectors of and the infected with a vaccine-targeted disease)⁴¹⁵ and inter-community risk position (wherein “[r]isks are imposed by members of one community on members of another community when potential injurers and potential victims engage in distinct activities, which do not impose equivalent risks on one another”—i.e., the community of the unvaccinated, the community of those to be vaccinated, the community of vaccine manufacturers, and the community of governmental public policy regulators).⁴¹⁶

In mediating fairness in this context, the legal approach cannot aspire to eliminate the nonreciprocal nature of inter-community risks, which are—as we have seen in specific taxonomy of vaccine injuries—reasonable risk impositions because, consistent with the Social Compact Principle, “those risks are to the long-run advantage of the prospective victims that they imperil, but not mutually beneficial in the strong sense

⁴¹⁰ *Id.* at 1860.

⁴¹¹ *Id.*

⁴¹² *Id.* at 1866.

⁴¹³ *Id.* at 1868.

⁴¹⁴ *Id.* at 1872.

⁴¹⁵ *Id.* at 1873.

⁴¹⁶ *Id.* at 1874.

that reciprocal risks are.”⁴¹⁷ The general conduct underlying these risks—the creation of vaccines and the mandate of general vaccination to prevent disease transmission both to society and to the individuals of whom it is comprised—is not itself unjustifiable or unreasonable.⁴¹⁸

We do not want law to discourage vaccination and thereby encourage disease epidemics, but law would do precisely that if it were to treat the vaccination programs as creating unreasonable risks. To the contrary, the nonreciprocity of risk does not answer the central question that liability for vaccine injury must address: What is “a fair distribution of *harm*”?⁴¹⁹ As Professor Keating notes, “the distribution of harm is more important than the distribution of risk” because, among other things, “[i]t is the ripening of risk into harm—not the chance of such ripening—that is the real burden of risk.”⁴²⁰ According to Professor Keating:

Risk rarely impairs the ability to pursue a conception of the good over the course of a complete life. It is harm—physical injury and death—that wreaks havoc with people’s lives. Risk can be fairly distributed, even when the costs of the accidental harm which results from that risk is unfairly concentrated, and the distribution of harm matters more than the distribution of risk. Fairness requires that those who benefit equally from the imposition of a risk share equally in the burden of that risk—the loss of life, limb, and property that is its cost.⁴²¹

It therefore is that “the costs of harm, if not harm itself, may be fairly distributed by the enterprise form of strict liability.”⁴²² Enterprise liability, however, has become a somewhat loaded—and distorted—term in debates about public policy and tort law; it has been looked at primarily as a form of redistribution of wealth.⁴²³ We prefer to view the matter in the broader sense of determining the scope of financial responsibility for harms among risk communities—as the fair distribution of harms, i.e., “the fair distribution of the costs of accidental injury among those who benefit from the imposition of the underlying risks.”⁴²⁴ We call this approach the “distribution of the costs of nonreciprocal harms” based on notions of “reciprocity of harms.”⁴²⁵ As we observed in Part III.B.3.

⁴¹⁷ *Id.* at 1881.

⁴¹⁸ *Id.* at 1883.

⁴¹⁹ *Id.* at 1884.

⁴²⁰ *Id.*

⁴²¹ *Id.*

⁴²² *Id.* at 1886.

⁴²³ See, e.g., *id.* at 1897 n.85.

⁴²⁴ *Id.* at 1858.

⁴²⁵ *Id.* at 1859.

above, this approach give us a more philosophically sophisticated approach to grapple with injuries that result from the polycentric decisions inherent in complex decisions of public policy and science.

2. Distribution of the Costs of Vaccine-Injuries and Broader Policy Implications

Considering the question of vaccine injury liability as a question of fair distribution of the costs of the risks of harm generated by vaccines and vaccination programs allows us to sharpen the inquiry we undertook using Fletcher's theory. By looking at the problem as one of fair distribution of the costs of harm rather than imposition of tort liability on those who create nonreciprocal risks, we open out the paradigm beyond the confines of tort law liability adjudications and into the realm of a more holistic perspective. That perspective starts from the question "of who benefits—of what relevant community of benefit is or ought to be for purposes of apportioning the costs of accidents."⁴²⁶ The answer to that question is not a legal one, in the sense of being the ineluctable product of our application of the principles of enterprise regulation, corrective justice, and social compact. Rather, the consideration of that question "*can* be given such widely varying construction, so that fixing the proper scope" of the community of benefit (which would be called "the enterprise" in the parlance of enterprise liability theory) would be a "normative and political judgment."⁴²⁷

"Judgments about communities of benefit," observes Professor Keating, "are eminently political judgments about how we should order our lives in common."⁴²⁸ Indeed, "[b]ecause risky activities radiate their benefits out across a variety of actors, and because the boundaries of communities of risk may be fixed in narrower and broader ways, the idea of fairness can give rise to industry-and society-wide liability as well as to enterprise liability in tort."⁴²⁹

The distribution of the costs of nonreciprocal harms approach opens up new horizons in policy setting. It opens the opportunity for Congress, making political decisions guided by principle, to consider vaccine injury within a broader policy context for vaccines and vaccination generally, outside of tort law, outside of a narrow view of protecting vaccine makers from bankruptcy versus compensating those who either fall within a vaccine injury-table or can summon the scientific resources to prove that

⁴²⁶ *Id.* at 1907. As Professor Keating observes, "[i]dentifying the relevant community of benefit and burden—the relevant enterprise—is a standing challenge for any form of enterprise liability. *Id.* at 1906.

⁴²⁷ *Id.* at 1907.

⁴²⁸ *Id.*

⁴²⁹ *Id.*

a specific administration of a specific vaccine was the but-for cause of a specific injury. In the following subsection, we propose that Congress recognize that vaccine-injury liability is not a *sui generis* question, but rather, merely a subset of issues within the larger need for establishing a comprehensive domestic vaccine policy—a holistic approach to planning the nation’s vaccine strategy, identifying the need for new vaccines and modifications to existing vaccines, providing coordinated and efficient research and development, ensuring the cost-effective and high-quality manufacture and distribution of vaccines, enhancing the reporting and quality of reporting of suspected vaccine-related injuries, changing the notion of compensation from lump-sum money payments to individualized long-term care and rehabilitation for individuals who may have been injured by vaccines, and establishing a source for funding, not merely for compensation for vaccine-injuries, but for a comprehensive program for vaccine development, delivery, monitoring, and continuous improvement.

3. Toward a Holistic National Vaccine Policy

Using the analytic tools we propose, Congress can rethink not only how to deal with vaccine injuries, but also how, as part of the same process, to rethink our national policy towards vaccination. Until now, much of vaccine policy has been made either by ad hoc federal efforts or by the states. Although an impressive network of regulation has been created in this patchwork process, the threats of global pandemics, vaccine shortages, fewer pharmaceutical companies working on vaccines, and rising costs of supporting systematic vaccination programs demand that Congress step back and take the look at the big picture with the objective of creating a coherent, coordinated, and compatible vaccine policy for all aspects of vaccines and vaccination.⁴³⁰ In this subsection, we outline some of the important issues that deserve congressional attention and suggest some specific features within a national vaccine policy that would, in its implementation, maximize the important principles we have discussed at length.

⁴³⁰ Others have called for intra-sector and international collaboration on vaccine research, development, and administration, but at a much more conceptual and soft-focused level. See, e.g., Gary R. Noble, *The Promise of Vaccines and the Influenza Shortage of 2004—Public and Private Partnerships*, in *ETHICS AND THE PHARMACEUTICAL INDUSTRY* 352–60 (Michael A. Santorso & Thomas E. Gorrie, eds., 2005) (calling for intra-sector and international collaboration on vaccine research, development, and administration, but at a much more conceptual and soft-focused level).

a. From Vaccine-Injury Claims to a Comprehensive National Vaccine Policy

The resolution of vaccine-injury claims should be thought of as an integral part of vaccine research and development. The presentation of claims should be encouraged not just for purposes of compensating the injured. Claims presentation should become an integral, matter-of-course step in a government-industry coordinated effort in pursuit of continuous improvement in vaccine efficacy and vaccine safety. Only when the government and industry (whose combined and intertwined efforts in the vaccine area we shall call “the government-industry vaccine complex”) are not on the defensive against claims, but rather, welcoming of them as part of a holistic vaccine program, can the approach to vaccine injuries be brought out of the swamp created by the caricature of the problem in the self-proclaimed battle lines of “tort reformists” pitted against “trial lawyers.”

Such caricatures actually impede an intelligent discussion of liability. For example, Dr. Paul Offit appears to blame tort liability for the consolidation of manufacturers in the vaccine market: “The revolution in liability law—designed to coerce companies to make safer products by threatening financial punishment—was causing companies to abandon safe products vital to the nation’s health.”⁴³¹ However, the state of the vaccine industry is the result of much more complicated—and important—factors than potential vaccine liability, as Offit appears to concede: “Unfortunately, despite protections afforded by the National Vaccine Injury Compensation Program, pharmaceutical companies are gradually abandoning vaccines.”⁴³² Vaccine manufacturers have shown a very pragmatic way of dealing with their liability experience—they pass on those expenses by raising the per-dose cost of the vaccine.⁴³³ This is an example of how the “narrow” view of vaccine liability encourages policy-makers to overlook the complexity of the context—which in the case of the government–industry vaccine complex is the result of other, more significant factors:

Liability was no doubt a problem and an expense, and it was easy to trash the trial lawyers, unless you happened to be defended by one. But lawsuits were not, in fact, the main force that had winnowed out vaccine makers.

The trouble with the American vaccine system was that the safe, effective shots we relied upon to protect us

⁴³¹ OFFIT, THE CUTTER INCIDENT, *supra* note 31, at 182

⁴³² *Id.*

⁴³³ See *id.* at 181 (noting that after a wave of pertussis vaccine-injury suits in the 1970s and 1980s, the pharmaceutical manufacturers raised the per-dose cost from seventeen cents to eleven dollars).

from the scourges of infectious disease were expensive and difficult to make—yet they had to be cheap enough to be widely used or they would not protect the community. Vaccines were square pegs that didn't fit into the triangular holes of market capitalism.⁴³⁴

Thus, consolidation of players among pharmaceutical companies engaged in vaccine manufacture, let alone research and development of new vaccines, were reduced because “these firms were getting out of the business because it wasn’t profitable” enough for their management and their shareholders.⁴³⁵ Indeed, the one-time nature of the transaction poses a particular problem when viewed from philosophy of the business enterprise that exalts maximizing of profits above all other objectives: “[P]reventive medicine isn’t too popular, because after you vaccinate people that’s it, right?”⁴³⁶ As another federal official put it, “You could develop the tenth cholesterol drug and make a zillion dollars even if you have a lot of competition. If you make a vaccine all you’re doing is asking for trouble. There are a few dedicated people who will do it but it’s not a born winner.”⁴³⁷ As Arthur Allen observes:

The transformation of the vaccine industry reflected trends in the overall transformation of late-twentieth-century American industry in general. Pharmaceutical companies expanded, merged, consolidated, and cast off less profitable ventures, including “loss leaders” like vaccines. Biologicals barely qualified as footnotes in the official histories of these firms. Vaccines were rarely blockbusters; in 2005, they made up 10 percent or less of the sales of the four big companies. These remaining firms had long historic commitments to vaccines.⁴³⁸

There are, as Allen observes, “many complex reasons why vaccine making incurred so many risks and made relatively meager profits”: [1] “The organisms were fickle”; [2] it is expensive and time consuming to wait for an outbreak of a disease to test a vaccine’s power on people; [3] some vaccines, like those for the flu, may have to be reformulated each year because flu strains, and their relative prevalence, change from year to year; [4] vaccine “producers ha[ve] no idea how much vaccine” will be purchased by public health sector; [5] in many instances, vaccines are

⁴³⁴ ALLEN, *supra* note 358, at 426.

⁴³⁵ *Id.* at 427 (quoting former federal vaccine licensing officer Don Hill).

⁴³⁶ *Id.*

⁴³⁷ *Id.* at 427–28 (quoting Allen’s interview with Paul Parkman, May 2004).

⁴³⁸ *Id.* at 428.

purchased by a single buyer: the federal government. This inherently puts pressure on the price of a vaccine.⁴³⁹

We must substantially change the terms of this conversation if vaccination is to continue providing the most stabilizing public health criterion in human history.⁴⁴⁰ We do not need an ad hoc approach to specific vaccines, federal regulators, vaccine funding, distribution channels, and strategic planning for vaccine-responsive disease—these must become facets of a comprehensive vaccine policy crafted by Congress.

This approach has not received much attention in the law review literature, but it has been the subject of recommendations to Congress by the Congressional Research Service (CRS). CRS has called upon Congress to legislate a comprehensive vaccine policy—which starts with unifying vaccine matters in an administrative agency dedicated to dealing with strategic vaccine planning. As it stands, vaccines are regulated, in overlapping fashion, by a hodgepodge of nearly a dozen federal agencies and their sub-agencies. As a 2005 report to Congress describes it:

[T]here is no central authority for vaccine policy within the federal government. In the Department of Health and Human Services (HHS), the National Vaccine Program Office (NVPO) coordinates vaccine-related activities and the FDA is responsible for the regulation of human vaccines and other biologics.

The FDA—mostly within its Center for Biologics Evaluation and Research (CBER)—bears the responsibility for vaccine regulation, primarily under the authorities granted the Secretary of HHS in the Federal Food, Drug and Cosmetic Act and the Public Health Service Act. To receive a license from FDA to market a vaccine, the sponsor (often the manufacturer) must demonstrate to the satisfaction of FDA that the product is safe and effective for human use. Data to support those claims come, primarily, from clinical trials. Once a product is approved, the sponsor must comply with detailed Good Manufacturing Practices (GMPs) and regulations concerning the surveillance of adverse reactions among individuals receiving the vaccine. FDA policies regarding vaccine approval are similar to FDA policies for prescription drugs.

⁴³⁹ *Id.* at 428–30.

⁴⁴⁰ See Edward Greg Koski, *Renegotiating the Grand Bargain—Balancing Prices, Profits, People, and Principles*, in SANTORRO & GORRIE, *supra* note 430, at 393–403.

The National Institutes of Health (NIH) conducts intramural vaccine research and development and funds research in universities. For example, the CDC, charged with protecting the health and safety of the population, houses the National Immunization Program (NIP) and its ACIP, which work to coordinate nationwide activities, including the Vaccines for Children (VFC) program and the state immunization grants program. Following a congressional directive in P.L. 99-660, in 1986 HHS established a National Vaccine Program within the Public Health Service's Office of the Assistant Secretary for Health to coordinate vaccine research, development, safety and efficacy testing, and production and procurement across federal agencies. Transferred organizationally in 1994 to CDC and then back to HHS, the National Vaccine Program Office manages the Inter-Agency Vaccine Group and the National Vaccine Advisory Committee, and works toward achieving the National Vaccine Plan [published in 1994], which involves "pursuing the prevention of infectious diseases through immunizations," maintains the Strategic –National Stockpile (SNS), which includes some vaccines against bioterror agents. The National Vaccine Injury Compensation Program (VICP), which is jointly administered by the Health Resources and Services Administration (HRSA), where it is located, and the U.S. Court of Federal Claims and the U.S. Department of Justice, "provides compensation for injuries judged to have been caused by certain vaccines." Also administered from HRSA is the Smallpox Vaccine Injury Compensation Program, set up in 2003.⁴⁴¹

It would seem to go without saying that consolidating these far-flung aspects of vaccine policy-making and regulation into a single agency dedicated to that task would create circumstances far more favorable to develop a comprehensive policy of vaccine strategy. In addition, the potential conflicts of interests of advisory committees to the

⁴⁴¹ SUSAN THAUL, CONGR. RESEARCH SERV., VACCINE POLICY ISSUES 3–4 (2005), available at <http://www.fas.org/sgp/crs/misc/RL31793.pdf> (text and footnotes combined). The web of regulators, however, doesn't stop there. Other regulators include: The Department of Defense, the Department of Veterans Affairs, the U.S. Agency for International Development, and state and local governments.

Id. at 4.

various federal agencies regulating vaccines may diminish should one agency be responsible for overall vaccine regulation.

To this end, the Institute of Medicine (IOM) has called for the creation of a National Vaccine Authority.⁴⁴² The envisioned agency would quarterback all aspects of vaccine research, development, production, distribution, and acquisition, and would provide a centralized vaccine production facility to be operated by contractors—including those currently engaged in vaccine manufacture and other innovators who might be willing to join and have something to offer under these more well-controlled economies of vaccine production.⁴⁴³

⁴⁴² Institute of Medicine Council, Statement on Vaccine Development, in STACEY L. KNOBLER ET AL., BIOLOGICAL THREATS AND TERRORISM: ASSESSING THE SCIENCE AND RESPONSE CAPABILITIES, 264–68 (2002), available at http://www.nap.edu/openbook.php?record_id=10290&page=262.

⁴⁴³ *Id.* Among the IOM's suggestions, the tasks of the National Vaccine Agency (NVA) would encompass—in addition to “identify[ing] mechanisms to expand current forms of liability protection for the adverse effects of vaccines, including expansion of federal efforts for indemnification of manufacturers”—developing a coherently and integrally related set of functions which currently are scattered to the four winds (if they are even currently addressed at all), including:

- 1) Define the need
- 2) Assess the market
- 3) Establish priorities for U.S. CVI vaccine development in conjunction with the global CVI
- 4) Characterize desired vaccine products
- 5) Assemble intellectual property rights
- 6) Advance CVI product development through the private sector
- 7) Conduct in-house vaccine-related research and development
- 8) Assist companies in the production of pilot lots of vaccine
- 9) Support clinical testing and field trials of candidate vaccines
- 10) Transfer CVI-related vaccine technology to developing country manufacturers
- 11) Train U.S. and overseas nationals in the principles of vaccine development, pilot manufacture, and quality control
- 12) Arrange and contribute to the procurement of NVA vaccines
- 13) Evaluate and redefine needs
- 14) Represent the United States in international CVI forums, such as the Consultative Group
- 15) Conduct in-house vaccine-related research and development
- 16) Assisting companies – particularly small biotechnology firms— in the production of pilot lots of vaccines
- 17) Arranging and contributing to the procurement of National Vaccine Authority vaccines
- 18) Producing vaccines when market forces are not sufficient to facilitate large-scale production
- 19) Facilitating communications among relevant contributors to vaccine research and development, including academic research efforts, manufacturers, regulatory agencies, and the public. The Authority should not interfere in any way with public or private research or development efforts to create new vaccines. It should be available to assist such efforts when opportunities arise
- 20) Interacting with other public and private entities to assure a timely and effective system for storage and distribution of appropriate vaccines

Consolidating numerous vaccine-related services is the foundation for effective and enduring solutions to liability and other inter-related challenges facing government-industry vaccine complex. In particular, the optimal approach to the polycentric quandary of vaccine-injury liability is to refine and expand the NCVIA program by eliminating resort to courts (other than one appeal of right for a vaccine Special Master's determination) and by expanding its coverage to all vaccines.⁴⁴⁴ Some might argue that this would be unfairly detrimental to claimants. To the contrary, by making three other significant adjustments in the program—as to the required proof of injury, damages caps, and funding source for the program (and the NVA generally)—the question of vaccine injury is taken out of tort law entirely⁴⁴⁵ and inserted, instead, into the public health context in which it has always belonged.⁴⁴⁶ Specifics of these—and other features—of an NVA program are discussed in the following subsections.

b. Causation and Determination

Compelling claimants of vaccine injury to prove causation⁴⁴⁷ has been a major stumbling block that has hampered NCVIA's success as an alternative to—and in our proposal, the replacement for—litigation.⁴⁴⁸ The nature of proving causation is extraordinarily difficult for vaccine

21) Creating a government-owned, contractor-operated national vaccine facility. The IOM Council believes this is one in a spectrum of public-private ventures by which a NVA could facilitate development and production of needed vaccines. The conduct of research, development, production, and distribution of vaccines in such a facility should be the responsibility of a private contractor selected by a competitive bidding process. This effort should not preclude other collaborations with private contractors in other public-private projects. Funding for such a facility will initially require a substantial financial investment. Although a major priority for this facility would be to develop vaccines necessary to protect American troops and for use against bioterrorism, the facility also should be charged with production of other vaccines that are in scarce supply and would not otherwise be provided in the public or private sectors. In some cases in which there are few private sector uses, the facility would become the principal source of such vaccines. In other cases, a variety of public and private partnerships could be undertaken to produce needed vaccines.

See id.

⁴⁴⁴ Other points ripe to be addressed by amendment including those made in our comparison of the original Swine-Flu Act and the NCVIA. *See supra* Parts II.A., II.B.

⁴⁴⁵ *See Keating, supra* note 346, at 1907 (referring to “abolish[ing] tort law entirely and replac[ing] it with a New-Zealand style scheme of society-wide liability”).

⁴⁴⁶ As such, cases like *Holder v. Abbot Labs.*, 444 F.3d 383 (5th Cir. 2006), which permitted parents of vaccine-injured children to bypass the NCVIA process and sue the suppliers of preservatives to vaccine manufacturers in state or federal court on the reasoning that a preservative contained in childhood vaccines was only a “component of vaccine,” not a vaccine, and therefore, parents’ claims against preservative manufacturers for vaccine-related injuries to their children were not governed by NCVIA, 42 U.S.C. § 300aa-11(a), need to be legislatively overruled.

⁴⁴⁷ *See* 42 U.S.C. § 300aa-13(a) (2000).

⁴⁴⁸ Strong, *supra* note 341, at 430, 437–38, 441–48.

claimants who lack the resources, scientific knowledge, and institutional bench strength to unravel the complex bodily and chemical functions underlying vaccine injuries that on their face are probative of cause and effect.⁴⁴⁹ At least one writer, who has assisted with representation of vaccine-injury claimants under the NCVIA, proposes that claimants not be required to meet an almost insurmountable burden of proving that a vaccine caused their injuries by a preponderance of the evidence, but rather—and in the spirit of the legislative history of the original NCVIA in 1986—that Congress adopt a “benefit of the doubt” standard.⁴⁵⁰ The proposal is well motivated—but does it really go far enough? For one thing, the standard does not make clear whether we are talking about giving the claimant the benefit of the doubt that she has shown “but for” causation or “substantial factor” causation—the traditional tort-law terminology for the stricter and less-strict standards. Surely it would seem that the Act favors a “substantial factor” formulation, for, as the Federal Circuit has noted, in “the system created by Congress, . . . close calls regarding causation are resolved in favor of injured claimants.”⁴⁵¹ The Federal Circuit’s articulation of the NCVIA burden appears closer to substantial-factor than but-for test.⁴⁵²

However, in the “distribution of the costs of harms resulting from nonreciprocal risks” in which we have examined vaccine liability, the focus on distributing the costs of harm, instead of on coercive punishment of “wrongdoers” and tortfeasors, “relax[es] the fairly stiff requirement of causation characteristic of negligence liability in tort.”⁴⁵³

⁴⁴⁹ See *id.* at 437, 441–48; see also *Hodges v. Sec’y of Dep’t of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993) (claimant’s burden of proving causation in cases where injuries do not fall within the Vaccine Injury Table “is heavy indeed” and requires “heavy lifting” claimant); Gordon Shemin, Comment, *Mercury Rising: The Omnibus Autism Proceeding and What Families Should Know Before Rushing Out of Vaccine Court*, 58 AM. U. L. REV. 459, 474–76 (2007).

⁴⁵⁰ See Strong, *supra* note 341, at 452, 457.

⁴⁵¹ *Capizzano v. Sec’y of Dep’ of Health & Human Servs.*, 440 F.3d 1317, 1324 (Fed. Cir. 2006).

⁴⁵² See *id.* (citation omitted). The Federal Circuit expressly endorsed the substantial factor test in both Table Injury and non-Table cases, but noted that for non-Table cases, “in order to show that the vaccine was a substantial factor in bringing about the injury, the petitioner must show ‘a medical theory causally connecting the vaccination and the injury.’ There must be a ‘logical sequence of cause and effect showing that the vaccination was the reason for the injury.’” *Shyface v. Sec’y of Dep’t of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999) (citations omitted).

⁴⁵³ Keating, *supra* note 346, at 1890. As Professor Keating articulates the theoretical underpinnings of this argument, “[f]airness favors dispersing the costs of blameless accidents among all who create similar risks of such accidents”—both blameless accidents and accidents caused by wrongdoers should be “pooled.” *Id.* at 1897. Professor Keating elaborates on the rationale for de-emphasizing causation:

This last argument of fairness highlights both the fact that enterprise liability relaxes the requirement of causation, and also the fact that the logic of fairness at work in enterprise liability criticizes—as arbitrary and unfair—the traditional tort insistence

Responsibility for discrete acts of negligence is not the appropriate model; rather, in the model of vaccine injury liability, we argue that the focus is on the integrity of the individual within a vaccine policy of integrity. Consistent with that objective, we think the better course is to change the emphasis on the burden of proof rule to reflect a true “close-calls” intent by shifting the burden to the government in vaccine injury proceedings to prove by a preponderance of the evidence that the claimant’s injury was *not* caused by a vaccine. Particularly with the powerful resources of an NVA as we have envisioned it, the government would be in a far better position to efficiently and effectively marshal the scientific, epidemiological studies data to rebut a *prima facie* presumption of causation. Of course, claimants would still need to satisfy a preliminary burden to show that they received the vaccine and the time frame within which the alleged injury occurred and medical diagnosis and confirmation of the injury was made—much as NCVIA claimants currently do in establishing their eligibility to proceed under so-called Injury Table claims.⁴⁵⁴ In fact, the current causation standard as articulated by the Federal Circuit might well still provide a fair screening device if implemented as the claimant’s *prima facie* case under a burden of production of evidence—with the government having the burden to rebut a presumption of causation by a preponderance of the evidence.⁴⁵⁵ Although this is a subtle change, it is important in setting a pro-compensation atmosphere for an expanded vaccine injury-program, and one that should ameliorate some of the daunting complexities facing claimants, reduce the large amount of attorneys’ fees expended by claimants and indemnified by the Vaccine Injury Fund, and incentivize the government to undertake an aggressive, proactive program of epidemiological studies in order to be ready to defend against vaccine injury claims.

Even with modified causation, the NCVIA’s adjudicatory process needs to be amended as part of a comprehensive national vaccine policy. All vaccine-injury claims need to proceed under the auspices of a vac-

on a fairly rigid sort of causation. When cause and cause alone distinguishes those who injure from those who do not, luck and luck alone distinguishes those who bear liability from those who escape it. Insisting on actual causation of harm as a necessary condition of liability when luck and luck alone determines who causes harm is arbitrary and unjustifiable. There is no good reason why a person unfortunate enough to have her carelessness issue in massive injury should bear massive loss, while many others who have been identically culpable are spared all responsibility.

Id.

⁴⁵⁴ See 42 U.S.C. § 300aa-11(c)(1)(C)(i)-13(a)(1)(B) (2006); Strong, *supra* note 341, at 437 (noting that the government “can still defeat a petitioner’s claim, however, if it can prove by a preponderance of the evidence that the petitioner’s injury was actually due to “factors unrelated” to the vaccine”).

⁴⁵⁵ This is similar to the burden borne by the government currently in rebutting presumptions of causation arising in claims made under the Injury Table of the NCVIA. See, e.g., *Shyface*, 165 F.3d at 1344 (quoting 42 U.S.C. § 300aa-13(a)(2)).

cine injury court constituted by the NVA. There should be no suits in either the federal or state courts. The challenging issues of vaccine cause-and-effect need to be entrusted to a process that is far more sophisticated for making such determinations, has heightened expertise requirements for the adjudicators, and provides stakeholders for the injured and for the governmental-industrial vaccine complex to have an equal choice in the selection of the ultimate decision makers in an arbitral process. The qualifications for Special Masters should be set at a level of expertise relevant to the kinds of issues facing vaccine-injury adjudicators. Buy-in to the exclusive adjudicatory system will be enhanced if the NVA provides that both stakeholders for the injured and for the governmental-industrial vaccine complex get to designate a scientific expert willing to serve as an arbitrator on a vaccine panel (a “vaccine-injury board of adjustment”) and deliberate with a highly qualified Special Master appointed by the NVA to each case. This will put the decision of difficult questions of science into the hands of true experts, but will allow the parties to have input into the deliberations by having experts of their choosing serve on an adjudication panel as “requested Special Masters” to decide the case along with the Special Master designated by the NVA. This process is similar to the appointment both of system boards of adjustment under the Railway Labor Act and of the tradition of “tripartite medical review boards developed in safety-sensitive industries years ago to permit medical professionals to make an informed determination of whether an individual meets the medical qualifications for employment,”⁴⁵⁶ which, one of us has previously demonstrated, provides an excellent structure for the composition of expert panels to arbitrate technical claims involving medical and allied sciences.⁴⁵⁷

c. Information

A comprehensive vaccine policy requires the gathering and careful assessment of millions of vaccinations in the United States, and abroad. Although the federal government has made some significant efforts in the last 20 years to improve the collection of data, there is much that an NVA, with a sufficient budget, could do to vastly improve the data needed to assess vaccine safety and vaccine injury risk. As *U.S. News &*

⁴⁵⁶ Jeffrey A. Van Detta, “*Typhoid Mary*” Meets the ADA: A Case Study of the “Direct Threat” Standard Under the Americans With Disabilities Act, 22 HARV. J. L. & PUB. POL’Y 849, 944–945, 949 (1999).

⁴⁵⁷ See *id.* at 936–58 (advocating a “bold stroke” . . . to designate the tripartite medical review process” used in safety-sensitive industries for years in determining fitness-for-duty questions “as the means by which ‘direct threat’ determinations are made in safety-sensitive occupations and industries,” rather than entrusting direct-threat cases arising under the Americans with Disabilities Act to judges or juries).

World Report described last year, the two-tiered data collection system utilized by all of the federal regulators identified above in Part I.B.:

The CDC's current system of detecting rare problems is hit or miss. Perhaps the crudest tool is the Vaccine Adverse Event Reporting system, which relies on doctors and patients to file a report if they suspect symptoms have been caused by a vaccine. Many problems filed with VAERS have nothing to do with vaccinations; real adverse events often go unreported. A better monitoring system, the agency's Vaccine Safety Datalink, regularly scans 5.5 million anonymous health records provided by managed care organizations to see whether new vaccines are associated with a spike in certain conditions.⁴⁵⁸

The Vaccine Safety Datalink (VSD) has proven the more useful tool of the two for policy planning purposes, but because it encompasses only vaccinees who belong to health maintenance organizations, and even then only those primarily in the West and Southwest, it is incomplete.⁴⁵⁹ While VSD has flaws, it provides more refined data than VAERS. At least one physician has reported that to test the credibility of the VAERS process, he submitted a vaccine injury report that stated that after taking a certain vaccine, he was transformed into the "Incredible Hulk."⁴⁶⁰ The report was accepted, and after alerting CDC of his test, he was told that the report would remain in the system—and part of data compilations that use the VAERS database—until he formally requested in writing that it be removed.⁴⁶¹ A recent study in a leading pediatrics journal concluded after an exhaustive analysis of VAERS reports related to autism that many who report autism events appear to be coordinating with vaccinees or their families who seek to influence the database to support their positions in litigation.⁴⁶² A commentator on that study observed

⁴⁵⁸ Deborah Kotz, *Vaccines Get New Scrutiny: Vaccinations are Supersafe, but Maybe Not All at Once, or for Certain Children*, U.S. NEWS & WORLD REP., Nov. 11, 2008, at 3.

⁴⁵⁹ See OFFIT, AUTISM'S FALSE PROPHETS, *supra* note 383, at 91; MYERS & PINEDA, *supra* note 352, at 62–66. Myers and Pineda note that only eight large HMOs post patient records to the VSD, covering only 5.5 million participants in the states of Washington, Oregon, California, Colorado, Minnesota, and Massachusetts. *Id.* at 62. They also discuss five significant limitations on the usefulness of VDS data because of the limited sample, numerically and geographically, and because of the HMO context, which leaves "few non-vaccinated people for comprehensive comparisons." *Id.* at 65.

⁴⁶⁰ See How Vaccine Litigation Distorts the VAERS Database, http://scienceblogs.com/insolence/2008/01/how_vaccine_litigation_distorts_the_vaer.php (Jan. 18, 2008, 8:30 EST).

⁴⁶¹ See *id.*

⁴⁶² See Michael J. Goodman, PhD & James Nordin, MD, MPH, *Vaccine Adverse Event Reporting System Reporting Source: A Possible Source of Bias in Longitudinal Studies*, 117 PEDIATRICS 387–90 (2006). Another important function of the NVA would be to do a much more thorough job of educating the public of why vaccines are necessary than the CDC and

that VAERS was never designed to be a tool for establishing vaccine policy:

This study once again hammers home the inherent unreliability of the VAERS database as a tool for longitudinal studies of the rate of vaccine-related complications. Not only can anyone access it and enter reports without verification, but there is no denominator, which means testing for causality is not even possible with VAERS.

The VAERS database may serve a very important function as an early warning system for potential vaccine-related complications that were not picked up in initial clinical trials used to gain FDA approval, but it was never intended to be a means of following the rates of these complications in a longitudinal fashion. Even if it had been, the ease with which the rate of entry of various complications can be influenced by media hype and activists, as well as the indiscriminate use of the database by litigants, long ago destroyed any usefulness that VAERS might have had for such a purpose.⁴⁶³

Therefore, it is critical that NVA devote substantial expertise, time, and resources to create a truly useful national reporting system and database. This may require proposing that Congress enact special exemptions from HIPAA restrictions⁴⁶⁴ in order to optimize the usefulness of the database in policy making—and as an agreed upon information source for assessing vaccine-injury claims. In addition, the NVA will need to develop responsible protocols for using data generated from any source. Misapplication and misuse of vaccine-related data poses serious problems for a coherent national vaccine policy.⁴⁶⁵

other current federal agencies have done. See Stephen Novella, Pockets of Vaccine Non-Compliance in California, Apr. 1, 2009, <http://www.sciencebasedmedicine.org/?p=436>.

⁴⁶³ How Vaccine Litigation Distorts the VAERS Database, *supra* note 460.

⁴⁶⁴ See *id.*; MYERS & PINEDA, *supra* note 352, at 65–66.

⁴⁶⁵ See ALLEN, *supra* note 358, at 318–26. Allen’s trenchant observation nicely encapsulates the data-use problem:

The vaccine safety system established by [the CDC] . . . was a wonderful tool, but it was a dangerous one, too, a sorcerer’s apprentice that cranked out the data *in the absence of a social agreement about how to assess the answers it produced*. If the Vaccine Safety Datalink spat out an equation of risk for a vaccine, what did you do with that? If no amount of risk is acceptable, how could we possibly convince drug companies to sink millions into developing vaccines that were almost sure to have at least *some* risk? How decided what level of risk was acceptable?

d. Services Instead of Payouts

One of the problems with the NCVIA program that does not receive a great deal of attention in law journals is the form of relief that is available to claimants whose claims are sustained. We have discussed these limitations in Part I.⁴⁶⁶

At least one anti-vaccine advocacy group, the National Vaccine Information Center, has objected to the way in which the prospective monetary awards for care are structured, as its president testified before Congress, because they are no more than “the Program’s best guess of what the child will require for life,” because “no one can precisely predict what the future needs of a vaccine-injured child will be or what future technologies or therapies may contribute to their care.”⁴⁶⁷ Vaccine injuries tend to be serious, long-lasting, and debilitating. A perusal of the NCVIA Injury Table, listing just the most well-settled complications of the childhood vaccines which it encompasses, makes that clear.⁴⁶⁸ Rather than putting parents or caretakers in the position of having to risk private investment advice for lump sums, or having to be supervised (and bear fiduciary duties) in the long-term management of ear-marked annuities—an approach more consistent with our examination of the animating principles and the fair distribution of the costs of vaccine-caused harms—Congress should legislate a Vaccine-Injury Care and Rehabilitation Program (VICRP). The purpose of a VICRP would be to reduce the emotional, temporal, and financial strains on vaccinees and their families who must deal with the long term effects of serious vaccine injuries.⁴⁶⁹ Those whose claims for vaccine injury are sustained under the revised adjudicatory system we have proposed should be given a choice between a one-time, lump sum payment with caps developed by the NVA in proportion to the present costs of dealing with the injury; or—a far better option—opting into the managed health-care, rehabilitation, and occupational therapy programs offered by a VICRP. The Department of Veterans Services programs provide the conceptual model

⁴⁶⁶ See U.S. Dep’t of Health & Human Services, Health Res. & Serv. Administration, National Vaccine Injury Compensation Program, Filing a Claim With the VICP, http://www.hrsa.gov/vaccinecompensation/filing_claim.htm (last visited Feb. 13, 2010).

⁴⁶⁷ See BARBARA LOE FISHER, NAT’L VACCINE INFORMATION CTR., TESTIMONY BEFORE THE HOUSE SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES, Sept. 28, 1999, available at <http://www.nvic.org/injury-compensation/congresstestimony.aspx>.

⁴⁶⁸ See U.S. Dep’t of Health & Human Services, Health Res. & Serv. Administration, National Vaccine Injury Compensation Program, Vaccine Injury Table, <http://www.hrsa.gov/vaccinecompensation/table.htm> (last visited Feb. 13, 2010).

⁴⁶⁹ Familial stress and financial ruin in dealing with post-vaccination injuries are well described at ALLEN, *supra* note 358, at 371–400; OFFIT, AUTISM’S FALSE PROPHETS, *supra* note 383, at 225–28; James R. Laidler, M.D., *Through The Looking Glass: My Involvement With Autism Quackery*, AUTISM WATCH, <http://www.autism-watch.org/about/bio2.shtml> (last visited Feb. 13, 2010).

for such a comprehensive VICRP program.⁴⁷⁰ Furthermore, that model is particularly appropriate—one can certainly see an analogy in the sacrifices that individual military personnel make both on behalf of themselves and the security society as a whole to the sacrifices made by those who submit to vaccines;⁴⁷¹ and viewed from that perspective, such systems are strong realizations of the three principles we have examined in this Article. Such a program would vindicate each of the three principles, and be consistent with the “distribution of the costs of nonreciprocal harms” approach. Funding for such an ambitious program, however, should, consistent with the enterprise regulation and societal principles, come primarily from the pharmaceutical industry itself, rather than principally from tax revenues, as described in the next subsection.

e. Funding—A Modest Proposal for a “Donative Excise”

Currently, compensation for vaccine injury—provided the vaccine is a “childhood” vaccine, is administered to a child after birth, and is on the table of covered vaccines—is drawn from the National Vaccine Injury Compensation Fund, into which taxes of 75 cents per dose of vaccine paid by purchasers of vaccine have amassed \$2.5 billion, and since 1988 has paid a total of \$1.79 billion to 2,365 claimants (while paying no compensation to 1,154 claimants), whose attorneys were awarded \$67 million in statutory attorneys’ fees, and denying compensation 2,229 claimants, whose attorneys were awarded \$41 million in statutory attorneys’ fees.⁴⁷²

⁴⁷⁰ See, e.g., Michael J. Jacksonis et al., *War, Its Aftermath, and U.S. Health Policy: Toward a Comprehensive Health Program for America’s Military Personnel, Veterans, and Their Families*, 36 J.L. MED. & ETHICS 677, 679–81 (2008) (describing programs); Donna Lee Yesner & Stephen Ruscus, *Selling Medical Supplies and Services Through the Department of Veterans Affairs Federal Supply Schedule Program*, 37 PUB. CONT. L.J. 489, 489 & n.2 (2008);

⁴⁷¹ See Jacksonis et al., *supra* note 470, at 678. The analogy between the purpose and function of Veterans compensation programs to the NCVIA is also extensively discussed by Strong, *supra* note 341, at 452–59. Of course, in application, the Veterans process is far from perfect; and the NVA can learn from its shortcomings and mistakes. See, e.g., Amy N. Fairweather, *Compromised Care: The Limited Availability and Questionable Quality of Health Care for Recent Veterans*, HUM. RTS., Spring 2008, at 2; Rory E. Riley, *Preservation, Modification, or Transformation? The Current State of the Department of Veterans Affairs Disability Benefits Adjudication Process and Why Congress Should Modify, Rather Than Maintain or Completely Redesign, the Current System*, 18 FED. CIR. B.J. 1 (2008); Howard Roitman, *Overview of Veterans Administration Disability Law*, NEV. LAW., Nov. 2008, at 6; Scott Simonson, Note, *Back From War—A Battle For Benefits: Reforming VA’s Disability Ratings System for Veterans with Post-Traumatic Stress Disorder*, 50 ARIZ. L. REV. 1177 (2008); Cynthia L. Williams, *The Continuous Readiness Process and Compliance: Ensuring Compliance Program Effectiveness in the Veterans Health Administration*, J. HEALTH CARE COMPLIANCE, Jan.–Feb. 2008, at 65.

⁴⁷² See Regina Moreland, *National Vaccine Injury Compensation Program: The Potential Impact of Cedillo for Vaccine-Related Autism Cases*, 29 J. LEGAL MED. 363, 368–69 (2008); HRSA, National Vaccine Injury Compensation Program, Statistics Report, Jan. 20, 2009, http:/

The modest proposal that we make to fund the comprehensive vaccine policy program to be administered by the NVA is a different kind of revenue-raising device than the current per-dose vaccine surcharge. While the Societal Principle supports maintaining that as one (but not the only) source of vaccine-injury compensation, it also supports a broader distribution of the costs of the nonreciprocal risk of vaccine injuries. We propose that the enabling legislation for the comprehensive program provide that most of its funding come out of a contribution—one that the applicable tax laws can be amended to treat as a deductible charitable donation—from the profits that every pharmaceutical manufacturers derive from FDA-approved products that are not on the World Health Organization's list of essential drugs.⁴⁷³ Congress could amend the Food and Drug Act to require that any pharmaceutical company that has one or more FDA-approved drugs, or has an application pending for FDA-approval of one or more drugs, must make the annual contribution to retain approval or to have applications processed. By directing the contributions towards drugs that are not “essential” within the WHO parameters, such a measure would not endanger the public health—particularly since the lure of profitability of so many non-essential drugs would overcome any company's hesitation or resistance to making the contribution.⁴⁷⁴ Simply put, there is still so much money in developing and manufacturing non-essential drugs that an excise from those profits would have negligible effect on drug availability—and, because the excise would be targeting only WHO non-essential drugs, there would be no pretext for increasing the price of or disrupting the supply of truly essential medicines, as defined by the WHO.⁴⁷⁵

/www.hrsa.gov/vaccinecompensation/statistics_report.htm. Moreland asserts that, including autism-claims, the Fund is facing up to 5,000 new claims which, she alleges, could bankrupt the Fund, particularly if autism becomes a compensated injury. *Id.* at 369–70.

⁴⁷³ For the latest list on the World Health Organization's website, separated by adult and pediatric medicines, see WHO, WHO Model Lists of Essential Medicines, <http://www.who.int/medicines/publications/essentialmedicines/en/> (last visited Feb. 13, 2010).

⁴⁷⁴ *The Lancet* published a detailed study of the pharmaceutical industry in 2002 that noted high profitability and year 2000 sales by “leading companies exceed[ing] U.S. \$320 billion,” of which “[o]ver 46% of the market value was from” North American sales. David Henry & Joel Lexchin, *The Pharmaceutical Industry as a Medicines Provider*, 360 LANCET 1590, 1591–92 (2002).

⁴⁷⁵ Some might question whether it would be constitutional—i.e., within Congress's interstate commerce powers or violative of the Equal Protection or Due Process Clauses—to impose such a “cover charge” for access to mandatory FDA processes. We have decided that extended explorations of the constitutionality of aspects of their comprehensive national vaccine program proposal are beyond the scope of this Article—we may take them up in a subsequent article. However, for now, we offer the following observations: Since the standard of judicial scrutiny of such matters asks simply whether Congress is regulating interstate commerce, as opposed to local commercial activity, and has a rational basis for imposing the requirement and making distinctions among essential drugs, non-essential drugs, and vaccines, it appears unassailable that congressional action of this sort would pass muster under the Com-

In addition, the pharmaceutical industry spends over \$30 billion annually in advertising and in direct-marketing of new drugs to consumers.⁴⁷⁶ This is a dubious practice at best.⁴⁷⁷ Congress members and consumer advocates have warned that “drug ads are intended to prompt people to diagnose themselves with chronic quality-of-life problems like insomnia or restless leg syndrome; lead people to pressure their doctors for prescriptions for expensive brand-name drugs to treat these conditions; and steer people away from cheaper generic pills.”⁴⁷⁸ In addition to vast sums for television and print ads, even internet direct-advertising has become a \$2 billion industry expenditure.⁴⁷⁹ Congress should seriously consider extending the donative excise we propose to this well-spring of finance, the engine that drives up sales of non-essential, designer drugs.⁴⁸⁰

This proposal would have distinct advantages. For instance, great concern has been expressed over the financial impact of autism claims on the current vaccine injury fund. With some 5,000 autism claims pending, and the average non-autism award under the NCVIA approaching \$800,000, serious questions are raised about maintaining the fund’s solvency if, at some point in the future, researchers establish one or more links between particular vaccines and the development of autism. To date, that has not happened; and the vaccine court recently rejected any causal connection in three recent cases.⁴⁸¹ However, research is ongoing

merce Clause as it has been interpreted since Justice Jackson’s opinion in *Wickard v. Filburn*, 317 U.S. 111 (1942), as well as under the Due Process and Equal Protection Clauses under the reasoning of the line of precedent extending back to Justice Douglas’ opinion in *Williamson v. Lee Optical*, 348 U.S. 483 (1955). Of course, the political practicalities of surmounting industry resistance and strong-arming in lobbies pose much more daunting challenges.

⁴⁷⁶ See Julie M. Donohue et al., *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, 357 NEW ENG. J. MED. 673, 673–81 (2007).

⁴⁷⁷ See *id.*

⁴⁷⁸ Natasha Singer, *Citing Risks, Lawmakers Seek to Curb Drug Commercials*, N.Y. TIMES, July 27, 2009, at B1.

⁴⁷⁹ See *Will Pharma’s Big Ad Spend Move Online?*, THE E-MARKETER, Apr. 22, 2008, <http://www.emarketer.com/Article.aspx?R=1006199; Big Pharma Spends More on Advertising than Research and Development, Study Finds>, Sci. DAILY, Jan. 7, 2008, <http://www.sciencedaily.com/releases/2008/01/080105140107.htm> (noting that advertising expenditures exceeded \$33 billion in 2004 , twice the sum pharmaceutical companies reported spending on R & D during 2004 (citing Marc-André Gagnon & Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, PLoS MED., Jan. 3, 2008, <http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0050001>)).

⁴⁸⁰ See Singer, *supra* note 478, at B6 (including the chart “As Seen on TV—and in Print,” which lists the 10 brands on which the most advertising money was spent in 2008, the uses of the drugs and their manufacturers, and the total 2008 sales of each drug).

⁴⁸¹ The British medical journal, *The Lancet*, which originally published the study linking the MMR vaccine to autism, formally retracted the study in February 2010. Gardiner Harris, *Journal Retracts 1998 Paper Linking Autism to Vaccines*, N.Y.TIMES, Feb. 3, 2010, at A9. This retraction will likely make establishing causation in autism cases that much more difficult, if not impossible. Moreover, judges recently ruled in three separate cases that there is no

ing. Even if such a causal link were established, the NVA could deal with this and preserve solvency by routing such claims exclusively through the VICRP program that we have proposed. Indeed, the main thing that most autistic children—and their parents—need is assistance in the home; learning, occupational, and behavioral therapy; and reliable medical advice. The VICRP can provide that, properly funded by the non-essential prescription profit contribution, rather than paying out large lump sums under the current vaccine injury fund.

Beyond the realm of non-essential drugs, Congress could also extend this donative excise to the incredible profits that are—and will be for some time—generated from the new generation of designer vaccines that target rare or less imminently life-threatening or epidemic-prone diseases. These vaccines are being marketed at astronomical prices—and once again, the sheen of great profitability would hardly be dimmed by requiring the companies and their shareholders benefiting by FDA approval of such vaccines to use some of those profits to maintain the integrity of a holistic vaccine regulatory approach under the direction of the NVA.

A good example of the kind of vaccine whose profit-generating ability could be tapped to help fund a comprehensive national vaccine policy is Gardasil, the latest in vaccines that has reached the public after expensive research and development by the one of the world's largest multinational enterprises in pharmaceuticals, Merck, and which is being sold at prices far above those that current childhood vaccines command.⁴⁸² Similarly, Sanofi-Aventis expects its recently introduced meningitis vaccine to generate sales approaching \$600 million, and Novartis has a meningitis B vaccine that some financial analysts estimate could reach sales of up to \$3.5 billion annually—more than the entire sales of all traditional children's vaccines in the United States combined.⁴⁸³

causal link between thimerosal and autism. *See* Donald G. McNeil, *3 Rulings Find No Link to Vaccines and Autism*, NYTIMES.COM, Mar. 12, 2010, <http://www.nytimes.com/2010/03/13/science/13vaccine.html?emc=eta1>.

⁴⁸² Garadasil, however, is virtually unique—while no widespread pandemic called for its development and approval, it was raced through the process as if it were. *See* Elisabeth Rosenthal, *Evidence Gap: Drug Makers' Push Leads to Cancer Vaccines' Rise*, N.Y. TIMES, Aug. 19, 2008, at A1.

⁴⁸³ *See* Jeanne Whalen, *Translating Genes to Drugs: Novartis May Be One of the First to Get a Payoff From Latest Know-How*, WALL ST. J., Dec. 17, 2007, at A12. Meningitis B is not exactly pervasive—worldwide reports of persons annually afflicted range from 20,000 to 80,000, with a 10% mortality rate and, for survivors, long-term brain damage, hearing loss, and limb-function loss. *Id.* Novartis has used gene-mapping technology to find genes that “would direct the body to make proteins that would generate antibodies capable of killing the bacteria” and the researchers “used high-speed computers to home in on 350 such genes on the surface of the bacteria.” *Id.* After several years of injecting these proteins into mice, Novartis’s researches have “found that several of the proteins stimulated a powerful immune response in mice.” *Id.*

Prevnar, a vaccine targeted against infantile pneumonia, meningitis, and assorted ear and blood-stream infections, sold nearly \$2 billion in doses in 2006, and sales continue to rapidly increase.⁴⁸⁴ Despite traditional poor-mouthing by pharmaceutical concerns with vaccine divisions about the limitations on size and revenue in the vaccine market, industry analysts reviewing these latest vaccines and examining the DNA-based vaccines in development have predicted the vaccine industry “‘to more than double’ by 2010”—with \$10 billion in sales just by Merck and Wyeth.⁴⁸⁵

Moreover, Congress could take the next step and address the problem of recurring instances of shortages in the basic, yet more price-controlled, vaccines such as flu, diphtheria, tetanus, chickenpox and measles.⁴⁸⁶ Congress could require pharmaceutical companies with the requisite capital and facilities to remain in, rejoin, or take up vaccine manufacture under the direction of NVA, as a condition of holding or seeking FDA approval of WHO non-essential drugs. This would remove market volatility from a commodity that is not just another product, but rather, a national resource produced in an activity of the highest calling of public service.

To those who may see this as based on over-reaction, exaggeration, or socialism, we need only point out one of many areas where the unregulated discretion of private enterprise to continue or discontinue essential health-care with the trend of the corporate philosophies du jour for maximizing shareholder profit. In July 2009, national reports broke the story that: “[a] global shortage of a radioactive drug crucial to tests for cardiac disease, cancer and kidney function in children is emerging because two aging nuclear reactors that provide most of the world’s supply [of the isotope technetium-99m] are shut for repairs.”⁴⁸⁷

Industry has idly permitted this situation despite full knowledge that the isotope—without which the quality of medical care will be “dropp[ed] . . . back into the 1960s”—is “used in more than 40,000 medical procedures *a day* in the United States” alone.⁴⁸⁸ The problem is not an inadequacy of technology, or excessive regulation of nuclear reactors, or governmental interference—the problem is the shareholder of pharmaceutical concerns—shareholders who do not share the vision that early twentieth century medical companies exemplify corporate social

⁴⁸⁴ See Aaron Smith, *Vaccines: Hot “New” Business for Drugmakers*, CNN MONEY.COM, May 30, 2007, <http://money.cnn.com/2007/05/30/news/companies/vaccine>.

⁴⁸⁵ See *id.*

⁴⁸⁶ See, e.g., Bernard Wysocki, Jr., *The Lack of Vaccines Goes Beyond Flu Inoculations—Eight Shortages Since 2000; Fewer Shots for Everything from Tetanus to Chickenpox*, WALL ST. J., Dec. 8, 2003, at A1.

⁴⁸⁷ Matthew L. Wald, *Radioactive Drug for Medical Tests is in Short Supply*, N.Y. TIMES, July 24, 2009, at A10.

⁴⁸⁸ *Id.* at A10 (emphasis supplied).

responsibility. As Dr. Dale E. Klein, a member of the United States Nuclear Regulatory Commission, recently observed, “a big pharmaceutical company ‘can make more on Viagra in two days than on tech-99m in a year.’”⁴⁸⁹ Without Congress using the gate-key to the FDA approval process as a major incentive, similar problems have occurred—and can be expected to increase—within the vaccine realm.⁴⁹⁰

As a final note, the federal government’s latest vaccine response—encouraging the rush manufacturing by pharmaceutical companies of swine-flu vaccine—demonstrates the problems with the current chaotic, fractured approach, both in terms of crafting an effective, holistic vaccine policy—as well as, specifically, figuring out how to handle liability and fund compensation in any manner approaching the fine balances we have established in this Article.⁴⁹¹

CONCLUSION

The problem of vaccine-liability involves clashing interests and polycentric policy decisions. The instrumentalist approach that had placed protecting manufacturers from legal liability as its foremost goal—leading to the NCVIA and more recent FDA-preemption theories—distorts the nature of the issue by shifting the focus away from the relationship of distributing vaccine-injury costs to the larger problem of integrating injury compensation into a coherent national policy of vaccine funding, research, development, distribution, and reporting of complications.

When considered in light of three fundamental principles relevant to developing rules in this area (enterprise regulation, corrective justice, and social compact) and the polycentric nature of dealing with the balancing of those principles in the six classifications of risk into which vaccine-related injuries can be sorted, the problem is clearly one that requires political policy-making from a holistic perspective. Congress needs to act, and needs to act now, to transcend their previously disjointed and episodic legislative response to a randomly arising assortment of lobby-

⁴⁸⁹ *Id.* at A14.

⁴⁹⁰ See, e.g., Denise Grady, *Swine Flu Plan Would Put Some at Head of Line for Vaccine*, N.Y. TIMES, July 30, 2009, at A20 (discussing a severe rationing plan recommended by an advisory panel to the CDC “in the likely event that not enough swine flu vaccine will be available to immunize every American in time for the expected surge of cases this fall and winter” and noting that advisory panel members “struggled and argued about what to do if there was a severe shortage of the vaccine and the eligibility requirements had to be drawn even tighter,” leaving “some shaking their heads in confusion and dismay”); see generally Donald G. McNeil, Jr., *U.S. Declares Health Emergency as Cases of Swine Flu Emerge*, N.Y. TIMES, Apr. 27, 2009, at A1.

⁴⁹¹ See Mike Stobbe, *Legal Immunity Set for Swine Flu Vaccine Makers—In Past, Thousands Filed Claims Contending They Suffered Side Effects*, SFGATE.COM, July 17, 2009, <http://www.sfgate.com/cgi-bin/article.cgi?f=/N/a/2009/07/17/national/a161229D59.DTL>.

ists and vaccine-related crises. Instead, as the role of the vaccine promises to increase substantially in the genetic engineering world of a rapidly increasing global population and concentration of people in cities, Congress needs to step back and rethink a series of vaccine-related issues in order to assure the integrity of the individual, society, and of the pharmaceutical development and manufacturing industry. Only by re-thinking vaccine-injury liability within this larger context, and legislating to address such questions as part of comprehensive regulation to ensure vaccine accessibility and continued development, can Congress advance the dialogue beyond partisan questions driven by trial lawyers and tort reformists—a myopic focus that threatens, metaphorically, to allow Washington to burn while Congress fiddles.

Vaccines have become a fundamental aspect anchoring the modern human condition at its optimal realization—not a luxury, nor a cause against which social non-conformists can rally to rebel, nor just another profit center or loss leader for pharmaceutical industry shareholders. Holistic vaccine policy must wield the power of Congress to control the pharmaceutical industry's access to the riches awaiting those who gain the favor of FDA-drug approval in order to finance a national program of vaccine research, development, manufacture, distribution, and injury compensation.

A Coda

When Edward R. Murrow enquired of Dr. Jonas Salk over a half century ago, “who owns the patent on the vaccine?”—Dr. Salk replied, with a note of surprise and incredulity at Murrow’s question: “Well, the people, I would say. There is no patent. Could you patent the sun?”⁴⁹²

Vaccination is a national resource. Congress should act to preserve it as one—while recognizing the needs of those whose injuries are the individual sacrifices that make it possible to secure the general public health through vaccination programs. We have laid the theoretical foundation and suggested a path for doing just that. One must fervently hope that half a century after Dr. Salk, Congress will at last act comprehensively.

⁴⁹² OSHINSKY, *supra* note 378, at 210–211, 316 n.62 (discussing and quoting from a transcript of Dr. Jonas Salk’s February 1955 appearance on *See It Now*, a CBS news show hosted by the legendary Edward R. Murrow); *but see* Stephan Kinsella, *Patent and Penicillin*, MISES ECON. BLOG, June 22, 2006, <http://blog.mises.org/archives/005216.asp> (asserting that “the idea of patenting the vaccine had been directly analyzed and the decision was made not to apply for a patent mainly because it would not result in one.” (quoting JANE SMITH, *PATENTING THE SUN: POLIO AND THE SALK VACCINE* (1990))).