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## Rethinking Liability for Vaccine Injury

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### I. INTRODUCTION

#### A. “A Pandemic is Declared”<sup>1</sup>

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.<sup>2</sup> To date, there have been 17,855 confirmed or probable cases of H1N1 infection and 45 deaths in the United States alone.<sup>3</sup> More than 70 countries have now confirmed human infection with novel H1N1 flu.<sup>4</sup> On June 11, 2009, the World Health Organization (“WHO”) raised the worldwide pandemic alert level to Phase 6.<sup>5</sup> The alert level is based on the spread of the virus, as opposed to the severity of the illness.<sup>6</sup> However, at this time, as H1N1 is a new virus, there is little human immunity to it. Moreover, there is no vaccine to prevent the spread of the virus. The Centers for Disease Control also warns that the virus could cause significant illness and deaths during the flu season in the fall and winter.<sup>7</sup>

The government is working aggressively to manufacture an H1N1 vaccine.<sup>8</sup> Such a vaccine would undoubtedly help 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? Currently, atypical but possible side-effects from the “generic” flu vaccine include severe allergic reactions or Guillian-Barré syndrome, a rare and occasionally fatal

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<sup>1</sup> <http://www.cdc.gov/H1N1FLU/>

<sup>2</sup> Id. The virus originated in Mexico, and has genes similar to those found in swine flu viruses in Europe and Asia, as well as avian genes and human genes. Id. Scientists refer to this as a “quadruple reassortant” virus. Id.

<sup>3</sup> <http://www.cdc.gov/H1N1FLU/>. Last updated June 16, 2009.

<sup>4</sup> Id.

<sup>5</sup> “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.” [http://www.who.int/csr/disease/avian\\_influenza/phase/en/](http://www.who.int/csr/disease/avian_influenza/phase/en/).

<sup>6</sup> <http://www.cdc.gov/H1N1FLU/>

<sup>7</sup> <http://www.cdc.gov/h1n1flu/update.htm>.

<sup>8</sup> Id.

paralytic condition.<sup>9</sup> Yet, all too often, significantly debilitating and sometimes deadly side-effects result from other vaccines which are routinely administered to the population. In an effort to prevent an avalanche of state-law tort claims against manufacturers of those vaccines, Congress has stepped in to create 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. As discussed below, these kinds of systems undoubtedly are flawed. Yet, they at least provide a potential method for acknowledging and providing some compensation to those injured by vaccines.

In other contexts where 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. 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.

Not surprisingly, the pharmaceutical industry — and their shareholder investors — would prefer no transactional costs for litigation; and with the NCVIA-style programs allowing claimants to opt for a regular tort lawsuit after having spent a period of time in the vaccine court, state-tort lawsuits remain a potential problem. In pursuit of a régime in which pharmaceutical companies would enjoy a 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 by the Food and Drug Administration (FDA). Should an H1N1 vaccine be created, 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. Even if Congress did not undertake to so act, preemption due to FDA approval of the vaccine would undoubtedly aggressively be argued 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 if, when, and how tort liability should be distributed 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 of the NCVIA program with no compensation at all. It then suggests a more appropriate compensation model for injured victims that borrows from the NCVIA, yet takes into consideration the unique role of vaccines within the pharmaceutical industry, medicine, and society as a whole. The authors propose that Congress should re-examine vaccine liability, not in

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<sup>9</sup> *Id.* See James M. Wood, et. al, *Product Liability Protection for Stem Cell Research and Therapies – A Proposal*, 18 NO. 1 HTHLAW 1, 8 (2005).

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 stone of modern public health out of the partisan arena of treating it as a manufacturer’s liability problem – pitting the perceived self-interests of “trial lawyers” against the pro-industry lobby of “tort reformists” -- and developing comprehensive legislation to shift the paradigm to one of holistic strategic planning, with the objective of assuring the maintenance of current vaccines, the development of new vaccines, the incentivizing of the expensive R & D required for vaccine development and renewal, and the protection of the public who both undertakes substantial risks and 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 that were supposedly eradicated by 20<sup>th</sup> 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 U.S.<sup>10</sup> and continuing socio-economic problems abroad. Moreover, 21<sup>st</sup> century society has been confronted with new, continually changing, and potentially devastating strains of pandemic flu virus, 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 as a cornerstone of societal stability and progress, rather than as an isolated pocket of tort or administrative law? These are the fundamental questions that drive the authors’ rethinking of vaccine-injury liability.

## B. Introduction To The Re-Examination

The liability scheme for vaccines was generally set out as a matter of pre-emptive federal law over 30 years ago. Before that time, traditionally, plaintiffs seeking compensation for vaccine-related injury used the civil tort system. Often, plaintiffs would bring a claim

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<sup>10</sup> The anti-vaccine movement consists both of those parents who oppose compulsory vaccination on grounds of personal autonomy as well as fear of injury (particularly from thimerisol preservatives), and parents who do not vaccination children because they are home schooled and therefore the state school-registration 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 (2007). See also *Jacobson v. Commonwealth of Massachusetts* 197 U.S. 11, 31 n. (1905) (lengthy footnote to Justice Harlan’s majority opinion reciting the history of compulsory vaccination around the world since creation of England’s National Vaccine Establishment in 1808)

against the manufacturer of the vaccine, alleging strict products liability, negligence or breach of warranty.<sup>11</sup> Unfortunately, these suits yielded inconsistent results<sup>12</sup> among plaintiffs and made vaccine manufacturers wary of entering (or staying in) the vaccine-production market without some measure of protection in the absence of liability insurance.<sup>13</sup> Over the past thirty years, the federal government has repeatedly responded to the variety of issues born of the American tort system and has directed the course of vaccine manufacturer liability, as well as compensation for those injured as a result of vaccination, with several vaccination liability and compensation programs. These include the National Swine Flu Immunization Program of 1976 (“Swine Flu Act”),<sup>14</sup> the NCVIA,<sup>15</sup> the Phase I smallpox vaccination program instituted by the administration of George W. Bush in 2003 and its subsequent compensation program,<sup>16</sup> and most recently, the Public Readiness and Emergency Preparedness Act, passed in 2005.<sup>17</sup>

While other commentators have reviewed the positive and negative aspects of these congressional programs, they have done so from the confines of the purely instrumentalist standpoint of the programs themselves. That is to say, the extant scholarship on vaccine-related tort liability proceeds from the author’s view of the practical allocation of risks, as determined by the author’s sense of the way things ought to be. It is on that instrumentalist foundation that commentators have suggested a variety of way to “fix” the problems inherent in these programs.<sup>18</sup>

However, principle, rather than instrument, is the animating force that drives the analysis in this article – and justifies, indeed mandates, that the vaccine liability question be treated now, and treated anew. For it is the very plethora of commentary that suggests that the current instrumentalist approach of these congressional policies does not yield satisfactory solutions that command a broad range of support. Rather, they lack persuasiveness precisely because they seem fashioned in the moment, rather than founded on principles of justice shared in the collective consciousness. Principles implicated by the problems of vaccine-created injury include the general principle of corrective justice - *i.e.*, that the tort system should fully compensate victims of torts – and the defining principle of non-reciprocal risks – *i.e.*, that injury-causing conduct should be deemed tortious not only in those activities where a “reasonableness” standard was not met, but also in those scenarios where the injury-causing conduct, no matter how socially

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<sup>11</sup> See Fay F. Spence, *Alternatives to Manufacturer Liability for Injuries Caused by the Sabin-type Oral Polio Vaccines*, 28 WM. & MARY L. REV. 711, 716-725 (1987).

<sup>12</sup> Compare *Reyes*, 498 F.2d 1264; *Givens v. Lederle*, 556 F.2d 1341 (5<sup>th</sup> Cir. 1977); *Davis v. Wyeth Lab., Inc.*, 399 F.2d 121, 128 (9<sup>th</sup> Cir. 1968) with *Johnson v. American Cyanamid co.*, 718 P.2d 1318, 1325-26 (Kan. 1986); *Magee v. Wyeth Lab., Inc.*, 214 Cal.App.2d 340 (1963).

<sup>13</sup> See generally H.R. Rep. No. 908, 99<sup>th</sup> Cong., 2d Sess. 4, 6 (1986), reprinted in 1986 U.S. CODE CONG. & ADMIN. NEWS 6344.

<sup>14</sup> National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380, 90 Stat. 1113 (1976) (codified as amended at 42 U.S.C.A. § 247b).

<sup>15</sup> National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1-300aa-34 (1989).

<sup>16</sup> Smallpox Emergency Personnel Protection Act, Pub. L. No. 108-20, 117 Stat. 638 (2003) (codified as amended at 42 U.S.C.A. §§ 233, 239 & 239a-h ).

<sup>17</sup> Public Readiness and Emergency Preparedness Act, Pub. L. No. 109-148, Div. C, Dec. 30, 2005, 119 Stat. 2818 (codified as amended at 42 U.S.C.A. § 247d-6d) (2005)).

<sup>18</sup> See *infra* Part III. A. (discussing the various criticisms of these congressional programs).

utilitarian, imposes on its victims risks that are seriously disproportionate to them and are beyond the victims' abilities (socially, economically or scientifically) to minimize or avoid.

This article thus examines vaccine-related liability specifically in the context of Professor George P. Fletcher's nonreciprocal risk theory of corrective justice, as modified into a model of distributing the costs of harms among those who benefit from the risks imposed by vaccine programs.<sup>19</sup> In other words, rather than proposing changes that mirror the instrumentalist, or outcome-driven, goals of these programs, this article offers modifications that illuminate Fletcher's proposition: the focus should not be based on a paradigm of the amorphous "reasonable person" standard of care evident in the past 150 years of tort law jurisprudence; rather, the focus must be fairness as between the two parties involved in a dispute.<sup>20</sup> Thus, rather than formulating the rules governing vaccine injury cases in a "reasonableness" framework whose overriding goal is "what result would most benefit society as a whole," as these congressional programs appear to do, Fletcher's nonreciprocal risk theory will persuade that these rules should focus on what is fair to the multiple stakeholders whose interests are implicated by vaccine injuries, within the broader context of vaccination policy as a whole.

The time has come for such an examination not only practically, as noted in Section I.A, but also legally. Between 1976 and the present, Congress has enacted several vaccine-injury liability control programs. And 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. Instead, traumatic events have dispelled the illusion, and among numerous, serious threats, the threat of bio-terrorism, employing cheap and deadly diseases (smallpox, anthrax and polio) has become a real concern. 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.<sup>21</sup> And as the war on terror diverts resources and political attention,

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<sup>19</sup> George P. Fletcher, *Fairness and Utility in Tort Theory*, 85 HARV. L. REV. 537 (1972); Gregory C. Keating, *Rawlsian Fairness And Régime Choice In The Law Of Accidents*, 72 FORDHAM L. REV. 1857 (2004).

<sup>20</sup> *Id.* at 556.

<sup>21</sup> See, e.g., Donald E. McNeil, Jr., *Clinical Trials for Flu Vaccine Are to Begin Soon*, N.Y. TIMES, July 23, 2009, at A4, available at <http://www.nytimes.com/2009/07/23/health/23vaccine.html> (last visited Aug. 11, 2009). The tenor of this news story should make any member of the public nervous about the corners being cut and the risks being imposed in what the reporter describes as a scramble with limited field testing:

*With pharmaceutical companies racing to have a swine flu vaccine ready for the fall flu season*, the federal government announced Wednesday that the first clinical trials of vaccine candidates would start shortly.

The trials are being conducted "in a compressed time frame in a race against the possible autumn resurgence" of the swine flu, possibly at the same time as the regular seasonal flu," said Dr. Anthony S. Fauci,

conditions in some countries have led to the resurgence of disease, such as polio, against which existing vaccines and vaccination programs in America may be vulnerable. 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 old question of the risks posed by vaccines and how they ought to be borne – among the public, individuals, manufacturers and governments.

Part II of this article describes the congressional vaccination programs to date and highlights the major differences between them. Part III introduces Fletcher’s nonreciprocal risk theory of corrective justice. In Part IV, the authors 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 IV opens, however, with a close look at an even more aggressive program of “tort-reform” that the pharmaceutical industry, enlisting the aid of the judiciary, has pursued to limit their liability for product-injuries: arguments that federal regulation, especially federal approval and labeling processes promulgated by the Food and Drug Administration (FDA), “pre-empt” any claims by injured persons, thereby effectively eliminating remedies for injuries that arise during post-approval actual experience, and leaving the injured with no source of compensation. In Part V, the authors suggest that the time has come for Congress to review vaccine liability, and the authors 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 Fletcher’s theory, as

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director of the National Institute of Allergy and Infectious Diseases, which will oversee the trials.

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If the shots seem safe in adults and the elderly, trials in teenagers and children as young as 6 months will be added.

About 2,400 volunteers will be tested in this round, Dr. Fauci said. All will be monitored for bad reactions, and, about three weeks after each shot, their blood will be tested to see how many antibodies to the swine flu were made. A high antibody level means the volunteer would not get the flu or would get only a mild case.

***In such a small trial, researchers will be able to pick up only obvious problems, Dr. Fauci said.*** Typical side effects of seasonal flu shots include sore arms, fever and aches. (These symptoms, echoing those of mild flu, lead to the persistent but false rumor that flu shots cause flu, experts say.) Rarer but more serious side effects like hives, dizziness and breathing problems usually stem from allergies to the chicken eggs that vaccines are grown in.

Researchers will also look out for Guillain-Barré syndrome, which can cause fever and serious nerve damage and muscle weakness.

Id. (emphasis supplied).

further refined by Professor Keating in what the authors call “the distribution of non-reciprocal harms,” the authors set out a new perspective from which Congress can perceive the intersecting legal principles implicated by the competing interests along a spectrum that ranges from strict liability for vaccine injury, argued successfully by attorney Melvin Belli fifty years ago in *Gottsdanker v. Cutter Laboratories*<sup>22</sup> that the process of vaccine manufacture “should and could be perfect”<sup>23</sup>; to government coercion, immune from tort liability, forcing individuals, particularly from discrete and insular minority groups, to submit to all the risks of vaccination involuntarily, as in the iconic case of *O’Brien v. Cunard Steamship Co.*, 154 Mass. 272, 28 N.E. 266 (1891), in which an immigrant woman from Ireland about to disembark at Ellis Island was coerced into having a smallpox vaccination<sup>24</sup>; to the role of the pharmaceutical industry in modern life and the social responsibilities that must attend the profits<sup>25</sup> reaped for shareholders from

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<sup>22</sup> 6 Cal. Rptr. 320 (Cal. Ct. App.1960); see Paul A. Offit, *The Cutter Incident*, Ch. 7 (2003). This case involved one of the seven laboratories who made the original issue of the Salk killed-virus polio vaccine, Cutter Laboratories, and its failure to ensure that all live polio virus 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. In the worlds of vaccinology and law, this event quickly acquired the moniker, “The Cutter Incident.” Offit, *supra*, at \_\_\_; see, e.g., N. Nathanson and A.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 *American Journal of Hygiene* 29-60 (1963).

<sup>23</sup> Offit, *supra* note 22, at 141-142. Dr. Offit quotes attorney Belli in 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. “there 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 non in yours — that the process could and should be perfect.”

*Id.* at 142 (quoting the reporter's transcript, *Gottsdanker v. Cutter Laboratories*, District Court of Appeal of the State of California, First Appellate District, 1 Civ. 18,413 and 18, 414, Nov. 20, 19857 – Jan. 31, 1958; see *id.* at 215-216, note on Ch. 7).

<sup>24</sup>See, e.g., *Five Approaches to Legal Reasoning in the Classroom: Contrasting Perspectives on O'Brien v. Cunard S.S. Co., Ltd.* 57 *Mo. L. rev.* 346 (1992); see also Jane E. Larson, “Women Understand So Little, They Call My Good Nature ‘Deceit’”: A Feminist Rethinking of Seduction, 93 *Colum. L. Rev.* 373, 403 (1993)(arguing that fraud includes “manipulation” of consent, in which “[t]he wrongdoer arranges the victim's world so that the act he wants her to perform appears as her best choice”).

<sup>25</sup> For example, Congressman Waxman compiled a table of leading drug company profit increases from 2005-2006 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.

the FDA-approval and the worldwide distribution and sale of “designer,” convenience pharmaceuticals such as Viagra, “me-too” drugs that are but prosaic variations of currently marketed drugs, and drugs which are the product of “promot[ing] diseases to fit their drugs,” rather than “promot[ing] drugs to treat diseases.”<sup>26</sup>

## II. 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.<sup>27</sup> The swine flu virus was the same virus that caused the 1918-1919 flu pandemic, which reportedly infected two billion people and killed twenty million worldwide.<sup>28</sup> In an attempt to avoid a similar pandemic, the administration of President Gerald Ford requested emergency funds be appropriated by Congress to support a nationwide vaccination initiative.<sup>29</sup> The need to include any liability protection in the Act for vaccine manufacturers was not raised as a concern until insurance companies declined to provide liability coverage for vaccine manufacturers for any liability alleged to have been caused by this particular vaccine.<sup>30</sup> This refusal was largely because of a federal appellate court’s decision in *Reyes v. Wyeth Laboratories*,<sup>31</sup> which held polio vaccine manufacturers liable for failure to provide adequate product warnings directly to vaccinees, even if they had provided them in package inserts. Writing in the *Reyes* case,

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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%).

Rep. Henry A. Waxman, *Analysis: Pharmaceutical Industry Profits Increase by Over \$8 Billion After Medicare Drug Plan Goes Into Effect*, at 2 (Sept. 2006), available at <http://oversight.house.gov/documents/20060919115623-70677.pdf> (last visited July 31, 2009).

<sup>26</sup> MARCIA ANGEL, *THE TRUTH ABOUT DRUG COMPANIES* xxv-xxvi, 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 noted that a common pharmaceutical business strategy as “treat[ing] the normal accompaniments of aging . . . as diseases” for which drugs must be developed. *Id.* at 86.

<sup>27</sup> 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).

<sup>28</sup> Charles F. Hagan, *Vaccine Compensation Schemes*, 45 FOOD DRUG COSM. L.J. 477 (1990).

<sup>29</sup> *Id.*

<sup>30</sup> Greenberger, *supra* note 10, at 11.

<sup>31</sup> 498 F.2d 1264, 1295 (5<sup>th</sup> Cir. 1974), *cert. denied*, 419 U.S. 1096 (1974). *Reyes* dealt with the manufacturer’s failure to provide a direct warning of the risks associated with the vaccine directly to the vaccine recipient. *Id.* 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. *See also* Greenberger, *supra* note 10, at 11.

federal appeals court judge John Minor Wisdom recognized the practical problems created by his panel's legal ruling and suggested to Congress an approach for coping with the brave new world the decision had inaugurated:

In closing, we feel that we should comment on the important policy considerations raised in the briefs of the amici curiae, the American Academy of Pediatrics [AAP] and the Conference of State and Territorial Epidemiologists [CSTE]. Both insist that the holding we 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. The crucial points of the argument are two: first, that any effort to warn vaccinees will be futile and frightening, leading only to confusion, and second, that a warning is unnecessary once epidemiologists have reached a deliberate medical judgment that universal vaccination is necessary. These public health policy questions cut across the law. We realize their importance.

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“Until 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.”

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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), 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.FN57

FN57. See, e.g., Calabresi & Bass, Right Approach, Wrong Implications: A Critique of McKean on Products Liability, 38 U.Chi.L.Rev. 74 (1970); Calabresi, Some Thoughts on Risk Distribution and the Law of Torts, 70 Yale L.J. 499 (1961); Morris, Enterprise Liability and the Actuarial Process- The Insignificance of Foresight, 70 Yale L.J. 554 (1961); 46 N.Y.U.L.Rev. 403 (1971); see also *Escola v. Coca Cola Bottling Co.*, Cal.Sup.1944, 24 Cal.2d 453, 150 P.2d 436, 440 (Traynor, J., concurring). *It 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.* Unless the doctrine of sovereign immunity is

significantly altered, however, such a loss distribution scheme does not appear to be likely. See Merrill, Compensation for Prescription Drug Injuries, 59 Va.L.Rev. 1, 102 (1973).<sup>32</sup>

Thus, a bill was introduced in Congress in June 1976, providing for government indemnification for swine flu vaccine manufacturers.<sup>33</sup> 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.<sup>34</sup> As a result, vaccine manufacturers ceased producing the swine flu vaccine.<sup>35</sup> 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.<sup>36</sup> Yet later that summer, the fear created by an outbreak of Legionnaire's disease, another infectious disease which is a type of pneumonia,<sup>37</sup> prompted Congress finally to pass the Swine Flu Act.<sup>38</sup> 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, thus providing to plaintiffs as their exclusive remedy a civil action directly against the United States under the Federal Tort Claims Act ("FTCA").<sup>39</sup>

The Swine Flu Act provided that the exclusive remedy against the United States was necessary due the government's "unique role in the initiation, planning, and administration of the swine flu program[.]"<sup>40</sup> Thus, the Act provided protection for not only manufacturers, but also distributors of the vaccine, as well as any administrator of the vaccine (collectively, defined in the Act as a "program participant").<sup>41</sup> 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.<sup>42</sup> 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 the vaccine.<sup>43</sup> 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.<sup>44</sup> Further, the Act did not

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<sup>32</sup> Id. at 1293-94 & n. 57 (citations and footnotes omitted)(emphasis supplied).

<sup>33</sup> Greenberger, *supra* note 10, at 11.

<sup>34</sup> Id. at 11, 12.

<sup>35</sup> Id. at 12.

<sup>36</sup> Id.

<sup>37</sup> [http://www.cdc.gov/legionella/patient\\_facts.htm](http://www.cdc.gov/legionella/patient_facts.htm)

<sup>38</sup> Greenberg, *supra* note 10, at 12.

<sup>39</sup> 42 U.S.C. § 274b(k)(1)(A)(i), (ii) (1976). See generally Greenberger, *supra* note 10, at 12.

<sup>40</sup> 42 U.S.C. § 274b(k)(1)(A)(ii).

<sup>41</sup> Id. § 274b(k)(1)(B)(ii)(2)(A).

<sup>42</sup> Id. § 274b(k)(1)(B)(ii)(2)(A)(ii).

<sup>43</sup> Greenberger, *supra* note 10, at 12.

<sup>44</sup> 42 U.S.C. § 274b(k)(5)(C)(ii) (1976).

place any limits on the amount of compensation that could be awarded to any particular plaintiff.<sup>45</sup>

Under the program, roughly forty million Americans were vaccinated in a two-month period.<sup>46</sup> And although the program achieved the goals of broad manufacturer and doctor participation, as well as high vaccination levels around the country, it has been criticized for being too hasty a reaction to a possible pandemic which never transpired.<sup>47</sup> Further, the program was abruptly halted because the vaccine itself created an increased risk to those who had been vaccinated of developing Guillain-Barré syndrome, a rare and occasionally fatal paralytic condition.<sup>48</sup> 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.<sup>49</sup> Litigation arose as a result of this condition, which was ultimately attributed to the vaccine.<sup>50</sup> By 1985, the federal government had paid over \$90 million in damages to injured plaintiffs who had contracted Guillain-Barré.<sup>51</sup>

## B. National Childhood Vaccine Injury Act

Vaccines administered in childhood have been part of the most pervasive vaccine program, originating with childhood vaccines against smallpox in colonial times,<sup>52</sup> and currently encompassing Diphtheria, tetanus, pertussis (DTP, DTaP, Tdap, DT, Td, or TT), Haemophilus influenzae type b (Hib), Hepatitis A (HAV), Hepatitis B (HBV), Human papillomavirus (HPV), # Influenza (TIV, LAIV) given each year during the flu season, measles, mumps, rubella (MMR, MR, M, R), meningococcal (MCV4, MPSV4), polio (OPV or IPV), pneumococcal conjugate (PCV), rotavirus (RV), varicella (VZV), and “[a]ny combination of the vaccines above.”<sup>53</sup> Sales of such vaccines generated \$16.3 billion for pharmaceutical companies in 2007.<sup>54</sup> Manufacturers of childhood vaccines have also

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<sup>45</sup> *Id.* §274b (1976).

<sup>46</sup> Greenberger, *supra* note 10, at 13. The program was discontinued after roughly two and a half months because a number of cases of Guillain-Barré syndrome had been reported as occurring shortly after the victim had been immunized. Hagan, *supra* note 6, at 478.

<sup>47</sup> 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).

<sup>48</sup> James M. Wood, et. al, *Product Liability Protection for Stem Cell Research and Therapies – A Proposal*, 18 No. 1 HTHLAW 1, 8 (2005).

<sup>49</sup> *Id.*

<sup>50</sup> Greenberger, *supra* note 10, at 13.

<sup>51</sup> *Id.*

<sup>52</sup> <http://www.news.harvard.edu/gazette/1999/05.20/waterhouse.html>.

<sup>53</sup> See U.S. Dep’t Health & Human Services, Health Resources & Services Administration, National Vaccine Injury Compensation Program—Covered Vaccines, available at:

[http://www.hrsa.gov/vaccinecompensation/covered\\_vaccines.htm](http://www.hrsa.gov/vaccinecompensation/covered_vaccines.htm) (last visited Aug. 11, 2009).

<sup>54</sup> Reuters, , Mon. Apr. 7, 2008, available at <http://www.reuters.com/article/pressRelease/idUS184052+07-Apr-2008+PRN20080407> (last visited Aug. 11, 2009). The Reuters article notes that figure “represents an increase of 38% over 2006 sales of \$11.7 billion.” *Id.* The article attributes that “healthy” growth to “[s]tronger than anticipated revenues for flu vaccines, and the surprising commercial success of Merck’s

incurred liability for injuries and death allegedly caused by a vaccine which was administered to a previously healthy child.<sup>55</sup> 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 than with less challenging to manufacture pharmaceuticals, but also relating 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

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Gardasilfor HPV, which causes most cervical cancers.” *Id.* Citing a report by an independent market research firm, Reuters puts these numbers into the following perspective:

According to the report, new products approved in recent years, in particular Gardasil, but also RotaTeq, Pentacel, Zostavax and FluMist, are now having an impact on the market. These new products, combined with a continued emphasis on flu vaccines in the U.S. healthcare system, have created a healthy environment for vaccine products.

Five major players -- Merck & Co., GlaxoSmithKline, Sanofi Pasteur, Wyeth and Novartis -- dominate vaccine sales. At these companies, as well as smaller producers, Kalorama Information has found increased interest in vaccines, and a willingness to look at products for conditions not historically addressed with vaccines, including diabetes, cancer and smoking cessation. Given this trend and strong sales, Kalorama Information expects vaccine sales to more than double in five years.

*Id.* Full, worldwide market reports on vaccines and their pharmaceutical manufacturers are proprietary and available only from research firms such as Kalorama. They cost upwards of \$4,000.00 —

<http://www.kaloramainformation.com/catalog/search.asp?query=World+Market+For+Vaccines> (last visited Aug. 11, 2009)

— and thus are beyond the academic budget allotted to the authors of this article. However, this price tag would be well within the reach of Congressional committees who might seek to study and implement the recommendations made in Section V, *infra*.

<sup>55</sup> H.R. Rep. No. 908, at 4. *See generally*, Susan G. Clark, M.Ed., The National Childhood Vaccine Injury Act – The National Vaccine Injury Compensation Program, 94 EDUC. L. REP. 671, 674 (1994) (“Following vaccination, there are cases of children left severely mentally retarded, neurologically impaired, developmentally delayed, brain damaged, epileptic, and otherwise severely multiply handicapped.”). 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. Keith E. Abbott, The National Vaccine Injury Compensation Program, 20 COLO. LAW. 1825 (1991). That component may contain whole cell pertussis bacteria, which has been linked with severe neurological impairment. *Id.* In 1992, the FDA licensed an acellular pertussis vaccine, made from portions of the pertussis cell, rather than the whole cell. The Food and Drug Administration (FDA) claims this version has fewer side effects. FDA website (<http://www.fda.gov/fdac/reprints/vaccine.html>).

unpredictability of tort liability.<sup>56</sup> This decline in available manufacturers affected the country's ability to maintain acceptable vaccine supply and vaccination levels.<sup>57</sup> In addition, as the occurrence of many historically common and very serious childhood diseases had seemingly been all but eradicated,<sup>58</sup> many people became less concerned with these diseases themselves and more concerned with the risk of potential side effects from the vaccinations.<sup>59</sup> Further, there was great uncertainty as to whether victims injured by vaccines would be able to obtain compensation.<sup>60</sup> 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.<sup>61</sup>

In response to the concerns of both manufacturers and vaccine recipients, Congress passed the National Childhood Vaccine Injury Act of 1986 ("NCVIA").<sup>62</sup> 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.<sup>63</sup> This system is designed to be a two-tiered system, whereby a claimant must first fully adjudicate her claims under the Program (for injuries arising after the NCVIA's effective date), and only to the extent the claimant is dissatisfied with the result under the Program is she then allowed to file a civil action against the manufacturer.<sup>64</sup> This system is intended to be a more efficient alternative to a civil action against a manufacturer with more consistent results for claimants.<sup>65</sup> Further, claimants are diverted away from the civil tort system, thereby limiting the potential financial exposure risked by the manufacturers.<sup>66</sup>

Claimants file their petitions with the United States Court of Federal Claims.<sup>67</sup> 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.<sup>68</sup> The claims are heard initially by a Special Master,<sup>69</sup> who

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<sup>56</sup> See notes \_\_\_-\_\_\_supra; see, e.g., H.R. Rep. No. 908, at 4-5; Hagan, *supra* note 6, 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. Centers for Disease Control and Prevention (CDC) website (<http://www.cdc.gov/nip/vacsafe/>).

<sup>57</sup> See H.R. Rep. No. 908, at 7.

<sup>58</sup> FDA website (<http://www.fda.gov/fdac/reprints/vaccine.html>).

<sup>59</sup> CDC website (<http://www.cdc.gov/nip/vacsafe/>).

<sup>60</sup> Hagan, *supra* note 6, at 479.

<sup>61</sup> 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 (1994); Mary Beth Neraas, *The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis?*, 63 WASH. L. REV. 149, 153-156, 159 (1988); Spence, *supra* note \_\_\_\_.

<sup>62</sup> 42 U.S.C. § 300aa-1 (1994).

<sup>63</sup> *Id.* at § 300aa-11(c).

<sup>64</sup> Neraas, *supra* note 36, at 162.

<sup>65</sup> H.R. REP. NO. 908, at 5. See Elizabeth A. Breen, *One Shot Deal: The National Childhood Vaccine Injury Act*, 41 WM. & MARY L. REV. 309 (1999); Neraas, *supra* note 36, at 164, 165.

<sup>66</sup> Neraas, *supra* note 36, at [165].

<sup>67</sup> 42 U.S.C. § 300aa-11

<sup>68</sup> *Id.*

decides whether compensation should be awarded under the Program and the amount of such compensation.<sup>70</sup> The judges of the Federal Court of Claims have sole discretion in determining the qualifications of and appoints to these Special Master positions, and no medical or scientific background has been mandated as a prerequisite to consideration for or appointment to a vacancy for a Vaccine-Court Special Master.<sup>71</sup> Generally, in order to

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<sup>69</sup> See, e.g., U.S. Court of Federal Claims, Vaccine Program/Office of Special Masters, available at <http://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters> (last visited Aug. 11, 2009); see also Wendy K. Mariner, Legislative Report: The National Vaccine Injury Compensation Program, *Health Affairs* 255, 257-258, 261-262 (Spring 1992), available at <http://content.healthaffairs.org/cgi/reprint/11/1/255.pdf> (last visited Aug. 11, 2009). Student author Elizabeth Breen had this to say about the selection, qualifications, and authority of Vaccine Court Special Masters:

The overwhelming discretion held by the special master in each petition filed under the Act represents one of the flaws inherent in the Act. After a petition is filed, a chief special master is responsible for distributing the claims to one of seven other special masters. The special master assigned to the claim has complete jurisdiction over the initial proceedings. Moreover, the means of selecting special masters compounds the effects of their unbridled discretion. The majority of the judges seated on the United States Federal Claims Court appoint each special master to a four-year term. Once chosen, special masters may be removed only for incompetence, misconduct, neglect of duty, or physical or mental disability.

Elizabeth A. Breen, Note, *A One Shot Deal: The National Childhood Vaccine Injury Act*, 41 WM. & MARY L. REV. 309, 321 (1999) (footnotes omitted).

<sup>70</sup> *Id.* § 300aa-12(d)(3)(A).

<sup>71</sup> See, e.g., Craig A. Conway, Federal Court Reverses Denial of Vaccination Compensation Claim, *Health Law Perspectives* (2009), available at [http://www.law.uh.edu/healthlaw/perspectives/2009/\(CC\)%20Vaccine.pdf](http://www.law.uh.edu/healthlaw/perspectives/2009/(CC)%20Vaccine.pdf) (last visited Aug. 11, 2009). As the Conway elaborates:

A Congressionally-created office within the U.S. Court of Federal Claims, the Office of the Special Masters, adjudicates claims brought under the Act in the often-termed “Vaccine Court.” There is one chief special master and five associate special masters appointed to four-year terms. As explained in a previous *Health Law Perspectives* article:

[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. PERSPECTIVES*, Feb. 18, 2008, available at [https://www.law.uh.edu/healthlaw/perspectives/2008/\(BP\)%20autism.pdf](https://www.law.uh.edu/healthlaw/perspectives/2008/(BP)%20autism.pdf) .)

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” (discussed below),<sup>72</sup> (2) they sustained injury, aggravation of an illness, disability, injury or condition listed on the Vaccine Injury Table, or died as a result of administration of the vaccine, (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, and (4) that the injury or death was not caused by factors unrelated to the administration of the vaccine.<sup>73</sup> 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.<sup>74</sup>

Any compensation paid to a claimant is based on the Vaccine Injury Table. 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. To the extent the claimant can establish these requirements, he is entitled to a presumption of causation. If, however, 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 claimant must establish by a preponderance of the evidence that the vaccine was a cause-in-fact of his injury.<sup>75</sup> This Table is periodically updated based on the most up-to-date data<sup>76</sup> in an attempt to more justly compensate those with “good” claims, while weeding out the “bad” claims.

Compensation awarded to a claimant under the Program shall include 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.<sup>77</sup> Determining these damages is a complicated process which requires the use of an expert; this expert 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.<sup>78</sup> However, compensation under the Program is secondary to all other sources of compensation, including state compensation programs or insurance policies.<sup>79</sup> Thus, a claimant must first exhaust those sources of payment before receipt of funds under the Program.

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<sup>72</sup> *Id.* § 300aa-14. See Appendix A attached hereto for Vaccine Injury Table.

<sup>73</sup> *Id.* § 300aa-11(c)(1), § 300aa-13(a)(1)(B).

<sup>74</sup> *Id.* §§ 300aa-12(e)(1), (f).

<sup>75</sup> *Id.* § 300aa-11(c)(1)(C). In addition to the information a claimant ordinarily would have to provide, a claimant whose injury is not on the Table, or falls outside the time periods specified in the Table, must provide some scientific study or expert medical testimony to support her claim. *Id.* at (13)(a)(1). H.R. Rep. No. 908 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, 157 (1994-1995).

<sup>76</sup> *Id.* § 300aa-14(c). Breen, *supra* note 32, at 326.

<sup>77</sup> *Id.* § 300aa-15.

<sup>78</sup> Abbott, *supra* note 24, at 1827.

<sup>79</sup> 42 U.S.C. § 300aa-15(g).

Unlike the Swine Flu Act, which did not place caps on any awards, the NCVIA caps compensation in the event of death at \$250,000 for the estate of the deceased, and pain and suffering and emotional distress is awarded in an amount not to exceed \$250,000.<sup>80</sup> Claimants are entitled to compensation for actual and anticipated loss of earnings; for those who have sustained a vaccine-related injury after age 18, such amount is determined in accordance with recognized actuarial principles and projections.<sup>81</sup> For those who have sustained a vaccine-related injury prior to age 18, loss of earning capacity is based on the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy.<sup>82</sup> Punitive or exemplary damages are not allowed, but reasonable attorney's fees and other costs will be awarded.<sup>83</sup> In the case of vaccine-related injury or death occurring after October 1, 1988, the award will be paid from the Vaccine Injury Compensation Trust Fund, funded by an excise tax charged on all childhood vaccines.<sup>84</sup>

If the claimant chooses to receive the compensation awarded under the Program, he is prohibited from bringing a civil suit against the vaccine manufacturer.<sup>85</sup> However, if he is unsatisfied with the administrative award, he can file a civil tort action against the manufacturer.<sup>86</sup> As this route is not the "desired" one in the NCVIA's two-tiered structure,<sup>87</sup> Congress amended certain aspects of traditional tort law in an effort to maintain protections for manufacturers.<sup>88</sup> 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 instructions and warnings.<sup>89</sup> Further, a vaccine is presumed by to be accompanied by proper instructions and warnings if the manufacturer shows it complied with the Federal Food, Drug and Cosmetic Act (FDCA) 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.<sup>90</sup>

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.<sup>91</sup> Recall that it was precisely the holding from this case that lead insurance companies to

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<sup>80</sup> Id. §§ 300aa-15(a)(2), (4)

<sup>81</sup> Id. §§ 300aa-15(a)(3)(A)

<sup>82</sup> Id. §§ 300aa-15(a)(3)(B).

<sup>83</sup> Id. §§ 300aa-15(d)(1), (e)(1).

<sup>84</sup> Id. § 300aa-15(i)(2); Hagan, *supra* note 6, at 482.

<sup>85</sup> Id. § 300aa-21(a).

<sup>86</sup> Id.

<sup>87</sup> Greenberger, *supra* note 10, at 15.

<sup>88</sup> 42 U.S.C. § 300aa-22.

<sup>89</sup> Id. § 300aa-22(b)(1).

<sup>90</sup> Id. § 300aa-22(b)(2).

<sup>91</sup> Id. § 300aa-22(c).

drop liability insurance for vaccine manufacturers in connection with liability associated with the swine flu vaccine.<sup>92</sup>

Thus, due to the government's increasing unwillingness to accept full financial responsibility for vaccine manufacturers,<sup>93</sup> the NCVIA did many things to change what the Swine Flu Act had provided. First, the Swine Flu Act created an exclusive civil tort remedy against the federal government, rather than a two-step program similar to that mandated by the NCVIA which requires the preliminary step of administrative adjudication of claims. 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, but yet certain tenets of tort law have been statutorily amended to claimant's detriment. Further, the NCVIA capped certain damages awards that the Swine Flu Act did not. 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."<sup>94</sup>

### 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.<sup>95</sup> 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.<sup>96</sup> Thus, the President requested that health care workers and emergency personnel, or "first responders," volunteer to receive the smallpox vaccination, providing them the ability to mobilize quickly in the event of a smallpox attack.<sup>97</sup> Even though the World Health Organization declared in 1980 that smallpox had been eradicated worldwide, the virus still exists in laboratories, and the President expressed concern that terrorist regimes may possess this virus.<sup>98</sup>

Unfortunately, Bush's vaccination plan was a "spectacular failure."<sup>99</sup> Section 304 of the Homeland Security Act (the "HSA"), 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

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<sup>92</sup> See *supra* note 14 and accompanying text.

<sup>93</sup> Greenberger, *supra* note 10, at 14.

<sup>94</sup> *Id.* at 16.

<sup>95</sup> White House website (<http://www.whitehouse.gov/news/releases/2002/12/20021213-7.html>).

<sup>96</sup> *Id.*

<sup>97</sup> *Id.*

<sup>98</sup> *Id.*

<sup>99</sup> Marcia Coyle, *Congress Tackles Vaccine Liability*, FULTON CO. DAILY REP., Dec. 15, 2005, at 5, quoting Michael Greenberger.

case of negligence.<sup>100</sup> These covered persons are made federal employees under the HSA.<sup>101</sup> Thus, any cause of action for injuries would have to be brought against the federal government under the FTCA. 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<sup>102</sup> (or presumably, manufacture) the vaccine. 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.<sup>103</sup> Further, under the FTCA, the federal government is immune from liability for any discretionary policy decision.<sup>104</sup> Thus, while it may be a poor public policy decision to vaccinate health care workers against smallpox, it is not necessarily a negligent decision.<sup>105</sup>

More importantly, the HSA provided no sufficient mechanism for compensation for those injured due to their inoculation.<sup>106</sup> 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.<sup>107</sup> However, the United States would only assume liability for negligence or any other wrongful act or omission by a covered person,<sup>108</sup> which, as stated above, would be very difficult to establish. Thus, in reality, those injured had as their only remedy either their own health insurance plans or state workers’ compensation laws.<sup>109</sup> However, one commentator has suggested that private insurance to cover this kind of injury is virtually

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<sup>100</sup> Homeland Security Act of 2002, Pub. L. No. 107-296, 116 Stat. 2135, 2165 (codified as amended at 42 U.S.C.A. § 233(p)).

<sup>101</sup> *Id.*

<sup>102</sup> Susan J. Landers, *Compensation Plan Needed to Offset Smallpox Vaccine Risks*, AMNEWS, Jan. 13, 2003.

<sup>103</sup> Greenberger, *supra* note 10, at 18.

<sup>104</sup> Federal Tort Claims Act, 28 U.S.C.A. §§ 2671, 2680(a) (1948).

<sup>105</sup> *For Victims of Vaccine*, NY TIMES, Dec. 13, 2002; *see also* Wood, *supra* note 23, at 12 (stating that under the Swine Flu Act, the federal government could not avail itself of the discretionary function exception).

<sup>106</sup> The CDC reports the following moderate to severe to life-threatening side effects caused by the smallpox vaccine (this information does not include all side effects that have been previously reported):

About 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.

CDC website (<http://www.bt.cdc.gov/agent/smallpox/vaccination/needtoknow.asp>).

<sup>107</sup> 42 U.S.C. § 233(a).

<sup>108</sup> *Id.*

<sup>109</sup> AFL-CIO website (<http://www.aflcio.org/issues/safety/smallpoxcomp.cfm#smact>).

impossible to secure;<sup>110</sup> further, it was not certain that all state workers' compensation laws would accept claims for sickness caused by the smallpox vaccine.<sup>111</sup>

Bush's plan was ambitious: beginning January 24, 2003 and continuing for the next month, 500,000 first responders would be voluntarily vaccinated.<sup>112</sup> However, within a month after the start of the program, only 5,000 first responders had been vaccinated, due in large part to the lack of compensation in the Act.<sup>113</sup> In response to the low success rate of the vaccination plan, Congress passed the Smallpox Emergency Personnel Protection Act ("SEPPA") on April 30, 2003.<sup>114</sup>

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.<sup>115</sup> Unfortunately (like the NCVIA), state workers' compensation and health insurance plans are still the primary source of recovery for smallpox-related injuries.<sup>116</sup> Benefits may be received upon request to the HHS Secretary, who will determine whether payment of benefits is appropriate based on a vaccine injury table.<sup>117</sup> Benefits include the following: 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.<sup>118</sup> These benefits seemingly cover significantly fewer medical expenses than those provided for in the NCVIA, which includes things like special education, counseling, special equipment, and the like. SEPPA, on the other hand provides only expenses necessary to "treat" the injury. 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.

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<sup>110</sup> Greenberger, *supra* note 10, at 18.

<sup>111</sup> Implications of Homeland Security Smallpox Vaccination Program for Workers' Compensation, IAIABC News Release, Jan. 6, 2003; the AFL-CIO website also maintains that, "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 41 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 14 states clearly guarantee coverage of smallpox injuries as of April 2, 2003." (<http://www.aflcio.org/issues/safety/smallpoxcomp.cfm#smact>).

<sup>112</sup> Donald G. McNeil Jr., Smallpox Inoculations Begin with Four Connecticut Doctors, NY TIMES, Jan. 25, 2003; AFL-CIO website (<http://www.aflcio.org/issues/safety/smallpoxcomp.cfm#smact>).

<sup>113</sup> AFL-CIO website (<http://www.aflcio.org/issues/safety/smallpoxcomp.cfm#smact>).

<sup>114</sup> 42 U.S.C.A. §§ 233, 239 & 239a-h.

<sup>115</sup> Id. § 239a(c).

<sup>116</sup> Id. § 239c(b).

<sup>117</sup> Id. § 239a. The vaccine injury table component is similar to that under the NCVIA. 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.

<sup>118</sup> Id. § 239c,d & e. 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.

And unlike under the NCVIA, there is no judicial review by any court of the HHS Secretary's determination as to whether and to what extent compensation is appropriate.<sup>119</sup> 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. 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.<sup>120</sup> Notwithstanding the government's attempt to reinvigorate the Program by passing SEPPA, as of October 31, 2005, only 39,608 individuals have been vaccinated.<sup>121</sup>

#### D. Public Readiness and Emergency Preparedness Act

Another recent congressional vaccine-related initiative is the Public Readiness and Emergency Response Act, or "Prep Act."<sup>122</sup> The news media was flooded recently with reports of bird flu and the possibility of a worldwide flu pandemic. The bird flu, or avian influenza, known as A (H5N1), has been in existence for the past 10 years in Southeast Asia.<sup>123</sup> 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.<sup>124</sup> Many scientists believe it is only a matter of time before the bird flu reaches North America.<sup>125</sup> Not only has the bird flu migrated across the globe, it has also infected other animals, such as ferrets and cats.<sup>126</sup> Further, influenza generally is a virus that can quickly mutate;<sup>127</sup> thus, the H5N1 virus could combine with a human flu strain and create a new virus that could cause a pandemic.<sup>128</sup> 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. To date, the virus has killed millions of birds and approximately 200 people.<sup>129</sup> However, this flu is still largely an avian disease, and the humans who have contracted the disease have mostly been exposed to infected birds.<sup>130</sup> And although there are people on both sides of the debate

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<sup>119</sup> *Id.* § 239a(f)(2).

<sup>120</sup> Greenberger, *supra* note 10, at 14, 16, 20.

<sup>121</sup> See Office of Enterprise Communication, Centers for Disease Control, Smallpox Vaccination Programs by State (<http://www.cdc.gov/od/oc/media/spvaccin.htm>) (website last visited on June 23, 2006).

<sup>122</sup> 42 U.S.C.A. § 247d-6d.

<sup>123</sup> Donald G. McNeil, Jr., *The Worrier: At the U.N.: This Virus Has an Expert 'Quite Scared'*, NY TIMES, March 28, 2006.

<sup>124</sup> *Id.*

<sup>125</sup> NY TIMES, March 28, 2006, p. D5.

<sup>126</sup> Elisabeth Rosenthal, *The Skeptic: On the Front: A Pandemic is Worrisome But 'Unlikely'*, NY TIMES, March 28, 2006.

<sup>127</sup> McNeil, *supra* note \_\_\_\_.

<sup>128</sup> Lawrence Altman, M.D., *With Every Epidemic, Health Officials Face Tough Choices*, NY TIMES, March 28, 2006.

<sup>129</sup> Denise Grady and Gina Kolata, *How Serious is the Risk?*, NY TIMES, March 28, 2006.

<sup>130</sup> *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. He lived near a live-poultry market and handled birds at cockfights. 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. Although

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.<sup>131</sup>

In December 2005, Congress passed bio-defense legislation as part of a Department of Defense appropriations bill.<sup>132</sup> 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[.]”<sup>133</sup> These appropriations would allow the federal government to procure and stockpile vaccines in the event of a bird flu pandemic. However, provisions were added to the bill after House-Senate conference committee which offered drug manufacturers “targeted liability protection,”<sup>134</sup> even though House Republicans had earlier promised that there would be no liability protections included in the legislation.<sup>135</sup> 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.<sup>136</sup>

These immunity provisions, collectively called the Prep Act,<sup>137</sup> 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.<sup>138</sup> The sole exception to immunity “shall be” for injury caused by willful misconduct.<sup>139</sup> 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.<sup>140</sup>

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the girl played and slept where chickens were kept, the mother lived in Bangkok and had no exposure to birds. The mother died 12 days after her daughter. NY TIMES, March 28, 2006, p. D4.

<sup>131</sup> NY TIMES, March 28, 2006, p. D3. In the few human autopsies that have been done, it appears that the virus can attack the lungs, the brain and possibly the intestines. *Id.* And of the 186 people in the world who have contracted the virus, 105 have died. Altman, *supra* note \_\_\_\_.

<sup>132</sup> 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).

<sup>133</sup> *Id.*

<sup>134</sup> 42 U.S.C.A. § 247d-6d.

<sup>135</sup> Sheryl Gay Stolberg, *Legal Shield for Vaccine Makers is Inserted into Military Bill*, NY TIMES, Dec. 20, 2005; *Democrats Blast ‘Midnight Rider’ Adding Rx Liability Shield to DOD Bill*, FDA WEEK, Dec. 23, 2005.

<sup>136</sup> Stolberg, *supra* note 107.

<sup>137</sup> Public Readiness and Emergency Preparedness Act of 2005, 42 U.S.C.A. § 247d-6d.

<sup>138</sup> *Id.* § 247d-6d(a)(1).

<sup>139</sup> *Id.* § 247d-6d(d)(1). “Willful misconduct” is defined to mean “an act or omission that is taken intentionally to achieve a wrongful purpose....” *Id.* at § 247d-6d(c)(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.* at § 247d-6d(c)(5).

<sup>140</sup> *Id.* § 247d-6d(a)(3). “[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).

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.<sup>141</sup> However, the fund is contingent – it will be funded only after the issuance of a declaration. The compensation amounts provided in the Prep Act are the same as those provided by SEPPA to victims injured by smallpox vaccinations.<sup>142</sup> 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 of onset of adverse side effects occur within a specified period of time.<sup>143</sup> Moreover, there is no judicial review of any action of the HHS Secretary taken under the Act, nor may one eligible for compensation bring a civil tort action without first exhausting his remedies available under these provisions.<sup>144</sup>

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,” and “without Congressional debate or public scrutiny,”<sup>145</sup> the compensation provided in the Act for victims of injury has been criticized as a “fig leaf” – a compensation fund that has not been funded ahead of time.<sup>146</sup> According to a statement by Senator Kennedy, “[t]here is no guarantee that any victim of a faulty or negligently made drug or vaccine will receive any compensation whatsoever.”<sup>147</sup> Finally, critics argue that the language of the Prep Act is too broad. 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.<sup>148</sup> Thus, the provisions could be used to allow the manufacturers of Vioxx, for example, to escape liability for any act other than the manufacturer's willful misconduct.<sup>149</sup> The HHS Secretary has not exercised any declaratory power as yet, so the effect this law will have is unclear.<sup>150</sup>

Many Democrats joined with Senator Kennedy in proposing what they call the Responsible Public Readiness and Emergency Preparedness Act of 2006.<sup>151</sup> 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. It would also include a

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<sup>141</sup> *Id.* § 247d-6e.

<sup>142</sup> *Id.* § 247d-6e(b)(2).

<sup>143</sup> *Id.* § 247d-6e(b)(5).

<sup>144</sup> *Id.* § 247d-6e(d).

<sup>145</sup> 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 [hereinafter Senator Kennedy, Colleagues].

<sup>146</sup> Stolberg, *supra* note 107.

<sup>147</sup> *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.* Rather, the compensation fund would be funded after an emergency has been declared. *Id.*

<sup>148</sup> Senator Kennedy, Colleagues, *supra* note \_\_\_\_.

<sup>149</sup> *Id.*

<sup>150</sup> See THOMAS O. MCGARITY, THE PREEMPTION WAR: WHEN FEDERAL BUREAUCRACIES TRUMP LOCAL JURIES 127 (2009).

<sup>151</sup> S. 2291, 109<sup>th</sup> Cong., 2d Sess. (2006).

fully funded compensation plan, modeled after the NCVIA. Further, manufacturers, distributors and administrators of certain countermeasures would be indemnified by the federal government. Thus, victims may choose to sue the federal government under any theory of liability. Moreover, indemnification for manufacturers would only be available (1) where 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. Thus, manufacturers of drugs, vaccines and the like that must be used, presumably 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. 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.<sup>152</sup> 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.<sup>153</sup>

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<sup>152</sup> Senator Kennedy, Colleagues, *supra* note \_\_\_\_.

<sup>153</sup> 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).

### III. Fletcher’s Nonreciprocal Risk Theory of Corrective Justice

The statutory programs examined in Section II may be a step in the right direction for dealing with the competing interests that must be accommodated in rethinking vaccine-injury liability. However, they have been offered up in virtual isolation, more as an intuitive reaction to only one part of the problem – controlling legal costs to vaccine manufacturers. As such, they suffer from their lineage as a product of narrow risk-benefit paradigm – a paradigm that reinforces an instrumentalist approach that, ultimately, will not accommodate the broader range of interests at stake in vaccination. In this section, we lay the groundwork for a broader rethinking of vaccine liability within a broader context of vaccine policy. We begin by looking at the role of risk and fault.

Over the past 150 years, tort doctrine has transitioned from a “paradigm of reciprocity,” or fairness, into a framework dominated by fault.<sup>154</sup> This fault-based paradigm focuses more on the reasonableness of the defendant’s conduct, as opposed to whether it is fair to allow the victim to recover.<sup>155</sup> As a result of this shift, to the extent the defendant’s conduct is “reasonable,” or in other words, bears some utility to society at large, then the defendant is considered not to be at fault, and thus, the plaintiff has no right to recover for injuries sustained.<sup>156</sup> This reasonableness, or fault-based, approach to tort liability has been called “instrumentalist,” or outcome-driven;<sup>157</sup> if a finding of no liability furthers a specific end goal of social utility, then the plaintiff has no “right” to recover, regardless of whether fairness dictates such a recovery.<sup>158</sup>

Professor Fletcher challenged this development of tort doctrine along instrumentalist lines in favor of a nonreciprocal risk theory of corrective justice.<sup>159</sup> According to Fletcher, the instrumentalist approach focuses on the following: “[w]hat social value does the rule of liability further in this case? Does it advance a desirable goal, such as compensation, deterrence, risk-distribution, or minimization of accident costs?”<sup>160</sup> The nonreciprocal risk theory of tort recovery, on the other hand, focuses on fairness as between the individual parties, rather than what result would be more beneficial to society as a whole.<sup>161</sup> Fairness is measured, not by fault or strict liability, but rather by “the nature of the victim’s activity when he was injured and on the risk created by the defendant. The social costs and utility of the risk are irrelevant.”<sup>162</sup> Thus, the “victim has a right to recover for injuries caused by a risk greater in degree . . . from those created

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<sup>154</sup> Fletcher, *supra* note 6, at 556.

<sup>155</sup> *Id.*

<sup>156</sup> *Id.*

<sup>157</sup> *Id.* at 537.

<sup>158</sup> *Id.*

<sup>159</sup> *Id.*

<sup>160</sup> *Id.* at 538.

<sup>161</sup> *Id.* at 540.

<sup>162</sup> *Id.*

by the victim and imposed on the defendant -- in short, for injuries resulting from nonreciprocal risk.”<sup>163</sup>

An example given by Fletcher of nonreciprocal risks is one of an airplane pilot; he subjects those on the ground beneath the path of the plane to a greater risk of harm than those to which they subject the pilot. Conversely, a reciprocal risk of harm is created by two pilots flying in the same vicinity; they subject one another to the same degree of risk of a mid-air collision.<sup>164</sup> Thus, the distinction as between these two theories is that liability based on fault would cause the plaintiff to absorb the loss created by a socially desirable risk, even if that risk was greater in degree than the risk the plaintiff imposed on the defendant. The reciprocity paradigm, on the other hand, would find that the plaintiff should recover, regardless of the social utility of defendant’s conduct, precisely because defendant subjected plaintiff to a disproportionate risk of harm than that to which the plaintiff subjected the defendant.<sup>165</sup>

According to Fletcher, nonreciprocal risk theory cuts across all theories of tort liability: strict liability, negligence and intentional torts.<sup>166</sup> Generally, defendants are held strictly liable in the contexts of abnormally dangerous activities and products liability. Under instrumentalist tort theory, liability for abnormally dangerous activities is premised on a “non-natural” use of one’s land; thus, even where the defendant has exercised the utmost care, if the activity in which he is engaged causes harm to plaintiff, defendant will be liable for his non-natural, or abnormally dangerous, use of his land.<sup>167</sup> In determining whether an activity is abnormally dangerous, the Restatement (Second) of Torts states that “the essential question is whether the risk created is so unusual, either because of its magnitude or because of the circumstances surrounding it, as to justify the imposition of strict liability for the harm that results from it, even though it is carried on with all reasonable care. In other words, are its dangers and inappropriateness for the locality so great that, despite any usefulness it may have for the community, it should be required as a matter of law to pay for any harm it causes, without the need of a finding of negligence.”<sup>168</sup> Thus, although the Restatement (Second) of Torts speaks in terms of “abnormally dangerous” activities, in essence the question is one of whether the risk

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<sup>163</sup> Id. at 542. Fletcher further states that “[c]ases of liability are those in which the defendant generates a disproportionate, excessive risk of harm, relative to the victim’s risk-creating activity. . . . Conversely, cases of nonliability are those of reciprocal risks, namely those in which the victim and the defendant subject each other to roughly the same degree of risk.” Id.

<sup>164</sup> Id.

<sup>165</sup> Id. at 543.

<sup>166</sup> Id.

<sup>167</sup> *Rylands v. Fletcher*, 159 Eng. Rep. 737 (Ex. 1865), *rev’d*, L.R. 1 Ex. 265 (1866), *aff’d* L.R. 3 H.L. 330 (1868); Restatement (Second) of Torts §§ 519-520 (1965).

<sup>168</sup> Restatement (Second) of Torts § 520 cmt. f (1965). The Restatement (Third) of Torts provides for strict liability for abnormally dangerous activity when the following elements are present: (1) defendant’s activity creates a reasonably foreseeable risk of physical harm; (2) the risk is a significant risk; (3) the risk remains even when reasonable care is exercised; and (4) the activity is not a matter of common usage. Restatement (Third) of Torts: Liability for Physical Harm § 20 (Tent. Draft No. 1, 2001). Thus, it appears that a finding of liability under the Third Restatement could be justified using nonreciprocal risk theory.

created by the defendant was nonreciprocal.<sup>169</sup> And although products liability encompasses many different theories of recovery, strict liability in tort can also be explained by nonreciprocal risks. For example, simply by virtue of the fact that a manufacturer places a product on the market which causes harm, whether by manufacturing defect or design defect, essentially the manufacturer has subjected the injured party to a risk greater in degree than that to which the injured party has subjected the manufacturer; *i.e.*, purchasing and/or using the product.

Similarly, Fletcher argues that negligence and intentional torts also lend themselves to a nonreciprocal risk analysis.<sup>170</sup> Generally speaking, one is negligent if his harm-causing activity is unreasonable, or in other words, if he has breached his standard of reasonable care to the plaintiff.<sup>171</sup> Yet, as Fletcher argues, an unreasonable risk is simply one that exceeds the bounds of reciprocity, again, regardless of the social utility of the activity.<sup>172</sup> Similarly, intentional actions are also a form of nonreciprocal risk.<sup>173</sup>

The reciprocity of risk paradigm is of great importance 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 the 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 regime 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 Sections IV and V, *infra*.

#### IV. Nonreciprocal Risk Theory as Applied to Vaccine-Related Injuries and the Appropriate Liability and Compensation Scheme

##### A. The Preemption Debate: FDA Preemption in Light of the Non-Reciprocal Risk Theory of Corrective Justice

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<sup>169</sup> Fletcher, *supra* note 96, at 547. Fletcher note that the paradigm of nonreciprocal risks accounts for other areas of strict liability besides abnormally dangerous activities, such as the keeping of wild animals. *Id.* Thus, where a defendant would be held liable for damage done by his unruly horse should he bring it into the city, he would not be held liable for damage done by his domesticated pet. *Id.*

<sup>170</sup> Fletcher, *supra* note 96, at 548.

<sup>171</sup> DAN B. DOBBS, THE LAW OF TORTS, § 116.

<sup>172</sup> Fletcher, *supra* note 96, at 548.

<sup>173</sup> *Id.* at 550.

Notwithstanding the current statutory regimes pursuant to which many vaccine injuries are adjudicated, the tort system still exists for injuries which fall outside of those prescribed thereunder. Yet tort liability is threatened by a new argument which has been 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 the corrective justice and enterprise regulation principles. FDA preemption of private tort claims is a widely debated issue.<sup>174</sup> The debate 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.<sup>175</sup> 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"<sup>176</sup> to one in which tort liability must yield to the administrative state.<sup>177</sup> Much scholarly commentary has been devoted to this debate, and the sometimes widely divergent views are dramatic in their breadth and depth.<sup>178</sup> Yet the recognition of corrective justice principles in any of these contexts is largely absent.<sup>179</sup> 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*.<sup>180</sup> 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)<sup>181</sup> to the Food, Drug, and Cosmetic Act of 1938 (FDCA).<sup>182</sup>

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<sup>174</sup> See *Wyeth v. Levine*, 129 S.Ct. 1187 (2009); *Riegel v. Medtronic*, 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); 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); Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 Geo. Wash. L. Rev. 449 (2008).

<sup>175</sup> 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).

<sup>176</sup> Nagareda, *supra* note 166, at 1.

<sup>177</sup> See *Wyeth v. Levine*, 129 S.Ct. 1187, 1201-1203; Epstein, *supra* note 166, at 4-7; Nagareda, *supra* note 166, at 37-40; Jonathan V. O'Steen & Van 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 166, at 472-476.

<sup>178</sup> See *supra* note 166.

<sup>179</sup> But see MCGARITY, *supra* note \_\_\_\_, 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.

<sup>180</sup> 518 U.S. 470 (1996).

<sup>181</sup> 21 U.S.C. §360c *et seq.*

The pacemaker at issue in *Lohr* was designated a “Class III” medical device.<sup>183</sup> 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.<sup>184</sup> 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.<sup>185</sup> Section 360k of the MDA provides that “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.”<sup>186</sup> The manufacturer 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.<sup>187</sup> The Court held otherwise; none of the legislative history with regard to the MDA suggested a comprehensive preemption of traditional common law remedies.<sup>188</sup> Moreover, had Congress intended such a result, it chose a very odd word with which to achieve it.<sup>189</sup> When it used the word “requirement,” Congress was primarily concerned with conflicting state statutes and regulations, not state common law duties and remedies.<sup>190</sup> 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.<sup>191</sup> 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.<sup>192</sup>

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<sup>182</sup> 21 U.S.C.A. §301 *et seq.*; *Lohr*, 518 U.S. at 487-89.

<sup>183</sup> *Lohr*, 518 U.S. at 476-77. 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.A. §360c(a)(1)(C)(ii).

<sup>184</sup> §360c(f)(1)(A).

<sup>185</sup> 21 U.S.C.A. §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* 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)).

<sup>186</sup> 21 U.S.C.A. §360k(a).

<sup>187</sup> *Lohr*, 518 U.S. at 486.

<sup>188</sup> *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.

<sup>189</sup> *Id.* at 487-88.

<sup>190</sup> *Id.* at 489.

<sup>191</sup> *Id.* at 492.

<sup>192</sup> *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

The Court changed course in *Riegel v. Medtronic* when it again considered the preemptive effect of § 360k.<sup>193</sup> In *Riegel*, however, the device at issue – a balloon catheter used for a coronary angioplasty -- had undergone the rigorous premarket approval process.<sup>194</sup> The Court reasoned that the premarket approval process does impose “requirements,” as it relates specifically to the “safety and efficacy” of a particular device.<sup>195</sup> Moreover, the Court held that a tort judgment does impose a requirement, insofar as it “‘establishes that the defendant has violated a state-law obligation.’”<sup>196</sup> 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.”<sup>197</sup>

The most recent Supreme Court case to address the tension between FDA preemption and common law tort claims is *Wyeth v. Levine*.<sup>198</sup> *Wyeth* involved a failure to warn claim against the manufacturer of Phenergan, an anti-nausea drug.<sup>199</sup> The plaintiff’s right forearm had to be amputated after she developed gangrene caused by injection of the drug by the “IV-push method,”<sup>200</sup> whereby the drug entered plaintiff’s artery.<sup>201</sup> The plaintiff alleged that Phenergan’s label was defective because it failed to instruct physicians to use the IV-drip method, rather than the higher-risk IV-push method of administration.<sup>202</sup> Moreover, she alleged that intravenous administration of the drug is not reasonably safe because the risk of gangrene and amputation outweigh the drug’s benefits.<sup>203</sup>

The FDA’s drug labeling regulations include no preemption provision similar to that found in § 360k in the medical device context. Thus, the preemption arguments advanced by the manufacturer of the drug focused on the FDA approval of Phenergan’s label generally. As FDA approval of a drug includes approval of the drug’s label, Wyeth

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context, tort liability could be a requirement that is different from, or in addition to, a federal requirement. *Id.* at 503-05, 512.

<sup>193</sup> *Riegel*, 128 S.Ct. at 1011.

<sup>194</sup> *Id.* at 1005.

<sup>195</sup> *Id.* at 1007.

<sup>196</sup> *Id.* at 1008 (citing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 522 (1992)).

<sup>197</sup> *Riegel*, 128 S.Ct. at 1008. 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.*

<sup>198</sup> 129 S.Ct. 1187 (2009).

<sup>199</sup> *Id.* at 1191.

<sup>200</sup> 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 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.

<sup>201</sup> *Id.* at 1191.

<sup>202</sup> *Id.* at 1192.

<sup>203</sup> *Id.*

claimed it could not have changed the Phenergan label without violating FDA regulations. In other words, it could not comply with both the FDA labeling requirements and the tort liability against it which would require it to change its label.<sup>204</sup> The Court rejected this argument; the FDA regulations allow a manufacturer to “add [to] or strengthen” a drug’s label without prior FDA approval.<sup>205</sup> Thus, Wyeth could have changed Phenergan’s label to contraindicate the IV-push method of administration without violating federal law. 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 State law.”<sup>206</sup> 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.<sup>207</sup>

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.<sup>208</sup> The vaccine receives FDA approval prior to its use, and perhaps receives “fast track approval”<sup>209</sup> 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? The current jurisprudential landscape yields little in the way of consistently preserving corrective justice principles in this context, particularly when the non-reciprocal risks created are so blatant. At this point, it is unclear whether and to what extent FDA approval of a vaccine would be considered as having imposed federal requirements on a manufacturer. 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.<sup>210</sup> 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.

Yet 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 which should counter-balance any preemptive

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<sup>204</sup> *Id.* at 1196.

<sup>205</sup> *Id.*

<sup>206</sup> *Id.* at 1200 (citing 71 Fed.Reg. 3922, 3934-3935 (2006)).

<sup>207</sup> *Id.* at 1200-1202. 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.

<sup>208</sup> <http://www.cnn.com/2009/HEALTH/07/09/obama.swine.flu/index.html>

<sup>209</sup> See *infra* pg. 28 and accompanying notes.

<sup>210</sup> See Sharkey (Preemption by Preamble), *supra* note 166 at 233-49.

effect FDA approval would have.<sup>211</sup> 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.<sup>212</sup> The NDA must contain reports of investigations which demonstrate the vaccine’s safety and effectiveness.<sup>213</sup> These investigations include such things as laboratory testing of the drug, as well as clinical trials on human subjects.<sup>214</sup> A team of CDER physicians, statisticians, chemists, pharmacologists, and other scientists reviews the NDA.<sup>215</sup> The NDA may be denied approval 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.<sup>216</sup>

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.”<sup>217</sup> These drugs have shorter review periods<sup>218</sup> and may require less in the way of safety and efficacy information prior to approval.<sup>219</sup> The drug may also receive accelerated approval.<sup>220</sup> 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 by the manufacturer.<sup>221</sup> 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

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<sup>211</sup> See *infra* pg. 24 and accompanying notes.

<sup>212</sup> 21 U.S.C. § 355(b); see <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm> [hereinafter FDA APPROVAL PROCESS] (describing the approval process for new drugs).

<sup>213</sup> 21 U.S.C. § 355(b).

<sup>214</sup> DRUG APPROVAL PROCESS, *supra* note 204.

<sup>215</sup> *Id.*

<sup>216</sup> 21 U.S.C. §355(d).

<sup>217</sup> 21 U.S.C. §356(a)(1).

<sup>218</sup> 21 U.S.C.A. §356(a)(3). The FDA designates certain fast-tracked drugs for Priority Review. The goal for completing a Priority Review is six months, as opposed to ten months for a drug receiving Standard Review.

<sup>219</sup> Kessler & Vladeck, *supra* note 166, 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* [www.gao.gov/cgi-bin/getrpt?GAO-06-402](http://www.gao.gov/cgi-bin/getrpt?GAO-06-402))).

<sup>220</sup> “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.”

<http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/SpeedingAccessToImportantNewTheRapiess/ucm128291.htm#priorityreview>

<sup>221</sup> 21 U.S.C.A. §356-1(c).

result in adverse health consequences or death.”<sup>222</sup> In other words, a vaccine used to ward off the H1N1 virus could 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.<sup>223</sup>

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.<sup>224</sup> First, the process focuses on the safety and efficacy of a drug or vaccine prior to its use by the general public.<sup>225</sup> 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;<sup>226</sup> clinical testing pre-approval generally would not reveal adverse effects which “occur infrequently, have long latency periods, or affect subpopulations not included or adequately represented in the studies.”<sup>227</sup> Thus, the FDA’s approval of a drug is premised on, arguably, fairly modest information as to the drug’s potential side effects.

Moreover, 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 which prevent it from adequately monitoring a drug’s safety post-approval and taking prompt corrective measures.<sup>228</sup> Congress recently enacted the Food

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<sup>222</sup> 42 U.S.C.A. §247d-6(e)(4).

<sup>223</sup> 21 U.S.C.A. §356(b)(2).

<sup>224</sup> See Kessler & Vladeck, *supra* note 166 at \_\_\_\_; see also Struve, *supra* note 166, at 598-606 (discussing why post-marketing surveillance is critical to the FDA’s process).

<sup>225</sup> Kessler & Vladeck, *supra* note 166 at \_\_\_\_ (arguing that premarket approval is generally incapable of detecting certain adverse effects)

[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); Struve, *supra* note 166 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).

<sup>226</sup> Kessler & Vladeck, *supra* note 166 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 Baciú, Kathleen Stratton & Sheila P. Burke eds., 2006) [hereinafter IOM Report]).

<sup>227</sup> *Id.* at 471; Struve, *supra* note 166 at 598-99..

<sup>228</sup> Kessler & Vladeck, *supra* note 166 at 465, 467-468. 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.* Moreover, “[t]he Institute of Medicine . . . 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); Struve, *supra* note 166 at 601.

and Drug Administration Amendments Act (FDAAA),<sup>229</sup> which provides the FDA with new resources to monitor a drug's safety once it has been approved.<sup>230</sup> Although 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 does not agree with the FDA's view that it is able adequately to monitor drug safety.<sup>231</sup> In addition, Congress did not include any preemption language in the FDAAA, much to the pharmaceutical companies' disappointment.<sup>232</sup>

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.<sup>233</sup> 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 be conclusively 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 remain to fill in the gaps. Allowing the two systems to parallel one another will best serve corrective justice principles.

These criticisms highlight as well that aspect of the preemption debate which focuses on whether the FDA regulates for “minimal” versus “optimal” safety.<sup>234</sup> 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 non-reciprocal risk theory of corrective justice would deem the distinction irrelevant and would demand

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<sup>229</sup> Food & Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007) [hereinafter FDAAA].

<sup>230</sup> FDAAA, tit. I, sec. 103(b)(4), § 736(b), 121 Stat. 823, 828 (2007).

<sup>231</sup> Kessler & Vladeck, *supra* note 166 at 468.

<sup>232</sup> FDAAA, tit. IX, sec. 901(a), § 505(o)(4)(I), 121 Stat. 823, 925-26 (2007); Kessler & Vladeck, *supra* note 166 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. Kessler & Vladeck, *supra* note 166 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.

<sup>233</sup> *Id.* at 486, 488-89, 491.

<sup>234</sup> Peter H. Schuck, *FDA Preemption of State Tort Law in Drug Regulation: Finding the Sweet Spot*, 13 *Rog. Wms. 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.* at 77-78.

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 which 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 for his injuries. Thus, as explained in greater detail in Part V 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.<sup>235</sup> Thus, although the preemption debate looms large in the face of tort lawsuits against manufacturers of vaccines, it need not eliminate compensation to victims. Corrective justice can still be furthered, given an appropriate compensation mechanism.

#### 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 shape the authors' determination of a more appropriate paradigm for determining liability and compensation in Part V below.

The current congressional vaccine programs have been shaped, and thus created, with an eye toward purely instrumentalist goals, *e.g.*, widespread vaccination levels and protection of vaccine manufacturers, which in turn facilitates continued production of vaccines. One goal of the NCVIA does appear to be ensuring compensation to certain victims as well. But the other more recent vaccine programs appear to eschew such a goal, with the sole objective seemingly favoring manufacturer immunity. Claimants' ability to recover for vaccine-related injuries has diminished substantially under the later congressional programs, while manufacturer liability has all but disappeared.<sup>236</sup> Although the concern regarding manufacturer liability, and the subsequent consequence of limited vaccine resources and vaccination levels, has most assuredly been solved by the federal government's programs, injured victims increasingly appear 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.

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<sup>235</sup> Nagareda, *supra* note 166 at 15-16; Sharkey (Products Liability Preemption), *supra* note 166 at 459-66.

<sup>236</sup> See *infra* notes \_\_\_\_\_ and accompanying text (re: criticisms of NCVIA, SEPPA and 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" for manufacturers has become a code word for instrumentalist thinking. However, Fletcher's nonreciprocal risk theory of corrective justice may be a more appropriate and principled basis 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 principals of corrective justice fail to underlie a particular vaccine program, the program fails, as in the case of SEPPA. When the possibility exists that a victim of a vaccine injury may not receive any damages for that injury, 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 of those injured by vaccines that are mandated by the government? What of those injured by vaccines when the threat of the disease for which the vaccine is created is real and imminent, as perhaps the H1N1 virus? This scenario is precisely that for which the nonreciprocal risk theory would demand corrective justice for the injured victim. Yet increasingly, these statutory programs are failing those injured by vaccines.

It is useful to keep in mind that these congressional programs were born from certain specific problems. The NCVIA was driven by the problems inherent in the civil tort system: inconsistent judgments for plaintiffs on the one hand,<sup>237</sup> and potentially crippling conditional liability for pharmaceutical companies on the other.<sup>238</sup> 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 difference in genesis among these programs, in conjunction with other criticisms of the programs, is significant in light of corrective justice principles. The shortcomings of these programs also provide the basis for the authors' construction of a more comprehensive compensation and liability model, focused on the intersection of a variety of risks implicated by vaccine injury.

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

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<sup>237</sup> See Steel, *supra* note \_\_\_, at 152. E.g., Reyes, 498 F.2d 1264; Givens v. Lederle, 556 F.2d 1341, 1345 (5<sup>th</sup> Cir. 1977); Davis v. Wyeth Lab., Inc., 399 F.2d 121, 128 (9<sup>th</sup> Cir. 1968). But see Johnson v. American Cyanamid co., 718 P.2d 1318, 1325-26 (Kan. 1986); Wyeth Lab., Inc. v. Fortenberry, 530 So. 2d 688, 691-93 (Miss. 1999).

<sup>238</sup> 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. Teresa Moran Schwartz, *Prescription Drugs and the Proposed Restatement (Third) of Torts*, 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. 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).

vaccine-related injuries, manufacturers must be protected so as not to threaten this nation's vaccine supply.<sup>239</sup> Governmental payment of claims may be somewhat appropriate in the context of these Acts considering the government is the one 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 is one that furthers the government's goal of public health,<sup>240</sup> 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.<sup>241</sup> In case of a flu pandemic or even bioterrorist attack, the American public must be immunized at a high rate and on a large scale to prevent the spread of disease.<sup>242</sup>

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<sup>243</sup> may very well dictate that the government should share in some responsibility for any injuries sustained. This reasoning appears to reflect the language in the Responsible Public Readiness and Emergency Preparedness Act of 2006, that indemnification should be available only to the extent a declaration has been issued by the HHS Secretary and the vaccine or other countermeasure has not received full FDA testing. In other words, the vaccine has been subject to an expedited FDA approval process. 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 suffer the liability.<sup>244</sup>

Yet the immunity for manufacturers under SEPPA and the Prep Act, in addition to the dim prospect of compensation for victims under these programs, is inconsistent with corrective justice principles. Not only does corrective justice seek to compensate victims, it does so from the standpoint of forcing the wrongdoer – here (at least at first blush), the manufacturer, not the government -- to pay a victim's damages.<sup>245</sup> Thus, it is important that some specter of liability remain to maintain vaccine manufacturers' consistent production of safe, effective vaccines.<sup>246</sup> Moreover, the compensation allegedly to be provided under these Acts has been criticized as being illusory. If a claimant has no realistic possibility for compensation, corrective justice principles are assuredly thwarted. That does not mean, of course, 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, though a comprehensive regulatory system and mandated

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<sup>239</sup> See Greenberger, *supra* note 10, at \_\_\_\_.

<sup>240</sup> 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).

<sup>241</sup> Steel, *supra* note 136, at 145.

<sup>242</sup> 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).

<sup>243</sup> *Id.* Greenberger, *supra* note 10, at \_\_\_\_.

<sup>244</sup> 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. FDA website (<http://www.fda.gov/cber/vaccine/vacappr.htm>).

<sup>245</sup> MCGARITY, *supra* note \_\_\_\_, at 232.

<sup>246</sup> 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).

contributions from all manufacturers in the pharmaceutical industry simultaneously be held and hold themselves accountable for injuries caused by vaccine. Notions of this kind of approach are sometimes referred to as “enterprise liability” – and we will take those up in more depth in Section V, *infra*.

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 he or she is enrolled at a day care or is in a public school.<sup>247</sup> 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 numbers of claimants under the program and the extent to which damages are paid to those claimants. Yet the NCVIA is still not an adequate model upon which to formulate a future liability and compensation program for injuries due to other vaccines, insofar as advancing corrective justice principles. First, although the government mandates childhood vaccines be administered to every school-age child in this country, 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.<sup>248</sup> 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.

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. 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 which 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. 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

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<sup>247</sup> 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. Hagan, *supra* note 6, at 479. “These federal grants require compliance with national objectives, such as ‘the rigorous enforcement of school immigration law.’” *Id.*

<sup>248</sup> See generally 42 U.S.C.A. §§ 300aa-1-5. “[The Center for Biologics Evaluation and Research (CBER)] and the [CDC] jointly manage the Vaccine Adverse Event Reporting System ([VAERS](http://www.fda.gov/cber/vaccines.htm)), 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 US licensed vaccines.” FDA website (<http://www.fda.gov/cber/vaccines.htm>). “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.” FDA website (<http://www.fda.gov/cber/vaers/vaers.htm>).

vaccination. Person A, who chooses not to receive a vaccination, may contract whatever disease the vaccine was intended to prevent. Person A may then pass the disease to Person B, who plans to get vaccinated, but hasn't yet. Now, Person B has the disease, yet has no recourse against anyone. If corrective justice principles played a more central role in this "front and center" view of non-reciprocity of risks as between the vaccine manufacturer and Person A, the risks Person A created with respect to Person B might be avoided. As discussed in more detail in Part V below, a liability and compensation scheme must take these other risks into consideration 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 set up in the NCVIA make proving causation considerably more difficult. And the extent to which establishing an element of one's claim is made more challenging under a statutory program, the less likely corrective justice principles are advanced. The NCVIA has been criticized for failing "to ensure the 'expeditious and fair' compensation of vaccine-injured persons."<sup>249</sup> While having proven successful at reducing the amount of lawsuits brought against vaccine manufacturers, it has proven very difficult for claimants to actually receive compensation because many claimants are turned away.<sup>250</sup> The broad authority of the Special Masters 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.<sup>251</sup>

As discussed earlier<sup>252</sup>, Special Masters in the vaccine court 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 United States Federal Claims Court.<sup>253</sup> They are appointed for a four-year term, and once appointed, may only be removed for incompetence, misconduct, neglect of duty, or physical or mental disability.<sup>254</sup> Each Special Master has total jurisdiction of the initial proceedings, and although a petitioner may seek review of the Special Master's determination of compensation, and even appeal that review to the United States Court of Appeals for the Federal Circuit, the standard of review of these courts is highly deferential to the Special Master's decision.<sup>255</sup> The United States Federal Claims Court will only set aside the

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<sup>249</sup> Breen, *supra* note 32, at 320. See H.R. Rep. No. 99-908, at 12 (describing congressional goals in passing the NCVIA).

<sup>250</sup> Ridgway, *supra* note 142, at \_\_\_; Steel, *supra* note 137, at \_\_\_.

<sup>251</sup> Breen, *supra* note 32, 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." Id., citing...; Ridgway, *supra* note 142, at \_\_\_; Steel, *supra* note 137, at \_\_\_.

<sup>252</sup> See note \_\_\_\_\_, *supra*.

<sup>253</sup> 42 U.S.C. § 300aa-12(c)(4).

<sup>254</sup> Id. at § 300aa-12(c)(2).

<sup>255</sup> Breen, *supra* note 32, at 322.

Special Master’s decision if it is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.”<sup>256</sup> 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.<sup>257</sup> This highly deferential standard of review of the Special Masters effectively ensures that a Special Master’s determination will not be overturned.

Not only has the authority of the Special Masters been called into question, the entire goal of the NCVIA of fair and efficient adjudication of claims has also been criticized. The system has become increasingly adversarial, and the government has taken to arguing “technical and aggressive” defenses, comparable to a trial.<sup>258</sup> 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.<sup>259</sup> 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 (NVICP)] 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 NVICP contains no provision to deflect accusations of the same sort brought against the no-fault claims process.”<sup>260</sup>

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.<sup>261</sup>

NCVIA’s procedures with respect to claimants’ attorneys also may undermine the fairness that was intended by the program. 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.”<sup>262</sup> The attorney is thus required to prove that the fee requested was

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<sup>256</sup> 42 U.S.C. § 300aa-12(e)(2)(B); Breen, *supra* note 32, at 322.

<sup>257</sup> Breen, *supra* note 32, at 323.

<sup>258</sup> Steel, *supra* note 137, at 159-160.

<sup>259</sup> Ridgway, *supra* note 142, at 68.

<sup>260</sup> *Id.* at 69.

<sup>261</sup> Steel *supra* note 137, at 169.

<sup>262</sup> 42 U.S.C. § 300aa-15(e).

reasonable.<sup>263</sup> However, as these claims have become more adversarial in nature, attorneys have spent many more hours on them than was initially anticipated.<sup>264</sup> As such, Special Masters have determined in some cases that the attorney's fee was not reasonable.<sup>265</sup> Moreover, if a claimant wants the Special Master's decision reviewed, and then even appeals that review, the attorney will not be compensated until a final decision has been reached.<sup>266</sup> As a result, many attorneys are reluctant to take NCVIA cases.<sup>267</sup>

Similarly, expert witness testimony, which is necessary to establish causation in many cases, is paid for by the attorneys; thus, the expert cannot get paid until all of the subsequent judicial reviews have been exhausted.<sup>268</sup> 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.<sup>269</sup> 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.<sup>270</sup> 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.<sup>271</sup> This system effectively places the attorney's interests at odds with the claimant's interests.<sup>272</sup>

Finally, although the NCVIA may provide adequate compensation 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 suffering – and it covers no injuries that are suffered in vitro when an expectant mother receives a vaccine. Arguably, the caps on those awards should be increased from what was established twenty years ago,<sup>273</sup> death benefits should be significantly enhanced, the scope of covered vaccines should be expanded, and the vaccination of expectant mothers encompassed. This certainly seems possible, as the fund from which these benefits are paid currently has a balance of over \$2 billion<sup>274</sup>-- and 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 Section V, *infra*.

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<sup>263</sup> Steel *supra* note 137, at 161.

<sup>264</sup> *Id.* at 162.

<sup>265</sup> *Id.*

<sup>266</sup> *Id.* 160-161.

<sup>267</sup> *Id.* at 161.

<sup>268</sup> *Id.* at 166.

<sup>269</sup> *Id.*

<sup>270</sup> *Id.* at 166-167.

<sup>271</sup> *Id.* at 165.

<sup>272</sup> *Id.*

<sup>273</sup> 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).

<sup>274</sup> United States Dept. of Health and Human Services Health Resources and Service Administration website: ([http://www.hrsa.gov/vaccinecompensation/strategic\\_plan.htm](http://www.hrsa.gov/vaccinecompensation/strategic_plan.htm)).

In sum, while these programs arguably serve laudable goals, they are exactly that: goal, or outcome, 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 coherent 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 Section V.

## V. Rethinking The Model For Vaccine Injury Regulation: A Paradigm For Congressional Action

### A. Introduction

As Professor McGarity recently observed in his book *The Preemption War*, “Congress is the only institution which can bring an end to the preemption war” – and, as the authors here contend, to prevent that war from making the 21<sup>st</sup> century world of vaccination its latest front – “for the simple reason that Congress is the only institution with the power to preempt.”<sup>275</sup> Congress should, therefore, take up the question of FDA preemption generally – and the related question of whether the current statutory preemption by the NCVIA and similar laws specifically – and do so with special regard to vaccines. The time for re-thinking 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

### B. Using Principles And A Depechage Approach To Begin The Re-Thinking Of Approaches To Vaccine-Injury Liability

#### 1. Principles

The non-reciprocal risk theory calls into question some aspects of the current schemes in use or proposed to deal with vaccine caused injuries: [1] the NCVIA provided table of injuries and vaccine court; [2] the nascent but unenacted FTCA-based Section 304 of the Homeland Security Act; [3] the SEPP act; and [4] the Prep Act. Each of these schemes distorts the nature of the risks--both reciprocal and non-reciprocal--in favor of vaccine manufacturers and the federal government. These bills strike a balance at various points along a risk continuum in favor of a governmental interest in widespread vaccination by incenting the pharmaceutical industry with liability sieves--and in some of the legislation--outright shields.

The non-reciprocal risk theory also calls into question the “tort-reform” effort du jour – the activist wielding of federal pre-emption.

The balance is struck, of course, at the expense of each individual member of the public who is subjected to vaccine-associated risks; and the subset of individuals who actually suffer when the risks eventuate in their case. This is fairly typical of the tort-reform movement.<sup>276</sup>

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<sup>275</sup> THOMAS O. MCGARITY, *THE PREEMPTION WAR: WHEN FEDERAL BUREAUCRACIES TRUMP LOCAL JURIES* 247 (2008).

<sup>276</sup> See, e.g., Kathleen E. Payne, *Linking Tort Reform To Fairness And Moral Values*, 1995 Det. C.L. Mich. St. U. L. Rev. 1207, 1215-1236 (1995).

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. Vaccines reduce the risk that each of us, as individuals, poses to every other individual in our community and, on a more attenuated yet palpable level due to modern car and air travel<sup>277</sup>, to our state and the nation as extended communities. 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 themselves carriers and victims. To that extent, the risks appear reciprocal. On the other hand, with some illnesses--for example, anthrax<sup>278</sup>--there are subpopulations of individuals who are much more likely to come in contact with the disease in their work

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<sup>277</sup> 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., L. Masae Kawamura, *Have Germs Will Travel*, N.Y. Times, Op-Ed, June 2, 2007. Dr. Kawamura, the director of the tuberculosis control section of the San Francisco Department of Public Health, highlighted the danger posed by international air travel as a transmission medium of potential pandemics:

If it turns out that none of his fellow passengers were actually infected with the dangerous form of tuberculosis he carries, then Andrew Speaker, the young honeymooner who recently eluded government efforts to keep him off commercial flights, may actually have done a favor to public health. His case has brought to light the neglected but growing problem of super drug-resistant tuberculosis, and the ease with which this deadly airborne disease can travel around the world.

Id. (available at <http://www.nytimes.com/2007/06/02/opinion/02kawamura.html?>) (visited Sept. 5, 2008); 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); see generally David P. Fidler, Lawrence O. Gostin, Howard Markel, *Through The Quarantine Looking Glass: Drug-Resistant Tuberculosis And Public Health Governance, Law, And Ethics*, 35 J.L. Med. & Ethics 616 (2007 Symposium Global Health Law, Ethics, and Policy).

<sup>278</sup> As the CDC notes:

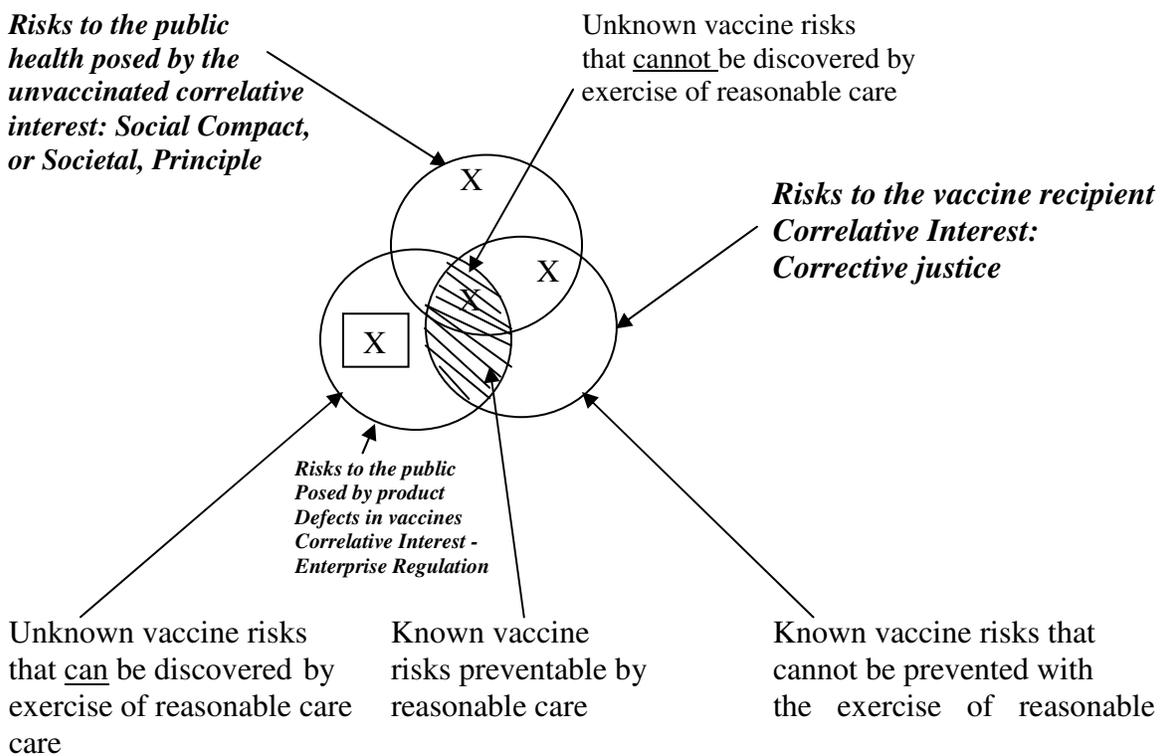
Anthrax is most common in agricultural regions where it occurs in animals. These include South and Central America, Southern and Eastern Europe, Asia, Africa, the Caribbean, and the Middle East. When anthrax affects humans, it is usually due to an occupational exposure to infected animals or their products. 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.

[http://www.cdc.gov/nczved/dfbmd/disease\\_listing/anthrax\\_gi.html#common](http://www.cdc.gov/nczved/dfbmd/disease_listing/anthrax_gi.html#common) (last visited May 26, 2008).

and life. Such subpopulations pose greater risks of spreading disease than others in the population present of spreading it to them. Of course, 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.

A visual metaphor for this inter-relationship of issues might be helpful. For example, we might portray them as follows:

DIAGRAM ONE: OVERVIEW OF RISKS AND PRINCIPLES RELEVANT TO VACCINE-INJURY POLICY



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 are since the 1980s -- the adjudicatory process itself becomes an extension of the tort injury and the limitations that the régime imposes operates 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.<sup>279</sup> That principle intersects with the broader principle of what enterprise regulation.<sup>280</sup> What we typically describe as tort law are substantive rules that emanate from one or both of those principles. In the context of an individual tort claim, the rules of law we choose to apply—including both the substance of the law as well as the procedure of decisionmaking—should reify the corrective justice and enterprise regulation principles in a Dworkinian model.<sup>281</sup> Conversely, those principles justify the rules for framing and pursuing a tort cause of action.

However, in the matter of vaccines, there is a third principle that must be recognized. That principle shall be called the “Social Compact or Society Principle”.<sup>282</sup> This principle embodies the philosophical view of various philosophers since the European Enlightenment that humankind organizes into a civil society in which individuals are afforded 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

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<sup>279</sup> DAN B. DOBBS, *THE LAW OF TORTS*, Ch.1, §9, at 13-16 (2000); see, e.g., Gregory C. Keating, *Distributive And Corrective Justice In The Tort Law Of Accidents*, 74 S. CAL. L. REV. 193 (2000) (“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 of agency and responsibility, carelessness and wrongdoing, harm and reparation.”); 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 (1996) (Corporate Tort Liability Symposium); JULES L. COLEMAN, *The Practice of Corrective Justice*, in *PHILOSOPHICAL FOUNDATIONS OF TORT LAW* 53 (David G. Owen ed., 1995); Ernest J. Weinrib, *The Idea Of Private Law* 84-113 (1995); 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.”); Catharine Pierce Wells, *Tort Law as Corrective Justice: A Pragmatic Justification for Jury Adjudication*, 88 MICH. L. REV. 2348 (1990); Jules L. Coleman, *RISKS AND WRONGS* (1992); Alan Schwartz, *Responsibility and Tort Liability*, 97 ETHICS 270 (1986); R. Posner, *The Concept of Corrective Justice in Recent Theories of Tort Law*, 10 J. LEG. STUDIES 187, 188 (1981); George P. Fletcher, *Fairness and Utility in Tort Theory*, 85 HARV. L. REV. 537, 538 (1972).

<sup>280</sup> See text and notes at nn.\_\_\_\_, *infra*.

<sup>281</sup> “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” Eric Dworkin, *Debunking Integrity’s ‘Equality Advantage’: The Absence of Coordination in Ronald Dworkin’s Law’s Empire*, 83 IOWA L. REV. 1071, 1080 (1997-1998); Ronald M. Dworkin, *Model of Rules*, in *TAKING RIGHTS SERIOUSLY*. 22 (1978); RONALD DWORKIN, *A MATTER OF PRINCIPLE* 147 (1978); See 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”).

<sup>282</sup> See Joseph Kary, “Contract Law and the Social Contract: What Legal History Can Teach Us About the Political Theory of Hobbes and Locke”, 31 *Ottawa Law Review* 73 (Jan. 2000); Thomas Hobbes, *Leviathan* (1651 ); John Locke, *The Second Treatise On Government* (1689 ); Jean-Jacques Rousseau, *The Social Contract, or Principles of Political Right* (1762).

the health and liberty of all members of society as a whole, including that individual.<sup>283</sup> The inherent duality in the nation of benefits and obligations – including the obligation to incur risks to the individual in pursuit of society goals – make the evaluation of scenarios of individual sacrifice for what is perceived as the social good potentially complex as an equation of polycentric decisions.<sup>284</sup>

Viewed from the perspective of the corrective justice principle substantive rules and procedural rules cannot be separated into the neat, artificial compartments — a habit of intellectual sloth to which most lawyers at times succumb. Both “sets” of rules serve the same animating corrective justice principle that requires compensating individuals for injury caused to their persons and property when individuals, partnerships, or corporations engage in commercial activity that creates a nonreciprocal risk to those individuals and that causes that risk to eventuate in personal injury. The non-reciprocal risk articulation of the corrective justice principle provides a substantive objective that the substantive and procedural court-access rules are designed to achieve. The enterprise regulation principle makes it legitimate for a sovereign to act to affect the corrective justice principle. 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.<sup>285</sup> 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.

We may get a better understanding of the intersection of these three principles in vaccine-injury cases by, once again, resorting to a visual metaphor:

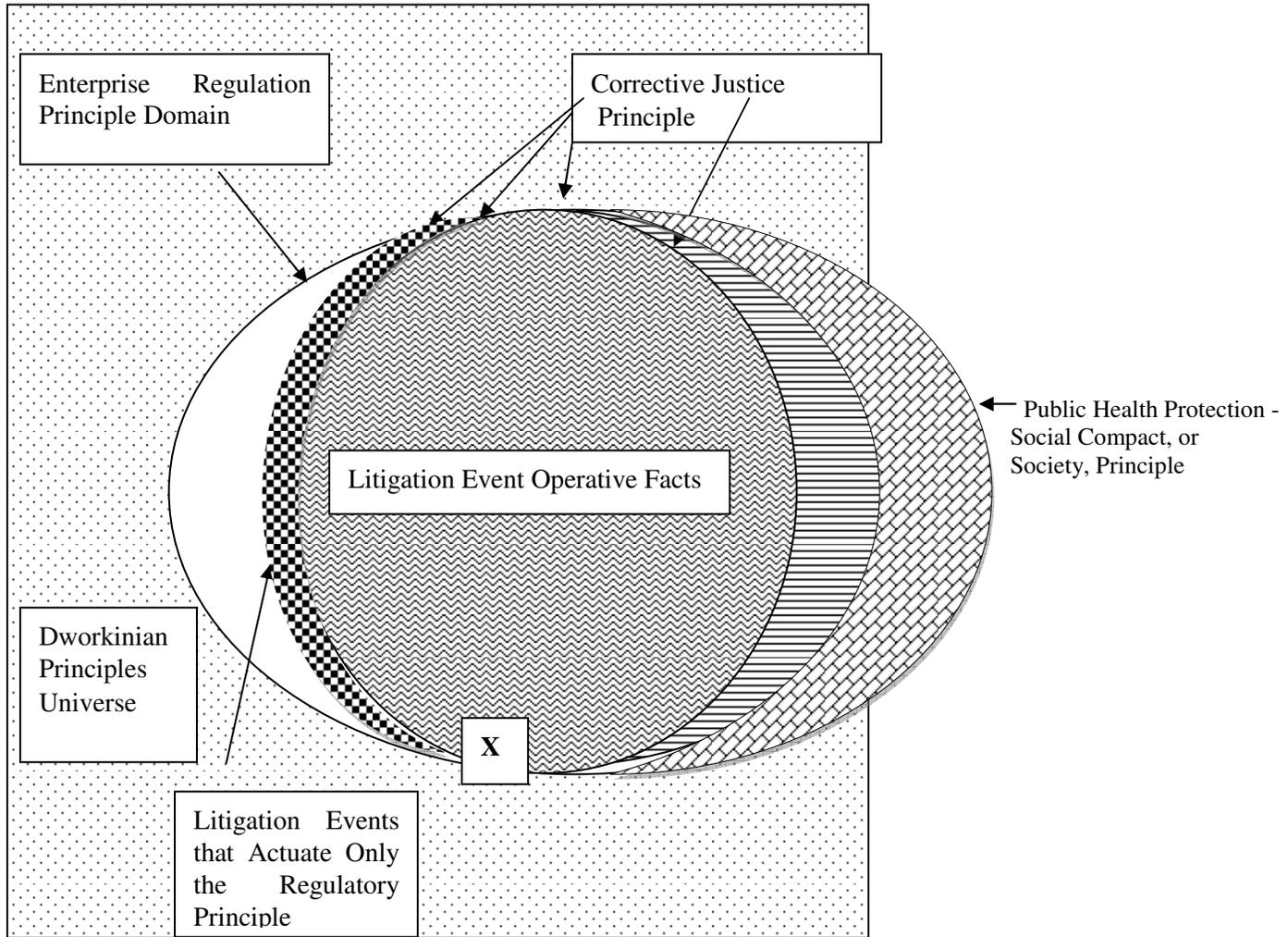
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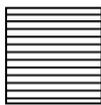
<sup>283</sup> See, e.g., 1 CHRISTOPHER G. A TIEDEMAN, TREATISE ON STATE AND FEDERAL CONTROL OF PERSONS AND PROPERTY IN THE UNITED STATES CONSIDERED FROM BOTH A CIVIL AND CRIMINAL STANDPOINT 39 (1900); see also Jeffrey A. Van Detta, Comment, *Compelling Governmental Interest Jurisprudence Of The Burger Court: A New Perspective On Roe v. Wade*, 50 Alb. L. Rev. 675, \_\_\_\_ (1986).

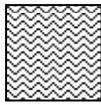
<sup>284</sup> See, e.g., RANDY BARNETT, RESTORING THE LOST CONSTITUTION: THE PRESUMPTION OF LIBERTY \_\_\_\_ (Princeton, 2004), ; see also GEORGE WILLIAM WINTERBURN, THE VALUE OF VACCINATION: A NON-PARTISAN REVIEW OF ITS HISTORY AND RESULTS 145-150 (expressing contrarian view, suggestive of polycentrism) (available at GoogleBooks.com)

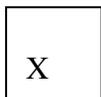
<sup>285</sup> See Ronald Dworkin, *The Model of Rules*, \_\_\_\_ U. CHI. L. REV. \_\_\_\_ (1967)

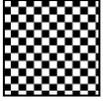
DWORKINIAN PRINCIPLES AND VACCINE-INJURY LIABILITY:  
A METAPHORIC VENN DIAGRAM



 Operative facts of litigation events fall within domain of 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 drug, device or pharmaceutical 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 health – 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, persons entering military service, for example. 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, 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.<sup>286</sup>

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<sup>286</sup> See, e.g., Jody Amour, *Just Deserts: Narrative, Perspective, Choice, And Blame*, 57 U. Pitt. L. Rev. 525 (1996) (discussing the teaching of *O’Brien v. Cunard S.S. Lines*, 154 Mass. 272, 28 N.E. 266 (1891)). Professor Amour makes our point about how legal principle must be informed by the real-world knowledge that “yes” does not always mean “consent”:

Before informing my students of key aspects of the narrative that the court left out, I correct a basic and commonplace flaw in the students’ logic. “Just because one submits to the demands of another does not mean that the person consents to those demands, does it?” I query rhetorically. “If someone points a gun at you and says ‘you should give me your wallet,’ you would not say that your act of handing over your wallet—your choice to give him the wallet rather than risk a bullet—was a consensual act, a free choice, would you?” The students immediately comprehend that focusing too narrowly on a transaction without considering its context undermines clear thinking about consent and choice.

*Id.* at 532. Similarly, as some critical race scholars have observed of how this century-old vaccine case raises acute issues of what “consenting” to societally compelled injury contemplates:

To show them how judicial command and structural power work intimately, [Professor] Brown points to *O’Brien v. Cunard S.S. Co.* . . .

*O’Brien*, Race Critics would argue, represents differences in structural power. Brown told the students that power differentials, especially around class, gender, and race, have real meaning. As instruments of state authority, judges can use their power to probe deeper and wider so that plaintiffs can tell their story, thus preventing traditional interpretations

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of evidentiary rules from reducing ordinary people and their values to mere doctrinal decision nodes. By failing to appreciate the status difference between an Irish immigrant woman who was in steerage and who was dealing with an English Bostonian, the court views *O'Brien* and the ship's surgeon through the doctrinal lens of the reasonable person, rejecting her subjectivity and burdening her with the cost of miscommunication.

. . . . In *O'Brien*, Judge Knowlton could not see gender subordination. He presumed the naturalness of his institutional power and his male perspective. Power has this habit. Thus, in *O'Brien*, Judge Knowlton construes Mary O'Brien not as consenting under duress, but as simply failing to speak, thus "telling" the ship's surgeon to inject her. In the end, it is her burden, her cost.

. . . . From a male hegemonic perspective, Judge Knowlton and the ship's surgeon were of one "cultural" mind. He could relate to the doctor. "How's a man to read a woman's mind?" I could also hear the judge's private thoughts. Having the ability to speak, but failing to do so, the *O'Brien* court refuses sua sponte to draw on non-legal facts. It would not place Mary O'Brien against the background of society's hegemonic practices.

Status, for the court, was thus not the central issue; it was her legal pleadings. Beyond the evidentiary scope of the case, this court would not go. For Judge Knowlton, social structure would constitute non-justiciable claims. He'd brook no political, structural inquires. In the end, Mary O'Brien could read. She could speak. Doing neither well, the court would not delve deeper.

Reginald Leamon Robinson, *The Sacred Way Of Tibetan CRT Kung Fu: Can Race Crits Teach The Shadow's Mystical Insight And Help Law Students "Know" White Structural Oppression In The Heart Of The First-Year Curriculum? A Critical Rejoinder To Dorothy A. Brown*, 10 Mich. J. Race & L. 355, 380-382 (2005)(footnotes omitted)(describing views of the *O'Brien* case expressed in DOROTHY A. BROWN, CRITICAL RACE THEORY: CASES, MATERIALS, AND PROBLEMS 99-101 (2003)); accord Ann C. Shalleck, *Feminist Legal Theory and the Reading of O'Brien v. Cunard*, 57 Mo. L. Rev. 371 (1992) ; Richard W. Bourne, *Five Approaches to Legal Reasoning in the Classroom: Contrasting Perspectives on O'Brien v. Cunard S.S. Co.*, 57 Mo. L. Rev. 351 (1992). It is worth nothing that Oliver Wendell Holmes, Jr., was a member of the *O'Brien* court, a member of the court that upheld the state's power to compel vaccination in *Jacobsen v. Massachusetts*, 197 U.S. 11 (1905), affirming a decision by the Supreme Judicial Court shortly after Holmes had been confirmed to the U.S. Supreme Court, 183 Mass. 242, 66 N.E. 719 (1903), and upheld forced sterilization in *Buck v. Bell*, 274 U.S. 200, 207 (1927), where he made the infamous, pro-eugenics comment about "three generations of imbeciles are enough." Holmes was certainly no friend to women, or to other politically disempowered groups confronting the superior power of the state, though a good deal of modern "consent" theory underlying the extent of governmental intrusion in private lives can be traced to the influence of his positivist legal philosophy. See, e.g., *Buck v. Bell*, 274 U.S. at 207, where he cites the vaccine cases in support of his views of "constructive" consent of the individual in the service of the collective interests of society:

We have seen more than once that the public welfare may call upon the best citizens for their lives. It would be strange if it could not call upon those who already sap the strength of the State for these lesser sacrifices, often not felt to be such by those concerned, in order to prevent our being swamped with incompetence. It is better for all the world, if instead of waiting to execute degenerate offspring for crime, or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind. The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes. *Jacobson v. Massachusetts*, 197 U. S. 11 . . .

Id.; see ALBERT W. ALSCHULER, LAW WITHOUT VALUES: THE LIFE, WORK, AND LEGACY OF JUSTICE HOLMES (2000).

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 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 choice(s) to be made among these six rule outcomes, there are also choices to be made about both the adjudicatory forum and the form of adjudication in which the chosen rule outcomes will be applied. The adjudicatory for a include courts of general jurisdiction, courts of special jurisdiction, government-facilitated arbitration, privately facilitated arbitration, administrative agency adjudication, or administrative agency pre-emption. 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 pre-emptive 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 multiples because of the tangle between the group 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] member 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 the excess of overemphasis that came from focusing on a particular identity perspectives, or underlying principle, to the diminution, or even exclusion, of others. Thus, it focuses too much on enterprise regulation, corrective justice, and the injured’s individual autonomy to argue, as Melvin Belli did in *Gottsdanker v. Cutter Laboratories*<sup>287</sup> that the process of vaccine manufacture “should and could be perfect”<sup>288</sup> – i.e., that both the public expects, and the law should demand,

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<sup>287</sup> 6 Cal. Rptr. 320 (Cal. Ct. App.1960); see Paul A. Offit, *The Cutter Incident*, Ch. 7 (2003). This case involved one of the seven laboratories who made the original issue of the Salk killed-virus polio vaccine, Cutter Laboratories, and its failure to ensure that all live polio virus 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. In the worlds of vaccinology and law, this event quickly acquired the moniker, “The Cutter Incident.” Offit, *supra*, at \_\_; see, e.g., N. Nathanson and A.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 *American Journal of Hygiene* 29-60 (1963).

<sup>288</sup> Offit, *supra* note 22, at 141-142. Dr. Offit quotes attorney Belli in 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. “there 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 non in yours — that the process could and should be perfect.”

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 when applying Fletcher's theory. Second, there is a problem that already troubles many a vaccine-injury claimant even under present régimes – the perennial problem of causation.

*First, the peculiar, multi-layered nature of the risk-reciprocity analysis.* Reciprocity must be viewed not in the monochromatic, illustrative risk-creating pairs analysis that characterized the examples Fletcher used in his iconic article – i.e., the risk that the manufacturers of vaccine 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. 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 vaccines), versus the risk society poses to that unvaccinated individual or group. The reciprocity analysis is further complicated because the entity creating the vaccine-injury risk to individuals is not merely another person in the victim's space-time. Instead, it is a collection of entities, in addition to the pharmaceutical entities which design, manufacture, and/or distribute the vaccine. This collection of entities includes representatives of the military-industrial complex, composed of research laboratories, public health agencies, public health 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<sup>289</sup>), as well as the circumstances of

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Id. at 142 (quoting the reporter's transcript, *Gottsdadanker v. Cutter Laboratories*, District Court of Appeal of the State of California, First Appellate District, 1 Civ. 18,413 and 18, 414, Nov. 20, 19857 – Jan. 31, 1958; see id. at 215-216, note on Ch. 7).

<sup>289</sup> An adjuvant is an agent that may stimulate the immune system and increase the response to a vaccine, without having any specific antigenic effect in itself. It includes any substance that acts to accelerate, prolong, or enhance antigen-specific immune responses when used in combination with specific vaccine antigens. See, e.g., U. S. Institutes of Health, National Cancer Institute, Dictionary of Cancer Terms, available at [http://www.cancer.gov/templates/db\\_alpha.aspx?CdrID=43987](http://www.cancer.gov/templates/db_alpha.aspx?CdrID=43987) (last visited July 21, 2009); Shin Sasaki and Kenji Okuda, *The Use of Conventional Immunologic Adjuvants in DNA Vaccine Preparations*, in D.B. LOWRIE AND R.G. WHALEN, *DNA VACCINES: METHODS AND PROTOCOLS*, CH. 21 at 241 (Humana Press 2000).

the vaccine's marketing, field testing, approval process, governmental adoption or mandate, and systematic distribution.<sup>290</sup> The relationships are too heterogeneous and the process too blurry in its complexity in actual operation to admit of fine distinction and categorization of vaccine-to-injury encounters. Therefore, we must work with an approximation of the typical risk reciprocities created in the aggregate by the operation and interplay of these forces. Recognizing their existence and constituency, however, is critical to the construction of a tenable assessment model.

*Second, the perennial problem of causation* – i.e., the linkage of vaccine administration to individual injuries across large populations of vaccine takers and an unpredictable, and sometimes unidentifiable, source contributing to, and perhaps even solely causing, the injury that a vaccine is asserted to have caused (typically because of temporal proximity). The elusive problem of causation dominates all but the most well-documented and directly discernable vaccine-injuries.<sup>291</sup> The experience under the NCVIA is emblematic of what the experience is like generally in realm of state-and-federal-court 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. The difficulties come in three 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] clinical, rather than epidemiological, nature of the evidence that typically is available; [5] disagreement by judges over “whether circumstantial evidence alone can

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<sup>290</sup> The politics of the post-approval process itself are frighteningly complex, and involve internecine disputes within the Centers for Disease Control and the National Institutes for Health, complications presented by “junk science” that professional expert witnesses would purport to give on a systemic basis, lobby groups for both the injured and the industry, competing studies with disparate results mounted by industry and government, both at home and abroad, and the occasional and narrowly focused oversight that some members of Congress seek to exercise from time to time based on pressure from their constituents. See, e.g., Arthur Allen, *Vaccine: The Controversial Story Of Medicine's Greatest Life-Saver*. Congressional funding for and assignment of oversight of vaccine development, testing, field deployment, and injuries has varied widely over the last 50 years. See, e.g., *id.* at 316-318 (describing the creation during the Clinton Administration of the National Immunization Program, the Vaccine Adverse Events System for reporting injuries, and the Vaccine Safety Datalink), 306-315 (describing the variables in vaccine distribution and funding over the last 30 years).

<sup>291</sup> 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, 445-448 (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)

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.”<sup>292</sup>

The next step in our process of re-thinking 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 may be caused by vaccines into classes based on attendant risks and their degree of foreseeability.

### 3. Depepage 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 can 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 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 (i.e., making health people sick so that they don’t become sick and make others sick) and of the social context of vaccination programs (i.e., the governmental compulsion behind many vaccines). As one of the authors called for in rethinking the

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<sup>292</sup> See Kathleen A. Strong, *supra* note 223, at 445-448 (citations omitted).

liability landscape for medical malpractice claims<sup>293</sup> 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*.<sup>294</sup>

The *dépeçage* approach to re-thinking tort liability is particularly well-suited for decisional processes that are polycentric in nature, as one of the authors demonstrated 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.<sup>295</sup> The following is a chart-summary of one *dépeçage*

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<sup>293</sup> 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. Pitt. L. Rev. \_\_\_\_ Issue 1 (Summer 2009)(lead article)

<sup>294</sup> *Dépeçage* refers to interstate or international cases in which choice-of-law questions have arisen with respect to more than one issue.<sup>294</sup> Willis L. M. Reese, *Dépeçage: A Common Phenomenon In Choice of Law*, 73 Col. L. Rev. 58, 58 (1973). 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. SYMEON C. SYMEONIDES, ET AL., *supra* note 86, at 134 & n. As applied to rule-formulation in substantive tort law, rather than procedural adjudications in conflict of laws, Professor Van Detta has written,

Much the same can be argued for transporting *dépeçage* into the substantive realm of adjudicating random malpractice claims. A finer-tuned approach will scrutinize the kind of error alleged to have occurred; the base of knowledge required to adjudicate whether the error is within or without the professional standard of care; and, considering the kind of error and the knowledge base required, the most appropriate resolution technique to effect that adjudication. I call this the *dépeçage* model for classifying errors and associating specific classes of error with optional resolution techniques. Association with optional resolution techniques requires evaluation of the two competing principles underlying professional malpractice claims—the enterprise regulation principle and the corrective justice principle. The operating assumption of the *dépeçage* model is elegant in its simplicity.

. . . Resolution techniques chosen to adjudicate (a) liability and (b) damages, where appropriate, should be those that are most reasonably calculated to vindicate both the enterprise regulation and the corrective justice principles. With respect to some classes of error, the optimal resolution technique will vindicate both principles; as to other classes of error, a comparative impairment approach must be employed to determine which combination of resolution techniques most advances the corrective justice principle while least impairing the principle of enterprise regulation. This comparative impairment approach is founded on the assumption that the corrective justice principle holds the highest position in what may be called a hierarchy of values that are reified through tort principles and rules of law.

Jeffrey A. Van Detta, *Dialogue With A Neurosurgeon*, *supra* note \_\_\_, at \_\_\_\_.

<sup>295</sup> Jeffrey A. Van Detta, *Dialogue With A Neurosurgeon*, *supra* note \_\_\_, at \_\_\_\_.

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:

**DEPEÇAGE MODEL FOR CLASSIFICATION OF VACCINE INJURIES AND  
RESOLUTION ISSUES FOR VACCINE CLAIMS ARISING FROM EACH INJURY**

**PRINCIPLES AND RESOLUTION ISSUES**

**CLASSIFICATION OF VACCINE INJURIES**

	<b>ENTERPRISE REGULATION</b>	<b>CORRECTIVE JUSTICE</b>	<b>SOCIAL COMPACT, or SOCIETAL PRINCIPLE</b>
<b>CLASS 1</b> 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?
<b>CLASS 2</b> 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 proof is even more problematic in this class of cases.	The balance in Class 2 may differ from Class 1. If the imminency 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.

**PRINCIPLES AND RESOLUTION ISSUES**

**CLASSIFICATION OF VACCINE INJURIES**

	<b>ENTERPRISE REGULATION</b>	<b>CORRECTIVE JUSTICE</b>	<b>SOCIAL COMPACT, or SOCIETAL PRINCIPLE</b>
<p><b>CLASS 3</b> Injury risk known, probability significant, and can be eliminated by exercise of at least reasonable care.</p>	<p>Business must be encouraged to bear the expense of eliminating known risks that are not remote and can feasibly be eliminated.</p>	<p>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 is [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 non-reciprocal – 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.</p>	<p>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 <i>in toto</i>.</p>

**PRINCIPLES AND RESOLUTION ISSUES**

**CLASSIFICATION OF VACCINE INJURIES**

	<b>ENTERPRISE REGULATION</b>	<b>CORRECTIVE JUSTICE</b>	<b>SOCIAL COMPACT, or SOCIETAL PRINCIPLE</b>
<p><b>CLASS 4</b> Injury risk known, probability remote, and can be eliminated by exercise of at least reasonable care.</p>	<p>Cases at this margin push the economics of the enterprise regulation to the edge. Relevance of the enterprise principle could be measured by the <i>U.S. v. Carroll Towing</i> 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.</p>	<p>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 is [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 non-reciprocal – 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.</p>	<p>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 remoter, 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 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.</p>

**PRINCIPLES AND RESOLUTION ISSUES**

**CLASSIFICATION OF VACCINE INJURIES**

	<b>ENTERPRISE REGULATION</b>	<b>CORRECTIVE JUSTICE</b>	<b>SOCIAL COMPACT, or SOCIETAL PRINCIPLE</b>
<p><b>CLASS 5</b> Injury risk unknown, but could be discovered by exercise of at least reasonable care.</p>	<p>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, 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 non-reciprocal risk in vaccine recipients.</p>	<p>Persons injured by palpable injuries that were not reasonably foreseeable have normally 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.</p>	<p>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 <i>in toto</i> – 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.</p>

CLASSIFICATION OF VACCINE INJURIES

<p><b>CLASS 6</b> Injury risk unknown, but could have not have been discovered even by exercise of reasonable care.</p>	<p>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 a risk, precaution against a risk, or prediction of a 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 regime (and thus no liability) versus a strict liability regime (always liability). Considerations here most clearly and marketedly makde the non-reciprocal risk model, by itself, inadequate to reach a model of fair distribution of harm among those who benefit from the relevant risks. See Gregory C. Keating, Rawlsian Fairness And Regieme Choice In The Law Of Accidents, 72 Ford. L. Rev. 1857, 1860-72, 1870-80 (2004).</p>	<p>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. See Gregory C. Keating, supra.</p>	<p>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 <i>in toto</i>. 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 regime of no liability, but rather for one based on fairly distributing burdens of harm among those who benefit from the risk-creating activity. See Gregory C. Keating, supra.</p>
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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 non-reciprocal 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 re-think vaccine-injury liability.

1. Class One Risks—In Which The Injury Risk Is Known, Its Probability Significant, And *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<sup>296</sup> as an example of a vaccine that is “unavoidably unsafe” because of its inherent, serious side effects<sup>297</sup>, yet persons bitten by rabid animals submitted to it because the disease was still

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<sup>296</sup> Comment k states in pertinent part:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warnings, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts, § 402A, Comment k.

<sup>297</sup> The Pasteur rabies vaccine, administered without any means to confirm that the patient exposed to rabies actually has it (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, *J. Neurol.* 214, 71--74 (1976), available at:

<http://www.springerlink.com/content/g7024683333887r0/fulltext.pdf> (last visited July 26, 2009).

A list of medical journal articles detailing neurological complications of the Pasteur rabies vaccine may be found at:

<http://www.whale.to/vaccines/rabies1.html> (last visited July 26, 2009)

worse (100% fatal) than the cure.<sup>298</sup> 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, according to the Restatement.<sup>299</sup> 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

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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., Rabies Vaccine at Scientific Anti-Vivisection, available at [http://www.freewebs.com/scientific\\_anti\\_vivisectionism16/rabiesvaccine.htm](http://www.freewebs.com/scientific_anti_vivisectionism16/rabiesvaccine.htm) (last visited July 26, 2009); see also GERALD L. GEISON, *THE PRIVATE SCIENCE OF LOUIS PASTEUR* \_\_\_ (1996). The problems were due to the fact that 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, David W. Dreesen, William H. Wunner, *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. *Id.* at 380-394. The rabies vaccine is not the only vaccine that carried the risk of neuroparalytic adverse reactions, such as encephalomyelitis; the smallpox vaccine was reported to involve that complication in 1/400 to 1/1000 administrations versus results of 1/3000 to 1/35,000 for the Pasteur rabies vaccine. 2 WALTER GEORGE BRADLEY, ET AL., *NEUROLOGY IN CLINICAL PRACTICE: THE NEUROLOGICAL DISORDERS* 1660 (4<sup>th</sup> ed. 2004) (also observing that “[t]he occurrence of neuroparalytic accidents as a consequence of the Pasteur rabies vaccine prepared from spinal cords of rabbits inoculated with fixed rabies virus was recorded soon after the introduction of the treatment. Similar neurological complications were observed as a consequence of the Jenner vaccine used for the prevention of smallpox.”). A more modern example is the Sabin live-virus polio vaccine, of which a federal court observed “that the 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 miniscule risk that the vaccine may cause poliomyelitis. Thus, it is not unreasonably dangerous per se.” *Needham v. White Labs.*, 639 F.2d 394, \_\_\_ (7<sup>th</sup> Cir. 1980) (describing the holding in *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5<sup>th</sup> Cir.), cert. denied, 419 U.S. 1096 (1974)),<sup>298</sup> American Law Institute, Restatement (Second) of Torts, § 402A, comment k; see, e.g., *Allison v. Merck & Co.*, 878 P.2d 948, \_\_\_ (1994).

<sup>299</sup> American Law Institute, Restatement (Second) of Torts, § 402A, comment k. However, theories of liability have been recognized when the warnings are not communicated to the vaccine recipient. See, e.g., *Reyes v. Wyeth Labs.*, 498 F.2d 564, 573 (5<sup>th</sup> Cir. 1974).

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 non-reciprocal 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.

## 2. 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. 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.<sup>300</sup> When properly manufactured according to industry standards, OPV still carried a 1 in 2.4 million risk of causing Vaccine-Associated Paralytic Polio (VAPP) in recipients.<sup>301</sup> In addition, “[a]

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<sup>300</sup> See, e.g., MARTIN G. MYERS, M.D., & DIEGO PINEDA, DO VACCINES CAUSE THAT? A GUIDE FOR EVALUATING VACCINE SAFETY CONCERNS 26-27 (2008)(hereafter MYERS & PINEDA)

<sup>301</sup> MYERS & PINEDA, *supra* note \_\_\_\_, at 27. In the 1970s, the CDC apparently was estimating this number as 1 in 20 million. See, e.g., *Plummer v. Lederle Laboratories*, 819 F.2 349, \_\_\_\_ (1987). By 1984, Oramune package inserts were providing the following data summary and caveat:

The Centers for Disease Control report that during the years 1969 through 1980 approximately 290 million doses of [ ]OPV were distributed in the United States. In the same 12 years, 25 “vaccine-associated” and 55 “contact vaccine associated” paralytic cases were reported. Twelve other “vaccine-associated” cases have been reported in persons (recipients and contacts) with immune deficiency conditions. These statistics do not provide a satisfactory basis for estimating these risks on a per person basis.

*Graham, v. American Cyanamid Co.*, 350 F.3d 496, \_\_\_\_ (6<sup>th</sup> Cir. 2003). However, at the same time, the State of Ohio was providing vaccine consent forms that stated that –

characteristic of [OPVs] such as Orimune is that not only is the vaccine's recipient immunized from polio, but unimmunized persons who come into close contact with the recipient also are immunized through a shed virus which spreads from the recipient to the 'contact.' Because Sabin strains contain the live polio virus, there is a risk that either a recipient or a contact could develop polio."<sup>302</sup> 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 1 in 6 million.<sup>303</sup>

When applied to Class 2 risk scenarios, the principles strike a balance that favors vaccination yet also 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 that scientists had at first thought. Second, that additional 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 alternatives should be developed by

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“[O]nce in about every 4 million vaccinations, persons who have been vaccinated or who come in close contact with those who have recently been vaccinated are permanently crippled and may die. Even though these risks are low, they should be recognized.”

Id. at \_\_\_\_\_. Subsequent data apparently shows that VAPP is somewhat less a remote risk than was thought at one time.

<sup>302</sup> Loge v. United States, 662 F.2d 1268, \_\_\_\_ (8<sup>th</sup> Cir. 1981). As the Court of Appeals 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. at \_\_\_\_\_.

<sup>303</sup> See, e.g., Plummer v. Lederle Laboratories, 819 F.2d 349, \_\_\_\_ (2d Cir. 1987). The Court of Appeals explained this secondary, “contact” or “shedding” mechanism as follows:

To understand the risks inherent in OPV, it is necessary to comprehend the immunization process. The live but weakened viruses of OPV grow in the intestinal tract of the vaccinee. The growing viruses trigger the vaccinee's immune system to produce antibodies which render the vaccinee immune to the disease after 30 days. Rarely, but at a statistically predictable rate, the virus reproduced in the vaccinee's intestinal tract reverts to the virulent form. When this occurs, the vaccinee or persons coming in close contact with the vaccinee during the 30-day period may contract polio. Unvaccinated adults can take two precautions to avoid the risk of "contact polio": (i) alternative vaccination with IPV prior to contact with the vaccinee; and (ii) avoidance of contact with the vaccinee for one month, during which time live polio viruses are being shed from the intestinal tract of the vaccinee via the saliva and feces.

Id. at \_\_\_\_\_.

the vaccine development community.<sup>304</sup> Global data gathering, analysis, strategic modeling, and disseminating of paradigms in field are critical components. The essence of addressing Class 2 risks is – as reflected in numerous vaccine-injury cases of the 1970s and 1980s – creating and disseminating proper warnings of the remote risks.<sup>305</sup>

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 players in the vaccine industry since the 1950s consistently point out.<sup>306</sup> The question remains how to establish the entitlement? Proof of causation is most

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<sup>304</sup> 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*, Ch. 9, pp. 207 et seq. (1989). They are beyond the scope of the authors’ mission in this article. Therefore, the authors 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 20<sup>th</sup> century, see SYDNEY A. HALPERN, *LESSER HARMS: THE MORALITY OF RISK IN MEDICAL RESEARCH* (2004).

<sup>305</sup> See, e.g., *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5<sup>th</sup> Cir. 1980); *Plummer v. Lederle Laboratories*, 819 F.2 349, \_\_\_\_ (1987); , v. *American Cyanamid Co.* , 350 F.3d 496, \_\_\_\_ (6<sup>th</sup> Cir. 2003); see ARTHUR ALLEN, *VACCINE: THE CONTROVERSIAL STORY OF MEDICINE’S GREATEST LIFE SAVER* 264-265 (2008). Of course, meaningful warnings of remote risks are difficult for non-statisticians to interpret and contextualize. See, e.g., JOHN ALLEN PAULOS, *INNUMERACY: MATHEMATICAL ILLITERACY AND ITS CONSEQUENCES* (1988).

<sup>306</sup> PAUL A. OFFIT, M.D., *THE CUTTER INCIDENT: HOW AMERICA’S FIRST POLIO VACCINE LED TO THE GROWING VACCINE CRISIS* (2008). As an example, Offit cites *Toner v. Lederle Laboratories*, a vaccine injury lawsuit involving the partial paralysis of an infant after receiving a pertussis vaccine and a \$1.13 million damages verdict. “At the time of the award,” Offit writes, “gross sales from the pertussis vaccine in the United States were about \$2 million, and the gross sales from all vaccines were about \$ 7 million.” *Id.* Offit continues:

The case of *Toner v. Lederle Laboratories* [779 F.2d 1429 (9<sup>th</sup> Cir. 1986)] showed exactly what can happen when unanticipated events occur. The framers of the revolution in liability law reasoned that pharmaceutical companies should pay for harm caused by their products because by increasing the price of the products, they were in

significant hurdle.<sup>307</sup> 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.<sup>308</sup> The balance in Class 2 may differ from Class 1. If the immanency of the risk of the illness,

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the best position to defray the cost of increased insurance. But the framers didn't predict how massive those awards would become, and they didn't predict that awards would be made when products weren't harmful. The award in the Toner case was the equivalent of one half of the pertussis vaccine market in the mid-1980s. Pharmaceutical companies looked at this situation and decided to leave the vaccine business. 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.

Offit, *supra* note \_\_\_\_, at 181-182. Offit argues that even the NCVIA did not solve the problem – since, as discussed above (see text and notes \_\_\_\_, *supra*), its court-diversion program isn't ultimately mandatory – marshalling some very sobering industry statistics:

In 1957, when Cutter Laboratories made a vaccine that wasn't safe, twenty-six companies were making five vaccines. In 1980, when the first lawsuits against the makers of pertussis vaccine were filed, seventeen companies were making eight vaccines. In 2004 four big companies (GlaxoSmithline, Sanofi-Aventis, Merck, and Wyeth) were making twelve vaccines. Although some of this decrease can be accounted for by merger, most is the result of dropouts. For example, Eli Lilly and Parke-Davis – the two large companies that made Jonas Salk's polio vaccine for the 1954 field trial – eventually abandoned vaccines. Of the twelve vaccines routinely given to young children, seven are made by a single manufacturer; only one vaccine is made by more than two companies. Because fewer companies make vaccines, limited supplies and scant reserves are available to meet a crisis.

*Id.* at 182-183. However, others reject Offit's attribution of blame to facts—or fears—of products liability, and make a very compelling case that the consolidation and attrition among vaccine manufacturers is due to nothing more, or less, than 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, e.g., ARTHUR ALLEN, *VACCINE: THE CONTROVERSIAL STORY OF MEDICINE'S GREATEST LIFE SAVER* 426-435 (2008).

<sup>307</sup> See, e.g., Myers and Penada, *supra* note \_\_\_\_, 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. These came from an IOM Committee on Immunization Safety Review. These causation categories are: [1] No Evidence (complete 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 text and notes \_\_\_\_ - \_\_\_\_, *supra*.

<sup>308</sup> ALLEN, *supra* note \_\_\_\_, at 325.

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 non-reciprocal and that the recipient is put at a greater risk – particularly since the risks at issue in Class 2 cannot be eliminated – but the small possibility of the risk eventuating into actual harm pushes the notion of non-reciprocity 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 2 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, the risks between government that does not mandate the vaccination and the risk of disease posed to society. The remote risk of harm to the vaccine seems least compelling when compared to other risks, such as the risk of the illness to the vaccine, the risk to society if the vaccine isn't used. Pure reciprocity alone, between manufacturer and vaccine, is hardly sufficient as the sole basis on which to predicate questions of liability and compensation for Class 2 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.

3. 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.”<sup>309</sup> Cutter Laboratories was one of six companies licensed by the federal government to make the first production run of the Salk polio vaccine, a form of vaccine in which polio virus material, not live polio virus itself, is used to stimulate the immune system to develop polio immunity. As such, the polio virus is supposed to be killed during the production process. 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. The protocols developed for manufacturing of the vaccine called both for a filtration process designed to capture and remove live polio viruses from the vaccine and a testing process to ascertain whether that in fact happened. In production, Cutter Laboratories made errors at both critical stages of the process. These errors resulted in the production of 120,000 doses of polio vaccine that contained

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<sup>309</sup> Nathanson N. and Langmuir AD. (1963). *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*". Am. J. Hyg. 1963 Jul;78:29-60; see generally PAUL A. OFFIT, M.D., *THE CUTTER INCIDENT: HOW AMERICA'S FIRST POLIO VACCINE LED TO THE GROWING VACCINE CRISIS* (2008).

live polio virus.<sup>310</sup> 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), 56 developed paralytic poliomyelitis and of these 5 children died as a result of polio infection.<sup>311</sup> 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. That resulted in a considerable secondary exposure to parents, other adults, and children. As one writer summarized the widening ripple from the Cutter Laboratories error, “it 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.”<sup>312</sup>

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.<sup>313</sup> 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.<sup>314</sup> 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.<sup>315</sup> As Dr. Paul Offit, 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 [such as Eli Lilly and Parke-Davis]. As a consequence, it made a vaccine that was far more dangerous than any other polio vaccine made in the United States or in the world.”<sup>316</sup>

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<sup>310</sup> Offit, supra note \_\_, at 87.

<sup>311</sup> Nathanson and Langumuir, supra note \_\_. Offit gives the numbers as “200,000 people were inadvertently injected with live virulent polio virus: 70,000 became ill, 200 were permanently paralyzed, and 10 died.” OFFIT, supra note \_\_, at \_\_\_\_.

<sup>312</sup> Offit, note \_\_, at 89.

<sup>313</sup> OFFIT, supra note \_\_ at 67.

<sup>314</sup> OFFIT, supra note \_\_ at 14-18. Kolmer and Brodie presented their results at a November 1935 meeting of the American Public Health Association; James Leake, the Public Health Service’s Medical Director, publicly asserted that the vaccines had infected children with polio and “point-blank accused Kolmer of being a murderer.” Id. at 17. As Offit notes, “[t]he vaccine trials of Kolmer and Brodie had a chilling effect on polio vaccine research. Twenty years passed before anyone dare try again.” Id. at 18.

<sup>315</sup> OFFIT, supra note \_\_ at 59-61

<sup>316</sup> OFFIT, supra note \_\_ at 114. Among other things, Cutter did not follow the Salk protocol of using so-called Seitz filters (made of asbestos layers), but rather used not only glass filters, but glass filters not made to the industry standard. See id. at 106, 108. As a result, cell and cell-debris from the monkey kidney tissue in which the polio virus was cultured would harbor live virus that would not be killed during the formaldehyde treatment process. Id. at 106. Cutter also “let filtered virus sit in the refrigerator for long periods before inactivating it with formaldehyde. ... Long period of storage caused fine clumps of monkey kidney cell debris to form on the bottoms of the flasks.” Id. at 110. Most significantly, notes Offit, “Cutter never constructed a graph to determine how long to treat polio virus with formaldehyde,” and thus could not implement Salk’s protocol of doubling the killing-treatment period to “provid[e] the margin of safety that Salk deemed critical to the production of safe vaccine.” Id. at 111-112. Cutter “never determined

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 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, when it partners with business, government, 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, 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 is [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 non-reciprocal – 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 – 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.<sup>317</sup>

The somewhat simpler picture when looking at the scenario only through the lens of enterprise regulation and corrective justice becomes more complicated when we add the perspective of the societal principle. The balance in Class 3 is typically the closest

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when live virus was first eliminated and, therefore, couldn’t determine how long to treat with formaldehyde.” *Id.* at 112. Cutter’s production chief appeared to have ignored results that showed that infectious particles were actually almost tripling in number in some vaccine lots after formaldehyde treatment,” never informed his superiors or the federal government regulators, and “never made eleven consecutive lots of vaccine that passed safety tests” or even “four such lots.” *Id.* at 113. As Offit observes, “[i]t remains incomprehensible how [Cutter’s production chief] could look at the inactivation data for [a vaccine lot in which infectious particles were increasing after formaldehyde treatments] and conclude anything other than he could not reproduce Salk’s inactivation results” that defined a safe lot of vaccine. *Id.* at 112. Although Offit also makes the argument, based on a written jury “statement” purporting to explain its pro-plaintiff verdict in the *Gottsdanker* suit against Cutter, that Cutter was not “negligent,” *id.* at 149-153, 154, the omissions of Cutter’s production chief alone are surely enough to support a negligence verdict. As it stand, the verdict in *Gottsdanker* was based on the jury’s finding that Cutter breached an implied warranty.” *Id.* at 148-149, 150. In fact, Offit’s own Chapter 6 examination of the seven errors he attributed to Cutter demonstrates that is misleading for him to assert that the Cutter Incident stood for the untenable legal proposition that “if pharmaceutical companies made a product according to industry standards, using the best science that was available, and found months or years after its sale that it caused harm – a harm not predictable – they were liable for the damage.” *Id.* at 154. This flies in the face of Offit’s careful demonstration that Cutter had not, in fact, followed “industry standards” or “us[ed] the best science that was available”, *id.* at 154—for those standards and science were contained in Salk’s protocols, which other pharmaceutical companies hewed more closely to, with far better results in 1955.

<sup>317</sup> Offit, *supra* note \_\_\_, at \_\_\_.

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*. 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.<sup>318</sup>

If we view this Class from the perspective of the risks posed between manufacturer and recipient, it is clear that the risk is non-reciprocal 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 1 and 2 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.

#### 4. 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. “According to the Advisory Committee on Immunization Practices (ACIP), the risk of a developing fetus being harmed by vaccination of the mother during pregnancy is only theoretical.”<sup>319</sup> 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.<sup>320</sup>

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<sup>318</sup> See, e.g., DAVID M. OSHINSKY, *POLIO: AN AMERICAN STORY* \_\_\_ 45, 53-91 (2005).

<sup>319</sup> MYERS AND PINEDA, *supra* note \_\_, at 210-211.

<sup>320</sup> *Id.* at 211; see also Advisory Committee on Immunization Practices Workgroup on the Use of Vaccines During Pregnancy and Breastfeeding, *Guiding Principles for Development of ACIP Recommendations for Vaccination during Pregnancy and Breastfeeding* (April 2008) (noting paucity of data, theoretical concerns, and FDA classification of risks to pregnant women), available at <http://www.cdc.gov/vaccines/recs/ACIP/downloads/preg-principles05-01-08.pdf> (last visited July 29, 2009). ACIP –

consists of 15 experts in fields associated with immunization who have been selected by the Secretary of the U. S. Department of Health and Human Services to provide advice and guidance to the Secretary, the Assistant Secretary for Health, and the Centers for Disease Control and

The injury is readily preventable – pregnant women should not get the vaccine while pregnant. 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.<sup>321</sup> 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 that vaccination could cause the condition of autism<sup>322</sup>; yet, that move did create a cost, for a leading vaccine maker, Wyeth, closed its Diphtheria-Tetanus-Pertussis (DPT) vaccine manufacturing plant and withdrew from DPTD vaccine production rather than retrofit the existing production facility to a thimerisol-free production process.<sup>323</sup>

Cases at this margin push the economics of the 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*<sup>324</sup>. 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 3 injuries, the compensation interest is particularly strong where the risk they expect to encounter in vaccine administration is [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 non-reciprocal – i.e., absent the manufacturer’s reasonable care, the

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Prevention (CDC) on the control of vaccine-preventable diseases. The Committee develops written recommendations for the routine administration of vaccines to children and adults in the civilian population; recommendations include age for vaccine administration number of doses and dosing interval, and precautions and contraindications. The ACIP is the only entity in the federal government that makes such recommendations.

<http://www.cdc.gov/vaccines/recs/ACIP/default.htm> (last visited July 28, 2009).

<sup>321</sup> MYERS AND PINEDA, *supra* note \_\_\_, at 212-214.

<sup>322</sup> *Id.* at 148, 149-174; 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).

<sup>323</sup> ARTHUR ALLEN, *supra* note \_\_\_, 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.

<sup>324</sup> 159 F.2d 169 (2d. Cir. 1947).

risk to 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 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 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 non-reciprocal risk theory can guide our thinking, the polycentric nature of the problem is not entirely resolvable on non-reciprocal risk grounds alone.

5. 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 wasn't 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 though 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 casually 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. The decisions that go into the scope of research and risk-planning when vaccines are made – i.e., how far afield do 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.<sup>325</sup> Since that is an ever-evolving body of context, the point in time when

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<sup>325</sup> 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 research Simon Flexner than 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

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.

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 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. In 1954, Eli Lilly's researchers commenced work to classify the simian viruses they found in monkey kidney tissues. The number escalated to 40 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.<sup>326</sup>

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developed would be insufficient to provide adequate protection to vaccinees. See David M. Oshinsky, *supra* note \_\_, 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 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.

<sup>326</sup> There is still considerable debate about whether SV40, which unquestionable causes fatal cancerous tumors in a variety of laboratory animals, is a cause of human cancer. Compare, e.g., OSHINSKY, *supra* note \_\_, at 281-282 (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 DEBBIE BOOKCHIN AND JIM SCHUMACHER, *THE VIRUS AND THE VACCINE* (2004) (marshalling contrary information and argument that SV40 is a human carcinogen). See also Arthur Allen, *supra* note \_\_, at 209-213 (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”). To show just how far the jury is out on this causation question, we need only look to the latest, seemingly vacillating, pronouncement by the National Cancer Institute, posted at its joint website with the National Institute of Health:

In conclusion, although SV40 causes cancer in laboratory animals, substantial epidemiological evidence has accumulated to indicate that SV40 likely does not cause cancer in humans. However, additional laboratory research is needed to better define methods for SV40 detection, as laboratory studies looking for SV40 DNA in human tumors have offered conflicting results. There is also a need to conduct additional studies evaluating cancer patients and controls for antibodies to SV40, which would be present in cancer patients if SV40 causes cancer.

NCI-NIH, *Studies Find No Evidence That SV40 is Related to Human Cancer* (August 2004/March 2005), available at <http://www.cancer.gov/newscenter/pressreleases/SV40> (last visited July 30, 2009). See also Rochelle Cutrone, John Lednický, Glynis Dunn, Paola Rizzo, Maurizio Bocchetta, Konstantin Chumakov, Philip Minor4 and Michele Carbone, *Some Oral Poliovirus Vaccines Were Contaminated with Infectious SV40 after 1961*, *Cancer Research* 65, 10273-10279, November 15, 2005 (noting that although “[i]t has been assumed that all polio vaccines were SV40 free in the United States after 1961 and in other countries after 1962,” there were “SV40-contaminated vaccines . . . produced from early 1960s to about 1978 and were used throughout the world, “ and that these “findings underscore the potential risks of using primary monkey cells for preparing poliovirus vaccines, because of the possible contamination with SV40 or other

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 polio virus—not the unknown SV40). “This meant that close to 100 million American children had been inadvertently exposed to SV 40 in the years between 1954 and 1963, when the government began to carefully screen all new lots of polio vaccine for” SV40.<sup>327</sup>

Of course, it would hardly seem foreseeable that SV40, hitherto unknown, would be imparted by polio vaccines into human populations, at 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.<sup>328</sup> But the vaccines continued to be administered -- even after SV40 was isolated and suggested as a cause of cancer. Further research wasn’t undertaken at the time, in part because both Salk and Sabin deemed SV40 as “harmless,” and no intensive research efforts were undertaken.<sup>329</sup> Thus, there is ground in this scenario to find a point in time during the polio vaccination campaign, the government and pharmaceutical manufacturers made the conscious decision to risk expose of 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 non-reciprocal 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*<sup>330</sup>, 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. 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 non-reciprocal risk in vaccine recipients.

The corrective justice principle continues to have the some 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 afforded compensation in this tort system. However, where the exercise of reasonable care to discover unknown risks more likely

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monkey viruses, and emphasize the importance of using well-characterized cell substrates that are free from adventitious agents”), available at <http://cancerres.aacrjournals.org/cgi/content/abstract/65/22/10273> (last visited Aug. 12, 2009); Institute of Medicine of the National Academies of Science, SV40 Contamination of Polio Vaccine and Cancer Meeting. June 11, 2002, available at <http://www.iom.edu/CMS/3793/4705/6696/7341.aspx> (last visited Aug. 12, 2009).

<sup>327</sup> Oshinsky, supra note \_\_\_, at 280-282.

<sup>328</sup> Arthur Allen, supra note \_\_\_, 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.”).

<sup>329</sup> See Oshinsky, supra note \_\_\_, at 281.

<sup>330</sup> 60 F.2d 737 (2d Cir.), cert. denied, 287 U.S. 662 (1932).

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. 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.<sup>331</sup> 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.

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<sup>331</sup> 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 Arthur Allen, *supra* note \_\_\_\_, at 429-431; Julie Milstien, *The Economics of Vaccine Development and Implementation: Changes Over The Past 20 Years*, at 6-9, available at [http://www.who.int/immunization\\_supply/introduction/economics\\_vaccineproduction.pdf](http://www.who.int/immunization_supply/introduction/economics_vaccineproduction.pdf) (last visited July 30, 2009). 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. Julie Milstien, *supra*, at 6-7. For illustration, Milstien describes how searching for unknown risks affected the cost and timing of the rotavirus vaccine's development:

The story of RotaShield®, a tetravalent rhesus-based recombinant rotavirus vaccine licensed by the FDA on 31 August, 1998, is illustrative. At that time clinical trials included over 10,000 vaccine recipients, sufficient for demonstration of efficacy not enough to demonstrate a statistically significant increase in intussusception. The Advisory Committee on Immunization Practices of the US Centers for Disease Control and Prevention (CDC) recommended post-licensing surveillance for this adverse event, 21 and by June 1999, following distribution of 1.8 million doses of vaccine, the CDC had noted increased reports of intussusception in recipients of the vaccine. This event could not have been picked up in any reasonably-sized clinical trial. Especially for vaccines for universal use in children, 23 the US FDA is considering requiring expanded phase III trials with more attention to safety monitoring, a direction which could increase time to market and thus raise development costs significantly. Other regulatory authorities, for example, in Europe, seem likely to impose instead more formal phase IV post-marketing safety studies to carefully monitor potential adverse events for vaccine candidates. There are benefits and drawbacks to either approach; both will impact costs.

*Id.* at 7-8 (footnotes omitted). Addressing these kinds of concerns requires much more comprehensive clinical and field trials than the polio vaccine developers undertook – estimates are that new vaccines today take 12 to 15 years of development at a cost to the developer approaching \$ 1 billion. See *The Vaccine Industry: An Overview*, available at [http://www.vaccineethics.org/issue\\_briefs/industry.php](http://www.vaccineethics.org/issue_briefs/industry.php) (last visited July 30, 2009).

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 non-reciprocal risk theory can guide our thinking, the polycentric nature of the problem is not entirely resolvable on non-reciprocal risk grounds alone.

6. Class Six Risks— In Which The Injury Risk Is *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 a risk, precaution against a risk, or prediction of a 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 non-reciprocal risk model, by itself, inadequate to reach a model of fair distribution of harm among those who benefit from the relevant risks.<sup>332</sup> 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 non-reciprocal 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 re-think 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. As Professor Keating succinctly states it, 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 – i.e., “the costs of accidental injury among those who benefit from the imposition of the underlying risks.”<sup>333</sup> In so doing, Professor Keating's approach, which we shall call “distribution of the costs of non-reciprocal harms” based

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<sup>332</sup> See Gregory C. Keating, *Rawlsian Fairness And Régime Choice In The Law Of Accidents*, 72 *Ford. L. Rev.* 1857, 1860-72, 1870-80 (2004).

<sup>333</sup> Gregory C. Keating, *supra* note \_\_, at 1858.

on notions of “reciprocity of harms,”<sup>334</sup> 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.

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.<sup>335</sup> 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.<sup>336</sup>

In the following subsection, we discuss how Congress might use the perspective afforded by Professor Keating’s transformation of non-reciprocal 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 Non-Reciprocal Harms” Approach To Re-Thinking Vaccine-Injury Liability

#### 1. Beyond Non-Reciprocal Risks To Non-Reciprocal Harms

The basis for Professor Keating’s approach is explained extensively in his article<sup>337</sup>, and will not be repeated here. Instead, we will explain how his approach extends—and supersedes—basic non-reciprocal risk theory for the context of polycentric problems. We will then, in the spirit 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 non-reciprocal harms.”

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<sup>334</sup> Id. at 1859.

<sup>335</sup> Id. at \_\_\_\_.

<sup>336</sup> Id. at \_\_\_\_.

<sup>337</sup> Gregory C. Keating, *Rawlsian Fairness And Régime Choice In The Law Of Accidents*, 72 FORDHAM L. REV. 1857 (2004).

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"<sup>338</sup> – trapping us within a framework that, as "a king 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."<sup>339</sup>

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."<sup>340</sup> While "[t]he reasonableness of risk impositions . . . turns on the way that the impositions reconcile the competing claims of liberty and security,"<sup>341</sup> risk impositions in polycentric policy matters like vaccination "arise against a background of mutually beneficial cooperative conduct among"<sup>342</sup> 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)<sup>343</sup> and inter-community risk position (wherein "members of one community" impose risks "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, the community of governmental public policy regulators).<sup>344</sup>

In mediating fairness in this context, the legal approach cannot aspire to eliminate the non-reciprocal 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" although "not mutually beneficial in the strong sense that reciprocal risks are."<sup>345</sup> The general conduct underlying these risks – the creation of vaccines and the mandate of general vaccination to prevent serious transmittable diseases both to society and to the individuals of whom it is comprised – is not itself unjustifiable or unreasonable.<sup>346</sup>

The law certainly does not want to be in the position of discouraging vaccination and encouraging epidemics of disease – but that is the position in which the law would leave us if it were to treat the vaccination programs as creating unreasonable risks. To the contrary, the non-reciprocity of risk does not answer the central question that liability for

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<sup>338</sup> Keating, *supra* note \_\_\_\_, 72 *Fordham L. Rev.* at 1860.

<sup>339</sup> *Id.* at 1860.

<sup>340</sup> *Id.* at 1866.

<sup>341</sup> *Id.* at 1868.

<sup>342</sup> *Id.*

<sup>343</sup> *Id.* at 1873.

<sup>344</sup> *Id.* at 1874.

<sup>345</sup> *Id.* at 1881.

<sup>346</sup> *Id.* at 1883.

vaccine-injury must address: What is “a fair distribution of harm”?<sup>347</sup> As Professor Keating notes generally, “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.”<sup>348</sup> As Professor Keating elaborates:

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, limp, and property that is its cost.<sup>349</sup>

It therefore is “the costs of harm, if not harm itself” that “may be fairly distributed by the enterprise form of strict liability.”<sup>350</sup> 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.<sup>351</sup> 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 costs of accidental injury among those who benefit from the imposition of the underlying risks.”<sup>352</sup> We call this approach the “distribution of the costs of non-reciprocal harms” based on notions of “reciprocity of harms.”<sup>353</sup> As we observed in Section V.B[6], 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 non-reciprocal 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

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<sup>347</sup> Id. at 1884.

<sup>348</sup> Id. at 1884.

<sup>349</sup> Id. at 1885.

<sup>350</sup> Id. It 1886.

<sup>351</sup> See, e.g., the sources cited id. at 1897 n. 85.

<sup>352</sup> Gregory C. Keating, *supra* note \_\_\_, at 1858.

<sup>353</sup> Id. at 1859.

costs of accidents.”<sup>354</sup> 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.”<sup>355</sup>

“Judgments about communities of benefit,” observes Professor Keating, “are eminently political judgments about how we should order our lives in common.” 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.”<sup>356</sup>

The distribution of the costs of non-reciprocal 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 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 compensation for vaccine-injuries, but a comprehensive program for vaccine development, delivery, dedicated monitoring, and

### 3. Toward A Holistic National Vaccine Policy

Using the analytic tools and perspectives developed in the preceding Subsections of Section V, Congress can re-think not only how to deal with vaccine injuries, but also how, as part of the same process, to re-think our national policy towards vaccination. Until now, much of vaccine policy has been made either by ad hoc federal efforts or by the states. While an impressive network of regulation has been created in this patchwork process, the demands created by threats of global pandemics, vaccine shortages, fewer pharmaceutical companies working on vaccines, and rising costs of supporting systematic

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<sup>354</sup> Id. at 190. 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.

<sup>355</sup> Id. at 1907.

<sup>356</sup> Id. at 1907.

vaccination programs call for Congress to step back and take the big picture, long view, with the objective of creating a coherent, coordinated, and compatible vaccine policy for all aspects of vaccines and vaccination.<sup>357</sup> 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.

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.”<sup>358</sup>

Such caricatures actually impede an intelligent discussion of liability. For example, Dr. Paul Offit, former vaccine research scientist and current, prolific author on vaccine-related issues, appears to blame 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.”<sup>359</sup> However, the state of the vaccine industry is the result of much more complicated – and important factors – than potential vaccine liability, as Offit’s own seemingly contradictory statement suggests: “Unfortunately, despite protections afforded by the National Vaccine Injury Compensation Program, pharmaceutical companies are gradually abandoning vaccines.”<sup>360</sup> 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.<sup>361</sup> 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 what has happened to the vaccine manufacturing industry since the Salk vaccine 55 years ago is the result of a number of other, far more important factors. As Arthur Allen cogently summarized:

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<sup>357</sup> 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 MICHAEL A. SANTORRO & THOMAS E. GORRIE (eds.), *ETHICS AND THE PHARMACEUTICAL INDUSTRY*, Ch. 20, at 352-360 (2005).

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<sup>359</sup> Offit, *supra* note \_\_\_\_, at 182

<sup>360</sup> *Id.*

<sup>361</sup> See, e.g., Offit, 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 17 cents to 11 dollars).

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 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.<sup>362</sup>

Thus, the consolidation of 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.<sup>363</sup> 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?”<sup>364</sup> 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.”<sup>365</sup> As Allen further 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 footnoted 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.<sup>366</sup>

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”;

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<sup>362</sup> Arthur Allen, *supra* note \_\_, at 426.

<sup>363</sup> *Id.* at 427 (quoting former federal vaccine licensing officer Don Hill).

<sup>364</sup> *Id.*

<sup>365</sup> *Id.* (quoting Allen's interview with Paul Parkman, May 2004)

<sup>366</sup> *Id.* at 428.

[2] “It was expensive and time consuming to test vaccines on people because such efficacy trials required “wait[ing] for an outbreak of the disease to test your products powers,” since the manufacturers cannot “expose masses of people to dangerous pathogens”;

[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, and public health officials are hard pressed to make accurate predictions;

[4] Vaccine economics can be volatile and risky when “productes ha[ve] no idea how much vaccine” would be purchased by public health officials, hospitals, and doctors in a given year.

[5] “The other price constraint” is “the trap of the single buyer. Under the Vaccines for Children program roughly 55 percent of vaccines are now purchased by the federal government, which guarantees a market for produces, but also puts pressure on the price” – and while “vaccine producers support the program because it guarantees a market for their product, . . . they want the government to pay more.”<sup>367</sup>

The terms of the conversation need to be substantially changed if vaccination is to continue providing the most stable public health criterion in human history.<sup>368</sup> What is needed is not 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 stand, vaccines are regulated, in overlapping fashion, by a hodge podge of nearly a dozen federal agencies and their sub-agencies. As Susan Thaul, Social Legislation Specialist in CRS’s Domestic Social Policy Division described this crazy quilt in a 2005 report to Congress:

There 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

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<sup>367</sup> Arthur Allen, *supra* note \_\_, at 428-430.

<sup>368</sup> See Edward Greg Koski, *Renegotiating The Grand Bargain—Balancing Prices, Profits, People, and Principles*, IN SANTORRO & GORRIE, *supra* note \_\_, Ch. 24, at 393-403

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. See CRS reports focusing on drugs: CRS Report RL30989, *The U.S. Drug Approval Process: A Primer*, by Blanchard Randall IV; CRS Report RL30913, *Pharmaceutical Research and Development: A Description and Analysis of the Process*, by Richard E. Rowberg; and CRS Report RS20033, *Food and Drug Administration: Selected Funding and Policy Issues*, by Donna U. Vogt.

The National Institutes of Health (NIH) conducts intramural vaccine research and development and funds research in universities, for example. 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" (<http://www.hhs.gov/nvpo>], visited Nov. 10, 2004). 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.”<sup>8</sup> Also administered from HRSA is the Smallpox Vaccine Injury Compensation Program, set up in 2003.<sup>369</sup>

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.

To this end, the Institute of Medicine (IOM) has called for the creation of a National Vaccine Authority.<sup>370</sup> The agency created 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.<sup>371</sup>

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<sup>369</sup> Susan Thaul, Specialist in Social Legislation Domestic Social Policy Division, Congressional Research Service Report: Vaccine Policy Issues 3-4 (May 2005)(text and footnotes combined). The web of regulators, however, doesn’t stop there, as Ms. Thaul explains:

Vaccine responsibilities lie outside of HHS as well. The Department of Defense (DOD) maintains research and development programs for vaccines against both naturally occurring infectious diseases and bioweapons. DOD administers routine and deployment-related vaccines to military personnel and some civilian employees and contractors. As a primary health care provider, DOD also administers vaccines as necessary to its retirees and current personnel and their families. The Department of Veterans Affairs administers vaccines to U.S. veterans who seek care in its facilities. The U.S. Agency for International Development (USAID) supports routine immunization programs in developing countries and works to reduce the impact of vaccine-preventable disease worldwide. State and local governments conduct vaccine activities within their public health role, such as conducting vaccine clinics, maintaining immunization registries, and establishing immunization requirements for school attendance. Veterinary biologics are regulated by the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, under authority of the Virus, Serum and Toxin Act. These products must meet similar standards of safety, efficacy, purity and potency as do human products.

Id. at 4.

<sup>370</sup> Council of the Institute of Medicine, *Statement on Vaccine Development*, Nov. 5, 2001, at <http://www.iom.edu/report.asp?id=5487> (last visited Aug. 1, 2009)

<sup>371</sup> 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” —

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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
- [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. While 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

Consolidating the 22 vaccine-related functions set out in the previous footnote will be a far more effective and long-lasting solution to the liability problem, as well as to the many inter-related problems that affect vaccines. In particular, the optimal way to deal with the polycentric quandary that the three principles in their interaction pose for dealing with vaccine-injury liability is to refine and expand the NVCIA 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.<sup>372</sup> 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 entirely<sup>373</sup> and inserted, instead, into the public health context in which it has always belonged.<sup>374</sup> 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 causation<sup>375</sup> has been a major stumbling block that has hampered NVCIA's success as an alternative to—and in our proposal, the replacement for—litigation.<sup>376</sup> The nature of proving causation is extraordinarily difficult for vaccine claimants who lack the resources, scientific knowledge, and

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See *id.*

<sup>372</sup> Other points ripe to be addressed by amendment including those made in our comparison of the original Swine-Flu act and the NCVIA. See text and notes \_\_ - \_\_\_\_, *supra*.

<sup>373</sup> Gregory C. Keating, *supra* note \_\_, at 1907 (referring to “abolish[ing] tort law entirely and replac[ing] it with a New-Zealand style scheme of society-wide liability”).

<sup>374</sup> As such, cases such as *Holder v. Abbot Labs.*, 444 F.3d 383 (5<sup>th</sup> Cir. 2006), which permitted parents of vaccine-injured children to bypass the NCVIA process and sue the suppliers of preservatives to vaccine manufacturers to be sued in state or federal court — on the reasoning that 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.A. § 300aa-11(a) — need to be legislatively overruled.

<sup>375</sup> 300aa-13(a) General Rule, states:

(1) Compensation shall be awarded under this Program to a petitioner if the special master or court finds on the record as a whole -

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300-11-119c)(1) of this title, and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

<sup>376</sup> Katherine E. Strong, *Proving Causation Under The Vaccine Injury Act: A New Approach For A New Day*, 75 *Geo. Wash. L. Rev.* 426, 430, 437-38, 441-48 (2007)

institutional bench strength to unravel the complex bodily and chemical functions underlying vaccine injuries that on their face are probative of cause and effect.<sup>377</sup> 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 – but rather that Congress adopt a “benefit of the doubt” standard<sup>378</sup>, which the writer explains as follows:

When discussing the burden of proof faced by petitioners in causation-in-fact cases, the Federal Circuit stated that “close calls regarding causation are resolved in favor of the injured claimant.” The court, however, also emphasized that the burden of proof for causation petitioners is the statutorily prescribed preponderance-of-the evidence standard. This has created confusion among the Special Masters, but the confusion would be resolved if Congress amended the Vaccine Injury Act, as proposed here, to specify that petitioners in close cases would receive the benefit of the doubt.<sup>379</sup>

The proposal is well motivated – but does it really go far enough? For one thing, the standard does not make clear whether we’re talking about benefit of the doubt that the claimant has shown “but for” causation or benefit of the doubt that the claimant has shown “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.”<sup>380</sup> The Federal Circuit’s articulation of the NCVIA burden appears closer to substantial-factor than but-for:

[The claimant’s] burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the

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<sup>377</sup> Id. at 437, 441-448; 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, 474-476 (2007); see, e.g., *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 . . . by the” claimant)

<sup>378</sup> Katherine E. Strong, *supra* note \_\_\_, 72 Geo. Wash. L. Rev. at 452.

<sup>379</sup> Id. at 457 (quoting *Althen v. Sec’y of HHS*, 418 F.3d 1274, 1280 (Fed. Cir. 2005)).

<sup>380</sup> *Capizzano v. Sec’y of HHS*, \_\_\_ F.3d \_\_\_ (Fed. Cir. 2006).

injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.<sup>381</sup>

However, in the “distribution of the costs of harms resulting from non-reciprocal risks” in which we have examined vaccine liability, the focus on distributing the costs of harm – rather than on coercive punishment of “wrongdoers” and tortfeasors, “relax[es] the fairly stiff requirement of causation characteristic of negligence liability in tort.”<sup>382</sup> Responsibility for discrete acts of negligence are not the appropriate model—rather, in the model of vaccine injury liability we advance, 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, rebuttable 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.<sup>383</sup> In fact, the current causation standard as

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<sup>381</sup> Id. at \_\_\_\_ (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, the claimant must 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 HHS*, \_\_ F.3d \_\_ (Fed. Cir. 1999).

<sup>382</sup> Gregory C. Keating, *supra* note \_\_, 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. This leads Professor Keating to elaborate on the rationale for de-emphasizing causation in detail:

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 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. at 1897.

<sup>383</sup> The Injury Table claims are described by Strong:

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.<sup>384</sup> While this is a subtle change, it is important in setting a pro-compensation atmosphere for an expanded vaccine injury-program, and one which should ameliorate some of the daunting complexity 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 vaccine 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

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If a petitioner can prove by a preponderance of the evidence that he suffered an injury listed in the Table within the prescribed time period after receipt of the vaccine, a rebuttable presumption that the vaccine caused the injury is created. The Department of Health and Human Services ("HHS") 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.

Katherine E. Strong, *supra* note \_\_, at 437; see 42 U.S.C. §§ 300aa-11(c)(1)(C)(i), -13(a)(1)(B).

<sup>384</sup> 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:

The Secretary points out that in rebutting with evidence of factors unrelated to the vaccine, it is not enough for the Secretary to establish that other factors merely contributed to producing the injury;. Instead, the Secretary must prove that the "factors unrelated" were "principally responsible" for causing the injury.

'300aa-13(a)(2) For purposes of paragraph (1), the term "factors unrelated to the administration of the vaccine" -

(A) does not include any idiopathies, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which is the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

*Shyface v. Sec'y HHS*, \_\_ F.3d \_\_ (Fed. Cir. 1999).

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 decisionmakers 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 NCVIA 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 NCVIA. 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,”<sup>385</sup> which one of the authors has previously demonstrated provides an excellent structure for the composition of expert panels to arbitrate technical claims involving medical and allied sciences.<sup>386</sup>

### c. Information

A comprehensive vaccine policy requires the gathering and careful assessment of millions of vaccinations in the U.S. and abroad. While 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 & World Report described last year the two-tiered data collection system utilized by all of the federal regulators identified above in Subsection V.B.1:

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

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<sup>385</sup> 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, 945, 949 (June 1999)

<sup>386</sup> See Jeffrey A. Van Detta, *supra*, “*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 at 936-955, 955-958 (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)

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.<sup>387</sup>

The Vaccine Safety Datalink 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.<sup>388</sup> While VDS has flaws, it provides more refined data than VAERS. At least one physician has reported that to test the credulity 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." 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.<sup>389</sup> A recent study in a leading pediatrics journal<sup>390</sup> concluded after an exhaustive analysis of VAERS reports related to autism that many who report autism events appear to be coordinating with vaccines or their families who seek to influence the database to support their positions in litigation. A commentator on that study observed 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,

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<sup>387</sup> Deborah Kotz, *Vaccines Get New Scrutiny: Vaccinations are supersafe, but maybe not all at once, or for certain children*, U.S. News & World Reports at 3 (Nov. 11, 2008), available at:

<http://health.usnews.com/articles/health/childrens-health/2008/12/11/vaccines-get-new-scrutiny.html?PageNr=3>

(last visited Aug. 3, 2009).

<sup>388</sup> Offit, *False Prophets*, supra note \_\_, at 91; Myers and Pineda, supra note \_\_, 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. Myers and Pineda, supra note \_\_, 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.

<sup>389</sup> See *How Vaccine Litigation Distorts The VAERS Database* (January 18, 2008), available at [http://scienceblogs.com/insolence/2008/01/how\\_vaccine\\_litigation\\_distorts\\_the\\_vaer.php](http://scienceblogs.com/insolence/2008/01/how_vaccine_litigation_distorts_the_vaer.php)

<sup>390</sup> Michael J. Goodman, PhD and James Nordin, MD, MPH, *Vaccine Adverse Event Reporting System Reporting Source: A Possible Source of Bias in Longitudinal Studies*, 117 PEDIATRICS 387-390 No. 2 (February 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 other current federal agencies have done. See, e.g., Stephen Novella, *Pockets of Vaccine Non-Compliance In California* (posted April 1, 2009), available at <http://www.sciencebasedmedicine.org/?p=436> (last visited Aug. 4, 2009).

which means testing for causality is not even possible with VAERS.

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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.<sup>391</sup>

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 HIPPA restrictions<sup>392</sup> 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.<sup>393</sup>

#### d. Services Instead Of Payouts

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<sup>391</sup> Id.

<sup>392</sup> How Vaccine Litigation Distorts The VAERS Database (January 18, 2008), available at [http://scienceblogs.com/insolence/2008/01/how\\_vaccine\\_litigation\\_distorts\\_the\\_vaer.php](http://scienceblogs.com/insolence/2008/01/how_vaccine_litigation_distorts_the_vaer.php); Myers and Pineda, supra note \_\_, at 65-66.

<sup>393</sup> See, e.g., Arthur Allen, supra note \_\_\_\_, at 318-326. 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?

Id. at 326 (original supplied followed by original emphasis).

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 which is available to claimants whose claims are sustained. As summarized by the Institute for Vaccine Safety, the NCVIA provides specific items of relief – and only this relief – and differentiates the relief depending on whether the vaccine caused injury versus death:

#### Types of Payments Awarded

For an injury, you may be paid:

- \* a reasonable amount for past and future nonreimbursable medical, custodial care, and rehabilitation costs, and related expenses (There is no limit on the amount a person with an injury may be paid for these types of expenses. Payments are based on your vaccine injury needs.);

- \* up to \$250,000 for actual and projected pain and suffering;

- \* lost earnings; and/or

- \* reasonable lawyers' fees and other legal costs or legal costs, not fees, of petitioners representing themselves, if your claim was filed on a reasonable basis and in good faith.

For a death, you may be paid:

- \* up to \$250,000 as a death benefit for the estate of the deceased; and

- \* reasonable lawyers' fees and other legal costs or legal costs, not fees, of petitioners representing themselves, if your claim was filed on a reasonable basis and in good faith.<sup>394</sup>

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:

**Amend regulatory language to require a return to lump-sum payments, or the removal of final "stipulation labels" from the life care plans used to determine settlement**

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<sup>394</sup> Dep't HHS, National Vaccine Injury Compensation Program, Filing A Claim With The VICP, available at [http://www.hrsa.gov/vaccinecompensation/filing\\_claim.htm](http://www.hrsa.gov/vaccinecompensation/filing_claim.htm) (last visited Aug. 3, 2009).

amounts and payment schedules. Require that any release of the final stipulation be accompanied by a formal statement from the Vaccine Injury Compensation Program clarifying the right of legal guardians to utilize settlement funds in the most appropriate manner on behalf of the injured individual in their care.

*Explanation:*

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, the final stipulation labels applied to settlement awards by the Compensation Program, specifying how funds must be spent on behalf of the injured child, represent the Program's best guess of what the child will require for life. The Program tells parents that the labels will not be strictly enforced.

However, the state guardianship courts, which frequently serve as executors for the distribution of the government annuities which constitute the bulk of the award, are less flexible with respect to spending funds for purposes other than those which are explicitly prescribed by the labels. At times, families have been threatened with the possibility that settlement award checks might not be cashed if previously dispensed funds were not spent as explicitly prescribed. (For example, a parent may be prohibited under final stipulation labels to spend more on diapers every week than was originally determined by federal officials involved in negotiating terms of the child's life care plan).

If the Program will not dispense the award as a lump-sum payment to parents as it did in the past, preferring that parents purchase federal annuities for the care of their vaccine injured children, then the final stipulation labels must be removed when it leaves the U.S. Court of Claims or a letter must accompany the final stipulation clarifying the right of legal guardians to utilize settlement funds in the most appropriate manner on behalf of the vaccine injured child in their care.<sup>395</sup>

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<sup>395</sup> Statement of the National Vaccine Information Center Barbara Loe Fisher, Co-founder & President, Hearing of the House Subcommittee on Criminal Justice, Drug Policy and Human Resources, *Compensating Vaccine Injuries: Are Reforms Needed?*, at ¶ 7 (1999), available at <http://www.nvic.org/injury-compensation/congresstestimony.aspx> (last visited Aug. 3, 2009).

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.<sup>396</sup> 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 earmarked annuities, an approach more consistent with our examination of the animating principles and the fair distribution of the costs of vaccine-caused harms is for Congress to 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.<sup>397</sup> Those whose claims for vaccine-injury are sustained under the revised adjudicatory system we've 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 for such a comprehensive VICRP program.<sup>398</sup> Furthermore, that model is particularly appropriate – one can certainly see

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<sup>396</sup> <http://www.hrsa.gov/vaccinecompensation/table.htm>

<sup>397</sup> Familial stress and financial ruin in dealing with post-vaccination injuries are well described at Arthur Allen, *supra* note \_\_\_, at 371-400; Paul Offit, *False Prophets*, *supra* note \_\_\_, at 225-228; James R. Laidler, M.D., *Through The Looking Glass: My Involvement With Autism Quackery*, available at Autism Watch, <http://www.autism-watch.org/about/bio2.shtml> (last visited Aug. 4, 2009).

<sup>398</sup> See, e.g., Donna Lee Yesner and Stephen Ruscus, *Selling Medical Supplies And Services Through The Department Of Veterans Affairs Federal Supply Schedule Program*, 37 Pub. Cont. L.J. 489 (2008) (“The Department of Veterans Affairs (VA) is the largest integrated health care system in the United States. As such, it spends billions of dollars annually on medical supplies, high-tech medical systems, diagnostic tests, and health care-related services, from MRI equipment to scalpels, and laboratory tests to nursing care, primarily through the Federal Supply Schedule (FSS) program, which the VA administers under a delegation of authority from the General Services Administration (GSA). The VA's National Acquisition Center (NAC) in Hines, Illinois, is responsible for managing the FSS program.”); Michael J. Jackonis, Lawrence Deyton, William J. Hess, *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, 679-681 (2008) (describing programs). Yesner and Ruscus also note that:

Professional medical health care services were added to the schedules in 2001. There are currently nine active schedules administered by the VA: 621 I (Professional Medical Healthcare Services); 65 I B (Pharmaceutical and Drugs), 65 II A (Medical Equipment and Supplies); 65 II C (Dental Equipment and Supplies); 65 II F (Patient Mobility Devices); 65 V A (X-Ray Equipment and Supplies); 65 VII (In Vitro Diagnostics, Reagents, Test Kits and Test Sets); 66 III (Cost-Per-Test for Clinical Laboratory Analyzers); and 621 II (Medical Laboratory Testing & Analysis Service). U.S. Dep't of Veterans Affairs Office of Acquisition & Logistics, National Acquisition Center, Federal Supply Schedule Service, <http://www1.va.gov/oamm/oa/nac/fss/index.cfm> (last visited Feb. 27, 2008); U.S. Dep't of Veterans Affairs, Office of Acquisitions, Doing Business with VA, <http://www1.va.gov/oamm/oa/dbwva/index.cfm> (last visited Mar. 7, 2008) [hereinafter Doing Business with VA].

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<sup>399</sup>; and viewed from that perspective, such systems are strong realizations of the three principles we've examined in this article. Such a program would vindicate each of the three principles, and be consistent with the "distribution of the costs of non-reciprocal 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 \$1.78 billion to 2322 claimants (while paying no compensation to 1,154 claimants), whose attorneys were awarded \$ 66 million in statutory attorneys fees, and denying compensation 2188 claimants, whose attorneys were awarded \$ 34 million in statutory attorney's fees.<sup>400</sup>

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37 Pub. Cont. L.J. at. at 489 n.2.

<sup>399</sup> Michael J. Jacksonis, Lawrence Deyton, William J. Hess, *supra* note \_\_, at 678. There, the authors make the following observation that seems applicable in the context of national vaccine policy:

Although not widely appreciated, the availability of appropriate health care for service members, veterans, and their families is of vital matter to national security, particularly in a nation that depends on voluntary service. For this reason, assuring quality and harmonization within the military and veteran's health systems, in conjunction with improved coordination with other federal health care programs and the civilian health care system, is now understood as a central dimension of U.S. health reform.

*Id.* (footnotes omitted). The analogy between the purpose and function of Veterans compensation programs to the NCVIA is also extensively discussed by Strong, *supra* note \_\_, at \_\_\_ - \_\_\_\_\_. Of course, in application, the Veterans process is far from perfect; and the NVA can learn from its shortcomings and mistakes. See, e.g., Howard Roitman, *Overview Of Veterans Administration Disability Law*, 16-NOV Nev. Law. 6 (2008); Amy N. Fairweather, *Compromised Care: The Limited Availability And Questionable Quality Of Health Care For Recent Veterans*, 35-SPG Hum. Rts. 2 (2008). To that end, see, e.g., Cynthia L. Williams, *The Continuous Readiness Process And Compliance: Ensuring Compliance Program Effectiveness In The Veterans Health Administration*, 10 No. 1 J. Health Care Compliance 65 (2008); Scott Simonson, Note, *Back From War--A Battle For Benefits: Reforming Va's Disability Ratings System For Veterans With Post-Traumatic Stress Disorder*, 50 Arizona L. Rev. 1177 (2008); 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. B.J. 1 (2008).

<sup>400</sup> Dep't HHS, National Vaccine Injury Compensation Program, Statistics Report (2009) available at [http://www.hrsa.gov/vaccinecompensation/statistics\\_report.htm](http://www.hrsa.gov/vaccinecompensation/statistics_report.htm) (last visited Aug. 3, 2009); Regina

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 non-reciprocal 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 manufacturer derives from FDA-approved products that are not on the World Health Organization’s list of essential drugs.<sup>401</sup> 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 hesitance or resistance to making the contribution.<sup>402</sup> 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.<sup>403</sup>

In addition, the pharmaceutical industry spends over \$30 billion annually in advertising and in direct-marketing of new drugs to consumers<sup>404</sup> This is a dubious

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Moreland, National Vaccine Injury Compensation Program: The Potential Impact of Cedillo for Vaccine-Related Autism Cases, 29 J. Legal. Med. 363, 368-69 (2008). 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.

<sup>401</sup> See the latest list on the World Health Organization’s website, separated by adult and pediatric medicines, at <http://www.who.int/medicines/publications/essentialmedicines/en/> (last visited Aug. 4, 2009).

<sup>402</sup> *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 and Joel Lexchin, *The Pharmaceutical Industry As A Medicines Provider*, *Lancet* 2002; 359 (9345): 1590-1595 (Nov. 16, 2002).

<sup>403</sup> 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. The authors have decided that extended explorations of the Constitutionality of aspects of their comprehensive national vaccine program proposal are beyond the scope of this article – they may be taken up in a subsequent article by the authors. However, for now, the authors 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 Commerce Clause as it has been interpreted since Mr. 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 Mr. 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.

<sup>404</sup> See, e.g., Donohue, J. *The New England Journal of Medicine*, Aug. 16, 2007; vol 357: pp 673-681

practice at best.<sup>405</sup> 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.”<sup>406</sup> In addition to vast sums for television and print ads, even internet direct-advertising has become a \$ 2 billion industry expenditure.<sup>407</sup> Congress should seriously consider extending the donative excise we propose to this wellspring of finance, the engine that drives up sales of non-essential, designer drugs.<sup>408</sup>

This 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. However, research is ongoing. 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 fund 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.

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<sup>405</sup> See, e.g., Meredith B. Rosenthal and Julie M. Donohue, *Direct-To-Consumer Advertising Of Prescription Drugs: A Policy Dilemma*, in *ETHICS AND THE PHARMACEUTICAL INDUSTRY*, Ch. 9 (Michael A. Santorro & Thomas M. Gorrie, eds. 2007).

<sup>406</sup> Natasha Singer, *Citing Risks, Lawmakers Seek To Curb Drug Commercials*, N.Y. Times, July 27, 2009, at B1, B6.

<sup>407</sup> Will Pharma’s Big Ad Spend Move Online?, *The E-Marketer* (Apr. 22, 2008), available at <http://www.emarketer.com/Article.aspx?R=1006199> (last visited Aug. 5, 2009); Big Pharma Spends More On Advertising Than Research And Development, Study Finds, *Science Daily* (Jan. 7, 2008), available at <http://www.sciencedaily.com/releases/2008/01/080105140107.htm> (last visited Aug. 5, 2009) (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 Medicine*, Jan. 3, 2008, an online journal published by the Public Library of Science).

<sup>408</sup> See *id.* at A6 (note especially 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).

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 MNEs in pharmaceuticals, Merck, and which is being sold at prices far above those that current childhood vaccines command.<sup>409</sup> Similarly, Sanofi-Aventis

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<sup>409</sup> Gardasil, however, is virtually unique – while no wide-spread 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 A-1, available at [http://www.nytimes.com/2008/08/20/health/policy/20vaccine.html?\\_r=1&scp=2&sq=Gardasil&st=cse&oref=slogin](http://www.nytimes.com/2008/08/20/health/policy/20vaccine.html?_r=1&scp=2&sq=Gardasil&st=cse&oref=slogin) (last visited September 1, 2008). Rarely has such a brand been marketed so aggressively, and so globally. *Id.* (noting also that Gardasil advertisements in the theatre preceded the premiere of the feature film, *Sex and the City*); accord Claire Dederer, *Pitching Protection, to Both Mothers and Daughters*, N.Y. Times, Feb. 18, 2007 (discussing effectiveness of Merck's television advertising campaign for Gardasil). As the *New York Times* recently observed, Gardasil's rise leaves even the iconic Salk polio vaccine in the dust:

The lightning-fast transition from newly minted vaccine to must-have injection in the United States and Europe represents a triumph of what the manufacturers call education and their critics call marketing. The vaccines, which offer some protection against infection from sexually transmitted viruses, are far more expensive than earlier vaccines against other diseases — Gardasil's list price is \$360 for the three-dose series, and the total cost is typically \$400 to nearly \$1,000 with markup and office visits (and often only partially covered by health insurance).

Elisabeth Rosenthal, *supra*. Similar observations have been made by leaders in the immunology community. For example, Professor Diane Parker of Dartmouth College's Medical School recently voiced substantial reservations about how Gardasil has been approved, marketed – and targeted:

“Merck lobbied every opinion leader, women's group, medical society, politicians, and went directly to the people — it created a sense of panic that says you have to have this vaccine now . . . . Because Merck was so aggressive, it went too fast . . . I would have liked to see it go much slower.”

*Id.* (quoting interview). Reporter Rosenthal also noted that “[i]n receiving expedited consideration from the Food and Drug Administration, Gardasil took six months from application to approval and was recommended by the C.D.C. weeks later for universal use among girls. Most vaccines take three years to get that sort of endorsement, Dr. Harper said, and then 5 to 10 more for universal acceptance. “In that time, you learn a lot about safety and side effects and how to use it,” Dr. Harper said.” *Id.*

Indeed, the great profit to be made from 21<sup>st</sup> century designer vaccines such as Gardasil also carries with it risks for which it must be made to pay its own freight. Among the things smoothed over in the public relations juggernaut that only got the vaccine approved, but has lobbied hard state legislatures to mandate Gardasil vaccinations, is that “[s]o far more than 40 cases of Guillian-Barre syndrome - a dangerous immune disorder that causes tingling, numbness and even paralysis of the muscles have been reported in girls who have received the HPV vaccine in combination with the meningitis vaccine.” Cindy Bevington, *Researcher Blasts HPV Marketing*, *fwnews* September 1, 2008, available at [http://www.kpcnews.com/articles/2007/03/14/online\\_features/hpv\\_vaccine/hpv01.prt](http://www.kpcnews.com/articles/2007/03/14/online_features/hpv_vaccine/hpv01.prt) (extended comments of Dr. Harper). Similar sentiments were voiced by Sigrid Fry-Revere in a 2007 editorial, Sigrid Fry-Revere, *The Rush To Vaccine*, N.Y. Times March 25, 2007, available at <http://www.nytimes.com/2007/03/25/opinion/25CIfry-revere.html?scp=18&sq=Gardasil&st=cse> (last visited September 1, 2008); Professor R. Alta Charo in *The New England Journal of Medicine* in 2007, R.

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 U.S. combined.<sup>410</sup> 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.<sup>411</sup> 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 just in sales by Merck and Wyeth.<sup>412</sup>

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,

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Alta Charo, Politics, Parents, and Prophylaxis — Mandating HPV Vaccination in the United States, N. Engl. J. Med. May 2007 19: 356:1905-1908; and Dr. Charlotte Haug in The New England Journal Of Medicine in 2008. Charlotte J. Haug , Human Papillomavirus Vaccination — Reasons for Caution, N. England J. Med. 2008 Aug 21;359(8):821-32

The rush to Gardasil may raise even more questions when one considers public health experts’ call for world-wide vaccination, Jan M. Agosti & Sue J. Goldie, Introducing HPV Vaccine in Developing Countries — Key Challenges and Issues, N. Engl. J. Med. May 2007 19: 356:1908-1910; – in many nations where there is no effective civil litigation system to provide any compensation for injuries that eventuate over long-term and widespread administration – and without realistic access to pursue claims in American courts against the manufacturers. See, e.g., Jeffrey A. Van Detta, *Justice Restored: Using A Preservation-Of-Court Access Approach To Replace Forum Non Conveniens In Five International Product-Injury Cases*, 24 Northwestern J. OF Int’l L. & Bus. 53 (Fall 2003)

Most remarkable is that Gardasil has been accorded a wide tort “immunity” under the National Childhood Vaccine Injury Act (NCVIA), despite its hurried approval and rush to being mandated. This means that the vast majority of those injured by the vaccine over time will have only a limited amount of compensation for injuries that may be disabling for life – just as vaccines for pandemic illnesses have enjoyed. Yet vaccines like polio and \_\_\_ are needed to prevent pandemics and have a much longer track record of use. Of course, if Merck did not enjoy some predictability of tort payouts for Gardasil-related injuries, it would be less likely to have invested the kind of resources into its research and development that it has – and perhaps not to undertake the project at all.

<sup>410</sup> Jeanne Whalen, Translating Genes To Drugs: Novartis May Be One Of The First To Get A Payoff From Latest Know-How, Wall St. J., Monday, 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.

<sup>411</sup> Aaron Smith, Vaccines: Hot “New” Business For Drugmakers: Gardasil, Prevnar Give Once-Sluggish Industry Shot In The Arm; Business Seen Doubling By 2010, But No HIV Vaccine In Sight, CNN Money.com, May 30, 2007, available at <http://money.cnn.com/2007/05/30/news/companies/vaccine/index.htm> (last visited Aug. 5, 2009).

<sup>412</sup> Id.

diphtheria, tetanus, chickenpox and measles.<sup>413</sup> 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 off for repairs.<sup>414</sup>

Industry had idly permitted this situation – described by one expert as “dropping [the quality of medical care] back into the 1960s” – is “used in more than 40,000 medical procedures *a day* in the United States” alone.<sup>415</sup> The problem isn’t 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 20<sup>th</sup> century medical companies exemplified of corporate social 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.’”<sup>416</sup> 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.<sup>417</sup>

As a final note, the federal government’s latest vaccine response – encouraging the rush manufacturing by pharmaceutical companies of swine-flu vaccine – demonstrates

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<sup>413</sup> 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., Monday, Dec. 8, 2003, at A1

<sup>414</sup> Matthew L. Wald, *Radioactive Drug For Medical Tests Is In Short Supply—A Shortage Is Expected To Lead To A Loss In Diagnostic Capability*, N.Y. TIMES, Fri., July 24, 2009, at A10, A14.

<sup>415</sup> *Id.* at A10 (emphasis supplied).

<sup>416</sup> *Id.* at A14.

<sup>417</sup> See, e.g., Denise Grady, *Swine Flu Plan Would Put Some At Head Of Line For Vaccine*, N.Y. Times, Thus., July 30, 2009, at A18 (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, Mon., Apr. 27, 2009, at A1, A10.

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’ve established in this article. The disarray of HHS and its new Secretary Kathleen Sebelius speaks for itself:

Vaccine makers and federal officials will be immune from lawsuits that result from any new swine flu vaccine, under a document signed by Secretary of Health and Human Services Kathleen Sebelius, government health officials said Friday.

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The document signed by Sebelius last month grants immunity to those making a swine flu vaccine, under the provisions of a 2006 law for public health emergencies. *It allows for a compensation fund, if needed.*<sup>418</sup>

“Allows” for “a” compensation fund “if needed”? Not very well considered, it appears, and hardly inspiring of confidence that there is anything other than a piecemeal, reactive approach at work. Noting that “[t]he government will likely call on millions of Americans to get the vaccinations to prevent the disease from spreading,” New York attorney Paul Pennock observed:

"If you're going to ask people to do this for the common good, then let's make sure for the common good that these people will be taken care of if something goes wrong."<sup>419</sup>

## VI. 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-pre-emption 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

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<sup>418</sup> Mike Stobbe, *Legal Immunity Set For Swine Flu Vaccine Makers--In Past, Thousands Filed Claims Contending They Suffered Side Effects*, ASSOCIATED PRESS, July 17, 2009, available at:

<http://www.clickondetroit.com/health/20088640/detail.html> (last visited August 5, 2009).

<sup>419</sup> Id.

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 lobbyists 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, of our society of individuals, and of the industry of pharmaceutical development and manufacture. Only by rethinking vaccine-injury liability within this larger context, and legislating to address that question as part of comprehensive regulation to ensure vaccine accessibility and continued development, can Congress advance the dialogue beyond partisan questions of trial lawyers versus 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?<sup>420</sup>

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<sup>420</sup> OSHINSKY, *supra* note \_\_\_\_, 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); see also JANE SMITH, *PATENTING THE SUN: POLIO AND THE SALK VACCINE* \_\_ (1990). But see Stephan Kinsella, *Patent and Penicillin*, *Mises Economics Blog*, June 22, 2006. Kinsella writes:

When Jonas Salk asked rhetorically "Would you patent the sun?" during his famous television interview with Edward R. Murrow, he did not mention that the lawyers from the National Foundation for Infantile Paralysis had looked into patenting the Salk Vaccine and concluded that it could not be patented because of prior art - that it would not be considered a patentable invention by standards of the day. Salk implied that the decision was a moral one, but Jane Smith, in her history of the Salk Vaccine, *Patenting the Sun*, notes that whether or not Salk himself believed what he said to Murrow, the idea of patenting the vaccine had been directly analyzed and the decision was made not to apply for a patent mainly because it

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. The authors have laid the theoretical foundation and suggested a path in Section V, *supra*, for doing just that. One must fervently hope that half a century after Dr. Salk, Congress will at last heed the call and “have the courage . . . [to] dare the journey.”<sup>421</sup>

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would not result in one.

Id.

<sup>421</sup> MAYA ANGELOU, EVEN THE STARS LOOK LONESOME \_\_\_\_ (\_\_\_\_\_) (“ . . . one has to have a calling to become a true teacher. And above all things, one needs a bounty of courage. The calling informs the teacher that her knowledge is needed in new, uncharted areas, and the courage makes the teacher dare the journey.”)

APPENDIX A

***National Childhood Vaccine Injury Act***  
***Vaccine Injury Table***<sup>a</sup>

<b>Vaccine</b>	<b>Adverse Event</b>	<b>Time Interval</b>
I. Tetanus toxoid-containing vaccines (e.g., DTaP, Tdap, DTP-Hib, DT, Td, TT)	A. Anaphylaxis or anaphylactic shock B. Brachial neuritis C. Any acute complication or sequela (including death) of above events	0-4 hours 2-28 days Not applicable
II. Pertussis antigen-containing vaccines (e.g., DTaP, Tdap, DTP, P, DTP-Hib)	A. Anaphylaxis or anaphylactic shock B. Encephalopathy (or encephalitis) C. Any acute complication or sequela (including death) of above events	0-4 hours 0-72 hours Not applicable
III. Measles, mumps and rubella virus-containing vaccines in any combination (e.g., MMR, MR, M, R)	A. Anaphylaxis or anaphylactic shock B. Encephalopathy (or encephalitis) C. Any acute complication or sequela (including death) of above events	0-4 hours 5-15 days Not applicable
IV. Rubella virus-containing vaccines (e.g., MMR, MR, R)	A. Chronic arthritis B. Any acute complication or sequela (including death) of above event	7-42 days Not applicable
V. Measles virus-containing vaccines (e.g., MMR, MR, M)	A. Thrombocytopenic purpura B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient C. Any acute complication or sequela (including death) of above events	7-30 days 0-6 months Not applicable
VI. Polio live virus-containing vaccines (OPV)	A. Paralytic polio --- in a non-immunodeficient recipient --- in an immunodeficient recipient --- in a vaccine assoc. community case B. Vaccine-strain polio viral infection --- in a non-immunodeficient recipient --- in an immunodeficient recipient --- in a vaccine assoc. community case C. Any acute complication or sequela (including death) of above events	0-30 days 0-6 months Not applicable 0-30 days 0-6 months Not applicable Not applicable
VII. Polio inactivated-virus containing vaccines (e.g., IPV)	A. Anaphylaxis or anaphylactic shock B. Any acute complication or sequela (including death) of above event	0-4 hours Not applicable

VIII. Hepatitis B antigen- containing vaccines	A. Anaphylaxis or anaphylactic shock B. Any acute complication or sequela (including death) of above event	0-4 hours Not applicable
IX. Hemophilus influenzae type b polysaccharide conjugate vaccines)	A. No condition specified for compensation	Not applicable
X. Varicella vaccine	A. No condition specified for compensation	Not applicable
XI. Rotavirus vaccine	A. No condition specified for compensation	Not applicable
XII. Pneumococcal conjugate vaccines	A. No condition specified for compensation	Not applicable
XIII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by Secretary, HHS of a notice of coverage	A. No condition specified for compensation	Not applicable

Effective date: November 10, 2008 As of **December 1, 2004**, hepatitis A vaccines have been added to the Vaccine Injury Table (Table) under this Category. As of **July 1, 2005**, *trivalent* influenza vaccines have been added to the Table under this Category. Trivalent influenza vaccines are given annually during the flu season either by needle and syringe or in a nasal spray. All influenza vaccines routinely administered in the U.S. are trivalent vaccines covered under this Category. As of **February 1, 2007**, meningococcal (conjugate and polysaccharide) and human papillomavirus (HPV) vaccines have been added to the Table under this Category. See *News* on the VICP website ([www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation)).

