ARTICLES

THE 800 POUND GORILLA SLEEPS: THE FEDERAL GOVERNMENT'S LACKADAISICAL LIABILITY AND COMPENSATION POLICIES IN THE CONTEXT OF PRE-EVENT VACCINE IMMUNIZATION PROGRAMS

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INTRODUCTION

Three years after September 11, 2001, the United States is beginning to implement a biodefense strategy. The National Institute of Allergy and Infectious Diseases (NIAID) is providing substantial research grants to universities so that they can, *inter alia*, research next generation biodefense vaccines.[1] In addition, on July 21, 2004, President Bush signed the Project Bioshield Act, which authorizes the spending of $5.6 billion to advance the development and acquisition of vaccines and other countermeasures to biological agents.[2] Currently, a next-generation smallpox vaccine is in Phase I trials and an Ebola vaccine is slated to begin Phase I trials soon.[3] Furthermore, it is the Bush Administration's goal to develop at least two countermeasures for each of the Category A bioterrorism agents, as listed by the Centers for Disease Control and Prevention.[4] These are but a few of the federal government's efforts. While the funding and progress are welcome signs for our national defense, the federal pre-event Phase I smallpox vaccination program for first responders recently demonstrated that other serious

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1. Press Release, National Institute of Allergy and Infectious Diseases, HHS Announces New Regional Centers for Biodefense Research (Sept. 4, 2003), http://www2.niaid.nih.gov/Newsroom/Releases/hhs_rce.htm (last visited Feb. 24, 2005).

2. President George W. Bush, *Remarks by the President at the signing of S.15 – Project Bioshield Act of 2004*, 40 WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS 1346, 1347 (July 21, 2004), http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2004_presidential_documents&docid=pd26jy04_txt-12.pdf (last visited Feb. 24, 2005).

3. Mike Nartker, *NIH Official Touts Progress on Biological Defenses*, GOV'T EXEC., June 10, 2004, http://www.govexec.com/dailyfed/0604/061004gsn1.htm (last visited Feb. 24, 2005).

4. *Id.*

obstacles remain to the implementation of a successful pre-event vaccination program – namely, the federal government's inability to provide *both* sufficient liability protection for vaccine administrators *and also* adequate compensation to those injured by the vaccine.

This article grows out of my work on a recently published, interdisciplinary, and peer reviewed article in the Journal of Homeland Security, *The Threat of Smallpox: Eradicated but Not Erased*,[5] that discussed the failure of the federal Phase I smallpox vaccination program – a program launched on January 24, 2003 to preemptively vaccinate 500,000 civilian first responders against smallpox with an existing smallpox vaccine.[6] The most recent data as of this writing reveals that only 39,608 people have been vaccinated under the auspices of the federal Phase I program.[7]

The Threat of Smallpox grew out of a field study of several states' health departments, performed at the Analytical Services, Inc. (ANSER).[8] Subsequent analysis of that data revealed that three principal problems were to blame for the failure of the Phase I smallpox vaccination effort: overextended public health and hospital resources; an uncertain risk benefit calculus that likely preceded a decision to take the smallpox vaccine; and, the single largest obstacle to Phase I's success, an inadequate federal liability and compensation scheme to effectively remedy injuries stemming from the vaccine.[9] The first two findings are described very briefly below. This article, however, greatly expands the third finding of the ANSER study and offers suggestions to create a robust, yet well-tailored, liability and compensation regime, which would help ensure success of future pre-event biodefense vaccination programs.[10]

As mentioned above, the first reason for Phase I's failure was that it further strained already burdened public health and hospital resources.[11] Aside from the Phase I initiative, public health departments had many other problems to consider, including a panoply of chronic and emerging diseases.[12] In addition to those existing duties, the federal government initially asked states to implement Phase I with Fiscal Year 2002 funding that had already been encumbered for other

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5. Holly Myers et al., *The Threat of Smallpox: Eradicated but Not Erased*, J. HOMELAND SECURITY (Feb. 20, 2004), *at* http://www.homelandsecurity.org/journal/articles/gursky_smallpox.html (last visited Feb. 24, 2005) [hereinafter *The Threat of Smallpox*].

6. *Id.*

7. *See* OFFICE OF COMMUNICATION, CENTERS FOR DISEASE CONTROL, SMALLPOX VACCINATION PROGRAM STATUS BY STATE (Jan. 31, 2005), http://www.cdc.gov/od/oc/media/spvaccin.htm (last visited Feb. 24, 2005) [hereinafter CDC SMALLPOX PROGRAM BY STATE]. These figures are now updated on the web on a monthly basis. *Id.*

8. *The Threat of Smallpox*, *supra* note 5.

9. *Id.*

10. *Id.*

11. *Id.*

12. *Id.*

purposes.[13] As a result, public health departments had little capacity to take on a full-fledged smallpox vaccination program that had not been utilized in civilian life for over thirty years.[14]

The second finding from *The Threat of Smallpox* was that the risk of injury posed by the smallpox vaccine versus the general uncertainty over the threat of smallpox being used as a weapon also contributed to low numbers of first responders volunteering for vaccination.[15] When smallpox ran rampant in the world, thirty percent of those who contracted the disease died.[16] In today's world, one free of smallpox (except for the known samples stored at the Centers for Disease Control and Prevention in Atlanta, Georgia and the Vector facility in Russia), the risk of being infected by smallpox from a bioterrorist attack is virtually unknown.[17] But, in contrast, the risk of being harmed or killed by the smallpox vaccine is certainly calculable.[18] Because study participants felt that they received poor communication from the Bush Administration about the threat of a smallpox attack, it was difficult for prospective Phase I volunteer vaccinees to accept the vaccine's risks of harm or death.[19]

Finally, *The Threat of Smallpox* explained that liability and compensation concerns were the biggest roadblocks to full participation in the Phase I smallpox initiative.[20] Liability coverage was ambiguous for certain parties, and those injured or killed by the vaccine were initially given very little chance of receiving compensation from the federal government.[21] When the federal government belatedly offered a compensation package to those harmed by the smallpox vaccine under the Phase I program, it was not enough to attract volunteers. As of this writing, Phase I has not even achieved one tenth of its goal of vaccinating 500,000 first responders against smallpox.[22]

If the government is serious about developing a successful biodefense strategy, it must begin by implementing a successful pre-event vaccination program. In order to do so, the federal government must provide the financial support necessary to *both* protect manufacturers, sellers, and distributors of the vaccine from liability *and also* compensate those injured by the vaccination. A pre-event program that does not include *both* of these characteristics is destined to

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13. *Id.*

14. *Id.*

15. *Id.*

16. *Id.*

17. Participants in the ANSER study felt that the threat of smallpox being used as a weapon was never adequately communicated to them. *Id.*

18. *Id.*

19. *Id.*

20. *Id.*

21. *Id.*

22. *See* CDC SMALLPOX PROGRAM BY STATE, *supra* note 7.

fail. Although the cost of providing both liability protection and also adequate compensation at the pre-event stage may seem large, it pales in comparison to what the cost would be should an outbreak occur without the benefit of vaccinated first responders.

For example, at the pre-event stage, the targeted vaccination population is relatively small and the threat of the disease is virtually unknown. In contrast, at the post-event stage, the targeted population becomes enormous, the threat of contracting the disease suddenly becomes very real, and, as a result, the cost of confronting the problem increases astronomically.[23] In order to avoid post-event catastrophe, it is imperative for the government to minimize the risks associated with both administering and receiving the vaccine. The government can achieve this by providing liability protection to administrators and adequate compensation to those injured by the vaccination.

The remainder of this paper will analyze past and current vaccine liability and compensation regimes as a basis for suggesting changes for future pre-event vaccination programs.[24] These programs are important because they are the most effective (and, in the case of smallpox, the only) method of confronting the threat of an outbreak. In order to implement a successful pre-event vaccination program, the government must begin by assuming more of the risk, on behalf of both providers and first responders.

I. THE REGRESSING GENEROSITY OF THE UNITED STATES GOVERNMENT IN ITS VACCINE LIABILITY AND COMPENSATION REGIMES

The United States government has implemented three primary vaccine liability and compensation schemes over recent years. Ranging from the National Swine Flu Immunization Program of 1976 to the most recent Phase I Smallpox Vaccination Program, the government's willingness to provide liability protection

23. A recent study has indicated that at the post-event stage, only forty-three percent of the American people would go to a vaccination site to get vaccinated after a smallpox outbreak. ROZ D. LASKER, THE NEW YORK ACADEMY OF MEDICINE, REDEFINING READINESS: TERRORISM PLANNING THROUGH THE EYES OF THE PUBLIC 8 (2004) The study, which stems from a random telephone survey of 2,545 adult residents of the continental United States, offers four reasons why most people are unlikely to cooperate: (i) people are not worried about catching the disease; (ii) people do not trust what government officials say or do; (iii) people are worried about the vaccine's risks; and, (iv) people have conflicting worries about getting the disease and getting sick from the vaccine. *Id.* at 8-14. As the study asserts, fear – of getting vaccinated, of the disease itself, or both – is a significant obstacle to post-event cooperation. *Id.* at 15-18.

24. Liability and compensation for post-event biodefense vaccinations, though important, are beyond the scope of this article. As discussed above, the risk-benefit calculus for post-event biodefense vaccinations changes too dramatically to include in this discussion of pre-event biodefense vaccinations.

and vaccine compensation has dwindled, primarily due to financial considerations. However, as bioterrorism continues to threaten the nation's homeland security, it is becoming increasingly important for the government to rediscover much of the financial liberality – particularly at the pre-event stage – that it has lost along the way. Otherwise, the nation will be ill-equipped to adequately and sufficiently handle an outbreak of an infectious disease.

A. The National Swine Flu Immunization Program of 1976

The National Swine Flu Immunization Program of 1976 [hereinafter the Swine Flu Act] was the federal government's first foray into a vaccine liability and compensation program. Fear of a flu pandemic began in January of 1976 when four cases of swine flu were discovered at Fort Dix, New Jersey.[25] This raised grave concerns in the public health community because the community feared a repeat of the swine flu pandemic that had killed millions in 1918-1919.[26] While neither a swine flu epidemic nor a pandemic materialized in the early months of 1976 (the flu season generally runs from September though March),[27] Congress quickly authorized the procurement of nearly 200 million doses of the swine flu vaccine in April of 1976.[28]

Concerns over vaccine manufacturer liability did not arise until insurers declared that they would end coverage for vaccine manufacturers as of June 30, 1976.[29] This refusal stemmed in large part from the case of *Reyes v. Wyeth Laboratories*, which held polio vaccine manufacturers strictly liable for failing to provide product warnings directly to vaccinees which would have allowed vaccinees to assess the risks of the vaccine.[30] Insurers maintained that it would be cost prohibitive to litigate "frivolous suits" for strict liability; therefore, they could not offer that kind of insurance to vaccine manufacturers.[31]

A swine flu manufacturer indemnification bill went to Congress on June 16, 1976, but Congress did not act on it because of the government's reluctance to

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25. Arnold W. Reitze, *Federal Compensation for Vaccination Induced Injuries*, 13 B.C. ENVTL. AFF. L. REV. 169, 171 (1986).

26. *See id.* at 170 (noting that 500,000 Americans died in 1918-1919 from the swine flu, which paled in comparison to the estimated twenty million who died worldwide from the disease).

27. Alvarez v. U.S., 495 F. Supp. 1188, 1190 (D. Colo. 1980) (citing U.S. COMPTROLLER GEN., THE SWINE FLU PROGRAM: AN UNPRECEDENTED VENTURE IN PREVENTIVE MEDICINE (1977)).

28. Reitze, *supra* note 25, at 173.

29. *Id.* at 175.

30. 498 F.2d 1264, 1295 (5th Cir. 1974), *cert. denied*, 419 U.S. 1096 (1974). Such a warning was required when the manufacturer had reason to know that the vaccinator would not be using "individualized medical judgment" concerning potential harm to the vaccinee. Reitze, *supra* note 25, at 175-76 (citing *Reyes*, 498 F.2d at 1277).

31. *Alvarez*, 495 F. Supp. at 1191 n.6 (citing RICHARD E. NEUSTADT & HARVEY V. FEINBERG, THE SWINE FLU AFFAIR 58-59 (1978)).

accept the financial responsibility.[32] As a result, swine flu manufacturers stopped producing the vaccine that would potentially save the lives of thousands, if not millions, of Americans if the swine flu returned for the fall flu season.[33] However, Congress eventually passed the Swine Flu Act[34] on August 12, 1976, largely as a result of the fear created by the discovery of Legionnaires Disease on August 1, 1976.[35] Not only did the Swine Flu Act provide liability protection, which changed the risk benefit calculus for the manufacturers, it also created federally funded compensation for those harmed by the vaccine.[36] Through its action, Congress hoped to ensure that a sufficient number of swine flu vaccines would be available to inoculate an overwhelming majority of the American population.[37]

1. Liability Protections

The Swine Flu Act protected manufacturers and distributors of the swine flu vaccine, as well as those who administered the vaccine.[38] Plaintiffs asserted claims directly against the United States through the Federal Tort Claims Act rather than against the alleged "wrongdoer,"[39] and the United States assumed the liability of manufacturers, distributors, and vaccinators, "based on any theory of liability . . . including negligence, strict liability in tort, and breach of warranty."[40] In addition, the courts consistently interpreted the "any theory of liability" language as establishing a no-fault compensation system that made the government liable to all plaintiffs who could demonstrate that their injuries were caused by the swine flu vaccine.[41] However, the United States would seek indemnification from negligent organizations or individuals covered by the Swine Flu Act's liability protections.[42]

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32. Reitze, *supra* note 25, at 175.

33. *Id.*

34. National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380, 90 Stat. 1113 (codified as amended at 42 U.S.C.A. § 247b (West 2003 & Supp. 2004)).

35. Reitze, *supra* note 25, at 178-79.

36. Unthank v. United States, 732 F.2d 1517, 1519 (10th Cir. 1984) (quoting Unthank v. United States, 533 F. Supp. 703, 719 (D. Utah 1982)). In fact, Congress accomplished this after only two days' consideration, without prior hearings or a committee report. *Id.*

37. Reitze, *supra* note 25, at 173.

38. National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380, § 2, 90 Stat. 1113, 1114-15 (codified as amended at 42 U.S.C.A. § 247b (West 2003 & Supp. 2004)).

39. Alvarez v. U.S., 495 F. Supp. 1188, 1190 (D. Colo. 1980).

40. National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380, § 2, 90 Stat. at 1115 (codified as amended at 42 U.S.C.A. § 247b (West 2003 & Supp. 2004)).

41. EDWARD P. RICHARDS ET AL., SMALLPOX VACCINE INJURY LAW PROJECT, SMALLPOX VACCINE INJURY AND LAW GUIDE 7 (June 7, 2004), http://biotech.law.lsu.edu/blaw/bt/smallpox/svlaw.htm (last visited Feb. 24, 2005).

42. National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380 § 2, 90 Stat. at 1117 (codified as amended at 42 U.S.C.A. § 247b (West 2003 & Supp. 2004)).

2. Compensation Provisions

Claimants had an exclusive remedy for compensation against the federal government for personal injury or death arising from the swine flu vaccine.[43] Because the Swine Flu Act used the Federal Tort Claims Act as a vehicle for liability and compensation, claimants first had to file an administrative claim with the agency before proceeding to federal district court.[44] The Swine Flu Act did not place limits on the amount of an award that could be obtained.[45]

3. Results of the Swine Flu Act of 1976

The swine flu vaccination program was successful in terms of getting a large number of people vaccinated in a short period. During the two-month run of the program, over forty million Americans – nearly a third of the adult population of the United States – received the swine flu vaccination.[46] However, a vast field of vaccine injury litigation subsequently began in which attorneys and medical experts readily attributed injuries to the vaccine.[47] By 1985, the government had paid out $90 million to those that developed Guillain-Barre syndrome, an often reversible, but sometimes fatal, form of paralysis, which had been attributed to the swine flu vaccine.[48] As a result, the government became increasingly reluctant to assume the financial risks associated with vaccination initiatives.

B. National Childhood Vaccine Injury Act of 1986

Prior to 1986, the number of manufacturers making childhood vaccines had "declined significantly."[49] In addition, the early 1980s exhibited an increase in vaccine tort litigation, which in part grew out of the fact that injuries previously unrecognized as arising from childhood vaccines were starting to be connected to those vaccines.[50] Injured children "often" did not have a source of compensation for their injuries, so these children and their families turned to the legal system for help.[51] At the time, vaccine manufacturers faced grave difficulty in obtaining liability insurance, which caused one vaccine manufacturer to stop producing

43. National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380 § 2, 90 Stat. at 1115 (codified as amended in 42 U.S.C.A. § 247b (West 2003 & Supp. 2004)).

44. *Alvarez*, 495 F. Supp. at 1191 n.8.

45. *See generally*, 42 U.S.C.A. § 247b (West 2003 & Supp. 2004)).

46. David Brown, *A Shot in the Dark: Swine Flu's Vaccine Lessons*, WASH. POST, May 27, 2002, at A9.

47. RICHARDS ET AL., *supra* note 41.

48. Brown, *supra* note 46.

49. H.R. REP. NO. 99-908, pt. 1, at 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345.

50. *Id.*

51. *Id.*

vaccines temporarily in 1984.[52] Others were threatening to follow suit.[53] Because "the withdrawal of even a single manufacturer would present the very real possibility of vaccine shortages,"[54] Congress once again involved the federal government in vaccine liability and compensation through the National Childhood Vaccine Injury Act of 1986 (NCVIA).[55] However, NCVIA's liability and compensation provisions were crafted differently from the Swine Flu Act, largely due to the government's increasing reluctance to accept financial responsibility.[56]

Specifically, NCVIA established a two-staged, no fault compensation system for specific childhood vaccines (exclusive of the smallpox vaccine).[57] The first stage was a mandatory "no-fault" system, administered by a special master of the federal district court, which compensated specific injuries resulting from childhood vaccination.[58] This administrative hearing provided compensation regardless of the party alleged to have caused the injury, and the respondent was always the United States.[59]

However, unlike the Swine Flu Act of 1976, which did not limit awards, NCVIA capped certain types of awards.[60] Under the no-fault system in NCVIA, the plaintiff could recover actual unreimbursable and reasonable projected unreimbursable expenses, such as medical expenses, lost wages, reasonable attorneys' fees, and secondary transmission costs; but, "actual and projected" pain and suffering were limited to $250,000.[61] Awards for a vaccinee's death were capped at $250,000.[62] Both of the aforementioned caps were adjusted for inflation in accordance with the Consumer Price Index.[63] Lost wages were explicitly limited to "compensation for actual and anticipated loss of earnings determined in accordance with generally recognized actuarial principles and projections" for

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52. *Id.* at 6, *reprinted in* 1986 U.S.C.C.A.N. 6344, 6347.

53. *Id.*

54. *Id.* at 7, *reprinted in* 1986 U.S.C.C.A.N. 6344, 6348. At the time NCVIA was being debated in Congress, "there [was] only one manufacturer of the polio vaccine, one manufacturer of the measles, mumps, rubella (MMR) vaccine, and two manufacturers of the DPT vaccine." *Id.* In addition, Michigan and Massachusetts had the ability to produce DPT vaccine. *Id.* Even with these manufacturers operational, the Centers for Disease Control and Preventioin's vaccine stockpile had never reached the recommended six month supply. *Id.*

55. H.R. REP. NO. 99-908, pt. 1, at 3, 7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6348. National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3756 (1986) (codified at 42 U.S.C.A. § 300aa-1 to 300aa-33 (West 2003 & Supp. 2004).

56. *The Threat of Smallpox*, *supra* note 5.

57. 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, 389-90 (1987).

58. *Id.*

59. *Id.*

60. *See infra* notes 59-63 and accompanying text.

61. 42 U.S.C.A. § 300aa-15(a)(4) (West 2003 & Supp. 2004).

62. 42 U.S.C.A. § 300aa-15(a)(2).

63. 42 U.S.C.A. § 300aa-18 (repealed 1987).

those injured by a vaccine after turning eighteen years old.[64] Those injured before turning eighteen could recover lost wages in anticipation of turning 18 in amounts 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."[65] Although this was a limitation, injured parties could generally recover lost wages without the benefit of knowing what their actual wages would have been.

If unsatisfied with an administrative award, the plaintiff could enter NCVIA's second stage[66] and commence traditional tort litigation against the vaccine manufacturer.[67] However, Congress hoped to avoid the litigation alternative by providing a compulsory, no-fault, quick, and fair administrative system in which injured parties could be compensated.[68] If a plaintiff chose litigation, Congress made certain alterations to traditional tort law to protect vaccine manufacturers, as the government would not pay awards that arose from litigation.[69] First, the manufacturer was not liable for injuries or death that resulted from "unavoidable" side effects that were inherent in properly prepared, labeled, and administered vaccines.[70] Next, Congress legislatively altered the rule established in *Reyes*[71] by declaring that childhood vaccine manufacturers were not liable for failing to provide such warnings.[72] Rather, simply providing those warnings to the administering physician or nurse was adequate.[73] Protection of this sort was important, given that insurers dropped vaccine manufacturers from coverage largely because of the *Reyes* rule during the swine flu crisis in 1976.[74] Finally, a manufacturer was immune from punitive damages in a civil trial if it complied with the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act when manufacturing the vaccine, unless the manufacturer engaged in fraudulent, wrongful, or criminal action when submitting information for the vaccine's approval.[75] Congress created none of these presumptions when it enacted the Swine Flu Act.

A final retreat from the generosity of the Swine Flu Act was that NCVIA made its compensation secondary to state and private sources of compensation as

64. 42 U.S.C.A. § 300aa-15(a)(3)(A).
65. 42 U.S.C.A. § 300aa-15(a)(3)(B).
66. 42 U.S.C.A. § 300aa-21(a) (West 2003).
67. *Id.*
68. Schwartz & Mahshigian, *supra* note 57, at 391-92.
69. *Id.* at 392-93.
70. 42 U.S.C.A. § 300aa-22(c) (West 2003).
71. *See supra* notes 30-31 and accompanying text.
72. 42 U.S.C.A. § 300aa-22(c).
73. *See id.*
74. *See supra* notes 30-31 and accompanying text.
75. 42 U.S.C.A. § 300aa-23(d) (West 2003).

well as federal sources.[76] NCVIA clearly stated that the federal government had liability in this area secondary to state compensation programs; private or public health benefits; private insurance; state "health benefits programs."[77] In contrast, under the Swine Flu Act, the "exclusive remedy" was an action directly against the United States.[78]

As demonstrated above, NCVIA was more stringent in terms of liability and compensation compared to the Swine Flu Act. While NCVIA did have a no fault liability and compensation system, as did the Swine Flu Act, NCVIA's litigation stage potentially exposed vaccine manufacturers and others to liability, if claimants were not satisfied with their administrative awards.[79] In the Swine Flu Act, the federal government still inserted itself as the defendant and paid the awards if a plaintiff decided to take a case to federal district court.[80] Also, unlike the Swine Flu Act, NCVIA limited awards for pain and suffering, death, and lost wages through its no fault administrative process[81] and disallowed punitive damages in most cases, if a claimant chose to litigate in court.[82] Finally, NCVIA made its compensation secondary to federal, state, and private compensation programs, whereas the Swine Flu Act did not reduce awards because of contributions from collateral sources. [83] Consequently, 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.[84]

C. Phase I Smallpox Vaccination Program

Believing that regimes and persons hostile to the United States may possess *Variola major*, the etiologicial agent of smallpox, President Bush announced the Phase I smallpox vaccination program in December of 2002 – a program which aspired to vaccinate 500,000 first responders against smallpox.[85] While the

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76. 42 U.S.C.A. § 300aa-15(f)-(g) (West 2003 & Supp. 2004).

77. *Id.*

78. Charles F. Hagan, *Vaccine Compensation Schemes*, 45 FOOD DRUG COSM. L.J. 477, 478 (1990).

79. *See The Threat of Smallpox*, *supra* note 5.

80. *Id.*

81. 42 U.S.C.A. § 300aa-15(a), (b).

82. 42 U.S.C.A. § 300aa-23(d) (West 2003).

83. 42 U.S.C.A. § 300aa-15(g), (h) (West 2003 & Supp. 2004).

84. Although NCVIA was intended to be a model for vaccine liability and compensation, some feel that it has become too adversarial and is in need of reform. *See, e.g.*, Clifford J. Shoemaker, *A Call to Arms* (Apr. 9, 2003), *at* http://www.attorneyaccess.net/Mealeys_Paper_re_Vaccine_Litigation.htm (last visited Feb. 24, 2005) (citing difficulties such as proving causation and limitations on attorneys fees).

85. Press Release, The White House, President Delivers Remarks on Smallpox (Dec. 13, 2002), http://www.whitehouse.gov/news/releases/2002/12/20021213-7.html (last visited Feb. 24, 2005)

smallpox vaccine had been used routinely in America until 1972,[86] few in today's medical field have any experience administering the smallpox vaccine.[87] In addition, the smallpox vaccine available for the Phase I program has been referred to as the "least safe human vaccine" available today.[88]

Given the problems endemic to the smallpox vaccine, Congress and the President knew they had to protect a variety of entities and persons from liability and compensate those injured or killed by the vaccine.[89] Otherwise, the Phase I smallpox vaccination program would likely fail. However, for reasons discussed below, Congress cobbled together a new liability and compensation scheme for Phase I several months after the program began. Even when Congress finally completed that package, it was insufficient to attract vaccinees and/or providers to the Phase I program.

1. Liability and Compensation Provisions

Initially, the Phase I smallpox vaccination program relied upon Section 304 of the Homeland Security Act of 2002[90] (passed in November 2002) as its vehicle for providing liability protection and compensation to injured vaccinees. However, the liability protection afforded was ambiguous and the compensation available to those injured was inadequate.

With regard to liability, Section 304 provided protection to manufacturers, distributors, persons authorized to administer the vaccine, or an "official, agent, or employee of a person described" in the first three categories.[91] While this clearly gave liability protection to some, others questioned their coverage under Section

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[hereinafter White House Press Release]; David McGlinchey, *CDC Says It Never Aimed for 500,000 Smallpox Vaccinations,* GOV'T EXEC., Feb. 26, 2003, http://www.govexec.com/dailyfed/0203/022603gsn1.htm (last visited Feb. 24, 2005).

86. CDC, SMALLPOX FACT SHEET VACCINE OVERVIEW (2003), *at* http://www.bt.cdc.gov/agent/smallpox/vaccination/facts.asp (last visited Feb. 24, 2005) (stating that smallpox has a fatality rate of approximately 30%).

87. *The Threat of Smallpox*, *supra* note 5; *see also* CDC, FREQUENTLY ASKED QUESTIONS ABOUT SMALLPOX VACCINE (Dec. 29, 2004), *at* http://www.bt.cdc.gov/agent/smallpox/vaccination/faq.asp (last visited Feb. 24, 2005) (noting that "routine vaccination of the American public against smallpox stopped in 1972").

88. Susan J. Landers, *Smallpox Vaccine Hazards Dictate Cautious Approach*, 45 AM. MED. NEWS, Aug. 19, 2002, http://www.ama-assn.org/amednews/2002/08/19/hlsb0819.htm (last visited Feb. 24, 2005) (quoting Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases).

89. *See* White House Press Release, *supra* note 85 (acknowledging the risk of serious health concerns by being vaccinated).

90. Homeland Security Act of 2002, Pub. L. No. 107-296, 116 Stat. 2165 (2002) (codified as amended in 3 U.S.C.A.; 5 U.S.C.A.; 6 U.S.C.A.; 7 U.S.C.A.; 8 U.S.C.A.; 10 U.S.C.A.; 14 U.S.C.A.; 15 U.S.C.A.; 18 U.S.C.A.; 19 U.S.C.A.; 20 U.S.C.A.; 21 U.S.C.A.; 26 U.S.C.A.; 28 U.S.C.A.; 31 U.S.C.A.; 37 U.S.C.A.; 38 U.S.C.A.; 40 U.S.C.A.; 41 U.S.C.A.; 42 U.S.C.A.; 44 U.S.C.A.; 49 U.S.C.A.; 50 U.S.C.A.).

91. Homeland Security Act § 304(c), 116 Stat. at 2168 (codified at 42 U.S.C.A. § 233 (West 2003 & Supp. 2004)).

304. For example, it was unclear if persons involved in activities ancillary to administering the vaccine, such as infection control or contraindication screening, were covered under section 304's liability provisions.[92] As a result, the entire purpose of Section 304 – ensuring that those involved with making, distributing, and administering the smallpox vaccine to first responders were protected from liability – was unclear to key players, and it clearly hindered the preemptive vaccination effort.[93]

In January of 2003, former Secretary of the United States Department of Health and Human Services, Tommy Thompson, issued a declaration that initiated the Phase I program and its concomitant liability protections.[94] Cognizant of the ambiguities in Section 304's coverage described above, he also used the declaration to broaden liability coverage by including protection for actions ancillary to the actual smallpox vaccination.[95] However, many viewed Secretary Thompson's efforts as beyond his statutory power.[96] This only led to more confusion over Section 304's scope of protection.

With regard to compensation, Section 304 failed to provide an adequate scheme for those injured by the vaccine. In fact, unlike the Swine Flu Act or NCVIA, Congress did not create an administrative no-fault system to remedy injuries and deaths occasioned by the smallpox vaccine. Assuming that a party had coverage under Section 304, the United States would insert itself in place of the defendant in lawsuits against covered parties and would assume liability only for negligent conduct causing injury or death to a smallpox vaccine recipient.[97] Therefore, a person injured by a properly manufactured and distributed vaccine, which was properly prepared and administered, would not receive compensation under Section 304, even though the vaccine had inherent side effects of varying severity, including death.[98] As a result, parties injured by a smallpox vaccination under Phase I had little likelihood of recovering under Section 304.[99] In stark contrast, the Swine Flu Act and NCVIA had no-fault compensation schemes where injured parties only had to prove that their injuries stemmed from the pertinent vaccine.[100] As a result, claimants in the first two systems were much more likely to receive compensation.

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92. RICHARDS ET AL., *supra* note 41 (citing 42 U.S.C. § 233(p)(2)(A)(ii), (p)(7)(A)).

93. *The Threat of Smallpox*, *supra* note 5.

94. Declaration Regarding Administration of Smallpox Countermeasures, 68 Fed. Reg. 4,212, 4,212 (Jan. 28, 2003).

95. *Id.*

96. *See, e.g.*, RICHARDS ET AL., *supra* note 41.

97. 42 U.S.C.A. § 233(p)(1) (West 2003 & Supp. 2004).

98. *The Threat of Smallpox*, *supra* note 5.

99. *Id.*

100. RICHARDS ET AL., *supra* note 41; Schwartz & Mahshigian, *supra* note 57.

Former Secretary Thompson was aware that Section 304 would rarely compensate injured vaccinees, but he explained that private insurance or workers' compensation would cover injuries.[101] However, private insurance of this kind is virtually impossible to secure.[102] Furthermore, many doubted that workers' compensation programs would, in fact, pay these claims.[103] And, even if Phase I injuries were covered by private insurance or workers' compensation, state plans almost surely did not cover secondary transmission of vaccinia (the virus used to immunize humans against smallpox) to a family member or casual contact.[104] Therefore, uncertainty surrounding the scope of coverage led many first responders and providers to forego the vaccine altogether.[105]

2. Attempting to Improve the Compensation Provisions of Section 304

It was not until April 2003 – three months after Phase I began – that Congress passed a law, the Smallpox Emergency Personnel Protection Act of 2003[106] (SEPPA), to improve upon the compensation provisions of Section 304. Specifically, SEPPA aimed to "provide benefits and other compensation for certain individuals with injuries resulting from administration of smallpox countermeasures."[107] Like the Swine Flu Act and NCVIA, SEPPA created a no-fault compensation program for vaccinees injured or killed by the smallpox vaccine.[108] SEPPA supplied medical benefits, death benefits, and lost income benefits for covered injuries,[109] resulting from countermeasures administered to

101. DEMOCRATIC MEMBERS OF HOUSE SELECT COMM. ON HOMELAND SEC., 108TH CONG., A BIODEFENSE FAILURE: THE NATIONAL SMALLPOX VACCINATION PROGRAM ONE YEAR LATER 13 (2004), http://www.house.gov/hsc/democrats/pdf/press/040129_ABiodefenseFailureOneYearLater.pdf (last visited Feb. 24, 2005) [hereinafter BIODEFENSE FAILURE] (citing Teleconference with Tommy G. Thompson, Secretary, Department of Health & Human Services (Dec. 14, 2002) (transcript available at http://www.cdc.gov/od/oc/media/transcripts/t021214.htm (last visited Feb. 24, 2005)).

102. *Implementing the Safety Act: Advancing New Technologies for Homeland Security: Hearing Before the House Comm. on Government Reform,* 108th Cong. 16-17 (2003) (statement of Dr. Penrose Albright, Assistant Secretary for Science and Technology, Department of Homeland Security).

103. ROBIN J. STRONGIN & EILEEN SALINSKY, NAT'L HEALTH POL'Y FORUM, WHO WILL PAY FOR THE ADVERSE EVENTS RESULTING FROM SMALLPOX VACCINATION? LIABILITY AND COMPENSATION ISSUES 8-10 (2003), http://www.nhpf.org/pdfs_ib/IB788_Smallpox_3-12-03.pdf (last visited Feb. 24, 2005).

104. Press Release, American Public Health Ass'n, National Public Health Associations Urge Legislative Action to Protect Smallpox Vaccine Volunteers (Mar. 7, 2003), http://www.apha.org/news/press/2003/smallpoxvolunteers.htm (last visited Feb. 24, 2005).

105. *The Threat of Smallpox*, *supra* note 5.

106. Pub. L. No. 108-20, 117 Stat. 638 (2003) (codified as amended at 42 U.S.C.A. §§ 233, 239 & 239a-h (West 2003 & Supp. 2004)).

107. *Id.*

108. 42 U.S.C.A. § 239a (West Supp. 2004).

109. 42 U.S.C.A. §§ 239c – 239e (West Supp. 2004).

those volunteering before a confirmed active case of smallpox is discovered anywhere in the world.[110]

However, there are limits to SEPPA's compensation. For example, like NCVIA, SEPPA's benefits are also secondary to all other sources of compensation[111] and, the sections of SEPPA limiting lost employment and death benefits are worded almost identically.[112] In addition, SEPPA imposed caps on any award, which are more stringent than previous federal vaccine compensation and liability laws.[113] In particular, SEPPA limited compensation for lost employment income to two-thirds of the vaccinee's income, providing an additional 8.3% of their income if the person had one or more dependants,[114] while NCVIA allowed lost income awards equivalent to "actual and anticipated loss of earnings."[115] SEPPA further limited lost income awards to a maximum of $50,000 per year and a pre-determined lifetime total of $262,100 (as of May 2003) if injuries were not permanently disabling.[116] Finally, lost income benefits ceased to be payable if the injured person died and the survivors collected SEPPA's death benefits.[117] These death benefits were limited to a lump sum of $262,100 (as of May 2003) or a maximum annual payment of $50,000 until the deceased's youngest dependant reached eighteen years of age.[118]

To be sure, SEPPA remedied some of the confusion over liability protection offered by Section 304. For example, SEPPA broadened liability coverage to

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110. 42 U.S.C.A. § 239(a)(2)(C) (West Supp. 2004). However, those vaccinated after a confirmed case is discovered receive no compensation under SEPPA. *Id.*

111. 42 U.S.C.A. §§ 239c(b), 239d(c), 239e(b)(3)(B) (West Supp. 2004). Specifically, the section limiting medical benefits provides:

> Payment or reimbursement for services or benefits under subsection (a) of this section shall be secondary to any obligation of the United States or any third party (including any State or local governmental entity, private insurance carrier, or employer) under any other provision of law or contractual agreement, to pay for or provide such services or benefits.

42 U.S.C.A. § 239c(b).

112. 42 U.S.C.A. §§ 239d(c) & 239e(a)(3) (West Supp. 2004).

113. 42 U.S.C.A. § 239d(c) (West Supp. 2004). Specifically, the Swine Flu Act did not limit awards, and NCVIA's caps were generally more generous than SEPPA's caps. *See* 42 U.S.C.A. § 247b (West 2003 & Supp. 2004); 42 U.S.C.A. §§ 300aa-15 & 300aa-16 (West 2003 & Supp. 2004).

114. 42 U.S.C.A. § 239d(b) (West Supp. 2004).

115. 42 U.S.C.A. § 300aa-15(a)(3)(A) (West 2003 & Supp. 2004).

116. 42 U.S.C.A. § 239d(c)(3)(A) (West Supp. 2004); Press Release, DHHS, HHS Proposes Smallpox Vaccination Compensation Plan (Mar. 5, 2003), http://www.os.dhhs.gov/news/press/2003pres/20030305.html (last visited Feb. 24, 2005); *HHS Plan Would Aid Health Workers Injured by Smallpox Vaccine*, CIDRAP NEWS (Ctr. For Infectious Disease Res. & Pol'y (CIDRAP)) Mar. 6, 2003, http://www.cidrap.umn.edu/cidrap/content/bt/smallpox/news/compen.html (last visited Feb. 24, 2005). SEPPA does not create a lifetime limit on lost income benefits for persons permanently disabled by the smallpox vaccine. 42 U.S.C.A. § 239d(c)(3)(B).

117. 42 U.S.C.A. § 239d(c)(2). (West Supp. 2004).

118. 42 U.S.C.A. § 239e (West Supp. 2004). Of course, the $262,100 death benefit is only $12,100 more than the federal government's original death benefit cap established eighteen years ago under NCVIA. *See id.;* 42 U.S.C.A. § 239aa-15 (West Supp. 2004).

include many areas of concern not specifically addressed by Section 304 of the Homeland Security Act.[119] Specifically, it provided coverage for healthcare entities under whose auspices contraindication was conducted.[120] SEPPA also covered subsequent monitoring, management, or care for the site of vaccination to provide coverage for the secondary spread of vaccinia and to determine if the vaccination was successful.[121] Nonetheless, as shown below, SEPPA's remedies as a whole were insufficient to make the smallpox initiative successful.

3. Result of the Phase I Smallpox Vaccination Program

Ultimately, the liability protection offered to vaccine providers and the compensation available to first responders were the major inhibitors to the federal Phase I vaccination program's success. Even SEPPA's no-fault compensation package and added liability protections were not enough to invigorate the program. As of January 31, 2005 (the most recent data available online as of this writing), only 39,608 first responders have been vaccinated – far short of the government's goal of 500,000.[122] Former Secretary Thompson himself stated that the smallpox immunization program "certainly is stalled right now."[123] Furthermore, he has downplayed the government's failure in meeting its goal by contending summarily that a "vast majority" of states are able to immunize all of their residents within 10 days of a smallpox outbreak.[124] However, Thompson offered no evidence to suggest that states are actually capable of doing so.[125] In fact, the only evidence available suggests the opposite.

For example, Democrats from the House Select Committee on Homeland Security have reported that as many as twenty states could *not* vaccinate all their residents within ten days of an outbreak.[126] Furthermore, as Yale Professor Edward Kaplan has asserted, a ten day immunization period would require 1.25 million immunized health care workers.[127] Yet, as emphasized above, there are nowhere near that many immunized health care workers. Therefore, contrary to the contentions of former Secretary Thompson, states are not prepared to deal with a possible smallpox outbreak – and certainly not within ten days of the outbreak –

119. *See* 42 U.S.C.A. § 233 (West 2003 & Supp. 2004).

120. 42 U.S.C.A. § 233(p)(7)(D) (West 2003 & Supp. 2004).

121. *Id.*

122. CDC SMALLPOX PROGRAM BY STATE, *supra* note 7.

123. David McGlinchey, *HHS Secretary Says "Vast Majority" of States Ready for Smallpox*, GOV'T EXEC., Jan. 29, 2004, http://www.govexec.com/dailyfed/0104/012904d2.htm (last visited Feb. 24, 2005).

124. *Id.*

125. *See* BIODEFENSE FAILURE, *supra* note 101, at 5-7, 11; McGlinchey, *supra* note 123.

126. BIODEFENSE FAILURE, *supra* note 101, at 7.

127. McGlinchey, *supra* note 123.

unless a successful pre-event vaccination program is put into place that would achieve the 1.25 million minimum.

In order for the pre-event smallpox vaccination program – or any pre-event vaccination program – to be successful, it is critical that a liability and compensation program be put in place so that providers are protected from liability and first responders are compensated for the injuries that they may incur as a result. Otherwise, the cost-benefit analysis will push people away from both administering and receiving the vaccination. Although DHHS has extended Phase I for another year,[128] the government will continue to fall far short of its targeted goal until such a liability and compensation program is implemented.

D. The Support Anti-Terrorism by Fostering Effective Technologies Act

Cognizant of SEPPA's shortcomings, some experts are belatedly suggesting that the solution to the dilemma of vaccine liability protection and compensation lies in the Support Anti-Terrorism by Fostering Effective Technologies Act[129] (SAFETY Act). Congress passed the SAFETY Act in November of 2002 (as part of the Homeland Security Act of 2002) as a response to the growing concern of liability protection for technologies developed to combat terrorism.[130] Through passage of the Act, Congress aimed to ensure that the threat of liability would not discourage potential development of technologies that could significantly reduce the risks or mitigate the effects of large-scale acts of terrorism.[131]

However, the SAFETY Act is not an attractive option for a viable biodefense vaccine liability and compensation scheme for the following three reasons. First, as its legislative history illustrates, the Act was not drafted with biodefense vaccines in mind. Rather, the purpose of the Act was to encourage the development of anti-terrorism hardware such as computer systems, explosion detection services, and audio/video identifiers.[132] Accordingly, the drafters gave little – if any – thought to the issue of injury compensation because, unlike biodefense vaccines, SAFETY Act technologies do not involve intimate contact with people. Second, even if the SAFETY Act were applicable to biodefense

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128. Amendment to Extend the January 24, 2003, Declaration Regarding Administration of Smallpox Countermeasures, 69 Fed. Reg. 3,920, 3,921 (Jan. 27, 2004); CDC SMALLPOX PROGRAM BY STATE, *supra* note 7.

129. Support Anti-Terrorism by Fostering Effective Technologies Act of 2002, 6 U.S.C.A. §§ 441-44 (West Supp. 2003). For example, Frank M. Rapoport of McKenna Long & Aldridge LLP has asked the Department of Homeland Security to "consider this possibility." *Project BioShield: An Update from McKenna Long's Frank Rapoport,* 12 METROPOLITAN CORPORATE COUNSEL 25 (July 2004).

130. 6 U.S.C.A. §§ 441-44 (West Supp. 2003).

131. *See id.*

132. *See, e.g., Safety Act: DHS Recognizes Four Technologies,* VAR BUS., July 16, 2004, http://varbusiness.com/article/showArticle.jhtml;jsessionid=K0AZS50T2W3IMQSNDBCCKH0CJUMEKJVN?articleId=23901451 (last visited Feb. 24, 2005) [hereinafter *Safety Act*].

vaccines, the Act's procedural and insurance requirements are overly burdensome. In fact, the entire basis of liability protection in the SAFETY Act context hinges upon the ability to obtain private insurance,[133] which is virtually impossible in the vaccine context. Thus, it would be extremely difficult to obtain protection for pre-event biodefense vaccination programs under the Act. Third, even if the procedural and insurance requirements are satisfied, the level of liability protection available under the Act is far too broad and would be provided at the expense of those injured by the vaccine. Therefore, contrary to what has recently become a fashionable suggestion, the SAFETY Act is not the solution to the dilemma of vaccine liability protection and compensation.

1. The SAFETY Act is not Applicable to Biodefense Vaccines

As stated above, the SAFETY Act was not drafted with biodefense vaccines in mind. As its plain language explicitly suggests, the Act was passed to encourage the development of "equipment," "service[s]," and "devices" that could prevent, detect, identify, or deter acts of terrorism.[134] Although certainly capable of preventing an act of terrorism, biodefense vaccines were not among those technologies the drafters envisioned for SAFETY Act coverage. Rather, the drafters envisioned protection for technologies such as security services, electronic detection devices, and computer surveillance and identification programs.[135] In fact, the technologies that are currently covered by the Act include an anthrax-sniffing device, a giant water pick capable of cutting through steel and concrete, bomb detection canine teams, and an explosive screening computer system.[136]

Further evidence of the drafter's intent lies in the Act's lack of an administrative compensation scheme. In fact, the only compensation provided is the ability to sue and win in federal court. More specifically, the SAFETY Act gives federal district courts original and exclusive jurisdiction over all actions arising out of qualified anti-terrorism technology (QATT) deployment for injuries that are "proximately caused" by Sellers.[137] This differs from the previous vaccine liability and compensation regimes discussed above in that the claims go straight to federal district court without an administrative hearing. The fact that the drafters did not even remotely consider implementing any form of administrative

133. 6 U.S.C.A. § 443(a)(1) (West Supp. 2003).

134. 6 U.S.C.A. § 444(1) (West Supp. 2003).

135. *Implementing the Safety Act: Advancing New Technologies for Homeland Security: Hearing Before the House Comm. on Government Reform,* 108th Cong. 13 (2003) (statement of Parney Albright, Assistant Secretary for Plans, Programs and Budgets, Department of Homeland Security) (recognizing that the SAFETY Act is intended to cover "tangible products, software and services, including support services") [hereinafter *Implementing the Safety Act*]; Robert Block & J. Lynn Lansford, *U.S. Gives Liability Protection to Antiterror Firms*, WALL ST. J., June 18, 2004, at B2.

136. *Safety Act, supra* note 132.

137. 6 U.S.C.A. §§ 442(a)(1) & 442(a)(2) (West Supp. 2003).

compensation can only be indicative of their intention to protect technologies (unlike biodefense vaccines) that require little – if any – human contact. This virtually eliminates the need for a compensation scheme. Due to the types of technologies the SAFETY Act drafters intended to protect, concern for potential injuries was virtually non-existent. If the drafters had envisioned the SAFETY Act to apply to biodefense vaccines, they would have had no choice but to incorporate at least some form of compensation package – just as every other vaccine immunization program has done in the past. Yet, the SAFETY Act has no such package.

In addition, despite predating the smallpox program by only two months, the SAFETY Act was never mentioned by any party – including Congress – during implementation of either Section 304 or SEPPA. If the Act was truly drafted with biodefense vaccines in mind, it certainly would have been suggested as a possible solution to the liability and compensation concerns of the Phase I smallpox program during the administrative and legislative discussions that took place in late 2002 and early 2003.

2. The SAFETY Act's Requirements are Overly Burdensome

Even if the SAFETY Act was drafted with biodefense vaccines in mind, the Act's procedural and insurance requirements are so burdensome that it would be virtually impossible to obtain vaccine liability protection under the Act. Specifically, there are four requirements that must be met before *complete* liability protection is available.

First, the entity seeking protection must fit within the definition of a "Seller." The Act defines a Seller as "[a]ny person or entity that sells or otherwise provides a qualified anti-terrorism technology to Federal and non-Federal Government customers."[138] In addition, the term "Seller" also appears to cover manufacturers and distributors.[139] This assessment is confirmed by the SAFETY Act's interim regulations' definition of "Seller" as "any person or entity to whom or to which (as appropriate) a Designation has been issued under this Part (unless the context requires otherwise)."[140] However, it is doubtful that the term "Seller" would cover those involved with administering a vaccine, such as hospitals or local health departments.[141]

138. 6 U.S.C.A. § 443(a)(1) (West Supp. 2003).

139. 6 U.S.C.A. § 443(a)(3) (West Supp. 2003).

140. Regulations Implementing the Support Anti-terrorism by Fostering Effective Technologies (SAFETY) Act of 2002, 68 Fed. Reg. 59,684, 59,704 (proposed October 16, 2003) (to be codified at 6 C.F.R. pt. 25).

141. Nonetheless, while those that administer the biodefense vaccine may not get protection as a Seller, they will likely get some liability protection from the insurance that a Seller is required to maintain under the SAFETY Act. However, such coverage is ambiguous at best.

Second, the Seller must achieve designation for their product as a Qualified Anti-Terrorism Technology (QATT).[142] A QATT encompasses products "developed" for the very purpose of "preventing" and "limiting the harm" caused by an act of terrorism.[143] However, designees must satisfy a non-exclusive list of determinative criteria,[144] including, *inter alia*, an assessment of the magnitude of risk exposure to the public if the technology was not available,[145] scientific evidence of a technology's effectiveness,[146] and availability for immediate deployment.[147] The designation requirement becomes increasingly onerous for biodefense vaccines because of the added difficulty in assessing a vaccine's effectiveness and the risks associated with its administration.

Third, after designation, the Seller's product becomes eligible for certification and placement on the Approved Product List for Homeland Security,

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142. 6 U.S.C.A. § 444(1) (West Supp. 2003). This section defines qualified anti-terrorism as:

> any product, equipment, service (including support services), device, or technology (including information technology) designed, developed, modified, or procured for the specific purpose of preventing, detecting, identifying, or deterring acts of terrorism or limiting the harm such acts might otherwise cause, that is designated as such by the Secretary.

Id.

143. *Id.*

144. 6 U.S.C.A. § 441(b) (West Supp. 2003). To qualify for designation as a QATT, the technology must adhere to the following:

> (b) Designation of qualified anti-terrorism technologies- The Secretary may designate anti-terrorism technologies that qualify for protection under the system of risk management set forth in this part in accordance with criteria that shall include, but not be limited to, the following:
>
> (1) Prior United States Government use or demonstrated substantial utility and effectiveness.
>
> (2) Availability of the technology for immediate deployment in public and private settings.
>
> (3) Existence of extraordinarily large or extraordinarily unquantifiable potential third party liability risk exposure to the Seller or other provider of such anti-terrorism technology.
>
> (4) Substantial likelihood that such anti-terrorism technology will not be deployed unless protections under the system of risk management provided under this subtitle are extended.
>
> (5) Magnitude of risk exposure to the public if such anti-terrorism technology is not deployed.
>
> (6) Evaluation of all scientific studies that can be feasibly conducted in order to assess the capability of the technology to substantially reduce risks of harm.
>
> (7) Anti-terrorism technology that would be effective in facilitating the defense against acts of terrorism, including technologies that prevent, defeat or respond to such acts.

Id.

145. 6 U.S.C.A. § 441(b)(5) (West Supp. 2003).

146. 6 U.S.C.A. § 441(b)(6) (West Supp. 2003).

147. 6 U.S.C.A. § 441(b)(2) (West Supp. 2003).

which provides the Seller with an even greater level of liability protection. In order to become certified, the Secretary must review the product and determine whether it will perform as intended, conform to the manufacturer's specifications, and be safe for its intended use.[148] If the product meets these three criteria, the Secretary will issue a certificate of conformance to the Seller and place the QATT on the Approved Product List for Homeland Security.[149] Certification, like designation, becomes increasingly difficult for biodefense vaccines. Specifically, unlike computer systems or electronic identifiers, biodefense vaccines are often much more speculative in nature with regards to how they will perform. Furthermore, safety determinations pertaining to vaccines, as opposed to computers, are not within the statutory authority of the Secretary; rather, those determinations are to be made by the FDA.[150]

Fourth, and perhaps the biggest obstacle to obtaining complete liability protection under the Act, the Seller must conform to several insurance requirements, regardless of whether its product has achieved certification or just designation. In fact, if the Sellers do not satisfy the insurance requirements, their designations and/or certifications become obsolete.[151] Specifically, the Act requires both designees and those with certification to obtain liability insurance.[152] This insurance covers the contractors, subcontractors, suppliers, vendors, and customers of the manufacturer.[153] It also covers the contractors, subcontractors, suppliers, and vendors of the customer.[154] Moreover, Sellers, as well as the Sellers' contractors, subcontractors, suppliers, vendors, and customers, are protected from claims arising out of the "sale, use, or operation" of the QATT during the response or recovery phase of an act of terrorism.[155]

Next, the Sellers must purchase a specified amount of insurance "reasonably available from private sources on the world market at prices and terms that will not unreasonably distort the sales price of [the manufacturers'] anti-terrorism

148. 6 U.S.C.A. § 442(d)(2) (West Supp. 2003). However, the Secretary does not necessarily certify all of the QATTs he designates.

149. 6 U.S.C.A. § 442(d)(3) (West Supp. 2003).

150. *See* FDA, DHHS, FDA AND THE DRUG DEVELOPMENT PROCESS: HOW THE AGENCY ENSURES THAT DRUGS ARE SAFE AND EFFECTIVE (Feb. 2002), http://www.fda.gov/opacom/factsheets/justthe facts/17drgdev.html (last visited Feb. 24, 2005) (noting that the FDA conducts a "rigorous review" to ensure that drugs meet the "highest scientific standards").

151. *See* 6 U.S.C.A. § 443(a)(1) (West Supp. 2003).

152. 6 U.S.C.A. § 443(a)(1) (West Supp. 2003). "Any person or entity that sells or otherwise provides a qualified anti-terrorism technology to Federal and non-Federal Government customers ("Seller") shall obtain liability insurance . . . ." *Id.*

153. 6 U.S.C.A. § 443(a)(3)(A) (West Supp. 2003).

154. 6 U.S.C.A. § 443(a)(3)(B) (West Supp. 2003).

155. 6 U.S.C.A. § 443(a)(3) (West Supp. 2003). Accordingly, an administrator of a biodefense vaccine would be covered by the vaccine manufacturer's liability insurance if something were to go wrong while administering the vaccine.

technologies."[156] In addition, Sellers must enter into a "reciprocal waiver of claims" with all of their business correspondents.[157] In this waiver, the parties agree to be "responsible for losses . . . sustain[ed] . . . when qualified anti-terrorism technologies have been deployed."[158]

However, as testimony before the Committee on House Reform reflects, "insurance has become largely unattainable or so costly as to leave the technologies in question without a market."[159] This is largely attributed to the difficulty in quantifying "[t]he potential risks and liabilities that stem from the technologies deployed in our war against terrorism."[160] Biodefense vaccines present especially difficult challenges in this regard due to the added complexity of compensation. Furthermore, even if a vaccine manufacturer or provider is able to obtain insurance, the level obtained is often not enough to minimize the risk of liability to an acceptable level. For example, VaxGen – one of two firms under government contract to produce and test a new anthrax vaccine – faces potential liability that "will most likely exceed what the commercial insurance market [has provided them]."[161] Therefore, even if a vaccine manufacturer or provider is able to circumvent the many obstacles in obtaining insurance, the level obtained will almost certainly not be enough to minimize the risk of liability to an acceptable level.

In any event, even without the added complexities of offering protection of biodefense vaccines, the SAFETY Act has struggled to attract Sellers (of other anti-terrorism technologies) to its liability package. In fact, as a general matter, only nineteen out of the expected 500 companies have applied for the Act's protection, and only four of those companies have actually obtained protection under the Act.[162] If the SAFETY Act is suddenly offered to Sellers of biodefense vaccines as well, the percentage of those applying for and/or obtaining SAFETY Act protection will be even smaller.

3. Different Degrees of Liability Protection under the SAFETY Act

Even if a Seller is actually able to overcome all of the procedural (*i.e.*, designation and certification) and insurance requirements, the liability protection offered by the SAFETY Act is problematic. As shown below, the liability

156. 6 U.S.C.A. § 443(a)(2) (West Supp. 2003).

157. *See* 6 U.S.C.A. § 443(b) (West Supp. 2003).

158. *Id.*

159. *Implementing the Safety Act, supra* note 135, at 12.

160. *Id.*

161. *Biotechnology; BioShield Shortcomings Subject of Industry Conference*, BIOTERRORISM WK. (NewsRx.com & NewsRx.net), June 28, 2004, at 8, *available at* 2004 WL 55187482.

162. Gail Repsher Emery, *Four Companies are First to Get Safety Act Protection*, 19 WASHINGTON TECH. (June 18, 2004), http://www.washingtontechnology.com/news/1_1/daily_news/23831-1.html (last visited Feb. 24, 2005).

protection provided by the Act is so complete and absolute that those injured by the technology have little ability to be compensated.

The first level of liability protection under the SAFETY Act is provided if the Seller has achieved QATT designation for their product. Under this level of protection, plaintiffs are prohibited from receiving punitive damages[163] and/or proceeding under a theory of joint and several liability of the Sellers and their business counterparts.[164] In addition, Sellers are only responsible for noneconomic damages[165] in an amount directly proportional to the percentage of responsibility of the manufacturer for harm to the plaintiff.[166] Furthermore, no plaintiff can receive noneconomic damages unless the plaintiff suffered physical harm.[167] The SAFETY Act also limits the amount of recovery for plaintiffs by installing a cap on liability for the Seller.[168] Moreover, any recovery by a plaintiff is reduced by the amount of the plaintiff's collateral source compensation.[169]

Despite these protections, the SAFETY Act does not provide liability protection to designees comparable to the Swine Flu Act, NCVIA, and Section 304 of the Homeland Security Act. In particular, the SAFETY Act does not go so far as to immunize sellers from most liability. Certainly, under the SAFETY Act, the Sellers will not have to pay the awards, because their liability is capped at the level of their insurance. However, the Seller will ultimately pay that cost anyway since insurance companies will pass those costs on to their customers in increased premiums. The SAFETY Act also does not assist financially with any adverse decisions against the Seller (*i.e.*, the federal government does not operate a compensation fund as it does in the three vaccine programs discussed above, which makes direct payments to an injured person.) The equity of the compensation will depend on the insurance policy, which can change from term to term, and, as a result, it would be difficult for a vaccinee to determine his or her level of compensation before receiving a vaccination. Therefore, if a Seller is only able to achieve QATT designation (and not certification) for its product, the level of liability protection provided – while substantial – is not as broad as that provided in the Swine Flu Act, NCVIA, and/or Section 304 of the Homeland Security Act.

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163. 6 U.S.C.A. § 442(b)(1) (West Supp. 2003).

164. 6 U.S.C.A. § 442(b)(2)(A) (West Supp. 2003).

165. 6 U.S.C.A. § 442(b)(2) (West Supp. 2003). The term noneconomic damages means "damages for losses for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium, hedonic damages, injury to reputation, and any other nonpecuniary losses." 6 U.S.C.A. § 442(b)(2)(B).

166. 6 U.S.C.A. § 442(b)(2)(A) (West Supp. 2003).

167. *Id.*

168. 6 U.S.C.A. § 443(c) (West Supp. 2003). The manufacturer's liability will not be in excess of an amount greater than the manufacturer's liability insurance coverage. *Id.*

169. 6 U.S.C.A. § 442(c) (West Supp. 2003).

A second – even greater – level of protection is available to the Seller under the SAFETY Act if the Seller is also able to achieve certification (in addition to designation) for its product. In particular, once the Secretary certifies the QATT and places it on the Approved Product List for Homeland Security, the Seller is afforded the government contractor defense, which, if asserted successfully, provides the Seller with nearly absolute immunity.[170] The importance of this defense lies not only in the protection it provides for the Seller, but also in the difficulty it establishes for plaintiffs to recover.[171]

The government contractor defense[172] is an affirmative defense that immunizes Sellers from liability for certain claims from third parties injured by the Seller's QATT.[173] The defense broadly and completely protects manufacturers from being held liable for design defects or failure to warn claims.[174] The Supreme Court created this defense in order to encourage contractor participation in the design and manufacturing process of products used by the government.[175] The defense is nearly impermeable and a rebuttable presumption is overcome only by a showing that the Seller acted "fraudulently" or "with willful misconduct" when applying for liability protection under the SAFETY Act.[176] Therefore, a Seller with the protection of the government contractor defense is shielded from liability for almost all claims arising out of injuries as a result of the deployment of the Seller's QATT, leaving injured parties without compensation. If applied to biodefense vaccines, this protection would be far too broad – especially in the context of first responders, who will be even less likely to volunteer if they know from the outset that the vaccine is certified – and thus protect manufacturers and health providers from virtually all liability.

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170. 6 U.S.C.A. § 442(d)(1)-(3) (West Supp. 2003). Moreover, once the Seller achieves certification, there is "a rebuttable presumption" that the government contractor defense applies. 6 U.S.C.A. § 442(d)(1).

171. *See* Regulations Implementing the Support Anti-terrorism by Fostering Effective Technologies Act of 2002 (the SAFETY Act), 68 Fed. Reg. at 59,691.

172. Originally formulated in Boyle v. United Technologies Corp., 487 U.S. 500, 512 (1998), the government contractor defense is available when the following elements are proven: "(1) the United States approved reasonably precise specifications; (2) the equipment conformed to those specifications; and (3) the supplier warned the United States about the dangers in the use of the equipment that were known to the supplier but not to the United States." *Id.*

173. Regulations Implementing the SAFETY Act, 68 Fed. Reg. at 59,691. The defense is not only available to government contractors but to state and local governments as well as to the private sector. *Id.*

174. *Id.*

175. *Boyle*, 487 U.S. at 512-13.

176. 6 U.S.C.A. § 442(d)(1) (West Supp. 2003). Even if a plaintiff were able to prove a Seller "acted fraudulently" or "with willful misconduct," the plaintiff's compensation would still be limited by the liability protections afforded to a QATT designee, as listed above.

4. Final Analysis of the SAFETY Act

In the final analysis, the SAFETY Act does not offer the kind of liability and compensation scheme that would make it an attractive biodefense pre-event vaccination program. First, as is evident by its legislative history and lack of a sufficient compensation scheme, the SAFETY Act was not intended to apply to biodefense vaccines. Second, even if it were, the Act is filled with overly burdensome insurance requirements that make obtaining protection under the Act extremely rare, regardless of whether the Secretary designates and/or certifies the Seller's product. And, in the context of biodefense vaccines, the task of obtaining insurance becomes especially problematic. Third, even in the unlikely event that a biodefense vaccine Seller is actually able to satisfy all of the procedural (*i.e.*, designation *and* certification) and insurance requirements necessary to trigger SAFETY Act application, the liability protection available is far too broad, offering virtually no compensation to those harmed by the vaccination. Even if the Seller is only able to achieve designation (and not certification) for their vaccine, liability protection is still too broad, offering compensation that is vastly limited, as determined by the Seller's insurer. Therefore, regardless of the level of liability protection available, the Seller is protected at the expense of those injured by the vaccination. As such, the Act is not an attractive option for a pre-event biodefense vaccination program.

II. LESSONS LEARNED FROM THE PHASE I SMALLPOX VACCINATION PROGRAM: PREPARING FOR FUTURE PRE-EVENT BIODEFENSE VACCINATIONS

While several factors have contributed to the federal Phase I vaccination program's collapse, the study conducted by the ANSER Institute for Homeland Security showed that the most significant reason is the ineffective liability and compensation scheme created by Congress.[177] Understandably, the federal government does not want to embroil itself in vaccine claims in either the administrative or legal systems; however, the history of federal vaccine programs since the 1970s has shown that a generous liability and compensation scheme is vital to ensuring the success of a pre-event vaccination program.

A. Liability

Beginning with the Swine Flu Act of 1976 and continuing with NCVIA in 1986, it is clear that vaccine manufacturers (and others in the chain of distribution) demand liability protection from the federal government in the absence of

177. *The Threat of Smallpox*, *supra* note 5.

insurance coverage. Congress largely gave manufacturers and distributors adequate liability protection. However, as the failure of Section 304 demonstrated, it is crucial to define the scope of coverage unambiguously.[178] More specifically, under Section 304, hospitals and public health departments had little incentive to vaccinate workers because they could not ascertain the extent of their liability for biodefense vaccine-related injuries and deaths. Manufacturers, distributors, and those parties involved with the vaccination[179] must be assured that the government stands ready to assume liability for any adverse effects from a preemptive biodefense vaccination effort, except liability that results from grossly negligent, reckless, or intentional conduct. Therefore, Section 304 serves as a warning to future pre-event biodefense vaccination programs that liability coverage must be broad and precise.

Unambiguous liability protection will almost certainly be more important in future pre-event biodefense vaccination programs because the vaccine's risks may be relatively unknown. In contrast, the efficacy, side-effects, and contraindications of the smallpox vaccine were well documented,[180] (with the exception of the cases of myocarditis and periocarditis allegedly linked to the smallpox vaccine),[181] and parties could estimate the likelihood of injury. However, in future vaccination programs, we almost certainly will not know exactly how well a vaccine performs until a vaccinated human is exposed to a certain agent.[182] Accordingly, the effectiveness of a vaccine can only truly be determined for diseases that are naturally occurring, such as Ebola, by vaccinating persons likely to come in contact with the disease. But, as a result, claims will inevitably arise that allege the vaccine did not provide a suitable level of protection. Furthermore, side-effects that did not present themselves during testing may become apparent during a vaccination program, such as the emergence of Guillian-Barre syndrome

178. *See supra* notes 89-91 and accompanying text.

179. Certainly, federal liability protection should also cover non-negligent, secondary transmissions resulting from vaccines that contain communicable diseases.

180. *See* U.S. DEP'T OF HEALTH & HUMAN SERVICES, REACTIONS AFTER SMALLPOX VACCINATION (2002), *at* http://www.smallpox.gov/VaccineSideEffects.html (last visited Feb. 24, 2005).

181. *The Threat of Smallpox*, *supra* note 5. However, the New York City Department of Health and Mental Hygiene recently conducted a historical review of data from a mass smallpox vaccination of New York City in 1947 which revealed that the smallpox vaccine likely poses little to no risk of cardiac death. Thomas Frieden et al., *Cardiac Deaths After A Mass Vaccination Campaign – New York City, 1947*, 52 MORBIDITY & MORTALITY WKLY. 933 (OCT. 3, 2003), http://www.cdc.gov/mmwr/PDF/wk/mm5239.pdf (last visited Feb. 24, 2005); Richard Perez-Pena, *Checking City's Archives to Solve a Medical Mystery*, N.Y. TIMES, Oct. 3, 2003, at B2, http://www.nytimes.com/2003/10/03/nyregion/03SMAL.html?ex=1089864000&en=9ce12e92d338d2c1&ei=5070 (last visited Feb. 24, 2005).

182. It is unethical for researchers to intentionally expose humans to diseases such as smallpox that do not exist in nature. Griff Witte, *Government Considers New Smallpox Vaccine*, WASH. POST, Apr. 15, 2004, at E1, *available at* 2004 WL 74480051.

frequently associated with the swine flu vaccine.[183] Therefore, any new vaccine could cause unanticipated injuries. Certainly, parties involved with the manufacture, distribution, and administration of the next generation biodefense vaccines will want adequate assurances of protection before those vaccines are used by first responders or the general public.

In terms of a liability regime's procedure in a pre-event context, the government should insert itself as the defendant in any claim, so that manufacturers, distributors, and administrators need not be directly involved in litigating claims. Liability, as well as compensation, should be handled exclusively in an administrative hearing process, much like that of the NCVIA.[184] This would reduce the risk of litigation to vaccine administrators and provide vaccinees with a greater guarantee of compensation in the event that they are injured by the vaccination.[185] Both of these suggestions would sharply curtail the transactional costs associated with litigating claims. Finally, unlike what transpired in the Phase I smallpox program, a full liability and compensation scheme should be in place *before* any "pre-emptive" vaccination program begins.

B. Compensation

The success of a compensation program is closely linked to the federal government's ability to clearly articulate an imminent bioterrorist threat.[186] High vaccine risk coupled with low or ambiguous threat of bioterrorist attack will cause prospective vaccinees to weigh heavily vaccine injury compensation in their personal risk-benefit calculus.[187] In so doing, they may determine that the risk of known or potentially unknown side effects of a biodefense vaccine outweighs the

183. RICHARDS ET AL., *supra* note 41. As Professors Richards, Peltier, and Rathbun illustrate, the epidemiology of Guillian-Barre Syndrome (GBS) was primarily driven by plaintiff's attorneys and "friendly doctors" that readily attributed GBS to the swine flu vaccine. *Id.* To be sure, vaccine injury tables associated with future biodefense vaccines for which we will not have highly developed injury and mortality data will need to be developed as a vaccination program is launched. A well developed list of injuries for a new vaccine may not exist even after clinical trials, so the causal relationships between injury and a vaccine may need to be developed in court or an administrative hearing. *See* Edward Richards, Presentation at the University of Maryland's Symposium Eliminating Legal, Regulatory, and Economic Barriers to Biodefense Vaccine Development (June 9, 2004), (digital audio recording), *available at* http://media.umaryland.edu:8080/ramgen/oea/vaccine_conf/VACCINE_2004_RICHARDS_QA.rm (last visited Feb. 24, 2005). While a comprehensive discussion of this problem is beyond the scope of this article, one possibility may be to use court appointed experts to give testimony on whether a given injury has been caused by a vaccine.

184. Lauren Hammer Breslow, Note, *The Best Pharmaceuticals for Children Act of 2002: The Rise of the Voluntary Incentive Structure and Congressional Refusal to Require Pediatric Testing*, 40 HARV. J. ON LEGIS. 133, 190 (2003).

185. *Id.*

186. *The Threat of Smallpox*, *supra* note 5.

187. *Id.*

risk of coming into contact with a disease.[188] This may be especially true if an adequate compensation program does not exist. Each of these variables was present at the beginning of the Phase I program, including the almost complete absence of a federal system to compensate smallpox vaccine injuries or fatalities.

In the case of the federal Phase I program, the Bush Administration clearly sent mixed messages regarding the probability of terrorists using smallpox as a weapon. When President Bush formally announced the Phase I program in December of 2002, he stated, "One potential danger to America is the use of the smallpox virus as a weapon of terror . . . . We know, however, that the smallpox virus still exits in laboratories, and we believe that regimes hostile to the United States may possess this dangerous virus."[189] However, in the same speech he expressed the administration's belief that a smallpox attack was not "imminent."[190] Furthermore, a little more than a month before President Bush's announcement, D.A. Henderson, a highly respected science adviser for the U.S. Department of Health and Human Services, said, "I think we're looking at [smallpox] at this point as a low risk of it being used as a weapon."[191] This ambiguity helped doom Phase I. Certainly, the federal government will need to make a better effort to determine whether first responders need to receive biodefense vaccines, and then communicate the need for them to get vaccinated. Accordingly, adequate threat communication must be concomitant with a robust compensation program.

Moreover, a federal liability and compensation program must be in place before any pre-event biodefense vaccinations begin. The Phase I smallpox vaccination program taught us an important lesson: that without adequate compensation, it will be difficult to attract volunteer vaccinees. Indeed, days before President Bush formally announced the Phase I vaccination program, Service Employees International Union (SEIU), America's largest health care worker union, demanded that a "simple and fair compensation system – like [NCVIA] – should be made available to assist anyone who is injured from receiving the vaccine or coming into contact with someone who received it."[192] The limited compensation package offered by Section 304 failed to encourage first responders to volunteer for vaccination. Furthermore, even SEPPA's improved compensation scheme did little to increase participation in the program. In

188. The risk of coming into contact with some Category A bioterrorist agents in nature is very low. For example, smallpox has been eradicated from the world, except for a few samples stored in Atlanta, Georgia, and Russia. *The Threat of Smallpox*, *supra* note 5.

189. White House Press Release, *supra* note 85.

190. *Id.*

191. David Ruppe, *HHS Official Says Threat of Smallpox Attack Low*, GOV'T EXEC., Nov. 7, 2002, http://www.govexec.com/dailyfed/1102/110702gsn1.htm (last visited Feb. 24, 2005).

192. Press Release, Service Employees International Union, Nation's Largest Health Care Union Warns That, Without Better Safeguards, Plan Itself Poses Public Health Risks (Dec. 3, 2002), http://biotech.law.lsu.edu/blaw/bt/smallpox/SEIU-smallpox-.pdf (last visited Feb. 24, 2005).

particular, the limits and caps SEPPA placed on awards were more stringent than the previous federal vaccination programs, and thus less attractive to first responders.

Compensation should also restore injured vaccinees to their pre-injury positions. As mentioned above, SEPPA generally offered benefits that were less generous than those provided by either NCVIA or the Swine Flu Immunization Program.[193] In some cases, SEPPA's lost wages benefits for injured vaccinees do not maintain a high wage earner's (or their family's) standard of living. In the absence of an imminent bioterrorist threat, future biodefense vaccine compensation programs need to increase caps on injury, death, and lost wages awards, so that vaccinees are compensated more consistently with their current standard of living. Perhaps the language used in NCVIA,[194] that provides a formula to calculate an individual's lost wages, would be appropriate. Certainly, when a prospective biodefense vaccinee discovers that their household income would be markedly reduced if they were forced to rely on a federal compensation program, that person almost certainly will decide not to receive the vaccination.

Finally, federal biodefense compensation programs should also be easily accessible and offer "one-stop" shopping (*i.e.,* do not make federal compensation secondary to all other types of compensation, such as private health insurance and workers' compensation). On a personal level, potential volunteers may very well be confused and angry about the prospect of dealing with various sources of potential compensation to determine what revenue source should be compensating them. On a policy level, the adverse effects of a federal vaccination program (*i.e.*, compensation for vaccine related injuries and deaths) should not be cast upon the states, employers (through workers' compensation premiums), or private health insurers (which in turn will increase personal premiums). However, if federal biodefense vaccine compensation is made secondary to other sources of recovery, employers such as hospitals should be compensated for increased workers compensation premiums that may result from vaccinating employees. Additionally, the federal government should compensate employers if they need to furlough employees after they receive a vaccine.

C. Cost

Some assert that the abovementioned recommendations for a biodefense vaccine liability and compensation scheme would be too costly for the federal government.[195] However, when considering the Phase I smallpox program in comparison to other compensation programs, the cost is negligible. For example,

193. *See supra* notes 106-120 and accompanying text.

194. 42 U.S.C.A. § 300aa-15(a)(3) (West 2003 & Supp. 2004).

195. *The Threat of Smallpox*, *supra* note 5.

as of January 28, 2005, the federal government has paid out a total of over $629 million for 1,249 awards in NCVIA claims and attorneys' fees for childhood vaccine injuries since 1990.[196] That class is not only much larger than that of the Phase I smallpox vaccination program, which has only 500,000 prospective vaccinees for whom the United States would need to compensate (in the worst case scenario),[197] but it is also continuously growing. Even the ten million vaccinee figure projected for the Phase II smallpox vaccination is relatively small compared to the number of child vaccines under NCVIA, which requires every child in the United States, barring minor exceptions, to receive childhood vaccination as a prerequisite to entering school.[198]

In addition, outside the realm of vaccine compensation, the September 11th Victims Compensation Fund of 2001[199] will pay approximately 5,000 families nearly $7 billion.[200] The goal of that Act was not only to compensate victims, but also to offer liability protection to airlines so that their operations would remain viable.[201] Furthermore, in the Fall of 2003, Congress appropriated approximately $87 billion to sustain the "war on terror" in Afghanistan and Iraq for one year.[202] Congress also recently approved a $25 billion supplemental request, and Pentagon officials will soon ask the Bush administration for an additional $80 billion to help fund the "military presence" in Iraq and Afghanistan.[203] If vaccinations truly are an integral part of our national defense strategy, pre-event biodefense vaccine compensation and liability regimes are no less important than compensating September 11th victims or military operations in the war on terror. Pre-event biodefense vaccination programs are not where the government should be attempting to "save" funds.

Rather, the federal government must improve upon the previous liability and compensation schemes discussed above and recognize that providing liability

196. HEALTH RES. & SERVS. ADMIN., DEP'T OF HEALTH AND HUMAN SERVICES, NATIONAL VACCINE INJURY COMPENSATION PROGRAM MONTHLY STATISTICS REPORT (Dec. 1, 2004), http://www.hrsa.gov/osp/vicp/monthly_stats_post.htm (last visited Feb. 24, 2005).

197. Even if this figure were increased to include the family members of first responders, it is still relatively small in comparison to those that required vaccination under NCVIA.

198. K. Shaw et al., *Vaccination Coverage Among Children Entering School in United States, 2002-03 School Year*, 52 MORBIDITY & MORTALITY WKLY. REP. 791 (Aug. 22, 2003), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5233a3.htm (last visited Feb. 24, 2005).

199. The September 11th Victims Compensation Fund of 2001 was created on Sept. 22, 2001, by the Air Transportation Safety and System Stabilization Act, Pub. L. No. 107-42, 115 Stat. 230 (codified as amended at 49 U.S.C.A. § 40101 (West 2003 & Supp. 2004)).

200. David W. Chen, *After Weighing Value of Lives, 9/11 Fund Completes Its Task*, N.Y. TIMES, June 16, 2004, at A1.

201. 49 U.S.C.A. § 40101(a) (West 2003 & Supp. 2004).

202. Helen Dewar, *Senate Approves $87 Billion for Iraq; Bush Gets Package Largely as Requested*, WASH. POST., Nov. 4, 2003, at A1.

203. Greg Jaffe & Jackie Calmes, *Pentagon to Seek $80 Billion More: Request to Help Finance Iraq, Afghanistan Presence is Bigger than Expected*, WALL ST. J., Dec. 14, 2004, at A4.

protection and adequate compensation for biodefense vaccinations is part of the cost of doing business. For example, a cost-benefit analysis would reveal that the dangers of a smallpox outbreak far outweigh the cost of paying the potential claims of injured vaccinees in a pre-event phase. As the CDC explains, smallpox is a "serious, contagious, and sometimes fatal infectious disease."[204] Furthermore, the effects of a smallpox outbreak were explored in Dark Winter, a two day role-playing exercise based on a fictional bioterrorist smallpox attack.[205] Specifically, Dark Winter demonstrated that the impact of a smallpox attack would likely include overcrowded emergency rooms, large angry crowds demanding vaccination, closures of transportation links, food shortages, and billions of dollars in international trade losses.[206] In addition, the infection rate would increase tenfold every two to three weeks, translating into thirty million cases and ten million deaths by the fifth wave.[207] Cognizant of the catastrophic consequences of a smallpox outbreak, the best approach is to mitigate the damage of an attack via pre-event vaccination.[208] In order to do so, the federal government must begin by assuming more of the financial responsibility.

IV. CONCLUSION

In order to avoid future failures of pre-event vaccinations programs such as the Phase I smallpox initiative, the federal government must unambiguously convey the threat of a particular agent, provide clear and comprehensive liability immunity to those administering the vaccine, and adequately compensate those that are injured by the vaccination. The cost of providing such a pre-event liability and compensation scheme is a relatively small price to pay when compared to what the price would likely be at the post-event stage. At the pre-event stage, the population targeted for vaccination is manageable and the risks of receiving the vaccination are calculable. In contrast, once an outbreak occurs, the cost of confronting the catastrophic consequences that emerge grows exponentially – especially without the benefit of vaccinated first responders. The government must

204. CDC, SMALLPOX DISEASE OVERVIEW, *at* http://www.bt.cdc.gov/agent/smallpox/overview/disease-facts.asp (last visited Feb. 24, 2005) (stating that smallpox has a fatality rate of approximately 30%).

205. *Dark Winter: A Bioterrorism Exercise,* BIOHAZARD NEWS, SCENARIOS: SMALLPOX (June 2001), *at* http://www.biohazardnews.net/scen_smallpox.shtml (last visited Feb. 24, 2005).

206. *Id.*

207. *Id.*

208. CDC, WHAT YOU SHOULD KNOW ABOUT A SMALLPOX OUTBREAK, http://www.bt.cdc.gov/agent/smallpox/basics/pdf/outbreak.pdf (last visited Feb. 24, 2005).

recognize that the cost of pre-event vaccination programs is relatively small and a necessary cost of doing business in the post 9/11 world.