

The Smallpox Vaccination Campaign of 2003: Why Did It Fail and What Are the Lessons for Bioterrorism Preparedness?¹

Edward P. Richards*
Katharine C. Rathbun**
Jay Gold***

I. INTRODUCTION

On December 13, 2002, the White House announced a plan to vaccinate active duty military personnel and certain civilian hospital, health care, and emergency services workers against smallpox.² This announcement was accompanied by a Smallpox Vaccination FAQ.³ The goal was to vaccinate 500,000 military personnel as soon as possible, and then to vaccinate 500,000 civilians within a few weeks. There were no specific plans to vaccinate the general population, but there was discussion about making the smallpox vaccine available to the general public in 2004. President Bush was immunized first, with no reported ill effects.⁴

Copyright 2004, by LOUISIANA LAW REVIEW.

* Edward P. Richards, JD, MPH; Director, Program in Law, Science, and Public Health, Harvey A. Peltier Professor of Law, Paul M. Hebert Law Center, Louisiana State University.

** Katharine C. Rathbun, MD, MPH; Ochsner Clinic Foundation, Baton Rouge, Louisiana.

*** Jay Gold, JD, MPH, MD; MetaStar, Inc.

1. Available with hyperlinks at <http://biotech.law.lsu.edu/blaw/bt/smallpox/svlaw.htm>.

2. Press Release, Protecting Americans: Smallpox Vaccination Program, (December 13, 2002), *available at* <http://www.whitehouse.gov/news/releases/2002/12/20021213-1.html> (last accessed Aug. 14, 2004) and <http://biotech.law.lsu.edu/blaw/bt/smallpox/vaccination-program-statement.pdf> (a "Fact Sheet" issued with President Bush's statement announcing the new program). Only the Presidential Statement itself has been retained by the National Archives and Records Administration. Remarks Announcing the Smallpox Vaccination Plan, 38 Weekly Comp. of Pres. Doc. 2162 (Dec. 16, 2002), *available at* <http://www.gpoaccess.gov/wcomp/v38no50.html>. The supporting papers issued with the statement do not appear in the *Weekly Compilation of Presidential Documents*. *See id.*

3. Press Release, Frequently Asked Questions, Smallpox Response Teams (Dec. 13, 2002), *available at* <http://www.whitehouse.gov/news/releases/2002/12/20021213-3.html> and <http://biotech.law.lsu.edu/blaw/bt/smallpox/whfaq.htm>.

4. *See* Mike Allen, *Bush Receives Smallpox Vaccine*, Wash. Post, Dec. 22, 2002, at A11; *Bush Fine After Vaccine*, Wash. Post, Dec. 23, 2002, at A5.

By January 2004, 578,286 military personnel were vaccinated.⁵ During the same period, only 39,213 civilian health-care and public health workers were vaccinated, less than ten percent of the original goal.⁶ This article analyzes why the civilian smallpox vaccination campaign failed, the impact of this failure, and what it should teach us about future vaccination campaigns for smallpox and other bioterrorism agents. Some of the reasons for failure could have been averted with better planning and legislation, but others are intrinsic to the United States's medical and legal systems. Addressing these intrinsic problems demands fundamental modifications in the plans for bioterrorism preparedness.

This article does not discuss the control of a smallpox outbreak, beyond the use of smallpox vaccinations. Control measures would include stopping all transportation in and out of the affected area, identifying all cases, persons in contact with those cases or in contact with contacts of those cases, vaccinating and isolating the contacts, and trying to preserve social order and infrastructure in the affected region. Such measures would require military intervention as discussed in other papers in this symposium issue. It is possible that we would see the breakdown of civil order and imposition of martial law. The authors believe that such measures will be nearly impossible to carry out because they pose difficult moral and ethical dilemmas such as whether to shoot the soccer mom with the minivan full of kids trying to get out of the city. As a result, the authors stress the importance of a workable vaccination program which can stop the epidemic even if draconian control measures fail.

This article originated in the Smallpox Vaccine Injury and Legal Guide,⁷ an online analysis of the medical and legal issues posed by

5. Centers for Disease Control and Prevention, *Secondary and Tertiary Transfer of Vaccinia Virus Among U.S. Military Personnel—United States and Worldwide, 2002-2004*, 53 MMWR 103 (2004), available at <http://www.cdc.gov/mmwr/PDF/wk/mm5305.pdf> and <http://biotech.law.lsu.edu/cdc/mm5305.pdf#page=7>.

6. Centers for Disease Control and Prevention, *Update: Adverse Events Following Civilian Smallpox Vaccination—United States, 2003*, 53 MMWR 106 (2004), available at <http://www.cdc.gov/mmwr/PDF/wk/mm5305.pdf> and <http://biotech.law.lsu.edu/cdc/mm5305.pdf#page=10>. This number may include personnel who were vaccinated through the military reserves, further reducing the number of civilian volunteers.

7. Edward P. Richards & Katharine C. Rathbun, *Smallpox Vaccine Injury and Law Guide* (June 7, 2004), available at <http://biotech.law.lsu.edu/blaw/bt/smallpox/svlaw.htm>. For the chronologic develop of the Guide, see the earlier editions: May 19, 2003, available at <http://biotech.law.lsu.edu/blaw/bt/smallpox/svlaw19may2003.htm>; March 26, 2003, available at <http://biotech.law.lsu.edu/blaw/bt/smallpox/svlaw26march03.htm>; January 24, 2003, available at <http://biotech.law.lsu.edu/blaw/bt/smallpox/svlaw24jan03>; Edward P. Richards & Katharine C. Rathbun, *Rethinking smallpox Immunizations*

the smallpox vaccine campaign that was updated as the campaign progressed. Through the guide and discussions with health care institutions, unions, health departments, and reporters,⁸ Professor Richards and Dr. Rathbun helped many health care organizations tailor their response to the smallpox vaccine campaign.

II. WHAT WERE THE CORE PROBLEMS WITH THE SMALLPOX VACCINATION PLAN?

Most of the opposition to the civilian smallpox vaccination plan came from health care institutions. Their concerns revolved around six issues that the government failed to address properly when the plan was announced. While some of these issues have been clarified since the plan ended, some have yet to be satisfactorily resolved. The opposition of the health care institutions to the plan effectively stopped it, leaving open the question of whether the individuals who were the target of the plan would have cooperated if their institutions had supported the plan. This article analyzes the following six queries as they arose during the rollout of the smallpox vaccination plan, considering the extent to which they have been resolved:

- 1) What is the real complication rate for smallpox vaccine, and who is at greatest risk for complications?
- 2) Is the vaccine being administered in a safe manner?
- 3) Will worker's compensation cover worker injuries and lost time?
- 4) Are all members of the health care team protected by the legal immunity provisions of the Homeland Security Act?
- 5) How will persons injured by the vaccine be compensated?
- 6) Is this plan epidemiologically sound? In other words, does it improve smallpox preparedness sufficiently to be worth the risks? If not, is there a better alternative?

While the smallpox vaccination plan was in effect, the authors did not take a position on whether health care workers should participate. Such workers were advised to read the CDC's Smallpox Vaccination

in Hospitals—A Hospital Lawyer's Guide (last revised Nov. 30, 2002), available at http://biotech.law.lsu.edu/blaw/bt/smallpox/hosp_SP_old.htm; Edward P. Richards & Katharine C. Rathbun, Legal Issues Related to Smallpox Immunizations under the Homeland Security Act (last revised Dec. 14, 2002), available at http://biotech.law.lsu.edu/blaw/bt/smallpox/304_sp.htm; and Edward P. Richards & Katharine Rathbun, The Risks of Vaccinating Health Care Workers for Smallpox—Legal Issues (last revised Dec. 9, 2002), available at http://biotech.law.lsu.edu/blaw/bt/smallpox/hosp_SP.htm.

8. Robert Pear, *Threats and Responses: Legal Risks; For Victims of Vaccine Winning Case will be Hard*, N.Y. Times, Dec. 14, 2002, at 13.

and Adverse Reactions: Guidance for Clinicians,⁹ the Recommendations of the Advisory Committee on Immunization Practices (ACIP)—Smallpox,¹⁰ and the label¹¹ for the vaccine, which contains information that has been left out of the CDC and ACIP materials. Health care employers were advised to set up surveillance systems to assure that they are aware of every vaccinated employee so that they can monitor the employee's vaccine sore and control the exposure of at-risk patients. They were also advised to identify all independent contractors in their system who might have contact with vaccinated persons or who otherwise might be at risk for vaccine-related injuries. These contractors needed to sign agency agreements with the employer or the local health department to try to bring them under the immunity umbrella of the Homeland Security Act. When most health care employers considered the uncertainties in the plan along with the medical and legal risks, they decided not to participate.

III. SMALLPOX AS A BIOTERRORISM AGENT

The risk of any smallpox vaccination plans must be evaluated in the context of the risk of a smallpox outbreak. Smallpox is a highly contagious viral disease characterized by fever and an eruption of vesicles and pustules, which kills five to thirty percent of infected

9. Centers for Disease Control and Prevention, *Smallpox Vaccination and Adverse Reactions: Guidance for Clinicians*, MMWR Dispatch (Jan. 24, 2003), available at <http://biotech.law.lsu.edu/blaw/bt/smallpox/di52cha1/di52cha1.htm>. This document was originally published as a Dispatch from the Centers for Disease Control and Prevention's (CDC) Morbidity and Mortality Weekly Report (MMWR). However, the CDC no longer maintains the original document. An updated version was published by the CDC as an MMWR Recommendations and Reports on February 21, 2003. Centers for Disease Control and Prevention, *Smallpox Vaccination and Adverse Reactions: Guidance for Clinicians*, 52 MMWR Recommendations and Reports No. RR-4 (Feb. 21, 2003), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5204a1.htm> [Hereinafter CDC, *Guidance II*].

10. Centers for Disease Control and Prevention, *Recommendations for Using Smallpox Vaccine in a Pre-Event Vaccination Program—Supplemental Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Healthcare Infection Control Practices Advisory Committee (HICPAC)*, 52 MMWR Recommendations and Reports No. RR-7 (April 4, 2003), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5207a1.htm> and <http://www.cdc.gov/mmwr/PDF/RR/RR5207.pdf> [hereinafter CDC, *Recommendations*].

11. Wyeth Laboratories, Inc., Package Insert Dryvax[®] (Smallpox Vaccine, Dried, Calf Lymph Type), available at <http://www.fda.gov/cber/label/smalwye102502LB.htm>, <http://www.fda.gov/cber/label/smalwye102502LB.pdf>, and http://biotech.law.lsu.edu/blaw/bt/smallpox/DRYVAX_label.htm [hereinafter DryVax[®] Package Insert].

persons.¹² Infected persons who survive are often terribly disfigured by the smallpox scars and many are blinded by the disease.¹³ It is spread through close contact when infected persons cough out particles of the virus (*variola major*) from sores in their mouths and lungs.¹⁴ These particles can be inhaled, but are more commonly picked up as tiny dried droplets in the environment and inadvertently ingested or rubbed into the eyes.¹⁵ The period during which an infected person can spread the infection is about three weeks, from just prior to the appearance of the rash until the last scab disappears.¹⁶ About half of those exposed to the virus develop the infection.¹⁷ There is an incubation period of seven to nineteen days (mean: twelve days) during which the infected person exhibits no symptoms.¹⁸

Once infected, a person always goes on to develop symptoms, but the severity of the cases vary from mild illness to rapid death.¹⁹ Persons who recover from smallpox infection have a long-lasting immunity.²⁰

Smallpox infects only human beings. It has no animal reservoirs and persists in the environment for only a short period, except when properly prepared in a laboratory. Smallpox must be actively infecting a human population to survive. It did not exist until human beings reached a high enough density that it could spread from community to community, often not returning until there was a new generation of children or young adults who were susceptible to the disease.²¹

Since smallpox has no animal hosts and is not persistent in the environment, it would be eradicated if at any point in time there were no human beings infected. This became a theoretical possibility in the 1951 when Collier developed a freeze-dried smallpox vaccine

12. Frank Fenner, et al., *Smallpox and its Eradication* 5 (History of International Public Health No. 6, 1988), available at <http://www.who.int/emc/diseases/smallpox/Smallpoxeradication.html>. This is the definitive work on smallpox, compiled to “preserve for posterity” the story of the control of smallpox. See also W.H. McNeill, *Plagues and Peoples* 160–65 (1976) (detailing how disease really subdued the Aztecs, not the Spanish).

13. Fenner, *supra* note 12, at 49–50.

14. Joel G. Breman & Donald A. Henderson, *Diagnosis and Management of Smallpox*, 346 *New Eng. J. Med.* 1300, 1302 (2002).

15. *Id.*

16. *Id.* The typical period is about ten days, but stretches out to three weeks if the rash is slow to heal.

17. *Id.* The range is 37–88.

18. Fenner, *supra* note 12, at 5.

19. Breman & Henderson, *supra* note 14, at 1301.

20. *Id.*

21. Jonathan B. Tucker, *Scourge: The Once and Future Threat of Smallpox* 6 (2001).

that could be stored at room temperature and thus could be easily transported to remote locations.²² A Western Hemisphere smallpox eradication program was started by the Pan American Sanitary Organization in 1950.²³ At the suggestion of the Soviet Union, the World Health Organization began a worldwide eradication program in 1967.²⁴ This program combined intensive case finding and contract tracing—looking for persons infected with or exposed to smallpox—with mandatory vaccinations for all exposed persons. On October 26, 1977, the last known naturally occurring smallpox case was recorded in Somalia. In 1980, the WHO declared that smallpox had been eradicated. The United States ended routine smallpox vaccinations in 1972, and they were not routinely given anywhere after 1983.²⁵

Before eradication, many laboratories maintained stocks of the virus for research purposes. After eradication, a laboratory accident that led to a smallpox death reminded the world that these laboratory stocks of virus had the potential to reintroduce smallpox into the world.²⁶ All the remaining stocks were destroyed, with the exception of stocks maintained by the CDC in Atlanta and the Soviet Union. There was an ongoing debate over destroying these remaining stocks, until a defector who ran the Soviet Union's biological warfare operations claimed that the Soviet Union had produced thousands of pounds of smallpox virus in derogation of the Biological Warfare Treaty.²⁷ This claim has been impossible to verify, and there is no information about the current whereabouts of the virus if it was produced. This possible unaccounted-for smallpox virus fuels fears of the virus getting into the hands of terrorists.

22. Fenner, *supra* note 12, at 287.

23. *Id.* at 388–89.

24. *Id.* at 387.

25. *Id.* at 1265.

26. *See id.* at 1097. The victim, a 40-year-old woman, was “a medical photographer in the Anatomy Department of the Medical School of the University of Birmingham . . . [who] became ill with fever, headache and muscular pains on 11 August [1978].” *Id.* She had last been vaccinated in 1966. *Id.* A rash developed on August 15, and vesicles developed on August 24 (which “led to a suspicion of smallpox”), and she was placed in an isolation hospital later that day. *Id.* However, her health “deteriorated rapidly and she died on 11 September [1978].” *Id.* The specifics of this outbreak are in Chapter 23, “Smallpox in Non-endemic Countries.” *Id.* at 1069–1101.

27. *Terrorism and Intelligence Operations: Hearing Before the Joint Economic Comm.*, 105th Cong. (1998) (statement of Dr. Kenneth Alibek, Former Director, Soviet Union Offensive Biological Warfare Program), available at <http://www.house.gov/jec/hearings/intell/alibek.htm> and <http://biotech.law.lsu.edu/blaw/bt/smallpox/Congress/Alibek01.htm>.

Smallpox epidemics have always been horrific events in human history.²⁸ In most communities, however, the damage done by any given epidemic was limited because many people would be immune to the disease because of prior exposure. As vaccination became more common in the late nineteenth century, it dramatically reduced the number of persons infected during epidemics. This was critical because the real threat of epidemic disease is not individual deaths, but the collapse of society through fear and the loss of a critical mass of infrastructure workers. The impact of such societal collapse can be seen in the effect of an epidemic that is introduced into a society with no immunity. When measles, which does not have a high fatality rate, was introduced into native populations with no immunity, everyone became sick at the same time.²⁹ With no one to nurse the sick, prepare food, or provide water, the disease sometimes killed eighty percent or more of the community.³⁰

The eradication of smallpox, and the subsequent ending of vaccinations, has left the world in a unique position. Smallpox vaccination does not give life-long immunity, and approximately half of the world's population has never been vaccinated. For the first time since smallpox first attacked humankind, there is little natural immunity. Eradication of natural smallpox and the cessation of smallpox vaccination has put the whole world at risk for a massive smallpox epidemic. Even the data used to estimate smallpox transmission is suspect because it was derived from populations with significant immunity.³¹ We have no good information about the

28. Fenner, *supra* note 12, at vii.

29. William H. McNeill, *Plagues and Peoples* (1976); J.V. Neel, W.R. Centerwall, N.A. Chagnon, & H.L. Casey, *Notes on the Effect of Measles and Measles Vaccine in a Virgin-Soil Population of South American Indians*, 91 *Am. J. Epidemiology* 418 (1970):

The impact of measles on a primitive population is well known. It seems to have been generally assumed that this is a result of a greater 'constitutional' susceptibility. However, in 1877 Squire (1) describing the collapse of village life during an epidemic of measles in Fiji, clearly presented a contrary view: "Excessive mortality resulted from terror at the mysterious seizure, and the want of commonest aids during illness; there were none to offer drink during the fever, nor food on its subsidence. Thousands were carried off for want of nourishment and care as well as by dysentery and congestion of the lungs. We need to invoke no special susceptibility of race or peculiarity of constitution to explain great mortality."

30. For an example of the same effect from an outbreak of smallpox, see Fenner, *supra* note 12, at 175 ("[E]pidemics in previously unexposed subsistence-farming populations appeared often to have produced much higher mortalities than those seen in Asia [20% or more fatality in unvaccinated persons], owing to the social disruption and consequent starvation that they caused.").

31. See Martin I. Meltzer, et al., *Modeling Potential Responses to Smallpox as*

dynamics of the spread of smallpox in a large, dense, community with no immunity.³² Depending on the assumptions made about the

a Bioterrorist Weapon, 7 *Emerging Infectious Diseases* 959 (2001), available at <http://www.cdc.gov/ncidod/EID/vol7no6/meltzer.htm>. The base rate information used by Meltzer was from Fenner, *supra* note 12. Of course all of the earlier data was from populations long exposed to smallpox, so many, if not most, of the general population had lived through earlier outbreaks. Moreover, the model only assumed three persons infected per infectious person. However, any smallpox epidemic now would likely progress at a far higher rate than the historical rates since virtually no one born after 1972 in the United States (or after 1980 in the rest of the world) has immunity from previous exposure to the disease. Additionally, the older adults who have not been vaccinated in the last thirty years are unlikely to retain sufficient lingering protection from their earlier inoculations as children or young adults. Meltzer attempted to compensate for the unknown degree of residual smallpox protection from older Americans (older than thirty) previously vaccinated in their youth by

assum[ing] an unlimited supply of susceptible persons, so that disease transmission will not be halted because of lack of susceptible persons.

Although this scenario is unrealistic for modeling the natural spread of an infectious disease, it may be realistic for considering the initial spread of an infectious disease after deliberate infection of a small number of persons in a population with a relatively large proportion who are susceptible.

Id. at 961.

Of course, for almost all of human history, the “natural” spread of human disease was essentially limited by how far a sick person could walk. In an age when an infectious person can reach any spot on Earth in 24 hours, and do so repeatedly during the 10–12 days of prime infectious capability, the “natural” spread rate would be much higher. Fenner deals with this precise situation. Fenner, *supra* note 12, at 202, 1077–79.

32. The limited data we do have suggests the vulnerability of unprotected societies could be both quite severe and difficult to predict or control. For example, Fenner’s comprehensive history of the eradication of smallpox gives a revealing illustration of the problem. Fenner, *supra* note 12. In 1970, a German hospital in Meschede admitted an electrician into its isolation ward ten days after his return from Pakistan with a “feverish illness . . . suspected to be typhoid fever.” *Id.* at 192–93. Three days later, he developed a rash, confirmed, using an electron microscope, to be smallpox two days later. *Id.* At that time, after five days in the general hospital in full isolation, the patient was transferred to a specialized smallpox hospital. *Id.* Despite the “rigorous isolation of the patient” and “the vaccination of all of the patients and nurses in the general hospital,” nineteen additional cases of smallpox resulted from the electrician’s admission. *Id.* Several aspects of this event are quite chilling. The electrician was only on the first floor, yet persons on all three floors of the hospital developed smallpox. *Id.* One person, case 8, visited the ground floor of the hospital only once, fourteen days after the electrician was admitted, for no more than fifteen minutes. *Id.* Smoke tests performed by investigators of the outbreak revealed that eleven cases were in rooms outside of the smoke’s flow pattern; two cases upwind of the smoke pattern. *Id.* Case 17 developed twenty-one days after the electrician’s admission and case 19 developed fourteen days after a visit to case 17. *Id.* Perhaps the most sobering aspect of the Meschede outbreak is the contrast between the results of a fleeting exposure in an unprotected population with the results of prolonged exposure in a

speed with which smallpox would spread in such a community, many people believe there is a chance for a global pandemic that could disrupt modern society.³³ It is this fear that makes smallpox the most frightening bioterrorism agent.

Based on the potential damage from an outbreak, one could make a strong argument for smallpox vaccinations, even if there is significant risk of adverse reactions to the vaccine. For example, whatever tort liability might attach because of complications of vaccinations in health care workers or patients would be dwarfed by the catastrophic losses a hospital would face during a large scale outbreak of smallpox. The key to the risk calculus is the probability of an outbreak. Prior to 1999, the public health establishment was so convinced that the remaining smallpox virus was under proper control that they debated destroying the virus in the authorized research labs to assure that there would not be any more virus in the world, despite the fact that the information about the Soviet smallpox virus manufacture was given to national security agencies in 1993. Since the White House made no claims that the risk of smallpox bioterrorism had increased, it was not irrational for health care institutions to work on the assumption that the chance of an outbreak in their community was very small. Given that smallpox vaccine, as discussed below, is by far the most dangerous vaccine available, the low probability of an outbreak made the risk of vaccine-related injuries much more probable.

IV. THE HISTORY OF SMALLPOX VACCINATIONS

Persons who survive smallpox develop immunity to the disease, which lasts for many years. Observing this led those who sought to fight the disease to find ways to inoculate the population (“variolation”). In ancient China, a powder was developed to be inhaled.³⁴ In India, skin was inoculated with the contents of smallpox pustules.³⁵ These tactics, which were employed erratically over the centuries, lessened the severity of infections, but variolation transmitted the disease and often resulted in a fatal illness. Furthermore, those inoculated could transmit smallpox to others.

protected population. Fenner observed: “Especially in India, long-distance movements by train or bus of patients suffering from smallpox, with an overt rash, used to occur frequently, yet infection of casual fellow-travellers [sic] was rare indeed—so rare that instances of it were deemed unworthy of special report.” *Id.* at 191. Here, while contained in a controlled, isolated hospital room, one sick person infected nineteen more with smallpox, more than six times the 3:1 infection ratio assumed in the Meltzer model. Meltzer, *supra* note 31.

33. Tara O’Toole, Michael Mair, and Thomas V. Inglesby, *Shining Light on “Dark Winter,”* 34 *Clinical Infectious Diseases* 972, 975 (2002).

34. Fenner, *supra* note 12, at 252–53.

35. *Id.* at 253.

In the late eighteenth century, the English physician Edward Jenner observed that dairymaids who had been infected with cowpox, a mild pustular infection, thereafter were immune to smallpox.³⁶ In 1796, Jenner inoculated a young man with cowpox, and the boy developed smallpox immunity.³⁷ This led to widespread inoculation with cowpox starting in the nineteenth century. Genetic analysis indicates that since that time, the virus used for inoculation has been replaced by another virus called vaccinia, which is not cowpox nor any other known pox virus.³⁸ (It may be the now extinct horsepox, or a hybrid of horsepox and cowpox.) A person who is infected with vaccinia develops immunity to smallpox, but this immunity is not as effective as that from being infected by smallpox. While smallpox infection confers lifelong immunity on those who survive, those who are vaccinated with vaccinia have to be revaccinated every five to ten years to keep up their immunity, and need to be vaccinated again when exposed to smallpox.³⁹

The effectiveness of vaccination led states to adopt laws in the nineteenth century making it compulsory.⁴⁰ However, there is a long history of opposition to such laws in the United States.⁴¹ The leading United States Supreme Court case *Jacobson v. Massachusetts*⁴² involved a defendant who refused to be vaccinated. This refusal was not as unreasonable as it might seem at first glance: the vaccine was often contaminated with bacteria and other viruses, making the traditional immunization process dangerous. Still, Jacobson was prosecuted criminally for violation of the law and regulations of the Board of Health of Cambridge, Massachusetts.⁴³ He was found guilty, and appealed to the Massachusetts Supreme Judicial Court,

36. *Id.* at 258.

37. Edward Jenner, *The Three Original Publications On Vaccination Against Smallpox (1798)*, available at <http://www.fordham.edu/halsall/mod/1798jenner-vacc.html> and <http://biotech.law.lsu.edu/cphl/history/articles/jenner.htm>.

38. Tucker, *supra* note 21, at 37.

39. Fenner, *supra* note 11, at 175.

40. See *Allegany County Com'rs v. McClintock*, 60 Md. 559 (1883); *City of Ft. Wayne v. Rosenthal*, 75 Ind. 156 (1881); *Schmidt v. Bd. of County Com'rs of Stearns Co.*, 24 N.W. 358 (Minn. 1885); *Scripps v. Foster*, 3 N.W. 216 (Mich. 1879); *McIntire v. Town of Pembroke*, 53 N.H. 462 (1873); *Com. V. Pear* (66 N.E. 719 (Mass. 1903), *aff'd by Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11, 25 S. Ct. 358 (1905); *Carr v. Bd. of Educ. Of Columbus*, 1 Ohio N.P. (n.s.) 602 (Ohio Com. Pl. 1903).

41. MacLeod, *Law, Medicine and Public Opinion: The Resistance to Compulsory Health Legislation, 1870–1907* (1967).

42. *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11, 25 S. Ct. 358 (1905), available at http://biotech.law.lsu.edu/cases/vaccines/Jacobson_v_Massachusetts.htm.

43. *Id.* at 13, 25 S. Ct. at 359.

which upheld the conviction.⁴⁴ In an appeal to the Supreme Court, Jacobson argued that the compulsory vaccination violated the Preamble to the United States Constitution and the spirit of the Constitution.⁴⁵

The Supreme Court, in an opinion by the first Justice Harlan, invoked the traditional police power by which legislatures establish regulations to protect the public health and safety.⁴⁶ There is no absolute right, the Court said, to be free of all restraint.⁴⁷ It was appropriate, according to the Court, for the Massachusetts legislature to refer the issue of what is necessary for the public health and safety of a city to the Board of Health, and under such circumstances, the Court stated that it would not adjudge unnecessary the Board's vaccination requirement.⁴⁸ The Court declared:

We are not prepared to hold that a minority, residing or remaining in any city or town where smallpox is prevalent, and enjoying the general protection afforded by an organized local government, may thus defy the will of its constituted authorities, acting in good faith for all, under the legislative sanction of the state.⁴⁹

With regard to the defendant's offer to prove that the vaccine often injured those vaccinated, the Court pointed out that "The legislature assumed that some children . . . might not be fit subjects of vaccination, and it is suggested—and we will not say without reason—that such is the case with some adults."⁵⁰ But Justice Harlan noted that Jacobson never had offered to prove that he himself was not a fit subject of vaccination.⁵¹ The opinion went on to state that to exempt the defendant because the vaccine often injured people

would mean that compulsory vaccination could not in any conceivable case be legally enforced in a community, even at the command of the legislature, however widespread the epidemic of smallpox, and however deep and universal was the belief of the community and of its medical advisers, that a system of general vaccination was vital to the safety of all.⁵²

After *Jacobson*, requiring vaccinations as a prerequisite for children to attend school became common. Today, most—though not

44. *Id.* at 21, 25 S. Ct. at 359.

45. *Id.* at 22, 25 S. Ct. at 359–60.

46. *Id.* at 24, 25 S. Ct. at 360–61.

47. *Id.* at 26, 25 S. Ct. at 361.

48. *Id.* at 27, 25 S. Ct. at 362.

49. *Id.* at 37, 25 S. Ct. at 366.

50. *Id.* at 36, 25 S. Ct. at 365.

51. *Id.* at 36–37, 25 S. Ct. at 365–66.

52. *Id.* at 37, 25 S. Ct. at 366.

all—states prohibit school-age children from public or private educational facilities without having undergone the prescribed immunizations (though some states permit children to attend school while they are in the process of obtaining their immunizations).

Over time, religious exemptions from compulsory immunization has been raised in other cases. In *Prince v. Commonwealth*,⁵³ parents raised religious objections to child labor laws, citing the first amendment protection of the free exercise of religion.⁵⁴ The Supreme Court ruled against them:

Acting to guard the general interest in youth's well being, the state as *parens patriae* may restrict the parent's control by requiring school attendance, regulating or prohibiting the child's labor and in many other ways. Its authority is not nullified merely because the parent grounds his claim to control the child's course of conduct on religion or conscience. Thus, he cannot claim freedom from compulsory vaccination for the child more than for himself on religious grounds. The right to practice religion freely does not include liberty to expose the community or the child to communicable diseases or the latter to ill health or death.⁵⁵

Quite a few states have enacted statutes that provide exemptions from the requirement that children must be immunized to attend school.⁵⁶ Such exemptions can derive from religious beliefs and practices, from the possibility that immunization might endanger a child's life or health, and from personal beliefs. Where such exemptions exist, states may take action in the event of an epidemic for which a child is not immunized: the child may be suspended or excluded from school until the outbreak is over,⁵⁷ the child may be

53. 321 U.S. 158, 64 S. Ct. 438 (1943).

54. *Id.*

55. *Id.* at 166–67, 64 S. Ct. at 442.

56. Only Mississippi and West Virginia provide no religious exemption; the other forty-eight states do. Seventeen states currently provide for non-religious exemptions based upon either moral or philosophical objections. James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 Ky. L.J. 831, table 2 (2002). The fifteen states with moral/philosophical objections found by Hodge in 2002 were Arizona, California, Idaho, Indiana, Louisiana, Maine, Michigan, Minnesota, Nebraska, North Dakota, Ohio, Oklahoma, Vermont, Washington, and Wisconsin. *Id.* at 869–73. Two states added this exception in 2003: Arkansas and Texas. John Kasprak, Exemptions From Childhood Immunization Requirements (OLR Res. Rep. 2004-R-0263, 2004), available at <http://www.cga.ct.gov/2004/rpt/2004-R-0263.htm>.

57. Centers for Disease Control and Prevention, *Postexposure Prophylaxis, Isolation, and Quarantine to Control an Import-associated Measles Outbreak—Iowa, 2004*, 53 MMWR 969 (2004), available at <http://biotech.law.lsu>.

quarantined,⁵⁸ or the child may be required to be vaccinated despite religious objections.⁵⁹

State courts have varied in how they deal with religious exemptions to immunization requirements. In *Cude v. State*,⁶⁰ where a parent had kept his eight children out of school because of his refusal to have them vaccinated, the Arkansas Supreme Court upheld the constitutionality of an order turning children over to the Child Welfare Division of the state welfare department to have them vaccinated so that they could attend school.⁶¹ Other courts have recognized that the legislature has the right to create a religious exemption.⁶² Equal protection issues have also been raised. A statute that allowed exemptions only to members of a recognized church or denomination was struck down as improperly excluding those who do not belong to such a church.⁶³ Legislatures have responded by allowing exemptions from compulsory immunization for people who have strongly held beliefs, but who do not belong to any established or organized denomination.⁶⁴ Some states have even

edu/cases/pp/mm5341a.pdf.

58. *Id.*; see also Iowa Admin. Code r. 641-1.9(135,139A) (2004).

59. See Miss. Code Ann. § 41-23-37 (2002); W. Va. Code § 16-3-4 (2002). The religious exemption formerly in Mississippi's statute was struck down in *Brown v. Stone*, 378 So.2d 218 (Miss. 1979). The exemption discriminated against children "whose parents have no such religious convictions." *Id.* at 223.

60. 377 S.W.2d 816 (1964).

61. *Id.* The central ruling of this case—that the vaccination requirement is a proper exercise of the police power which will withstand a religious challenge—was reaffirmed one year later in *Wright v. Dewitt School District*, 385 S.W.2d 644 (1965), available at <http://biotech.law.lsu.edu/cases/vaccines/wright.htm>. The following year the Arkansas Court found that failure to comply with mandatory vaccination laws was neglect under the child welfare laws. *Mannis v. State ex rel. DeWitt School Dist. No. 1*, 398 S.W.2d 206 (1966). More generally, the Supreme Court has allowed police power regulations that interfere with religious practices if they are reasonably related to the public health and safety. *Employment Div., Oregon Dep't of Human Res. v. Smith*, 494 U.S. 872, 881, 110 S. Ct. 1595, 1601 (1990).

62. See *Sherr v. Northport-East Northport Union Free Sch. Dist.*, 672 F. Supp. 81 (E.D.N.Y. 1987); *Kleid v. Bd. of Educ.*, 406 F. Supp. 902 (W.D. Ky. 1976).

63. *Dalli v. Bd. of Education*, 267 N.E.2d 219 (1971).

64. These exemptions are undermining vaccination rates in some communities. They pose a special risk when unvaccinated children congregate in the same schools, as frequently happens because their parents share common beliefs. For example, Dr. Diane Griffin, Chair of the Department of Molecular Microbiology and Immunology at Johns Hopkins University's Bloomberg School of Public Health in Baltimore, agrees that outbreaks of contagious diseases, such as measles, "in other areas of the world pose a risk to the United States In Colorado, for example, there are communities 'where close to 20 percent of kids are not immunized All you need is the introduction of a case and since its [sic] constantly happening in the United States all you need is a case to occur in those vulnerable communities' for an epidemic to take hold" Steve Mitchell, *U.K.*

allowed exemptions for non-religious philosophical objections to vaccination.⁶⁵ As viewed by Steve P. Calandrillo, a “variety of factors are at play: religious and philosophical beliefs, freedom and individualism, misinformation about risk, and overperception of risk.”⁶⁶ Some observers find comfort in the fact that overall immunization rates remain quite high.⁶⁷ Regrettably, however, the combinations of relaxed immunization requirements and a self-selected small, dense group of unprotected people all too often produce “exemption clusters” which can lead to disease.⁶⁸ As Calandrillo so aptly points out, we simply must appreciate and “distinguish . . . the significance between nationwide versus local

Measles Outbreaks Pose Risk to U.S., UPI, Oct. 31, 2003. For a stark example of such an event, consider the 1994 measles outbreak originating at the Breckenridge ski resort in Colorado and subsequently intensely spread through two Christian Science religious communities in Illinois. For details, see Centers for Disease Control and Prevention, *Interstate Measles Transmission from a Ski Resort—Colorado, 1994*, 43 MMWR 627 (1994), available at <http://www.cdc.gov/mmwr/PDF/wk/mm4334.pdf>.

65. As of September 2004, 20 states allow, explicitly or by implication, parents to not immunize their children solely upon moral or philosophical grounds. For a comprehensive listing of each state’s specific statutes and exemptions as of late 2001, see Hodge & Gostin, *supra* note 56, at 869–73, table 2. Since then, two states have amended their statutes to allow philosophical objections by parents to override immunization laws. Texas amended its statute to add an exception “for reasons of conscience” in addition to “because of the person’s religious beliefs.” Tex. [Educ.] Code Ann. § 38.001(f) (2004), *as amended by* 2003 Texas Sess. Law Serv. Ch. 198, § 2.160 (Vernon). Similarly, Arkansas amended its statute to read “[t]he provisions of this section shall not apply if the parents or legal guardian of that child object thereto on the grounds that immunization conflicts with the religious or philosophical beliefs of the parent or guardian.” Ark. Code Ann. § 6-18-702(d)(4)(A) (Michie 2004), *as amended by* 2003 Ark. Acts 999.

66. Steve P. Calandrillo, *Vanishing Vaccinations; Why Are So Many Americans Opting Out of Vaccinating Their Children?*, 37 U. Mich. J.L. Reform 353, 353 (2004).

67. For example, a senior staff attorney in Connecticut’s Office of Legislative Research cites Hodges’ finding that “exemption rates range from 1% to 2.8% [. . . in] Arizona, California, Idaho, Indiana, Maine, Minnesota, Montana, Pennsylvania, Rhode Island, Utah, Vermont, and Wyoming.” Kasprak, *supra* note 56. His source was a shortened version (also prepared by James G. Hodge, Jr.), of Hodge and Gostin’s original article from the 2002 Kentucky Law Journal. See Hodge & Gostin, *supra* note 56. Kasprak updated his state exemptions table to February, 2004, from the similar table in a State Legislative Report Hodge wrote for the National Council of State Legislatures. James G. Hodge, Jr., *School Vaccination Requirements: Legal and Social Perspectives*, 27 NCSL State Legislative Report No. 14, 4-6 (Aug. 2002), available at <http://www.ncsl.org/programs/health/schoolvaccination.pdf>.

68. Calandrillo, *supra* note 66, at 422. “Religious exemptions to vaccination in Amish, Mennonite and Christian Science communities are responsible for the last two major outbreaks of polio in America.” *Id.* In fact, “nearly every major outbreak of vaccine-preventable diseases in the last 25 years has occurred among members of those [Amish and Christian Science] denominations.” *Id.* at 415.

exemption rates,” because, although “nationwide immunization rates are still quite high overall,” a concentration of exemption “can hide areas where exemptions are dramatically higher than overall averages indicate, making it possible for disease pockets to spring up.”⁶⁹ As a result, local exemption rates take on great significance.⁷⁰

V. CONTEMPORARY SMALLPOX VACCINE

The smallpox vaccine that is currently available, and the one used for the smallpox vaccination campaign, is called Dryvax[®], manufactured by Wyeth.⁷¹ It is the same vaccine that was developed during World War II, and the most recently produced lots have been in storage for more than thirty years.⁷² It contains live vaccinia.⁷³ Smallpox vaccine contains live virus because a person must be infected with vaccinia to develop immunity to smallpox. There is a new way of manufacturing the vaccine using cell culture that produces a vaccine with less contamination than the process used for making DryVax[®], but it poses the same risks because it uses the same live virus.⁷⁴ (Dead virus vaccine has been tried, but it does not work.⁷⁵)

69. *Id.* at 421-22.

70. *Id.* at 422. For example, Kasprak noticed the rise in total exemptions, the rate of increase in exemptions, and the occurrence of concentrated exemptions:

Colorado, which has the lowest vaccination coverage rate in the country, has seen a significant increase in exemption rates, from 0.3% of kindergarteners to 3% over a 10-year period. Michigan’s exemption rate is almost 6%, or more than 7,500 kindergarten-aged children. Washington’s exemption rate has increased from 3.4% of kindergarten-aged children five years ago to a current level of 4.1% (about 2,400 children.

Oregon’s number of exemptions has doubled since 1999, with the bulk of this due to an increase in religious exemptions. In particular, Ashland, a small city in Jackson County, Oregon, has a high rate of religious exemptions. In school year 2000-2001, 11% of school children in Ashland had a religious exemption to vaccination, compared to 3% for all of Jackson County and 2.7% for the state.

Kasprak, *supra* note 56, at 5.

71. Press Release, American Home Products Corp., American Home Products Submits Plan to Produce Smallpox Vaccine (Oct. 26, 2001), *available at* http://www.wyeth.com/news/Pressed_and_Released/pr10_26_2001.asp?archive=2001.

72. Wyeth-Ayerst Laboratories, a division of American Home Products Corporation, began manufacturing a vaccinia (smallpox) vaccine, DryVax[®], in 1944. *Id.*

73. DryVax[®] Package Insert, *supra* note 11.

74. Sharon E. Frey, et al., *Dose Related Effects of Smallpox Vaccine*, 346 *New Eng. J. Med.* 1275 (2002); Steven R. Rosenthal, Michael Merchlinsky, Cynthia Kleppinger, and Karen L. Goldenthal, *Developing New Smallpox Vaccines*, 7 *Emerging Infectious Diseases* 920, 922 (2001).

75. E.R. Freed, et al., *Vaccinia Necrosum and Its Relationship to Impaired*

The objective of vaccination is to produce a small infected sore on the patient's arm. To vaccinate a patient, a drop of solution containing vaccinia is put between the prongs of a very small two-pronged needle, which is then punched into the patient's arm multiple times.⁷⁶ This infects the person's skin with vaccinia. For most persons, the infection is limited to a small sore at the vaccination site, but the infection can be spread by scratching or other trauma.⁷⁷ As many as one-third of vaccinated persons suffer fever and malaise sufficient to interfere with work or recreation, but most of these persons recover quickly without permanent sequelae.⁷⁸ The sore lasts about two or three weeks and leaks live virus from the surface.⁷⁹ If a person scratches the sore and then scratches his/her eye or nose, or an insect bite or scratch, the virus will form sores at the scratched location. The virus can also be spread to others who come into contact with the sore or its dressing. Most authorities assumed that people without severe vaccinia complications do not spread the vaccinia virus by coughing, but this is not clear since it has never been carefully studied. This did not matter, of course, when everyone was immunized.

Part of the recommendation for caring for individuals who have been vaccinated is that the vaccination should be covered with a bandage and long sleeves should be worn to cover the bandage.⁸⁰ This is to prevent the virus from spreading to other parts of the body or to other people. The recommended bandage is a combination of gauze to absorb the fluids from the vaccination sore and a covering that will keep these fluids and the virus they contain from getting out of the bandage.⁸¹ The problem is that the sore needs to dry out in order to heal properly and any bandage that keeps the virus from getting out will keep the sore wet. In practice, there is only one way to keep a wet sore covered and dry for long periods of time: the bandage has to be changed every time it gets wet, sometimes several times a day. This involves more work and more potential spread of vaccinia than the recommendations acknowledged. There was documented secondary spread among the military vaccinees.⁸² While this was relatively rare, hospitals and health care are a much more

Immunologic Responsiveness, 52 Am. J. Med. 411 (1972). This article discusses the use of killed virus to screen for antibody response because it cannot cause infection. *Id.* There is no other discussion of the use of killed virus in the modern literature.

76. DryVax® Package Insert, *supra* note 11.

77. *Id.*; CDC, *Guidance II*, *supra* note 9.

78. CDC, *Guidance II*, *supra* note 9.

79. *Id.*

80. *Id.*

81. DryVax® Package Insert, *supra* note 11.

82. CDC, *Secondary and Tertiary Transfer of Vaccinia Virus*, *supra* note 5.

conducive environment for transmission.⁸³ There also have been anecdotal reports that vaccinations covered with the recommended occlusive bandage are creating larger vaccination sores (“robust takes”) which may heal more slowly and leave more scarring than those that are properly covered with simple gauze that allows the sore to dry and heal more effectively, but which does not prevent the spread of vaccinia as well.

VI. VACCINE COMPLICATIONS

Smallpox vaccinations have many complications. One of the most common serious sequelae is the spreading of the vaccination sore, leading to the development of sores on other parts of the body.⁸⁴ This can happen in people with eczema and other skin conditions. While not usually life-threatening, this is a painful, difficult to treat complication that can leave the patients permanently scarred. Others suffer neurologic sequelae, which can be permanent or even fatal in a small percentage of cases.⁸⁵ When the virus spreads from the original vaccination sore, the risk of infecting others with vaccinia through secondary spread is dramatically increased. Such persons must be managed so that they are never in contact with unvaccinated persons or persons who are susceptible to vaccinia injury. If they are treated in health care facilities or hospitals, they must be put in proper isolation and managed much as a smallpox case is managed.

The most predictable complications are those secondary to immunosuppression. Since the smallpox vaccine depends on infecting the vaccinee with vaccinia, it is not surprising that persons with immunosuppression are at particular risk of having this usually-minor infection spread. The most serious complication is disseminated vaccinia.⁸⁶ Disseminated vaccinia means that the immunized person’s immune system could not keep the vaccinia virus confined to the vaccination sore. The virus spreads as a whole body illness, creating sores that look very much like smallpox. Disseminated vaccinia is often fatal. It was very rare in the 1960s and early 1970s when the last smallpox vaccinations were done in the United States, accounting for about one death per million immunizations.⁸⁷ Studies at the time found that such cases could

83. *Id.*

84. Donald A. Henderson, et al., *Smallpox as a Biological Weapon: Medical and Public Health Management*, 281 JAMA 2127, 2134 (1999).

85. *Id.*

86. There is some confusion about the nomenclature. Disseminated vaccinia in this review means the generalized spread of vaccinia throughout the body.

87. Steven M. Gordon, *Pre-Event Smallpox Vaccination: Unresolved Issues*, 70 Cleveland Clinic J. Med. 80,81 (2003).

usually be traced to persons with defective immune systems. More importantly, the leading study determined that persons with defective cellular immunity were usually killed by the vaccine.⁸⁸

The only specific treatment for disseminated vaccinia is human vaccine immunoglobulin (VIG) which is made from the serum of persons recently vaccinated with smallpox vaccine.⁸⁹ There was very little VIG available when the smallpox vaccination campaign was announced. The government increased production as quickly as possible, but there was a serious question of whether there would have been enough VIG to treat the expected complications from vaccinating 1,000,000 persons over a few months.⁹⁰ The amount of available VIG has never been revealed to the general public. While there are no antiviral drugs that are known to treat vaccinia, there are drugs that are effective against other pox viruses, and it is hoped these will help cure vaccinia reactions. The lack of effective treatments contributed to the fear of vaccine injuries.

In 1972, the last year when smallpox vaccinations were routinely given in the United States, there were very few persons with such immune system defects. Most were children with genetic diseases, with the most severely affected dying shortly after birth because they could not fight off any infections.⁹¹ The others tended to be persons with undiagnosed cancers who were inadvertently vaccinated. Since 1972, the use of powerful cancer drugs, arthritis drugs, and transplant drugs, plus the emergence of HIV/AIDS, has increased the number of immunosuppressed persons. There are at least 100 times as many immunosuppressed people in the United States today as in 1972 and perhaps 1000 times as many.⁹²

We have little direct information on the consequences of vaccinating persons with pharmacologically-suppressed immune systems or those suffering from HIV. There is one case reported in the literature where a person with HIV was immunized with smallpox vaccine.⁹³ The victim was a healthy nineteen-year-old soldier who been tested and found to have normal blood work before immunization.⁹⁴ This was just before the HIV screening test was used for all military personnel (one of the results of this case).

88. Freed, *supra* note 75.

89. Henderson, *supra* note 84, at 2132.

90. *Id.*

91. Probably the best known case (Severe Combined Immunity Deficiency Syndrome) was David Vetter, the "bubble boy," who died in 1984, at 13. See Steve McVicker, *Bursting the Bubble*, Houston Press, April 10, 1997, at 10-20, available at <http://www.houstonpress.com/issues/1997-04-10/feature.html>.

92. Gordon, *supra* note 87, at 81-82.

93. R.R. Redfield, et al., *Disseminated Vaccinia in a Military Recruit With Human Immunodeficiency Virus (HIV) Disease*, 316 N. Engl. J. Med 316, 673.

94. *Id.*

Within three weeks of vaccination, the soldier developed disseminated vaccinia.⁹⁵ Despite intensive treatment, including many injections with VIG, he died after a prolonged illness.⁹⁶ It appeared that the vaccinia virus destroyed the reserve capacity of the patient's immune system, leading to a rapidly progressive case of AIDS.⁹⁷ His vaccinia did appear to resolve before his death.⁹⁸ Given the lack of knowledge about AIDS and HIV at the time, and the unavailability of modern anti-HIV drugs, it is unknown whether he would have had the same course with modern aggressive treatment.

Taken together, these two studies, plus the other work literature, must be read as indicating that immunizing or exposing a person with a cellular immunity defect such as HIV to smallpox vaccine has a high probability of serious illness and death. It has been informally reported that many military personnel with HIV were vaccinated without these side-effects. If true, these data should be made available to help health care workers and others make an informed decision about accepting vaccination. At this writing, these cases have still not been published, and they were not available at the time health care providers were asked to volunteer for smallpox vaccinations. This led to great uncertainty about the risk of vaccine to the general population, which, unlike the military, had not been screened to eliminate immunosuppressed persons.

As the vaccinations progressed, it was discovered that several vaccinees suffered symptoms of cardiac disease, and three died.⁹⁹ This unexpected complication, occurring in a relatively small population of civilian vaccinees, marked the end of the government's active support of the vaccination of civilian volunteers. While the program was not cancelled, there were few additional persons vaccinated. A retrospective study of cardiac deaths in New York City during the last mass vaccination program for smallpox in 1947 showed no excess cardiac deaths.¹⁰⁰ Given the high prevalence of cardiac illness in the general population, as represented by the civilian volunteers, it is likely that this cardiac illness was not vaccine related, but this is very difficult to prove.

95. *Id.*

96. *Id.*

97. *Id.*

98. *Id.*

99. Centers for Disease Control and Prevention, *Update: Cardiac and Other Adverse Events Following Civilian Smallpox Vaccination—United States, 2003*, 52 MMWR 639 (2003), available at <http://www.cdc.gov/mmwr/PDF/wk/mm5227.pdf> and <http://biotech.law.lsu.edu/cdc/mm5227.pdf#page=11>.

100. Centers for Disease Control and Prevention, *Cardiac Deaths After a Mass Smallpox Vaccination Campaign—New York City, 1947*, 52 MMWR 933 (2003), available at <http://www.cdc.gov/mmwr/PDF/wk/mm5239.pdf> and <http://biotech.law.lsu.edu/cdc/mm5239.pdf> [hereinafter CDC, *Cardiac Deaths*].

VII. LEGAL LIABILITY FOR VACCINE COMPLICATIONS

This section reviews the potential liability for vaccine-related injuries in the absence of any legal immunity under the Homeland Security Act.¹⁰¹ Immunity under the Act is discussed in a later section.

The first level of risk involves the primary immunization of hospital personnel. It is likely that state worker's compensation laws will require employers to pay worker's compensation for all vaccine-related injuries to their employees who are participating in the vaccine program at the hospital's request. Workers who are vaccinated as part of their military duty will be covered by the military's benefits program. Workers at hospitals who do not participate in the vaccination plan but who are vaccinated elsewhere may not be covered by worker's compensation and may not have any source of compensation if they are injured. The CDC recommendations did not include any medical testing to screen employees for immunosuppressive disease or other contraindications before vaccinating them.¹⁰² They were given a questionnaire about conditions such as HIV and cancer, and the decision to vaccinate was based on this self-reporting. Worker's compensation claims could be significant if a person with contraindications to vaccination is inadvertently immunized. There are conflicting reports about whether the vaccine is contaminated with latex, which would pose a significant risk to health care workers with latex allergies.¹⁰³ Some worker's compensation insurance plans have questioned whether they will cover vaccine-related injuries because they are part of a national defense program rather than a workplace activity. Irrespective of whether the insurance carrier pays the claim, the employer will probably be liable for the compensation.

If hospital personnel vaccinate any non-employees, the hospital will be open to the full spectrum of medical malpractice tort liability, in particular failure of informed consent and failure to screen adequately before vaccination. Smallpox vaccine was classified as an investigational new drug (an experimental drug) until recently.¹⁰⁴ In the clinical trials being conducted with the vaccine, all persons are

101. Homeland Security Act, Pub. L. No. 107-296, 116 Stat. 2135 (2002), available at http://biotech.law.lsu.edu/blaw/bt/smallpox/hls_final.htm.

102. See CDC, *Guidance II*, *supra* note 9.

103. DryVax[®] Package Insert, *supra* note 11.

104. Letter from Jerry P. Weir, Ph.D, Director, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, Public Health Service, Food and Drug Administration, to Amy J. Criswell, Wyeth Laboratories, Inc. (October 25, 2002), available at http://biotech.law.lsu.edu/blaw/bt/smallpox/DRYVAX_approval.htm.

tested for HIV, their medical histories are screened, and their family members' medical conditions are evaluated. While DryVax[®] is now an approved drug, the level of screening done in the clinical trials arguably sets the standard of care for pre-vaccination screening. Doing any less for routine immunizations is arguably malpractice. This is a critical issue because many persons do not know that they are immunosuppressed. For example, the CDC has estimated at various times that twenty-five percent to fifty percent of persons infected with HIV do not know they are infected.¹⁰⁵ Given the potential risks from inappropriate immunization, every person should be tested for immune system problems before vaccination. The CDC has not required this in its Smallpox Vaccination Recommendations (updated October 21, 2002),¹⁰⁶ which makes it difficult for hospitals to require it because of various state privacy laws and anti-HIV screening laws. However, an immunosuppressed person who suffered a vaccine injury could still sue for both improper screening and improper informed consent about the risks of vaccination.

The second level of risk involves the spread from an immunized person to an unimmunized person. When smallpox vaccination was performed routinely, such transmission was common. Vaccinia can be transferred to anyone the vaccinated person has close contact with. This can be a family member or fellow worker. Every person who is vaccinated should be counseled and educated about the possible risks to family members and significant others. If there is any question of risk, a public health investigator should review the situation and visit those in close contact.

The largest group at risk are patients in the hospital, especially those who are immunosuppressed. If a health care worker infects a patient with vaccinia, the patient can sue the health care worker and the employer for negligence, in the absence of any protections from the Act.¹⁰⁷ The FDA warning label for the vaccine will make it hard to defend such claims.¹⁰⁸

The third level risk is spread from a secondary case of vaccinia to other third parties. A person with wide-spread vaccinia lesions secondary to eczema or disseminated vaccinia sheds large amounts of virus and is a significant risk to unimmunized persons, especially those with immunosuppression. Persons caring for vaccine complications must be immunized and must follow usual infection

105. See Centers for Disease Control and Prevention, Division of HIV/AIDS Prevention, *Quick Facts: Rapid Testing, April 2003–April 2004*, at http://www.cdc.gov/hiv/rapid_testing/materials/QuickFact_April2004.htm.

106. CDC, *Guidance II*, *supra* note 9.

107. See *infra* Part VIII (discussing a hospital's decision whether to furlough employees).

108. DryVax[®] Package Insert, *supra* note 11.

control guidelines. These patients must be kept away from all immunosuppressed persons, both family members and other patients in the hospital. This will be easy if they are sick enough to require hospitalization because they can then be put in a negative pressure isolation room. Many will not be very sick, but may have large and/or multiple vaccine sores which will shed virus. They need to be very carefully managed, with the help of the health department, to assure that they do not come in contact with any immunosuppressed persons. It may be best to require that initial management of all vaccine complications be done at the health department rather than at the hospital, and that persons needing more intense care be sent to one designated facility which can set up appropriate isolation procedures. Depending on state informed consent law and precedent, the hospital may need to inform all patients admitted or in residence at the time of the immunization program that they may be exposed to smallpox vaccine virus.

Immunization programs pose difficult human resources issues. The military's campaign to immunize troops with anthrax vaccine, a relatively safe vaccine, resulted in many officers refusing immunization and, as reported by the GAO, some officers resigned rather than undergo immunization.¹⁰⁹ It should be expected that some hospital personnel will refuse immunization and others will not be candidates for immunization. Such personnel cannot care for persons with vaccine complications and must be excluded from any situation where they can encounter a person with smallpox in an outbreak. These issues should be worked out with employee representatives and unions before immunizations are offered.

VIII. FURLOUGHING EMPLOYEES

Hospitals traditionally had to decide whether to furlough vaccinated employees until their vaccination healed. Leaving them in the workplace risked spread to patients and other workers. Even if the Act protects against patient lawsuits, hospitals need to prevent patient injuries and the resulting adverse publicity. Furloughing employees is costly and disruptive. The Act is silent on who should pay the cost of furloughs. There is an OSHA ruling on hepatitis B immunizations that indicates that a waiver of liability would be a cost to the employee, and employees should not bear the costs of immunizations.¹¹⁰ Analogizing

109. Anthrax Vaccine: GAO's Survey of Guard and Reserve Pilots and Aircrew, (GAO Rep. GAO-02-445, 2002), available at <http://www.gao.gov/new.items/d02445.pdf> and http://biotech.law.lsu.edu/blaw/GAO/anthrax_military.pdf.

110. Letter from Roger A. Clark, Director, Directorate of Compliance Programs, Occupational Safety & Health Administration, U.S. Dep't of Labor, to Anne M.

to smallpox, the Act's requirement that the vaccination be voluntary seems to require that the employee not bear the cost. Having the employee bear both the risk of injury and the cost of a furlough seems to undermine the intent of the Act.

Hospitals are reluctant to remove workers because of the costs of paying them and hiring others to cover their shifts. If immunized persons stay in the workplace, they pose a risk to immunosuppressed patients and immunosuppressed co-workers. Co-workers are covered by workers compensation insurance, but there are no limits on liability for injuries to third parties, unless covered by the Act. Arguably, some state caps on medical malpractice claims would not apply, because this is not medical malpractice but, rather, a risk arising from an administrative decision.¹¹¹ Even with the Act's protections, the conflicting federal recommendations make deciding whether to furlough employees a difficult question. While the CDC recommendations allow employees to continue working with patients, this conflicts with the FDA approved label for DryVax[®] which states that "Recently vaccinated healthcare workers should avoid contact with patients, particularly those with immunodeficiencies, until the scab has separated from the skin at the vaccination site."¹¹²

This would seem to indicate that vaccinated employees should be removed from patient care, if not from the workplace. The CDC recommendations do not require workers to be removed from the workplace; instead, they recommend that the vaccination sore be carefully bandaged and that the health care workers wash their hands properly.¹¹³ However, the CDC recommendation provides no legal protection, implying that if there is spread, then there was negligent hand washing or vaccination care. If there is secondary spread to patients, the hospital will have to explain why it did not follow the FDA 's warnings. Even if the health care worker and employer are protected from legal liability by the Act, they will face public relations, community, and perhaps regulatory pressures if there are patient injuries.

Preventing spread from vaccinated workers to patients will require the vaccination of workers in small groups so that newly immunized persons can be assigned to work that will keep them away from immunosuppressed patients. This will also mean keeping them from

Sturtz, Assistant General Counsel, VOCA Corp. (July 22, 1993), *available at* <http://biotech.law.lsu.edu/cases/ocmed/07-22-1993.htm>.

111. While there are no direct cases on point, this argument would be based on the assumption that the hospital was not providing medical care when vaccinating employees, but was engaged in a workplace safety action. If the third parties were injured, it would be a business negligence case, not a medical malpractice case because the vaccination of the employee was not part of the patient's medical care.

112. DryVax[®] Package Insert, *supra* note 11.

113. CDC, *Guidance II*, *supra* note 9.

answering emergency calls or other situations where they cannot control the patients that they treat. The larger the population of immunosuppressed patients, the greater the risk. Cancer hospitals and other institutions with large concentrations of immunosuppressed persons should furlough vaccinated workers.

IX. THE HOMELAND SECURITY ACT PROVISIONS FOR LEGAL IMMUNITY

The Homeland Security Act¹¹⁴ (Act) provides general protections for persons and institutions assisting the government during a bioterrorism incident and specific protections for smallpox vaccination programs. The smallpox provisions are found in section 304 of the Act: Conduct of Certain Public Health-Related Activities.¹¹⁵ While the White House wanted to start civilian vaccinations before the Act went into effect, there would have been no legal protections for health care institutions had they proceeded. Health care institutions were unwilling to participate until the immunity provisions were in effect.

The Act went into effect on January 24, 2003, and the Secretary of Health and Human Services (HHS) issued the required Declaration that smallpox poses a potential public health emergency requiring smallpox vaccinations as a countermeasure at the same time.¹¹⁶ This declaration establishes who will be involved in providing the countermeasures. The Act only protects persons involved with the smallpox vaccination program as defined in the Secretary's Declaration.¹¹⁷ This section also gives the Secretary broad powers to define more general countermeasures for bioterrorism threats.¹¹⁸

The Act uses a strategy for legal immunity that has been used in other laws, including the immunity provisions for federally qualified community health centers:¹¹⁹

114. Homeland Security Act of 2002, Pub. L. No. 107-296, 116 Stat. 2135 (2002), available at http://biotech.law.lsu.edu/blaw/bt/smallpox/hls_final.htm. The Act changed numerous sections of the U.S. Code. *Id.* For example, section 214(a)(1)(A) was codified at 6 U.S.C. § 133(a)(1)(A) (2004).

115. *Id.* § 304, codified at 42 U.S.C. 233 (2004), available at <http://biotech.law.lsu.edu/blaw/bt/smallpox/5710-304.htm>.

116. Declaration Regarding Administration of Smallpox Countermeasures, 68 Fed. Reg. 4212 (Jan. 28, 2003), available at <http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2003/pdf/03-2012.pdf> and <http://biotech.law.lsu.edu/blaw/bt/smallpox/HHSdeclaration1-28-03.pdf> [hereinafter Smallpox Declaration]. This declaration has been extended to January 2005. 69 Fed. Reg. 3920 (Jan. 27, 2004), available at <http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2004/pdf/04-1631.pdf>.

117. Smallpox Declaration, *supra* note 116.

118. *Id.*

119. *Motley v. U.S.*, 295 F.3d 820 (8th Cir. 2002), available at <http://biotech.law.lsu.edu/cases/immunity/motley.htm>.

For purposes of this section, and subject to other provisions of this subsection, a covered person shall be deemed to be an employee of the Public Health Service with respect to liability arising out of administration of a covered countermeasure against smallpox to an individual during the effective period of a declaration by the Secretary under paragraph (2)(A).¹²⁰

Deeming covered persons to be employees of the Public Health Service means that any claims for their negligence must be filed against the Federal government under the Federal Tort Claims Act (FTCA),¹²¹ subject to its defenses as discussed below. The Federal Government is substituted for the defendant in such cases, which provides nearly complete legal protection for the hospital or the individual who is the real subject of the claim.¹²² Under the Department of Justice's opinion, reflected in the Secretary's letter, this provision should provide complete immunity for tort claims against health care workers and their institutions. However, there are very likely to be courts who will reject this immunity. At this point, the only way to clarify the immunity provisions will be further legislation by Congress.

Section 304 continues to define covered persons as:

(B) *Covered Person*—The term 'covered person', when used with respect to the administration of a covered countermeasure, includes any person who is—

- (i) a manufacturer or distributor of such countermeasure;
- (ii) a health care entity under whose auspices such countermeasure was administered;
- (iii) a qualified person who administered such countermeasure; or
- (iv) an official, agent, or employee of a person described in clause (i), (ii), or (iii).¹²³

120. Homeland Security Act of 2002, Pub. L. No. 107-296, § 304(p)(1), 116 Stat. 2135 (2002) (codified at 42 U.S.C. § 233(p)(1)), available at http://biotech.law.lsu.edu/blaw/bt/smallpox/hls_final.htm (amending the Public Health Service Act, 42 U.S.C. 233, by adding subsection (p)).

121. Federal Tort Claims Act, Pub. L. No. 79-601, 60 Stat. 842 (codified as amended in scattered sections of 28 U.S.C.). See, LSU Law Center, Medical and Public Health Law Site, *Federal Tort Claims Act*, at <http://biotech.law.lsu.edu/cases/immunity/ftca.htm>, for cases interpreting the FTCA.

122. 28 U.S.C. 2671–2680 (2004).

123. Homeland Security Act of 2002, Pub. L. No. 107-296, § 304(p)(7)(B), 116 Stat. 2135 (2002) (codified at 42 U.S.C. § 233(p)(7)(B) (2004)), available at http://biotech.law.lsu.edu/blaw/bt/smallpox/hls_final.htm.

Persons who actually perform vaccinations are clearly covered by clause (iii). The rest of the hospital's employees are covered by clause (iv). One major problem, however, is that most physicians who provide care in hospitals are independent contractors. Even in university teaching hospitals, where everyone appears to work for the hospital, it is common for the physicians to work for an independent company that contracts with the hospital. The law in most states recognizes this independent contractor arrangement and holds that physicians are not officials, agents, or employees of the hospital.¹²⁴ This is a basic premise of hospital liability law: in most states, a plaintiff cannot sue the hospital for the malpractice of a physician on the medical staff because the physician is not an agent or official of the hospital. Thus there is strong precedent, and even statutory law, that physicians do not meet the requirements of clause (iv) to be covered by the provisions of section 304 unless they are personally vaccinating others or are employees of the hospital.¹²⁵ A court could rule that a vaccinated physician who spreads the virus can be sued personally and is not covered by the Act.

On December 9, 2002, the CDC posted a Question and Answer on the immunity provided by section 304 of the Homeland Security Act.¹²⁶ Contrary to the reading of the Act by most other legal experts, the CDC has concluded that the Act would not cover most hospitals:

Q.16. Will hospitals or other institutions who employ vaccinees but who do not operate as a clinic administering countermeasures be covered by Section 304 protections?

A.16. Generally, no. Only hospitals and institutions under whose auspices countermeasures are administered are covered by Section 304 protections.¹²⁷

While the CDC's legal interpretation is not binding on the federal courts, it is a significant red flag because it must be assumed that the

124. *Grewe v. Mt. Clemens Gen. Hosp.*, 273 N.W.2d 429 (1978) (as expanded in *Chapa v. St. Mary's Hosp. of Saginaw*, 480 N.W.2d 590 (1991)). See also *Fiorentino v. Wenger*, 227 N.E.2d 296 (N.Y. 1967).

125. Some physicians, such as emergency room physicians, who look like employees to patients, have been found to be ostensible agents. See, e.g., *Torrence v. Kusminsky*, 408 S.E.2d 684 (W.Va. 1991); *Jacoves v. United Merchandising Corp.*, 11 Cal. Rptr. 2d 468 (Cal. Ct. App. 2d Dist.), review denied (1992); *Drennan v. Community Health Inv. Corp.*, 905 S.W.2d 811 (Tex. Ct. App.-Amarillo), rehearing overruled (1995), writ denied (1996); and *Burless v. W. Va. University Hospitals, Inc.*, 601 S.E.2d 85 (W.Va. 2004).

126. Centers for Disease Control and Prevention, *Smallpox Questions and Answers, Section 304 of the Homeland Security Act (Dec. 9, 2002)*, available at <http://biotech.law.lsu.edu/blaw/bt/smallpox/section-304-qa.pdf>.

127. *Id.*

CDC is privy to more information about the legislative intent of the Act than has been made generally available. It will also be given deference by any judges who want to limit immunity under the Act. The CDC is also recommending that the vaccine be administered by health departments; this would leave most hospitals subject to open-ended tort liability for all vaccine related claims. The CDC later issued a revised Q&A¹²⁸ and a Guidance for the Healthcare Community Concerning Section 304 of the Homeland Security Act,¹²⁹ which track the Secretary's views.

In addition, a group of Democratic senators filed Senate Bill 6¹³⁰ in the 108th Congress which claimed, as a sense of Congress, that the Homeland Security Act only grants immunity to hospitals that have their own staff administer the vaccine and that the vaccinated health care worker him/herself is not given immunity by the Act if he/she infects another person with vaccinia.¹³¹ Such a reading of the original clause (iv), the text in effect at the time of the vaccination campaign, is very strained—except for the independent contractor physicians on the medical staff, other health care workers in a hospital who are vaccinated should be agents or employees, and the hospital should be covered if it supports the vaccinations. It is unclear whether this “sense of the Congress” provision really reflects the legislative history of the Act or whether it was an

128. Centers for Disease Control and Prevention, Smallpox Questions and Answers (Revised), Section 304 of the Homeland Security Act (Jan. 17, 2003), available at <http://biotech.law.lsu.edu/blaw/bt/smallpox/section-304-qa-revised.pdf>. See also, Centers for Disease Control and Prevention, *Questions and Answers: Smallpox Vaccination Program Implementation: Liability Issues*, at <http://www.bt.cdc.gov/agent/smallpox/vaccination/vaccination-program-qa.asp?type=cat&cat=Smallpox+Program+Implementation&subCat1=Liability+Issues>.

129. Centers for Disease Control and Prevention, Guidance for the Healthcare Community Concerning Section 304 of the Homeland Security Act (Jan. 17, 2003), available at <http://www.bt.cdc.gov/agent/smallpox/vaccination/pdf/healthcare-304-guidance.pdf> <http://www.bt.cdc.gov/agent/smallpox/vaccination/healthcare-304-guidance.asp>, and <http://biotech.law.lsu.edu/blaw/bt/smallpox/healthcare-304-guidance.pdf>.

130. S. 6, 108th Cong. (2003), available at <http://biotech.law.lsu.edu/blaw/bt/smallpox/2003s6VII.htm>. As of mid-August, 2004, the bill was still waiting action in the Senate's Judiciary Committee.

131. *Id.* § 7001, available at <http://biotech.law.lsu.edu/blaw/bt/smallpox/2003s6VII.htm>.

"The Homeland Security Act of 2002 failed to protect from liability a vaccinated person who transmits vaccinia accidentally. This section should be amended to protect these people from liability. The section also failed to protect hospitals that did not administer the vaccine, but employ vaccinated health workers. The section should be amended to clarify which hospitals are covered." *Id.* § 7001(7).

attempt to undermine the immunity provisions to enable tort actions to be filed against hospitals who participate in the smallpox immunization program.

The Secretary of HHS has released a letter that contradicts the reading of the bill by the CDC and the Senators who filed it.¹³² He wrote:

You asked whether liability protection is available under the following scenario:

Healthcare worker from Hospital A is vaccinated at Hospital B and then sheds vaccinia to a patient at Hospital A while working within the scope of employment.

It is our intention to word the Section 304 Declaration to include the Secretary's determination that hospitals that designate employees to receive smallpox countermeasures under the state's smallpox vaccination plan are participants in the program and thus are healthcare entities under whose auspices the countermeasure is administered. After consulting with the U.S. Department of Justice, we believe that under this scenario Hospital A would be deemed a covered person under the Act.¹³³

The Declaration by the Secretary of HHS attempts to deal with the coverage of the Act in two ways.¹³⁴ First, it broadens the definition of a covered countermeasure:

Administration of a countermeasure such as smallpox vaccine is necessarily more involved than the act of placing a drop of vaccine on a two-pronged needle and inoculating a person's arm. Determining who is contraindicated; monitoring, management, and care of the countermeasure site; evaluation of countermeasure "takes;" and contact transmission of vaccinia, among other things, all arise out of and are directly related to and part of the administration of the countermeasure. All such acts also potentially give rise to legal liability that, without sufficient protections, may significantly discourage participation in the smallpox vaccination program.¹³⁵

132. Letter from Tommy G. Thompson, Secretary, U.S. Department of Health and Human Services, to Dick Davidson, President, American Hospital Association (January 9, 1993), *available at* <http://biotech.law.lsu.edu/blaw/bt/smallpox/hhs1-9letter.pdf>.

133. *Id.*

134. Smallpox Declaration, *supra* note 116.

135. *Id.*

This provision of the declaration must be read in conjunction with the language of the enabling statute giving the Secretary the authority to issue this part of the declaration:

(ii) *Covered Countermeasure*—The Secretary shall specify in such declaration the substance or substances that shall be considered covered countermeasures (as defined in paragraph (8)(A)) for purposes of administration to individuals during the effective period of the declaration.¹³⁶

The referenced paragraph (incorrectly referenced in the statute as (8)(A), which does not exist, rather than (7)(A)), uses a much narrower definition of covered measure:

(A) *Covered Countermeasure*—The term ‘covered countermeasure’, or ‘covered countermeasure against smallpox’, means a substance that is—
 (I) used to prevent or treat smallpox (including the vaccinia or another vaccine); or
 (II) vaccinia immune globulin used to control or treat the adverse effects of vaccinia inoculation; and
 (ii) specified in a declaration under paragraph (2).¹³⁷

When these provisions are read together, the Homeland Security Act seems to limit covered countermeasures to the vaccine, vaccine immunoglobulin, and other substances used to prevent or treat smallpox. Covered countermeasures seems to refer only to substances (drugs and vaccines), not to the service of administering them. Referring to the definition of a person who gets immunity, there is a service-based component: “a qualified person who administered such countermeasure.”¹³⁸ The Secretary’s definition of administer includes every conceivable health care service related to a vaccinated person. There are problems with this broad definition. There are three plain language meanings for “administer:”

1. To manage or conduct, as public affairs; to direct or superintend the execution, application, or conduct of; as, to administer the government or the state.
 2. To dispense; to serve out; to supply; execute; as, to administer relief, to administer the sacrament.
- [Let zephyrs] administer their tepid, genial airs.—Philips.
 Justice was administered with an exactness and purity not before known.—Macaulay.

136. 42 U.S.C. § 233(p)(2)(A)(ii) (2004).

137. *Id.* § 233(p)(7)(A).

138. *Id.* § 233(p)(1)(B)(iii).

3. To apply, as medicine or a remedy; to give, as a dose or something beneficial or suitable. Extended to a blow, a reproof, etc.

A noxious drug had been administered to him.—Macaulay.¹³⁹

While the first definition would seem to work for the Secretary, the Act does not refer to the administration of the vaccination program but the administration of a countermeasure, i.e., a drug or vaccine. This fits definition three much more closely—to give or apply a medicine. In no other context would we equate (a) administering a drug to treat or to prevent a disease with (b) the entire bundle of services involved with managing the disease. For example, would a law giving immunity for administering insulin be taken to protect every aspect of caring for a diabetic patient? The Secretary's reading of the Act might be found permissible, but could as easily be rejected.

The Secretary then tries to modify the statutory language itself:

“Official, agent, or employee” as used in Section 224(p)(7)(B)(iv) of the PHS Act and with respect to health care entities under whose auspices covered countermeasures are administered, includes health care workers who share any employment or other staffing relationship with the health care entity.¹⁴⁰

“Staffing relationship” is not defined in the statute or in health care law more generally. If it means “agent” or “official,” it is circular and does nothing to resolve the problem of independent contractor physicians. If it is an attempt to include independent contractor physicians by including medical staff members, then a court would have to read it against the plain language of the statute, which limits coverage to officials, agents, and employees. This might be a permissible broadening in states that do not recognize the independence of medical staff members. In most states, however, a court will read this provision in the light of specific state case law that says that medical staff members are not agents or officials or employees of hospitals. Those courts are unlikely to find that the secretary has the power to change the legally established standards for agent, official, or employee. This construction problem will be exacerbated by the policy arguments of the plaintiffs. They will argue that the Act's plain language says that it protects vaccine manufacturers, persons vaccinating other persons, persons treating vaccine complications, and the hospitals they work for. Plaintiffs will claim the language was never meant to cover the careless spread

139. Webster's Revised Unabridged Dictionary (1998).

140. Smallpox Declaration, *supra* note 116.

of vaccinia to innocent third parties, and following the Secretary's interpretation would deny compensation to deserving persons.

The simplest way for hospitals to manage the problem of independent contractor risk is to have them sign agency agreements that bring them under the clear language of the Act. Hospitals and health departments should sign written agreements with all independent contractor physicians they will be working with or who practice in their facilities. These agreements should include provisions:

- 1) that the physicians will be participating in the entity's administration of countermeasures as defined by Section 304 of the Homeland Security Act and the Declaration by the Secretary of HHS as authorized under the Homeland Security Act;
- 2) that for the purposes of Section 304 immunity the physicians are acting as agents of the hospital or health department and thus are covered by Section 304 immunity and that any claims against the physicians must be brought against the Secretary of HHS as provided in the Homeland Security Act; and
- 3) that this agency agreement for the purposes of participating in the smallpox vaccination plan does not make these physicians agents of the hospital or health department for any other purpose.

These agreements should be signed before the hospital participates in the plan. Ideally, the agreement will be between the health department and the contractors. This will prevent the agreements from being used as evidence of a general agency relationship in vicarious liability cases alleging that a negligent physician was an agent of the hospital.

X. NON-PARTICIPATING HOSPITALS

Many hospitals chose to defer their participation in the smallpox vaccination program. These decisions were based on many factors, including the continuing ambiguity of the legal protections provided by section 304, the problem of compensating injured workers and others, and fundamental questions about the epidemiologic soundness of the program. Nevertheless, these hospitals had to develop a policy to deal with health care workers who were vaccinated during military reserve duty or who want to be vaccinated outside the hospital's own program.

Workers vaccinated by the military are covered by the military's compensation program rather than the hospital's worker's

compensation insurance. This program probably does not provide protection for the hospital if a patient or a co-worker contracts vaccinia from a vaccinated reservist who has returned to the hospital before the vaccine sore has healed.¹⁴¹ Ideally, such vaccinated persons would be removed from patient care until they are no longer infectious, but many hospitals cannot afford the financial or staffing problems such removal would create.

Employees of a non-participating hospital who seek vaccination on their own pose more difficult issues. It is arguable that if these persons suffer a vaccine-related injury, they will not be covered by the hospital's worker's compensation program because they were vaccinated outside of work and there is no benefit to the employer. A non-participating hospital could establish a policy that any employee who undergoes vaccination elsewhere must take personal time off from work until the vaccine sore heals. Such a decision could have adverse consequences for a hospital's reputation; for instance, the hospital might be seen as unpatriotic. It is possible in some states that the person could sue under state law to be paid for the lost time, but the success of such an action would depend on specific state provisions that are beyond the scope of this article.

If the hospital wants to prevent vaccinated workers from returning until they are non-infectious, it should adopt a clearly argued policy statement about why the institution is not participating in the program and why vaccinated employees pose a threat to patients and other workers. Such a policy is apt to be critical in defending against claims for lost wages by furloughed employees.

If the hospital wants to allow these vaccinated workers to return to the workplace, it should enter into an agreement with the local or state health department. This agreement should state that while the hospital is not recommending that its employees be vaccinated at this time, it is participating in the smallpox immunization plan by allowing employees who have been vaccinated away from work to continue working in the facility. The purpose of this agreement is to

141. For example, the Army's smallpox web site contains only the following consideration of liability to third parties:

Civilian Healthcare Responsibilities

1) I just got vaccinated against smallpox and I "moon-light" at a civilian hospital downtown. Should I tell the civilian hospital?

Yes. You should inform the other hospital of your recent vaccination and tell them about your bandaging procedures and infection-control practices.

You should then abide by any further instructions from the civilian hospital.

Dep't of Defense Smallpox Vaccination Program, *Resource Center: Q&A: Civilian Healthcare Responsibilities*, at <http://www.smallpox.mil/resource/qaAll.asp?cID=140>.

deflect arguments that hospitals that do not recommend vaccinations are not covered by section 304.

XI. IS WORKER'S COMP COVERED BY THE ACT?

The Act's immunity applies to "liability arising out of administration of a covered countermeasure against smallpox to an individual"¹⁴² Such immunity clearly applies against a person suffering a vaccine complication who wants to sue for medical malpractice or products liability related to bad vaccine or negligent administration. It probably does not apply to worker's compensation claims by hospital employees injured by vaccination. Worker's compensation is a not a liability claim, but a statutory trading of liability claims for an insurance system that does not require a showing of fault for compensation. A court construing this section would also have strong policy grounds for finding that it does not apply to worker's compensation claims: if this provision blocks such claims, then an injured employee would receive no compensation at all. Thus, we predict that the court would likely find a manifest injustice if the employee is injured in the course and scope of his/her job, yet has no avenue for compensation for medical costs and lost wages.

XII. PROTECTIONS FOR SECONDARY SPREAD

Other provisions of the Act create a rebuttable presumption that secondary spread of vaccinia is due to the vaccination of a person covered by the Act and therefore is a case covered by the Act.¹⁴³ Thus, patients or family members who suffer vaccine-related injuries from contact with a vaccinated person would have to sue for compensation under the provisions of the FTCA. To rebut this presumption, the plaintiff would have to show that he/she was exposed to vaccinia through an unauthorized source of vaccine.

XIII. BLACK-MARKET VACCINE

Section 304 does not apply to claims for vaccine that is administered outside the federally-sponsored program, i.e., black-market vaccine, which is the only way someone could be exposed to vaccinia that did not originate with the federal immunization program. Given public demand for vaccine, some almost certainly will be diverted and used for family members or sold on the black

142. 42 U.S.C. § 233(p)(1) (2004).

143. *Id.* § 233(p)(2)(c).

market. Furthermore, it is relatively easy to use traditional vaccination techniques described in old texts to extract vaccinia-laden tissue from an active vaccine sore and use that tissue to immunize others. These activities are not covered by the Act and would be subject to existing state and federal tort and criminal laws.

XIV. RECOVERY UNDER THE FTCA

The FTCA waives the sovereign immunity of the United States and allows certain tort claims to be brought against the United States and its employees.¹⁴⁴ The FTCA applies to negligent torts, and the standard for proving negligence is drawn from the tort law of the state where the incident happened. The FTCA does not allow products liability or strict liability claims. It is an administrative compensation system and requires that a claim be filed with the government before the plaintiff can go to court.¹⁴⁵ If the government does not act on this claim or does not make a satisfactory offer of settlement, the plaintiff may then go to court.¹⁴⁶

The United States may use the tort defenses allowed by state law. The United States may also rely on a statutory defense provided in the FTCA, the discretionary authority provision:

based upon an act or omission of an employee of the Government, exercising due care, in the execution of a statute or regulation, whether or not such statute or regulation be valid, or based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the

144. The FTCA does not apply to active duty military personnel, whose only remedies are through military compensation systems. *Feres v. U.S.*, 340 U.S. 135, 71 S. Ct. 153, (1950), available at http://biotech.law.lsu.edu/cases/immunity/feres_v_us.htm.

145. Overview—Section 304: Liability Protection for Injury Claims Arising out of Administration of Smallpox Countermeasures (January 14, 2003), available at <http://www.bt.cdc.gov/agent/smallpox/vaccination/images/liability-protection-flowchart.gif>, and <http://biotech.law.lsu.edu/blaw/bt/smallpox/liability-protection-flowchart.gif> (CDC Claims Flowchart). The chart, captioned “Flowchart: Liability Protection for Injury Claims Arising out of Smallpox Countermeasures,” is included on the CDC web site in a series of questions and answers. at: <http://www.bt.cdc.gov/agent/smallpox/vaccination/vaccination-program-qa.asp?type=cat&cat=Smallpox+Program+Implementation&subCat1=Liability+Issues>. See also *Motley v. U.S.*, 295 F.3d 820 (8th Cir. 2002), available at <http://biotech.law.lsu.edu/cases/immunity/motley.htm>.

146. More information on this claims process see, LSU Law Center, Medical and Public Health Law Site, *Federal Tort Claims Act: Brief—Medical Malpractice Claims Against Public Health Service and Federally Funded Community Health Center Physicians*, at http://biotech.law.lsu.edu/cases/immunity/malpractice_ftca.htm.

Government, whether or not the discretion involved be abused.¹⁴⁷

*Varig Airlines*¹⁴⁸ was a tort claim which asserted that the FAA was negligent because it spot-checked a sample of airplanes for a particular problem rather than checking them all.¹⁴⁹ The United States Supreme Court ruled that since the statute and regulations were silent on the proper way to conduct inspections, it was within the agency's discretion to select the inspection technique and that the agency could not be sued for this decision.¹⁵⁰ In *Berkovitz by Berkovitz v. United States*,¹⁵¹ the FDA was sued for not requiring full testing information for all batches of polio vaccine.¹⁵² In that case, the United States Supreme Court found that the agency regulations mandated that the FDA have the full information before approving the vaccine, and thus that the agency had no discretion to approve vaccine without the complete information.¹⁵³ These two cases set out the key parameters for the discretionary authority defense: the agency must follow statutes and regulations, but if these allow a policy decision to be made by the agency, the agency cannot be sued on the plaintiff's allegation that this decision was negligent.

XV. CONTRAST WITH THE SWINE FLU LEGISLATION

Until the 1970s, there was no expectation of compensation if someone was injured by a vaccine. There had been some tort claims based on impure vaccines, but these were exceptional.¹⁵⁴ Most people obtained vaccinations for themselves and their children because they were frightened of contracting the diseases at which the vaccines were directed. While there have always been persons who opposed vaccination, they were a tiny minority, and legal policy reflected the majority view that vaccine injuries were the necessary cost of reducing one's risk of contracting a deadly disease. As these diseases were eradicated or reduced to sporadic outbreaks, people

147. 28 U.S.C. § 2680(a) (2004).

148. *United States v. S.A. Empresa de Viacao Aerea Rio Grandense (Varig Airlines)*, 467 U.S. 797, 104 S. Ct. 2755 (1984), available at <http://biotech.law.lsu.edu/cases/immunity/varig.htm>.

149. *Id.*

150. *Id.*

151. *Berkovitz by Berkovitz v. U.S.*, 486 U.S. 531, 108 S. Ct. 1954 (1988), available at http://biotech.law.lsu.edu/cases/immunity/Berkovitz_by_Berkovitz.htm.

152. *Id.*

153. *Id.*

154. For a compilation of vaccine liability cases see LSU Law Center, Medical and Public Health Law Site, *Vaccine Law*, at <http://biotech.law.lsu.edu/cases/vaccines/index.htm>.

became less tolerant of vaccine injuries, which led to the discontinuation of smallpox vaccinations in the early 1970s. As these diseases faded from memory, tort lawyers and vaccine opponents convinced people that vaccines were dangerous, fueling resistance to vaccinations and a tsunami of litigation.¹⁵⁵

The breakdown of community support for vaccinations and the resulting legal repercussions were exacerbated by the swine flu immunization program in 1976. Swine flu, so named because it was first detected in pigs, worried flu specialists at the CDC because they believed that it resembled the virus responsible for the 1918-1919 Spanish flu pandemic. Spanish flu had swept the world, killing hundreds of thousands in the United States and tens of millions worldwide.¹⁵⁶ The CDC pushed for an emergency vaccination program for swine flu. Given the time frame for vaccine production and testing, and given the legal climate in 1976, the vaccine manufacturers refused to produce vaccine unless they were given complete legal protection. Congress enacted legislation protecting the manufacturers by shifting the legal liability to the United States.¹⁵⁷ Since the backers of the immunization program did not foresee any significant complications, this was a generous fund which made it easy to recover against the government.¹⁵⁸

The Homeland Security Act provisions for smallpox vaccine injury compensation also treat all claims for liability as claims against the United States.¹⁵⁹ The plaintiff files a claim as if he is suing a United States Public Health Service employee. This makes

155. See Fenner, *supra* note 12, at 309-11, *see, e.g.*, *Gottsdanker v. Cutter Laboratories*, 6 Cal. Rptr. 320 (Cal. App. 1st Dist. 1960); *Reyes v. Wyeth Lab.*, 498 F.2d 1264 (5th Cir. 1974).

156. Public Broadcasting Service, *A Science Odyssey: People and Discoveries: Worldwide Flu Pandemic Strikes, 1918-1919*, at <http://www.pbs.org/wgbh/aso/databank/entries/dm18fl.html> (last accessed Oct. 6, 2004) [hereinafter PBS, *Worldwide Flu*]. The 1919 outbreak killed more civilians in peacetime than the contending militaries lost in combat in World War I. World War I military casualties amounted to 8.5 million killed and about 21 million wounded. Public Broadcasting Service, *World War I Casualty and Death Tables*, at http://www.pbs.org/greatwar/resources/casdeath_pop.html (last accessed Oct. 6, 2004). By contrast, the flue epidemic killed, worldwide, about 21 million people by late 1919. PBS, *Worldwide Flu*, *supra* this note.

157. National Swine Flu Immunization Program of 1976 (The Swine Flu Act), Pub. L. No. 94-380, 90 Stat. 1113 (1976) (codified at 42 U.S.C. § 247b(j)-(l) (1976)) (repealed by Pub. L. No. 95-626, 92 Stat. 3574 (1978)).

158. See *In re Swine Flu Immunization Products Liability Litigation*, 533 F. Supp. 703, 719 (D. Utah 1982), *aff'd by Unthank v. U.S.*, 732 F.2d 1517 (10th Cir. 1984).

159. Homeland Security Act of 2002, Pub. L. No. 107-296, 116 Stat. 2135 (2002) (codified at 42 U.S.C.), available at http://biotech.law.lsu.edu/blaw/bt/smallpox/hls_final.htm.

the FTCA the measure of damages and liability. This approach is superficially similar to the protections given the manufacturers of the swine flu vaccine. It is possible, but unknown, that Congress intended to give the same protections to persons injured by smallpox vaccine that it gave to persons injured by swine flu vaccine. However, despite the superficial resemblance of section 304 to the swine flu legislation, the language in the swine flu immunity statute was very different. The Swine Flu Act provides:

[T]he liability of the United States arising out of the act or omission of a program participant may be based on any theory of liability that would govern an action against such program participant under the law of the place where the act or omission occurred, including negligence, strict liability in tort and breach of warranty.¹⁶⁰

By contrast, the FTCA does not recognize strict liability claims and probably does not recognize breach of warranty claims. These theories were used in most of the swine flu cases but would not be available to persons injured by smallpox vaccine. More importantly, the *Unthank* court found that the legislative history of the swine flu legislation indicated that this language was intended to set up a no-fault compensation scheme:

The trial court was particularly impressed, as we are, with the explicit statements of Senator Harrison A. Williams, Jr. of New Jersey in discussing the reasons for enacting this bill establishing liability against the federal government. He said:

This is pioneering in the sense, it has never been done before, but it is in response to an emergency. That is the way the liability fixes upon the government, through the total class act, for *any misfortune which would follow, as defined, the administration of the inoculation and vaccine ...* 192 [sic] Cong.Rec. 26632 (August 10, 1976).

The trial court was also impressed, as we are, with the statement of Congressman Paul G. Rogers of Florida:

[W]e have asked the drug companies to produce this vaccine. We have told them how to do it. We have told

160. National Swine Flu Immunization Program of 1976 (The Swine Flu Act), Pub. L. No. 94-380, § 2, 90 Stat. 1113 (1976) (codified at 42 U.S.C. § 247b(k)(2)(A)(i) (1976)) (repealed by Pub. L. No. 95-626, 92 Stat. 3574 (1978)).

them the dosage we want, what strength. We gave them the specifications because we are the only buyers, the Government of the United States. This is not the usual process of going out and selling. *But if someone is hurt, we think people ought to have a remedy.* [122 Cong.Rec. at] p. 26796.¹⁶¹

Since the courts that considered the claims for injuries caused by swine flu vaccine believed that Congress intended the unusual language in the swine flu immunity law to create a no-fault compensation system, they awarded compensation to all persons who could show that their injuries were caused by the vaccine. Most of these persons claimed to have Guillain-Barré syndrome (GBS). GBS is a progressive paralysis that affects the legs first, and can become fatal if it progresses to the point where it affects the patient's breathing.¹⁶² In most cases it resolves after a few weeks with no long-term problems.¹⁶³ It is diagnosed based on physical examination and has no definitive laboratory findings.¹⁶⁴

Once physicians were notified that there might be a link between the swine flu vaccine and GBS, they were more likely to diagnose non-specific neurological disease such as GBS. More troubling, lawyers who represent injured persons, especially those injured in the workplace and covered by various compensation statutes, work with networks of physicians who can be relied on to provide diagnoses and treatments that support the worker's compensation claims. When patients in these cases were sent to physicians by lawyers, it can be assumed that, as in other compensation cases, these physicians were more likely to make a diagnosis of GBS.

This bias in diagnosis had two effects. First, it resulted in a flood of legal claims. Second, and more troubling, it likely distorted the conclusions that could be drawn about the relation between swine flu and GBS. GBS is rare, and the association with the swine flu vaccine was weak at best. Shifting even a few cases to a diagnosis of GBS would make a huge difference in the statistical association between the vaccine and GBS. Subsequent analysis indicates that there was probably no link between the swine flu vaccine and GBS.¹⁶⁵ This

161. *Unthank v. U.S.*, 732 F.2d 1517, 1520 (10th Cir. 1984), available at <http://biotech.law.lsu.edu/cases/vaccines/Unthank.htm> (emphasis added by the court).

162. National Institute of Neurological Disorders and Stroke, *Guillain-Barré Syndrome Fact Sheet*, at http://www.ninds.nih.gov/health_and_medical/pubs/guillain-barre.htm.

163. *Id.*

164. *Id.*

165. D.A. Freedman & Philip B. Stark, *The Swine Flu Vaccine and Guillain-Barré Syndrome: A Case Study in Relative Risk and Specific Causation*, 23

established the pattern for subsequent vaccine litigation wherein attorneys took the lead in finding experts to identify new injuries, leaving the epidemiologists to try to convince the public that the vaccines are really safe.

The flood of litigation and the interplay between the legal cases and the issue of scientific causation became characteristic of vaccine injury litigation. In the early 1980s, vaccine litigation over baseless claims threatened to drive all the manufacturers out of the business of making vaccines.¹⁶⁶ As vaccine injury litigation began to make it impossible to find companies willing to make vaccine, Congress passed the National Childhood Vaccine Injury Act in 1986.¹⁶⁷ This Act provided compensation for children allegedly injured by vaccines and provided some immunity for vaccine manufacturers.¹⁶⁸ The Act was good politics, if not good policy, and created the expectation that the federal government should provide compensation if it wants people immunized for communicable diseases. This expectation of compensation was heightened for the smallpox vaccine, which is much more dangerous than any other approved vaccine. Most health care providers have balked at being vaccinated because of their own fear of injury and because patients inadvertently injured through secondary transmission have no avenue for compensation under the Homeland Security Act, and hence might bring suit against the provider from whom the disease was contracted. At the same time, Congress was concerned about a law that would provide large financial incentives to persons injured by the vaccine and thus encourage unjustified claims.

XVI. COMPENSATION UNDER THE HOMELAND SECURITY ACT

In contrast with the swine flu law, the Act includes no extensions of liability or modification of the terms of the FTCA. There is also no congressional history to indicate that despite the absence of such language, the House intended that every injured person be compensated. Under the unmodified language of the FTCA, it is very hard to obtain compensation from the government for risks to which the government knew it was exposing people. Since most of

Evaluation Review 619 (1999).

166. Office of Technology Assessment, *Compensation for Vaccine-Related Injuries* (1980), available at <http://www.wws.princeton.edu/cgi-bin/byteserv.prl/~ota/disk3/1980/8005/8005.PDF>; Mary Beth Neraas, *The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis?*, 63 Wash. L. Rev. 149 (1988).

167. National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660 §§ 301-323, 100 Stat. 3755 (1986) (codified in scattered sections of 42 U.S.C.).

168. 42 U.S.C. § 300aa-11 (2004).

the risks of the smallpox vaccine are very well known, by choosing to immunize a given class of persons, the government is making a discretionary decision to expose that class of persons to the risks. This decision cannot be attacked under the FTCA, so it is a defense against claims for smallpox vaccine injuries. The best analogy is the cases in which persons downwind from nuclear test sites sued the government for injuries allegedly caused by exposure to fallout.¹⁶⁹ The district court, in a 255-page opinion, found that these persons had suffered injuries and that the government was liable for exposing them to fallout.¹⁷⁰ In little more than one page, the appeals court held that since the government had decided to expose the plaintiffs to fallout, knowing the risks, it was not liable under the FTCA.¹⁷¹ The court found that while there was statutory language urging the agency to balance the risk of harm to the population against the need for testing atomic bombs, this did not prohibit the agency from deciding that testing was more important than protecting the population from fallout.¹⁷²

In its plain language, without contrary legislative history, the Act appears to require that in order to recover under the FTCA, persons injured by smallpox vaccine must prove that the government or persons acting on its behalf were negligent in administering the vaccine,¹⁷³ simply proving that they were injured by the vaccine would not be enough. There are three areas where negligence is most likely to be alleged: in screening persons for contraindications, in preventing spread to third parties, and informing persons of the risks of the vaccine. If the government is careful to document its decisions in these areas and to explain why these decisions reflect its determination of public policy, it can probably escape liability for all injuries that it anticipates and addresses in a policy statement. For example, while it is clear that every person being immunized should undergo clinical testing for immune status (a complete blood count and an HIV test would be a minimum), if the government says that such testing would interfere with the protection of the public, and that it was aware that failing to test would injure some persons, then it would have no liability under the FTCA.

169. *Allen v. U.S.*, 588 F. Supp. 247 (D.C. Utah 1984).

170. *Id.*

171. *Allen v. U.S.*, 816 F.2d 1417 (10th Cir. 1987), available at <http://biotech.law.lsu.edu/cases/immunity/abomb03.htm>.

172. *Id.*

173. The Homeland Security Act is silent on the specific standard of proof, but it provides that these claims be brought as if they were claims against the Public Health Service. Claims against the Public Health Service are governed by the Federal Tort Claims Act. See *Berkovitz by Berkovitz v. U.S.*, 486 U.S. 531, 108 S. Ct. 1954 (1988); *Prescott v. U.S.*, 973 F.2d 696 (9th Cir. 1992); *U.S. v. St. Louis University*, 336 F.3d 294 (4th Cir. 2003).

The Act provides useful, but incomplete, protection for hospitals whose personnel are immunized against smallpox. It is the authors' opinion that the statute leaves the hospital liable for worker's compensation costs for injured employees. It does relieve the hospital of liability for secondary spread, which poses the greatest legal risk. It does not, however, make the government liable for such spread. Thus patients and family members injured by the vaccine will not have any recourse and will receive no compensation, even for permanent disability or death. In the worst-case scenario, their private insurance carriers will deny coverage because the injuries were related to the preparation for an act of terrorism or war, as specified in the required declaration by the Secretary.

The care of these injured persons would need to take place somewhere. Would hospitals refuse to care for their own patients or their workers' family members who are injured by the hospital's vaccination plan? Would state and local governments be prepared to bear the burden of caring for these people? Hospitals and health care unions have made it clear from the first discussions of a smallpox vaccination plan for health care workers that compensation for injured workers is a necessary part of any plan.¹⁷⁴

XVII. THE ROLE OF THE LOCAL PUBLIC HEALTH OFFICIALS

The smallpox vaccination plan was set up to be carried out through local public health agencies (LPHAs). This is consistent with the traditional role of the CDC, the implementation agency for the plan. Historically, the CDC has acted as an advisory agency to state and local health departments. With the exception of the inspection of cruise ships,¹⁷⁵ the CDC is not an enforcement agency and does not

174. Letter from Herb Kuhn, Corporate V. Pres., Premier Advocacy [of Premier Health Plan] and Michael Rodgers, V. Pres., Public Pol'y and Advocacy, Catholic Health Assoc. of the U.S., to Tommy G. Thompson, Secretary, U.S. Dep't of Health and Human Services (October 28, 2002), *available at* <http://biotech.law.lsu.edu/blaw/bt/smallpox/smallpox-ltr-1002.pdf>. (Note that their letter was written almost two months before President Bush made his program announcement on December 13, 2002. *See supra* note 2.); Press Release, Texas Nurses Association, Clair Jordan, MSN, RN, Executive Director, Texas Nurses Association Urges Caution For Texas Nurses Volunteering For Smallpox Vaccine (January 31, 2003), *available at* <http://biotech.law.lsu.edu/blaw/bt/smallpox/tna.pdf>; Press Release, Service Employees International Union, Nation's Largest Health Care Union Warns That, Without Better Safeguards, Plan Itself Poses Public Health Risks (December 3, 2003), *available at* <http://biotech.law.lsu.edu/blaw/bt/smallpox/SEIU-smallpox-.pdf>.

175. The Vessel Sanitation Program (VSP) is described by the CDC as "a cooperative activity with the cruise ship industry . . . in order to minimize the risk of gastrointestinal diseases." Centers for Disease Control and Prevention, *About the Vessel Sanitation Program*, at <http://www.cdc.gov/nceh/vsp/desc/aboutvsp.htm> (last accessed Oct. 6, 2004).

have local offices in the states. In theory, it comes into the states only at the request of the state for assistance. This role is reflected in the lack of a national disease reporting system or uniform standards for disease reporting. Individual states decide which diseases are reportable, the definition of reportable conditions, who has the duty to report, and how reporting is enforced. States then transmit whatever data they choose to the National Center for Health Statistics of the CDC. The result is a hodge-podge of reporting standards, with some states not requiring basic reporting data even on major disease threats such as HIV infection.

This role has changed dramatically, if quietly, as the CDC has become a conduit for federal public health funds, and as states have reduced their own support for public health. The CDC is now a critical source of funds for many public health efforts, and it uses its spending power to shape state and local public health programs. This dependence on CDC funding has reduced the independence of state health departments, especially those that have the least amount of state funding. They must meet CDC standards and objectives to obtain the federal money that is critical for their day-to-day operations. In general, this system improves the standards for local public health, but it also makes some state and local health departments less willing to speak up when they believe that a federal program is not in the best interest of their community or will cannibalize resources needed for other public health activities.

While the smallpox vaccination plan did include some funding, many departments feared, quite correctly, that the demands on their staff and resources would exceed the funding provided for the program. They were also concerned that they would not have the resources necessary to properly oversee a large-scale vaccination program that would primarily be carried out in hospitals. LPHAs should have been prepared to work with hospitals to train workers about the risks of smallpox immunization and the management of immunization complications. LPHAs should have been prepared to investigate home situations as appropriate to ensure the safety of the family members and significant others of persons who volunteer for vaccinations. All screening and immunization should have been carried out by state or local health department employees, not by hospital personnel. This approach would have solved many of the questions about privacy issues raised by screening and about liability for vaccinations. It would have shifted any liability for negligent screening or unforeseen reactions to the state. Few health departments were willing to take on these responsibilities because of legal and staffing concerns. Since smallpox vaccination was intended as a public health program, this further undermined the support of the plan by hospitals and other institutional health care providers.

XVIII. IS THE SMALLPOX VACCINATION PLAN WORTH THE RISK?

The biggest unknown about the smallpox vaccination plan was the risk of an outbreak of smallpox versus the risk of the vaccination plan. Unfortunately, of course, probability information is impossible to obtain for bioterrorist activities. As discussed previously, smallpox is more problematic than most possible bioterror agents because there is no clear evidence that the virus is available to terrorists. Unlike agents such as anthrax and plague, which are readily available because they are used by many laboratories and because they have animal reservoirs, smallpox virus will be available only if it has been diverted from the Soviet bioweapons program. It is assumed that this information was kept from the CDC and other public health experts until the late 1990s because the government did not think it posed a significant threat. Had there been a decision in 1993 that smallpox posed a threat, work should have begun then on a safe alternative vaccine.¹⁷⁶

The announcement of the smallpox vaccination plan was not accompanied by any information about why smallpox now had

176. Many public health experts were recommending the destruction of the remaining virus stocks as late as 1999, on the assumption that these laboratory stocks were the only remaining source of the smallpox virus. For a history of this movement and how destruction of the virus was postponed, see World Health Organization, Advisory Committee on Variola Virus Research, Report of the Fifth Meeting, Geneva, Switzerland (Nov. 4–5 2003), available at http://www.who.int/csr/resources/publications/WHO_CDS_CSR_GAR_2004_15/en/ and http://biotech.law.lsu.edu/blaw/bt/smallpox/who/WEBWHO_CDS_CSR_GAR_2004_15.pdf; World Health Organization, Executive Board, 111th Session, *Smallpox Eradication: Destruction of Variola Virus Stocks: Report by the Secretariat*, Provisional Agenda Item 5.3, EB 111/5 (Dec. 23, 2004), available at http://www.who.int/gb/ebwha/pdf_files/EB111/eeb1115.pdf and <http://biotech.law.lsu.edu/blaw/bt/smallpox/who/eeb1115.pdf>; World Health Organization, Executive Board, 109th Session, *Smallpox Eradication: Destruction of Variola Virus Stocks: Report by the Secretariat*, Provisional Agenda Item 3.14, EB 109/17 (Dec. 20, 2001), available at http://www.who.int/gb/ebwha/pdf_files/EB109/eeb10917.pdf and <http://biotech.law.lsu.edu/blaw/bt/smallpox/who/eeb10917.pdf>; World Health Organization, Executive Board, 106th Session, *Smallpox Eradication: Destruction of Variola Virus Stocks: Report by the Secretariat*, Provisional Agenda Item 5, EB 106/3 (Apr. 10, 2000), available at http://www.who.int/gb/ebwha/pdf_files/EB106/ee3.pdf and <http://www.biotech.law.lsu.edu/blaw/bt/smallpox/who/ee3.pdf>; World Health Organization, Fifty-Second World Health Assembly, *Smallpox Eradication: Destruction of Variola Virus Stocks: Report by the Secretariat*, Provisional Agenda Item 13, A52/5 (Apr. 15, 1999), available at http://www.who.int/gb/ebwha/pdf_files/WHA52/ewd2.pdf and <http://biotech.law.lsu.edu/blaw/bt/smallpox/who/ew5.pdf>; World Health Organization, *Smallpox Eradication: Destruction of Variola Virus Stocks*, 74 Wkly. Epidemiological Rec. 188 (1999), available at <http://www.who.int/docstore/wer/pdf/1999/wer7424.pdf> and <http://biotech.law.lsu.edu/blaw/bt/smallpox/who/wer7424.pdf>.

become a priority, and in fact, the announcement stated that there was no new, specific risk. There were heated debates in 1972 about whether smallpox vaccinations should be stopped, with a significant faction arguing that ending vaccinations would eventually create an environment that would support a global pandemic of smallpox.¹⁷⁷

That fear has now come to pass, with the events of 9/11 reopening the debate about the wisdom of continuing a world that is susceptible to smallpox. If there is a real risk of smallpox, then perhaps the question should be whether we resume routine vaccinations for healthy persons, not whether we will vaccinate a small group of volunteers. If a safer vaccine is developed, resuming smallpox vaccinations might make sense. With the current vaccine, on the other hand, the politics of immunosuppression secondary to HIV complicates the risk calculus—will it really be possible to protect immunosuppressed persons from vaccination and secondary spread while keeping their immune status secret?

The best rationale for the smallpox vaccination plan was to prepare a cadre of medical care providers and front-line emergency services providers who could deal with cases of smallpox as part of community response teams. If a smallpox case was identified, teams could focus on the patients while other health care workers were being vaccinated and were vaccinating others. This could have been accomplished if the plan had been set up to recruit volunteers with specific skills. Such volunteers would have been vaccinated by the health department personnel, would have been kept away from direct patient care until the vaccine sore had healed, and would have been assured of adequate compensation if they were injured. This would have solved the worker's compensation and liability issues for the hospitals, and would have addressed the volunteers' fears about whether they would be compensated if injured. By focusing on a team for the community, rather than requiring each hospital to have its own team, relatively few health

177. The American Journal of Epidemiology published a pair of contrasting articles contending this precise point. S.L. Katz, *The Case for Continuing "Routine" Childhood Smallpox Vaccination in the United States*, 93 Am. J. Epidemiology 241 (1971); J.M. Neff, *The Case for Abolishing Routine Childhood Smallpox Vaccination in the United States*, 93 Am. J. Epidemiology 245 (1971). Additionally, at least one monograph has been devoted to the issue. James C. Frauenthal, *Smallpox: When Should Routine Vaccination be Discontinued?* (UMAP Exploratory Monograph Series, 1981). Fenner alludes to this debate in Chapter 30, "Potential Sources for a Return of Smallpox," *supra* note 12, at 1341. Also note the reaction of many in the medical community to a smallpox death in an English laboratory accident in 1978: "[m]edical Health administrators in the developing countries of Africa, in particular, renewed their calls for the cessation of laboratory studies of variola virus and the destruction of all stocks of the virus." *Id.* at 1097.

care workers would have been needed, which would have reduced the cost of carrying out the plan.

Instead, the plan was oriented to individual hospitals, on the assumption that smallpox patients would be flooding the hospital emergency rooms and would be treated at every hospital. There were no distinctions drawn between general acute care hospitals and specialty hospitals such as cancer treatment centers which do not take walk-in patients. Vaccinated health care workers would care for these patients in their hospitals. This plan makes no provision for the other patients in the hospital. Hospitals have a very limited number of isolation beds suitable for smallpox, and almost no hospitals have a safe way to transport patients from the front door into those rooms without exposing others. If there are more than a small number of smallpox cases, a hospital will no longer be able to isolate them. At that point all the other patients and unvaccinated staff would have to be moved out and the facility converted to a smallpox hospital, or the smallpox patients would have to be sent away.

Smallpox cases should not be admitted or treated in every hospital in the community. They should be sent to designated regional smallpox hospitals. To minimize the risk of secondary spread of smallpox, a regional smallpox hospital should not house a significant number of immunosuppressed persons. There should be a plan for how to evacuate all patients and unimmunized staff to other facilities should smallpox be identified in the community. Ideally, a regional hospital should be run by a government entity that is shielded from lawsuits by sovereign immunity. This would allow compensation under a tort claims act. These regional hospitals should be federal hospitals such as Veterans Administration hospitals because the federal government has the best tort law protection and the best ability to absorb other costs such as worker's compensation claims. More importantly, a federal facility will be able to absorb the tremendous financial risks of treating smallpox cases, including the potential closing of the facility if decontamination proves impossible.¹⁷⁸ This is important even if the Homeland Security Act immunity is in place to prevent tort claims.

The plan also fails to deal with the health care workers who cannot be immunized. These workers will have to be kept away from any possible smallpox cases for their own safety and because unimmunized health care workers are a prime way to spread

178. Using a private facility is very problematic because decontamination will be very expensive and time consuming, and ultimately the public may be frightened to return to the facility. It may be more prudent to use a motel or other non-medical structure, which will be much cheaper and less disruptive to destroy rather than try to decontaminate.

smallpox. If the country is in a constant state of readiness for a smallpox outbreak, does this mean that such workers cannot be in any jobs where they might encounter an undiagnosed smallpox case? If there is a case identified in the community, should all unimmunized workers be sent home? Who will cover their duties? What about health care workers outside of hospitals? Patients are as likely to go to private physicians as to hospital-based clinics. How should such facilities handle potential smallpox cases?

XIX. THE SMALLPOX EMERGENCY PERSONNEL PROTECTION ACT OF 2003

After the smallpox vaccination plan had effectively ended, Congress heeded the call of hospitals and health care worker unions and enacted a compensation act for persons injured by smallpox vaccine. On April 30, 2003, President Bush signed HR 1770, the Smallpox Emergency Personnel Protection Act of 2003,¹⁷⁹ which, among other things, establishes a smallpox vaccine injury compensation fund. This fund is intended to encourage smallpox vaccinations by addressing fears that those vaccinated will not have any insurance coverage if they are injured by the smallpox vaccine.¹⁸⁰ As discussed *infra*, the fund proposed by this bill is very restrictive and may not go far enough to address the concerns of health care providers and their institutions. The fund is also limited to pre-outbreak vaccination.¹⁸¹ Once a case of smallpox has been identified, the compensation system is closed to persons subsequently vaccinated.

The Act is triggered by the Secretary's Declaration under the Homeland Security Act. The Act begins with the definition of a covered person:

179. Smallpox Emergency Personnel Protection Act of 2003, 42 U.S.C. §§ 261–269, *available at* http://biotech.law.lsu.edu/blaw/bt/smallpox/Congress/hr1770_passed.htm.

180. Susan Thaul, Smallpox Vaccine Injury Compensation 2 (Cong. Res. Serv. Rep. 31-960, 2001), *available at* <http://biotech.law.lsu.edu/blaw/bt/smallpox/Congress/RL31960.pdf>; Democratic Members of the House Select Committee on Homeland Security, A Biodefense Failure: The National Smallpox Vaccination Program One Year Later 13 (Jan. 2004), *available at* http://www.house.gov/hsc/democrats/pdf/press/040129_ABIodefenseFailureOneYearLater.pdf and http://biotech.law.lsu.edu/blaw/bt/smallpox/Congress/040129_ABIodefenseFailureOneYearLater.pdf.

181. A covered individual is someone “who has volunteered and been selected to be a member of a smallpox emergency response plan described in subparagraph (B) prior to the time at which the Secretary publicly announces that an active case of smallpox has been identified either within or outside the United States.” 42 U.S.C. § 239(a)(2)(C) (2004).

(A) who is a health care worker, law enforcement officer, firefighter, security personnel, emergency medical personnel, other public safety personnel, or support personnel for such occupational specialties;¹⁸²

(B) who is or will be functioning in a role identified in a State, local, or Department of Health and Human Services smallpox emergency response plan (as defined in paragraph (7)) approved by the Secretary;¹⁸³

(C) who has volunteered and been selected to be a member of a smallpox emergency response plan described in subparagraph (B) prior to the time at which the Secretary publicly announces that an active case of smallpox has been identified either within or outside of the United States;¹⁸⁴ and

(D) to whom a smallpox vaccine is administered pursuant to such approved plan during the effective period of the Declaration (including the portion of such period before the enactment of this part).¹⁸⁵

Sections (A) and (B) raise the questions of just what is an approved plan and what does identification mean—must each vaccinated person be identified in the plan, or just the role each will fill? What does it mean to be an approved plan, and what if the plan is not approved? These sections also exclude persons who get the vaccine outside of the official program, perhaps through theft or unauthorized vaccination by someone with legitimate access to the vaccine.

Section (C) poses two problems: (1) What does it mean to be a volunteer? If your employer requires you to participate, does this exclude you from coverage? Is this meant to exclude from coverage under the Act situations where worker's compensation is clearly available? (2) Why does eligibility for compensation under the Act end when a case of smallpox is identified? It is possible that this provision derives from an assumption that once there is a case of smallpox, everyone will want to be vaccinated, so the Act would become unnecessary as an incentive for vaccination. It could also result from a recognition that once there are mass immunizations there will be a large number of casualties, and Congress does not want the government to be responsible for the costs.

Section (D) makes clear that this is a vaccination injury compensation act and is not intended to address other claims. The definition of a covered injury is clear:

182. *Id.* § 239(a)(2)(A).

183. *Id.* § 239(a)(2)(B).

184. *Id.* § 239(a)(2)(C).

185. *Id.* § 239(a)(2)(D).

(3) COVERED INJURY—The term ‘covered injury’ means an injury, disability, illness, condition, or death (other than a minor injury such as minor scarring or minor local reaction) determined, pursuant to the procedures established under section 262, to have been sustained by an individual as the direct result of—

(A) administration to the individual of a covered counter-measure during the effective period of the Declaration; or

(B) accidental vaccinia inoculation of the individual in circumstances in which—

(i) the vaccinia is contracted during the effective period of the Declaration or within 30 days after the end of such period;

(ii) smallpox vaccine has not been administered to the individual; and

(iii) the individual has been in contact with an individual who is (or who was accidentally inoculated by) a covered individual.¹⁸⁶

An individual is covered by the Act if he/she is an eligible individual or someone who suffers a covered injury. This would include patients and family members who contracted secondary vaccinia from a vaccinated person.

The Act requires the Secretary to promulgate a regulation specifying what injuries are covered by the Act, and it allows the Secretary to make individualized decisions about injuries not included in the regulation:

(1) INJURIES SPECIFIED IN INJURY TABLE—In any case where an injury or other adverse effect specified in the injury table established under section 263 as a known effect of a vaccine manifests in an individual within the time period specified in such table, such injury or other effect shall be presumed to have resulted from administration of such vaccine.¹⁸⁷

(2) OTHER DETERMINATIONS—In making determinations other than those described in paragraph (1) as to the causation or severity of an injury, the Secretary shall employ a preponderance of the evidence standard and take into consideration all relevant medical and scientific evidence presented for consideration, and may obtain and consider the views of qualified medical experts.¹⁸⁸

186. *Id.* § 239(a)(3)(a).

187. *Id.* § 239a(c)(1).

188. *Id.* § 239a(c)(2).

The Secretary's determination of whether someone is injured and the compensation to which they are entitled is not reviewable in the courts:

(2) JUDICIAL AND ADMINISTRATIVE REVIEW—No court of the United States, or of any State, District, territory or possession thereof, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this section. No officer or employee of the United States shall review any action by the Secretary under this section (unless the President specifically directs otherwise).¹⁸⁹

The medical benefit is limited to second dollar coverage, paying only what is left after other insurance plans, including worker's compensation and state and federal coverage such as Medicare and Medicaid, have paid.

The lost wages benefit is paid at two thirds of the monthly wage (plus eight and one-third percent if there are dependents).¹⁹⁰ There is a cap on all payments of \$50,000 per year, with the aggregate not to exceed the death benefit described *infra*.¹⁹¹ As with the medical benefit, this is second dollar coverage and payment from any other sources will be deducted.

The Act provides a death benefit and a benefit for total and permanent disability equal to the benefits paid under the Public Safety Officers' Benefits Program, which, according to an announcement by the Secretary of HHS, are \$262,100 at this time.¹⁹² It appears that this benefit is to be added to any other benefits that the individual receives, except for benefits from the Public Safety Officers' Benefits Program or other payments, such as lost wages, that were made under the smallpox compensation program. If there are dependants under the age of eighteen, there is an alternative calculation that results in a yearly payout until the youngest dependant is eighteen. This is based on seventy-five percent of the decedent's income, with a cap of \$50,000 a year.¹⁹³ This alternative payment is reduced by any benefits paid to the dependants by a third party.¹⁹⁴

189. *Id.* § 239a(f)(2).

190. *Id.* § 239d(b).

191. *Id.* § 239d(c)(3)(A)(i).

192. News Release, Dep't of Health and Human Services, HHS Proposes Smallpox Vaccination Compensation Plan (Mar. 5, 2003), available at <http://www.hhs.gov/news/press/2003pres/20030305.html>.

193. 42 C.F.R. § 102.82(d) (2004).

194. *Id.* § 102.82(d)(3)(A).

The subsequent release of the administrative rules¹⁹⁵ for the smallpox compensation program did not solve the major problems of the compensation act: the definitions of covered persons can exclude some injured persons; the benefits are very limited and most are subrogated to any other benefits; there are no provisions for compensation to employers; and the provisions for making claims, even for immediate medical needs, are complex and time-consuming. Under every provision, the secretary does not *have* to pay, and ultimately there is no judicial review of the secretary's decisions.¹⁹⁶

The Smallpox Emergency Personnel Protection Act of 2003¹⁹⁷ represents an attempt to draft a compensation act that will not attract fraudulent claims while taking the fears of health care workers and others seriously. How well it succeeds in this goal may be questioned. For example, it appears to provide inadequate compensation for serious injuries, especially for better-paid workers.

Smallpox is a deadly threat and smallpox vaccinations may be a necessary part of domestic policy. So far, the federal funding for smallpox vaccinations for health care workers is much less than the total costs for health departments and health care institutions. Should the vaccinees and their employers also absorb some or all of the costs of injury, or should these be part of the defense budget? The Act only goes part of the way towards solving this problem. It will be up to health care providers and others to decide if this is enough, or if they want to be fully protected financially. If the Act is coupled with a better plan for handling a smallpox outbreak and with more information about the probability of a smallpox outbreak, health care providers might be more willing to accept the risk of vaccination.

XX. THE POST-OUTBREAK ALTERNATIVE

Unlike most vaccines, the smallpox vaccine is fully effective up to three days after a person is exposed to the virus, and somewhat effective for a few days more.¹⁹⁸ This is because the incubation time

195. 68 Fed. Reg. 70,080 (Dec. 16, 2003), available at <http://biotech.law.lsu.edu/blaw/hhs/42-crf-102.pdf>; Smallpox Vaccine Injury Compensation Program: Administrative Implementation; Correction, 69 Fed. Reg. 7376 (Feb. 17, 2004) (technical corrections).

196. 42 C.F.R. 102.92 (2004).

197. Smallpox Emergency Personnel Protection Act of 2003, Pub. L. No. 108-20, 117 Stat. 638 (2003) (codified at 42 U.S.C. §§ 239-239h (2004)).

198. D.A. Henderson, *Smallpox: Clinical and Epidemiologic Features*, 5 *Emerging Infectious Diseases* 537, 537 (1999), available at <http://www.cdc.gov/ncidod/EID/vol15no4/henderson.htm>. ("Vaccination before exposure or within 2 to 3 days after exposure affords almost complete protection against disease. Vaccination as late as 4-5 days after exposure may protect against death."). The CDC biographical note on Dr. Henderson describes him as

for smallpox is much longer than for the vaccinia in the vaccine. The vaccine sore develops quickly, driving the production of antibodies that then prevent the smallpox virus from gaining a foothold in the patient. This provides a window of opportunity to vaccinate persons after exposure and still stop the development of smallpox in most of them. Given the uncertain, but low, probability of a smallpox outbreak in any given city, and at any given hospital, an alternative to prophylactic vaccination is to wait until there is a case of smallpox and then be prepared to vaccinate people very quickly.

As was demonstrated in the 1947 New York smallpox vaccination campaign¹⁹⁹ and others around the world,²⁰⁰ large numbers of people can be vaccinated in a short period of time. Dealing with health care providers is the simplest case. Vaccine could be stockpiled locally, even at the hospital and clinic level. It is stable and easy to store, but would need to be secured. The technique for performing the vaccination is very simple, having been designed to be done by unskilled workers after very limited training. The current recommendations are focused on a zero risk approach, i.e., elaborate recordkeeping, detailed informed consent, and extensive safety precautions to prevent the person performing the vaccination from being exposed to vaccinia.²⁰¹ These are appropriate precautions for prophylactic vaccinations when there have been no reported cases of smallpox.

The risk calculus shifts dramatically as soon as there are active cases of smallpox in the community.²⁰² At that point, the risk of not

a distinguished service professor at the Johns Hopkins university, holding an appointment in the Department of Epidemiology. Dr. Henderson directed the World Health Organization's global smallpox eradication campaign (1966-1977) and helped initiate WHO's global program of immunization in 1974. He also served as deputy assistant secretary and senior science advisor in the Department of Health and Human Services.

Id. (Dr. Henderson is also one of the five co-authors of the definitive work on smallpox. See Fenner, *supra* note 12.).

Additionally, recent research has found that vaccination with 19 year old DryVax[®] (manufactured 1982; injected 2001) achieved highly effective reactions (97% success rate) even when diluted to 10% of the normal strength. Sharon E. Fry, et. al, *Dose-Related Effects of Smallpox Vaccine*, 346 N.Eng. J. Med. 1275 (2002), available at <http://content.nejm.org/cgi/content/full/346/17/1275>.

199. CDC, *Cardiac Deaths*, *supra* note 100.

200. During the Bradford, England outbreak of 1961 (the index case imported smallpox from Pakistan via air travel), “[p]ratically the whole of the town’s population of 250,000 was vaccinated within 5 days.” Fenner, *supra* note 12, at 1078–79.

201. CDC, *Recommendations*, *supra* note 10.

202. The 1961 Bradford outbreak highlights several key points:

1. “The response to the provision of vaccination clinics demonstrated the existence of considerable public fear and apprehension about smallpox.”

being vaccinated and developing smallpox is much greater than the risk of vaccine complications for all but the most severely immunocompromised individuals. The risk of exposure to vaccinia becomes much less significant when most people will already be exposed to vaccinia through vaccinations. Even in hospitals, most patients would be candidates for vaccination in an outbreak, and for those who are not, the low risk of vaccinia exposure from vaccinated health care workers would be much less than the risk of spread of the disease by unvaccinated workers. Stripped of the paperwork requirements, and with an adequate supply of vaccine and the bifurcated needles used to administer it, smallpox vaccinations take little time. A handful of nurses could train others very quickly, then fan out and vaccinate every health care worker in a facility. The same could be done by EMTs in ambulance services and in clinics. With the supplies in place ahead of time, some basic training, and a shift from worrying about vaccine injuries to worrying about smallpox, it should be possible to vaccinate health care workers very quickly.

The most important question in smallpox vaccination policy is how to handle the public demand for vaccinations. Under the federal

Fenner, *supra* note 12, at 1079.

2. All the indigenous infections were contracted in hospital, and 4 hospitals were involved, with the transmission in 3 of them . . . [which also] illustrates the unpreparedness of hospitals in the United Kingdom to cope with an outbreak of smallpox at that time [1961], given the large proportion of unvaccinated professional and domestic staff, the difficulty of recognizing haemorrhagic-type smallpox and the risks thereby incurred, and the problems encountered in effectively containing the outbreak once it had been recognized.

Id.

How difficult is recognizing a smallpox death in a country with no recent familiarity with the disease? One of the 14 cases resulting from the air travel index case, and also one of the six fatalities, was “the 37-year-old pathologist who had performed the post-mortem on the index case”

Id. at 1079, 1080.

3. The societal burden of even a relatively limited outbreak can be enormous: The outbreak was already rather large by the time it was recognized as being caused by smallpox, and there had been numerous opportunities for transmission, both within hospitals and in the general community. The task of identifying, tracing, and vaccinating more than 1400 contacts and keeping them under surveillance was expensive, difficult and time-consuming. Although mass vaccination was never contemplated, vaccination clinics were opened because so many people had been already exposed by the time the outbreak was recognized. *Id.* at 1079.

4. Finally, consider the difficulty of the target nation even discovering it has been attacked during the 10-12 day incubation period as well as the formidable response and recovery tasks of coping with, say, a dozen widely dispersed index cases traveling throughout a highly mobile and largely unrestricted society. *Id.* at 1079.

government's current ring immunization plan, cases will be investigated, as will all the contacts to the cases, and contacts will be vaccinated and isolated for two weeks to make sure that they do not develop smallpox. It is likely that the media will announce the smallpox cases to world before local emergency preparedness personnel are all notified. The first question they will likely ask will be, "where and how does everyone get vaccinated?"

Under a ring immunization plan, the answer is that the general public should not worry about getting vaccinated. Only persons in contact with a smallpox case or working in health care or emergency services should be vaccinated. Unfortunately, the vaccination of health care workers cannot be carried out in isolation from the rest of the population. Even with a cadre of pre-vaccinated health care workers, the rest of the health care work force would need to be vaccinated as soon as smallpox cases are identified in the community. Once the vaccination of health care workers starts, they will want their families, and then their friends, vaccinated. Once it hits the news that there are cases of smallpox and that people are being vaccinated, it is the authors' prediction that most of the population will want to be vaccinated. The federal government's plan, on the other hand, is based on the assumption that the population will wait quietly while the experts manage the epidemic.

Waiting quietly during an epidemic of one of history's great killers does not seem likely. It is more likely that people will demand vaccinations, perhaps storming health care institutions where vaccinations are being given. People will also want to flee, which is a rational response to smallpox. Not being able to obtain vaccinations may exacerbate the pressure to flee, further complicating efforts to keep the disease from being carried to new locations. It is likely that politicians will demand that the general public have access to smallpox vaccinations—the only question is how much public panic will there be before the order is given. Once vaccinations are available, it is critical that everyone who wants one be able to obtain it very quickly. A requirement that people wait for several days at a vaccination clinic, as contemplated in the federal mass vaccination plan, seems an invitation to public disorder.

Rather than a plan based on a relatively small number of vaccination clinics, with paperwork and consent requirements, everyone who can be trained to give smallpox vaccinations should be sent into the community to give them. The vaccinations should be given where people are, such as schools, churches, shopping centers, and sports stadiums. If the area is blanketed with people with vaccine, creating a public perception that everyone who wants it can obtain it, the public order problem will be lessened considerably. While many people will still want to flee, this approach may reduce the pressure to leave.

There are two benefits of rapidly vaccinating as many people as possible. First, it would be more likely that there will be enough herd immunity to stop the outbreak, even though not all second generation cases will have been eliminated. While there may still be many deaths, public order is more likely to be preserved. Second, and much more controversially, it means that more people would be vaccinated before reports of real and alleged vaccine-related injuries are publicized.²⁰³ This is critical if the federal government is to keep its promise that no one will be vaccinated against her/his will.²⁰⁴ If too many people decline vaccination, the choice may be between forced vaccinations and failure to stop the epidemic.

XXI. SUMMARY

It is a great irony that one of the greatest achievements of public health, the eradication of smallpox, has left the world susceptible to a global pandemic which could dwarf any plague in history. Was it hubris to assume that we could really eradicate something both so ancient and so attractive to the worst instincts of humankind? It was certainly right to eliminate the disease. The hubris was believing that we had done it so well that we need not be armed against it any more. This is a lesson we should take to heart as we near the eradication of measles and other potentially epidemic diseases. We should not be so quick to end our vaccination programs against diseases we no longer fear. Is there any doubt that, had we continued to vaccinate for smallpox, we would have developed a much safer vaccine?

If our national policy is that we should be prepared for the use of smallpox as an agent of bioterrorism, and that that our preparations should include immunization of specific groups of people with vaccinia virus to make them immune to smallpox, then we must address the issues that lead to the failure of the 2002-2003 civilian smallpox vaccination campaign. We should also reconsider present policy in the light of the uncertainty of an outbreak, the uncertain infectiousness of smallpox, and the risks of underestimating both the fear that an outbreak will engender and the consequences of failing to control an outbreak. Our current strategy does not address the issues in ways that will allow us to move quickly enough if we have guessed wrong in our estimation of the enemy.

203. Ironically, we may be worse off after the failed smallpox vaccination campaign because it so frightened health care workers and the general public that it will complicate mass vaccinations if they become necessary.

204. Senator Bill Frist, *When Every Moment Counts: What You Need to Know About Bioterrorism From the Senate's Only Doctor* 86 (2002).