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REACTIONS AND OVERREACTIONS: SMALLPOX VACCINATION, COMPLICATIONS, AND COMPENSATION

*George W. Conk**

ABSTRACT

In an address to the 9/11 symposium *Terror In the Ai*, and in a postscript which assesses the first mass smallpox immunization since the New York City Board of Health vaccinated 6.4 million in April 1947, Professor Conk examines a vaccination program that was unique in public health history. While the disease has been eradicated and no one is known to be at risk of infection, it is possible that scientific research stocks of the virus could be misappropriated, and the virus used as a weapon. The threat of a smallpox attack is unascertainable. There may be no benefit from vaccination, but there is danger to some in vaccination with the live vaccinia virus vaccine. Driven by a post-9/11 fear that the unthinkable may occur, the federal government has pressed for, and obtained, a reversal of the three-decade-old policy of non-vaccination against variola – the smallpox virus.

The government recently began a program in which it intended to vaccinate at first 500,000 volunteer health workers in the first stage, and eventually a total of 10 million. The President promised to vaccinate any civilian requesting it. But in the first 8 months of the civilian program led by the Centers for Disease Control & Prevention (CDC) only 38,000 volunteered. Furthermore, the Department of Defense (DoD) has vaccinated half a million soldiers and civilian employees who were required to submit to the measure.

Compensation programs and estimates of the adverse health effects of a resumed smallpox vaccination program were intensely debated.

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A very spare program of civilian compensation for such adverse effects was enacted. Few civilians volunteered and few were injured. Civilian public health and military medical units cooperated in active surveillance of the sequellae associated with the administration of the vaccinia live virus Dryvax smallpox vaccine. Previously unrecognized post-vaccination complications, such as myocarditis and pericarditis, were soon observed. Early identification of the possible cardiac hazard was followed by promulgation of new clinical guidelines excluding volunteers deemed to be at particular risk for such illnesses.

The conduct of the military program was exemplary in its commitment to the study of adverse health effects of vaccination. The military also cooperated superbly with public health authorities, enabling prompt adjustments to the protocols and exclusions by relying on the comprehensive database of the Defense Medical Surveillance System.

An important environmental effect of September 11, 2001 may be an epidemic of fear, which spurred government officials to make an alarmist assessment of the risks posed by bio-weapons and to downplay the risks of the proposed mass-vaccination program. The civilian vaccination program later faltered because of alarm about reported complications, uncertainty regarding compensation for those who fell ill, and the fact that no present risk could be identified.

Lessons were learned which can help improve our ability to respond to unexpected microbial outbreaks - whether natural or intentional. We now have trained military and civilian smallpox vaccination teams, as well as a large pool of vaccinees in the armed services.. This experience may help us to develop a more effective and comprehensive emergency preparedness public health network. Ideally, such a plan will ready us for all sudden infectious disease outbreaks, while reducing or eliminating the burden of preemptive vaccination for such remote possibilities as the use of weaponized smallpox virus.

INTRODUCTION

As the speakers and the downtown residents present at the "Terror in the Air" Symposium displayed, the ground beneath our feet, the air we breathe, and the water we drink can no longer be taken for

granted since September 11, 2001. On that day the 20th century, a century of total war¹ yielded to the 21st century, a century of war anywhere, anytime. There is nothing new about the bombing of cities. Dresden, Hiroshima, Nagasaki, and Tokyo all suffered attacks warranting the description of “terror.”² The Cold War was fought based on the assumption that peace could only be maintained by a balance of terror, a stabilizing effect of mutually assured destruction.³

September 11, 2001 was different. Ground Zero was not a nuclear target zone, but a pile of rubble where thousands of innocent civilians had gone to work that morning. The terror did not come from state actors, but from a lawless force unconstrained by the elements that had made the nuclear standoff between the U.S. and the U.S.S.R. seem predictable, even if periodically harrowing.⁴

Underscoring the message of vulnerability was the sense that the most ordinary of objects could herald the approach of danger. There followed a series of anonymous anthrax attacks, in which 22 were infected. Ten thousand people were placed on prophylactic antibiotics.⁵ Upon identifying anthrax in 1876, Robert Koch and Louis Pas-

1. See RAYMOND ARON, *THE CENTURY OF TOTAL WAR* (1954) (describing the 20th century as the century of total war).

2. See RAYMOND ARON, *PEACE AND WAR: A THEORY OF INTERNATIONAL RELATIONS* 169 (Richard Howard & Annette B. Fox trans., 1996) (1966) (using the term “terror” to describe the “bombing of cities”); see also GAR ALPEROVITZ, *ATOMIC DIPLOMACY: HIROSHIMA AND POTSDAM – THE USE OF THE ATOMIC BOMB AND THE AMERICAN CONFRONTATION WITH SOVIET POWER* (1967). Not only Japan’s wartime rulers, but also the leaders of the Soviet Union, were the “targets” of the atomic bombing of the Japanese cities. *Id.*

3. See STEPHEN E. AMBROSE, *EISENHOWER: SOLDIER AND PRESIDENT* 338 (1990). The former scientific head of the Manhattan Project, J. Robert Oppenheimer, described the U.S.S.R. and the U.S., the two Cold War Adversaries, as “scorpions in a bottle.” *Id.*

4. See STROBE TALBOTT, *THE MASTER OF THE GAME: PAUL NITZE AND THE NUCLEAR PEACE* (1988); DAVID HOLLOWAY, *STALIN AND THE BOMB: THE SOVIET UNION AND ATOMIC ENERGY, 1939 - 1956* (1994).

5. See CTR. FOR DISEASE CONTROL & PREVENTION, U.S. DEP’T OF HEALTH & HUMAN SERVICES, *Update: Investigation of Bioterror-*

teur had hailed their discovery as bringing “within the power of man to rid himself of every parasitic disease.”⁶ However, now anthrax is a threat that arrives by mail, in a plain white envelope. Similarly, the air in the subway tunnels and in the post office seem less secure. New York and the nation will never be the same. The National Institute of Allergy and Infectious Diseases of the National Institute of Health has declared “bioterrorism” to be a “clear and present danger.”⁷ We now face the “problem of biosecurity in an age of bioterrorism.”⁸

ism-Related Anthrax, 2001, 50 No. 45 MORBIDITY & MORTALITY WEEKLY REPORT 1008 (Nov. 16, 2001).

Since November 7, 2001, CDC and state and local public health agencies have identified no new cases of bioterrorism-related anthrax. As of November 14, a total of 22 cases of anthrax has met the CDC case definition; 10 were confirmed inhalational anthrax, and 12 (seven confirmed and five suspected) were cutaneous anthrax.

Id. See also, CTR. FOR DISEASE CONTROL & PREVENTION, U.S. DEP’T OF HEALTH & HUMAN SERVICES, *Evaluation of Postexposure Antibiotic Prophylaxis to Prevent Anthrax*, 51 No. 3 MORBIDITY & MORTALITY WEEKLY REPORT 59 (Jan. 25, 2002).

6. SHEILA M. ROTHMAN, *LIVING IN THE SHADOW OF DEATH* 180 (1994).

7. H. Clifford Lane, John La Montagne & Anthony S. Fauci, *Bioterrorism: A Clear and Present Danger*, 7 *NATURE MED.* 1271 (2001).

8. See Gigi Kwik, Joe Fitzgerald, Thomas V. Inglesby & Tara O’Toole, *Biosecurity: Responsible Stewardship of Bioscience in an Age of Catastrophic Terrorism*, 1 *BIOSECURITY AND BIOTERRORISM: BIODEFENSE STRATEGY, SCI. & PRAC.* 1, at 27-35 (2003). The problem includes the “Persephone effect” – the danger that the life sciences will be employed on the dark side – designing for death, rather than life. *Id.* Explaining its mission, the leaders of the Johns Hopkins Center for Civilian Biodefense Strategies write that in the life sciences we must assure a “responsible stewardship in an age of catastrophic terrorism.” *Id.* The problem is “how to constrain malignant applications of powerful bioscience responsibility without damaging the generation of essential knowledge.” *Id.*

In the aftermath of the anthrax attacks of 2001 and the terrorist assaults on the World Trade Towers, policymak-

This essay was presented early in the vaccination program, in March 2003, and has been supplemented by a postscript assessing the experience of the first smallpox vaccination campaign since the eradication of the disease among human populations and its consignment to research stocks.

In Part I, the threat and scenarios for the unquantifiable - indeed unidentifiable - risk of attack are described. Part II describes the disease, the vaccine countermeasure and the estimated health risks to vaccinees receiving the live vaccinia virus vaccine now administered. In Part III, the compensation options are explored - including the immunity granted to manufacturers and vaccinators by the Homeland Security Act, which limits claimants to the remedy against the United States provided by the Federal Tort Claims Act. Possible tort claims are briefly discussed, followed by an examination of alternatives to tort claims. The probable, although uncertain, availability of workers' compensation as a remedy for vaccine-related injury is addressed. Legislative no-fault compensation measures proposed by Congress are also described. The discussion focuses on the Democratic minority's proposal to add the smallpox vaccine to the products covered by the National Childhood Vaccine Injury Compensation Act; while the Republican majority pursued a more limited supplemental remedy, patterned after the Public Service Officers Benefit Program administered by the U.S. Department of Justice.

ers awakened to these inherent powers of biological research and began calling for more governmental controls. The Patriot Act (2001) (footnote omitted) and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (footnote omitted) imposed new regulations on the conduct of research involving "select agents" - the several dozen pathogens that the Center for Disease Control and Prevention judges to be the most dangerous potential biological weapons. In recent months, the White House Office of Science and Technology Policy has met with representatives of professional science societies, private industry, and others to discuss restricting access to "sensitive homeland security information" generated within government.

Id.

Part IV, a postscript, notes the apparent overstatement of the risk of chemical and biological weapons in the pre-war assessments as the nation prepared for the war to remove Saddam Hussein from power in Iraq. The experience of the military and civilian smallpox vaccination programs is assessed. Far fewer civilians than expected - 38,000 total - actually stepped forward to be vaccinated. Health data on civilians showed a lower rate of observed complications than historical data had led public health authorities to expect. The military vaccination program - which principally reached the unvaccinated - also showed lower than historical rates of disease. However, that program also showed an unexpected increase in the cardiac inflammatory conditions called myocarditis and pericarditis.

The active surveillance by military and civilian authorities must be commended. The program, although one may argue it was inspired by a panicky post-9/11 overstatement of the risk, is to be commended for demonstrating the direction necessary to better prepare for microbial outbreaks. Following the suggestions of the National Academy of Science's Institute of Medicine, an end to the civilian vaccination program, and a more nearly adequate compensation program are recommended.

I. SMALLPOX - THE THREAT

In 1999 in the new edition of the leading medical school textbook on vaccines began its chapter on smallpox saying "smallpox is now a disease of historical interest only, its eradication having been certified by the World Health Organization on May 8, 1980."⁹ Its distinguished author, Dr. Donald Henderson, then Deputy Assistant Secretary for Health and Science in the United States Department of Health and Human Services, was celebrating a public health triumph for which he had long labored: the death of a virus - variola - which had plagued human existence since 10,000 B.C.E. The Egypt of the pharaohs, ancient Athens, the Chinese empire of the fourth century C.E., India, and Europe all suffered from the disease.¹⁰ Mankind's

9. Donald A. Henderson & Bernard Moss, *Smallpox and Vaccinia*, in *VACCINES* 13 (Stanley A. Plotkin & Edward A. Mortimer, Jr., eds., 3d ed. 1999).

10. *See id.*

labor to eradicate the disease succeeded. The last known case was reported in 1977.¹¹

By 1999, Dr. Henderson, then director of the Johns Hopkins Center for Civilian Biodefense Studies, was worried about the security of one of the two known research stocks of the virus.¹² "Smallpox virus thus exists in Russia, probably at two sites, at least. How secure the stocks may be is uncertain, especially given the economic conditions in Russia today, and the fact that salaries for scientists are paid very late or not at all. Many have left their former institutions for other countries. Reasonable evidence exists that at least ten nations are now engaged in the development of bioweapons and some are actively recruiting scientists in Russia."¹³

In June 2001 the Advisory Committee on Immunization Practices [ACIP] of the Centers for Disease Control and Prevention [CDC] described the use of "smallpox virus as a biological weapon" as less likely than other biological agents because of its "restricted" availability. The ACIP recommended only surveillance by the CDC of

11. *See id.*

12. The World Health Organization campaigned for the destruction of the known stocks of the organism. *See* Lawrence K. Altman, *Health Group Votes to Kill Last Viruses of Smallpox*, N.Y. TIMES, May 26, 1996, at A4. Destruction was scheduled for June 30, 1999. *Id.* The last stocks of variola are kept frozen in laboratories at the Centers for Disease Control and Prevention in Atlanta and the Russian State Research Center for Virology and Biotechnology in Koltsovo. *Id.* The Clinton Administration finally decided against destruction of the U.S. supply, relying on a report by the Institute of Medicine, part of the National Academy of Sciences, which found that the complex DNA of the ancient virus was a valuable research subject. Judith Miller & William J. Broad, *Clinton to Announce that U.S. Will Keep Sample of Lethal Smallpox Virus*, Aides Say, N.Y. TIMES, Apr. 22, 1999, at A12. Dr. Henderson, who led the campaign to destroy the virus sample found the decision "very regrettable:" "Of all the potential organisms that might be used in bioterrorism, this is probably the most formidable, and I think we should do everything we possibly can to mitigate against the risk of that virus being released at any time in any way." *Id.*

13. Donald Henderson, MD, MPH, *Bioterrorism: Myths and Realities*, Calderone Lecture, Columbia University School of Public Health, April 5, 1999.

any suspected case, and “post release vaccination” of anyone “exposed to the initial release” or who came in close contact with or was likely to contact infectious materials or clinical specimens “[i]f an intentional release of smallpox (variola) virus does occur.”¹⁴

Those recommendations were not long-lived. The CDC asked the ACIP to reconsider its position due to the events that had occurred in the fall of 2001. In June 2002, Draft Supplemental Recommendations of the ACIP declared that “the risk for smallpox occurring as a result of a deliberate release is considered low, and the population at risk for such an exposure cannot be determined.”¹⁵ However, ACIP

14. ADVISORY COMM. ON IMMUNIZATION PRACTICES & CTR. FOR DISEASE CONTROL, U.S. DEP'T OF HEALTH & HUMAN SERVICES, *Vaccinia (Smallpox) Vaccine, Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2001*, 50 No. RR-10 MORBIDITY & MORTALITY WEEKLY REPORT 1 (June 22, 2001), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5010a1.htm> (last visited Nov. 7, 2003) [hereinafter ACIP Recommendations].

15. A Rand Corporation Study postulated the following attack scenarios:

Hoax - An activist obtains monkeypox under false pretenses from a laboratory-supply company and mails it with a threatening letter to a clinic in a city of 500,000 people. The nation is alarmed when field tests are positive for poxvirus, and health officials elect to vaccinate 25 health care workers and patients at the clinic. Luckily, no infections occur.

Laboratory release - A Biosafety Level 4 hood malfunctions, probably because of sabotage, in a metropolitan area of 4 million people. A previously vaccinated laboratory technician contracts a mild case of modified smallpox, but his two children become quite ill and infect others.

Human vectors - Three persons residing in a U.S. border city of 4 million people infect themselves with variola smuggled into a neighboring country by separatist radicals from their homeland and then return to the United States. They become only moderately ill, since they were vaccinated in the 1970s. As in the 1947 outbreak in New York City, they use the mass transit system while ill, coming into contact with many persons, and each infects five other persons.

Building attack - A rogue nation produces variola major virus from samples stealthily acquired during the worldwide eradication

campaign and makes a preparation available to terrorists for “testing.” A U.S. resident, who obtained the agent during training abroad, aerosolizes the liquid and sprays it into the ventilation system of a federal office building in a city of about 6 million people. Hundreds of workers and visitors are heavily exposed; some 350 are infected.

Low- and high-impact airport attacks - In response to military actions threatening their regime, a nation’s leaders activate 40 “sleeper” agents and instruct them to retrieve variola virus previously sent to the United States in a container ship. These agents go to the 10 largest U.S. airports during busy periods and distribute virus throughout the domestic terminals, using nebulizers. Up to 200,000 people are in the terminals during those times. In the low-impact case, they infect 5000 persons; in the high impact case, they infect 100,000 persons.

The researchers concluded:

Vaccination of contacts plus isolation is expected to result in 7 deaths (from vaccine or smallpox) in a scenario involving the release of variola virus from a laboratory, 19 deaths in a human-vector scenario, 300 deaths in a building-attack scenario, 2,735 deaths in a scenario involving a low-impact airport attack, and 54,728 deaths in a scenario involving a high-impact airport attack. Immediate vaccination of the public in an attacked region would provide little additional benefit. Prior vaccination of health care workers, who would be disproportionately affected, would save lives in large local or national attacks but would cause 25 deaths nationally. Prior vaccination of health care workers and the public would save lives in a national attack but would cause 482 deaths nationally. The expected net benefits of vaccination depend on the assessed probability of an attack. Prior vaccination of health care workers would be expected to save lives if the probability of a building attack exceeded 0.22 or if the probability of a high-impact airport attack exceeded 0.002. The probability would have to be much higher to make vaccination of the public life-saving.

Samuel A. Bozzette, Rob Boer, Vibha Bhaunagar, Jennifer L. Brower, Emmett B. Keeler, Sally C. Morton, & Michael A. Stoto, *A Model for a Smallpox-Vaccination Policy*, *NEW ENG. J. MED.* 348, 416 (Jan. 30, 2003).

now recommended “pre-release vaccination of selected groups to enhance smallpox response readiness.”¹⁶

The target groups were proposed federal, state, and local “smallpox response teams”.¹⁷ Smallpox vaccination would be implemented “for persons pre-designated by the appropriate bioterrorism and public health authorities to conduct investigation and follow-up of initial smallpox cases that would necessitate direct patient contact.”¹⁸ These teams would include medical team leaders, public health advisors, epidemiologists, disease investigators, laboratory scientists, nurses, vaccinators, and security/law enforcement personnel.¹⁹

The White House embraced the plan. On December 13, 2002 President George W. Bush announced that the Department of Health and Human Services (HHS) would work with state and local governments to form “volunteer Smallpox Response Teams...(who) will be asked to volunteer to receive the smallpox vaccine.”²⁰ President Bush also announced that the Department of Defense “will vaccinate” military and civilian personnel who “are or may be deployed in high threat areas.”²¹

Though the President anticipated 500,000 non-military vaccinees, the project had an unexpectedly slow start as “hundreds of hospitals and thousands of nurses across the country” declined to participate,

16. ADVISORY COMM. ON IMMUNIZATION PRACTICES & HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMM. & CTR. FOR DISEASE CONTROL, U.S. DEP'T OF HEALTH & HUMAN SERVICES, *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 RR07 MORBIDITY & MORTALITY WEEKLY REPORT 1 (Apr. 4, 2003), available at <http://www.bt.cdc.gov/agent/smallpox/vaccination/acip-guidelines.asp> (last visited November 7, 2003).

17. *Id.*

18. *Id.*

19. *See id.*

20. George W. Bush, *Protecting Americans: Smallpox Vaccination Program* at <http://www.whitehouse.gov/news/releases/2002/12/print/2002213-1.html> (Dec. 13, 2002).

21. *Id.*

according to a New York Times report in early February 2003.²² By March 7, 2003, as war in Iraq neared, 16,919 had been vaccinated, eight thousand of them in the previous two weeks,²³ as the Homeland Security Department declared a nationwide “amber alert”, and fumbling Federal Emergency Management Agency (FEMA) officials prompted a nationwide run on duct tape.²⁴

The slow response was due to dissent regarding the necessity of a shift from the June 2001 ACIP recommendations to the schema of “pre-release vaccination,”²⁵ and a cautionary approach by public health authorities such as the National Academy of Sciences’ Institute of Medicine (IOM), and the American Public Health Association (APHA). The APHA called for research into a safer vaccine, and worried that the CDC implementation plan did not provide adequate resources, “including costs derived from monitoring adverse events, treating complications and training personnel.”²⁶ Furthermore, APHA called for mechanisms “to compensate individuals for

22. Donald G. McNeil, Jr., *Threats and Responses: Bioterror Threat; Many Balking At Vaccination*, N.Y. TIMES, Feb. 7, 2003, at A1.

23. CTR. FOR DISEASE CONTROL, U.S. DEP’T OF HEALTH & HUMAN SERVICES, *Smallpox Vaccine Adverse Events Among Civilians – United States, March 4-10, 2003*, 52 No. 10 MORBIDITY & MORTALITY WEEKLY REPORT 201 (Mar. 14, 2003).

24. See Cecil Connolly, *Smallpox Compensation Proposed*, WASH. POST, Mar. 6, 2003, at A01; see also CTR. FOR DISEASE CONTROL, U.S. DEP’T OF HEALTH & HUMAN SERVICES *Smallpox Vaccine Adverse Events Among Civilians - United States, Feb. 18-24 2003*, 52 No. 8 MORBIDITY & MORTALITY WEEKLY REPORT 156 (Feb. 28, 2003), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5208a4.htm> (last visited Sept. 30, 2003).

25. See Thomas Mack, M.D., M.P.H., *A Different View of Smallpox Vaccination*, 348 NEW ENGL. J. MED. 460, 460-63 (2003). “A terrorist introduction of smallpox could produce a short outbreak of cases and deaths, but the current vaccination policy will provide little protection, and the cost in deaths from vaccine complications will outweigh any benefit.” *Id.*

26. AM. PUB. HEALTH ASSOC., *Policy Statement on Smallpox Vaccination (EB02-1)*, at <http://www.apha.org/legislative/policy/smallpox.htm> (last visited Nov. 7, 2003).

health care costs incurred as a result of adverse events resulting from smallpox vaccination.”²⁷

An IOM report expressed concern about the “unknown balance of risks and benefits” inherent in the CDC program.²⁸ Never before had a vaccination program been undertaken where there was no natural threat - only the hypothetical threat posed by the possibility of a terrorist attack. While the likelihood of attack could not be predicted, the rate of occurrence of adverse side effects from vaccination could be calculated. In its first report to the CDC, the IOM called for a slower approach, and careful monitoring of adverse effects: “[A]t a minimum . . . the CDC [should] develop and communicate the criteria (e.g., types and rates of adverse reactions) that would trigger a reconsideration of the current systems in place to protect vaccinees and their contacts (e.g., the October 2002 Advisory Committee on Immunization Practices (ACIP) recommendations on contraindications, screening, care of the vaccination site, and administrative leave).”²⁹

The IOM warned that without such careful study

...concerns about the financial burden for caring for the adverse reactions of the smallpox vaccine (and the sobering consideration that some small but real number of vaccinees or their contacts could die or suffer permanent disability subsequent to vaccination) could greatly decrease the number of people who volunteer for smallpox vaccination. This could seriously impact the program’s achievement of its overall goals of increasing United States terrorism preparedness. The committee recommends that CDC and the Department of Health and Human Services support all efforts, some of which might be administratively or legislatively bold and creative, to bring this issue of compensation for smallpox vaccine adverse reactions - including those reactions that occur

27. *Id.*

28. COMM. ON SMALLPOX VACCINATION PROGRAM IMPLEMENTATION, INST. OF MED. OF THE NAT’L ACADS., *Review of the Centers for Disease Control and Prevention’s Smallpox Vaccination Program Implementation, Letter Report #1*, at http://www.nap.edu/html/smallpox_vac/ltr_report.pdf (Jan. 16, 2003) [hereinafter *IOM Letter Report #1*].

29. *Id.*

despite nonnegligent manufacture and administration of the vaccine - to speedy resolution.³⁰

After a brief discussion of the disease and its history, we will return to the issue of whether, why, and how we should protect, care for, and compensate those whom we have asked to volunteer to receive a live virus vaccine. Volunteering for such a vaccination carries a risk of contracting a serious illness for a small, but unpredictable, number of volunteers, as well as those who come into contact with them.³¹

II. SMALLPOX: THE DISEASE

Variola virus is the etiological agent of smallpox. It is part of the family called Pox Viridae, which includes vaccinia, monkeypox, cowpox, camelpox, and ectromelia. The first four infect humans. During the smallpox era, the only known reservoir for the virus was humans; no known animal or insect reservoirs or vectors existed. Transmission was person-to-person. The disease was spread via direct deposit of infective droplets onto the nasal, oral, or pharyngeal mucosal membranes, or onto the alveoli of the lungs from close contact with an infectious person.

The symptoms of smallpox begin 12 to 14 days after exposure. They begin with 2 to 3 days prodrome of high fever, malaise, and prostration with severe headache and backache. This pre-eruptive stage is followed by the appearance of a distinctive rash, which progresses to papules 1 to 2 days after the rash appears. Vesicles appear on the fourth or fifth day; pustules appear by the seventh day; and

30. *Id.*

31. See Lawrence K. Altman, William J. Broad & Judith Miller, *Smallpox: The Once and Future Scourge*, N.Y. TIMES, June 15, 1999, at F1. The United States government last vaccinated infants for smallpox in 1972. *Id.* The scourge of smallpox, which is one of the largest, most highly elaborated viruses known to humankind, was most dangerous where smallpox was not endemic and natural immunities had not been developed. *Id.* It is speculated that the highly contagious disease was spread in the Americas from a slave in the camp of Spanish conqueror Hernando Cortes, causing the deaths of 3.5 million Aztecs. *Id.* Today, the fear is sometimes expressed that "we are all Indians now." *Id.*

scab lesions appear on the fourteenth day. During the smallpox era, overall mortality rates were approximately 30%, though virulence varied with the particular strain. Smallpox patients are most infectious during the first week of the rash when the oral mucosa lesions ulcerate and release substantial amounts of virus into the saliva. A patient is no longer infectious after all scabs have separated (i.e., 3–4 weeks after the onset of the rash).

Today many persons have no immunity, to smallpox. They are what researchers call “vaccine naïve”. Infant vaccination ceased in the United States in 1972. So no native-born person under the age of 30 was vaccinated as a child, and among those older, little is known of whether they retain sufficient immunity to fight off smallpox infection.³²

The Countermeasure and its Adverse Effects

Smallpox can be effectively prevented by inoculation with the live vaccinia virus. This measure successfully eradicated the disease world-wide.³³ However, the vaccine is not without risk. The CDC acknowledges that:

[a]dverse event rates in the United States today may be higher because there may be more people at risk from 1) immune suppression from cancer, cancer therapy, organ transplantation and other illnesses, such as HIV/AIDS, and 2) eczema or atopic dermatitis. The outcome associated with adverse events may be less severe than previously reported because of advances in medical care. Rates may be lower for persons previously vaccinated.³⁴

32. See Henderson & Moss, *Smallpox and Vaccinia*, in *VACCINES*, *supra* note 9 (displaying that morbidity and mortality rates vary: the Asian form of variola had a case-fatality rate of 20%; the African strain’s mortality rate was 20% to 30% less; and the variola minor strain had a mortality rate of only 1%).

33. See *id.* at 29.

34. CTR. FOR DISEASE CONTROL, U.S. DEP’T OF HEALTH & HUMAN SERVICES, *Smallpox Vaccine: Adverse Event Rates, 1968*, 52 No. RR 4:9 MORBIDITY & MORTALITY WEEKLY REPORT Table 1 (Feb. 21, 2003), available at <http://www.bt.cdc.gov/agent/smallpox/vaccine-safety/adverse-events-chart.asp> (last visited Nov. 7, 2003).

The CDC has described the historic rate of adverse effects of the vaccinia vaccination. The three recognized life-threatening reactions are post-vaccinal encephalitis (2.9/million vaccinees), progressive vaccinia (0.9/million vaccinees), and eczema vaccinatum (10.4/million vaccinees). Other adverse events include inadvertent inoculation and generalized vaccinia, which occurred historically in the United States at a rate of 25.4 and 23.4/million vaccinees, respectively.³⁵

35. *See id.*

(number per million vaccinees)

		NATIONAL SURVEY		TEN STATE SURVEY	
All primary (i.e., first-time) vaccinees	Vaccinees \geq 1 yr old	All primary (i.e., first-time) vaccinees	Vaccinees \geq 1 yr old	All primary (i.e., first-time) vaccinees	Vaccinees \geq 1 yr old
Serious, but not life-threatening reactions:					
Inadvertent Inoculation	25.4	27.1	529.2	532.0	
Generalized Vaccinia	23.4	17.7	241.5	222.8	
Erythema Multiforme	Not Available	Not Available	164.6	131.3	
Total number of serious, but not life-threatening reactions:	48.8		935.3*		
Life-threatening reactions:					
Postvaccinal Encephalitis	2.9	2.4	12.3	8.6	
Progressive Vaccinia (Vaccinia Necrosum)	0.9	1.0	1.5	1.7	
Eczema Vaccinatum	10.4	10.6	38.5	41.5	
Total number of life-threatening reactions:	14.2*		52.3*		
Deaths:	1.1*	0.6	1	None Reported	

The table above presents smallpox vaccine adverse event rates from two studies done in 1968 (see references below). *Id.* The two studies were carried out using different methodologies. *Id.* In the national survey, information was gathered from seven nationwide sources, with most of the information on adverse reactions coming from the American Red Cross Vaccinia Immune Globulin (VIG) distribution

Dr. Kent A. Sepkowitz, of the Infectious Disease Service of Memorial Sloan -Kettering Cancer Center, explains that because lesions caused by the vaccine shed the vaccinia virus, vaccinees may not only spread the infection to other parts of their bodies (e.g. genitalia and eyes), but also may pass the virus to persons with whom they come into close contact (e.g. intimate or face-to-face). Sepkowitz reports that:

Because of the risk of secondary transmission of vaccinia, many hospitals remain uncomfortable with the recent recommendation against the provision of administrative leave for newly vaccinated health care workers. Also, the advisability of immunocompromised workers' remaining on the job while colleagues receive vaccine has not been determined. Until these controversies are settled, hospitals must be certain that the rush to vaccinate health care workers does not result in a self-inflicted epidemic — not of smallpox, but of infection with the live, potentially fatal virus, vaccinia.³⁶

Against this background, we turn to the issues of compensation for the adverse effects of smallpox vaccination with vaccinia virus - the only method of inoculation now available.³⁷

system. *Id.* Reactions that did not require use of VIG (that is, less severe reactions) are less likely to be reported through this system. *Id.* In the ten-state survey on the other hand, doctors were directly surveyed to report all adverse reactions, even those considered less severe. *Id.* For this reason, the ten-state survey data may present a better estimate of the number of people having adverse reactions to the vaccine. *Id.*

36. Kent A. Sepkowitz, *How Contagious is Vaccinia?*, 348 N. ENGL. J. MED. 5, 5 (Jan. 30, 2003).

37. See Andrew Pollack, *Company Says It Will Test a Safer Smallpox Vaccine*, N.Y. TIMES, Dec. 18, 2002, at A1. VaxGen, a California biotech company recently reported that it had acquired the rights to a Japanese smallpox vaccine it says is safer than the current vaccine, known as Dry-Vax. *Id.* It hopes to begin clinical trials this year. *Id.* This vaccine is also a live vaccine. *Id.* The National Institutes of Health are looking at a strain that is made from a virus called MVA, which is so weak it is said not to have the capacity to replicate in humans. *Id.*

III. COMPENSATION OPTIONS

The principal health effects of the smallpox vaccination program will fall on health care workers, police, fire, and defense personnel. They will accept the risk in response to their employers', and the government's calls for volunteers. Their patients and household members of inoculated healthcare workers will be at some risk due to close contact during the two week infectious stage post-inoculation. Soldiers will also be subject to the risk of adverse effects due to mandatory vaccination.

The Homeland Security Act § 304: Immunity for Vaccinators

The Bush Administration first provided immunity from liability. Section 304 of the Homeland Security Act of 2002³⁸ indicates that if the Secretary of Health and Human Services declares smallpox vaccination to be a "countermeasure . . . to chemical, biological, radiological, nuclear, and other emerging terrorist threats," there shall be immunity from tort liability for "any person who is . . . a manufacturer, or distributor," or is a "health care entity under whose auspices any qualified person who administers the smallpox vaccine."³⁹ Each such "covered person" shall be deemed to be an employee of the (United States) Public Health Service "with respect to liability arising out of administration of a covered countermeasure against smallpox."⁴⁰

The exclusive tort remedy for anyone injured by a "countermeasure"⁴¹ is prescribed via the Federal Tort Claims Act (FTCA).⁴² The

38. Pub. L. No. 107-296, 116 Stat. 2135.

39. *Id.*

40. *Id.* at (p).

41. *Id.*

42. See Arnold W. Reitze, Jr., *Federal Compensation for Vaccination Induced Injuries*, 13 B.C. ENVTL. AFF. L. REV. 169 (1986). There is precedent for this measure in the Swine Flu Act. *Id.* The impending outbreak of vaccinia would not be the first self-imposed epidemic of vaccine-related injuries. *Id.* In 1976, fearing a massive winter epidemic of Swine Flu, the government began a campaign to vaccinate people for the dangerous strain. *Id.* Ultimately, 40 million were vaccinated. *Id.* In some small states the numbers reached 80% of adults. *Id.* In larger states, the percentages were much smaller. *Id.*

action must be brought against the United States of America.⁴³ Recovery shall be predicated on the plaintiff's ability to prove "a negligent or wrongful act or omission"⁴⁴ The causal relationship between vaccinia and the vaccination is a rebuttable presumption.⁴⁵

The tort cause of action is unlikely to benefit many persons injured by the smallpox vaccine. Section 304 serves mainly to immunize manufacturers, hospitals, and those who administer the vaccine. The persons most likely to be injured are the public health workers who administer or receive the smallpox vaccine, or who are infected by co-workers with whom they come into close contact. If one is infected accidentally by a co-worker (inadvertent inoculation), or if an immune-compromised worker falls ill due to inadequate warning of the risks of the smallpox vaccine, a tort action against the co-worker or employer would be barred by the exclusivity of the workers' compensation remedy.⁴⁶

The natural epidemic did not materialize, but an epidemic of vaccine-related illness did. *Id.* 4,000 administrative claims were filed, resulting in 1,500 federal lawsuits. *Id.* Approximately, 300 people were injured by the vaccine-related Guillain-Barr Syndrome. *Id.* In response, the Swine Flue Act amended the Federal Tort Claims Act, 28 U.S.C. §§ 1346, 1402, 1504, 2110, 2401, 2402, 2411, 2412, 2671-2680 (1982). *Id.* The bill directed all suits be brought against the United States of America, with the U.S. reserving the right to seek indemnification from the manufacturers for negligence. *Id.* A similar provision is contained in the Homeland Security Act, § 304, n46, to permit suits against the federal government by those who might be injured by the vaccine. *Id.* Manufacturers would be liable in subsequent indemnification suits by the government, but only if negligence was proven. *Id.*

43. *See supra* note 27; *see also* 28 U.S.C. 1346 (granting jurisdiction to federal district courts) and 28 U.S.C. 2674 (stating that "[t]he United States shall be liable, respecting the provisions of this title relating to tort claims, in the same manner and to the same extent as a private individual under like circumstances, but shall not be liable for interest prior to judgment or for punitive damages.").

44. 28 U.S.C. § 2679(b) (2000).

45. *See supra* note 27.

46. *See* ARTHUR LARSON & LEX K. LARSON, *LARSON'S WORKERS' COMPENSATION* § 100.01 (Desk Ed. 2000) [hereinafter *LARSON'S*].

Where the injury results from carelessness by someone other than a co-employee or the victim is a household or other close contact of the vaccinee, there is a possible cause of action against the United States. Such a cause of action will exist where there was negligence on the part of the administrator of the vaccine, including instances where the post-vaccination lesion lacked proper bandage. Claims may also arise for failure to implement the recommended precautions, for failure to obtain informed consent, or for failure to properly screen out those for whom smallpox vaccination is contraindicated. Contraindications include a history of eczema or other allergic dermatitis, acute exfoliative skin conditions, immune-suppression conditions (such as after chemotherapy or testing positive for HIV), pregnancy or breast-feeding, or allergy to any component of the vaccine.⁴⁷

A product liability action against the manufacturer is, of course, barred by Section 304. Although the United States stands in the manufacturer's stead, there is little chance of successfully conducting a product liability action against the United States at the present time. In almost every jurisdiction the Second Restatement of Torts § 402 A, comment K would be cited for the proposition that an unavoidably unsafe but useful product is not defective if it is administered with reasonable care, and the patient is given reasonable notice of the dangers presented by the product (either directly or by informing the prescribing physician), and the good done by the product exceeds the harm it causes.^{48 49}

Once a workers' compensation act has become applicable either through compulsion or election, it affords the exclusive remedy for the injury by the employee or the employee's dependents against the employer and insurance carrier. This is part of the *quid pro quo* in which the sacrifices and gains of employees and employers are to some extent put in balance, for, while the employer assumes a new liability without fault, it is relieved of the prospect of large damage verdicts. *Id.*

47. See *supra* note 13, at 9-13.

48. See RESTATEMENT (SECOND) OF TORTS § 402A, cmt. k (1965). The comment, in full, reads:

k. Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordi-

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

49. Some courts have construed comment k to be a rule of virtual immunity for drugs, which are presumed to carry risks that are unavoidable. *See, e.g. Brown v. Superior Court (Abbott Labs.)*, 751 P.2d 470 (Cal. 1988); *Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991); *Young v. Key Pharms.*, 922 P.2d 59 (Wisc. 1996) (en banc).

Support for the *Brown* approach appears to be eroding. *See, e.g. Freeman v. Hoffman LaRoche*, 618 N.W. 2d 827 (Neb. 2000) [Supreme Court overrules *McDaniel v. McNeil Labs. Inc.*, 241 N.W.2d 822 (Neb. 1976), and rejects its previous adherence to the minority view that a properly manufactured drug accompanied by an adequate warning of the risks known to the manufacturer at the time of sale is not defectively designed as a matter of law]. *Accord: Bryant v. Hoffman La Roche*, 2003 Georgia Lexis 945 (Ga. Ct. App.).

The live virus smallpox vaccine in current use, which successfully eradicated a worldwide scourge, undoubtedly would pass the gross test of product defect enunciated in the Third Restatement's net benefit rule.⁵⁰ But even if the injurious vaccine did not contain a manufacturing defect, and it was accompanied by adequate warnings, there may yet remain a product liability cause of action. There is another approach – the reasonable alternative design test which is the customary approach to proving product design defect regarding food and other manufactured goods.⁵¹ The essence of the approach is that an alternative safer design is proposed as the standard against which the reasonableness of the risks presented by the vaccine should be measured.

For example, the CDC endorses use of Dryvax "...prepared from calf lymph with a seed virus derived from the New York City Board of Health strain of vaccinia... It is a highly effective immunizing agent that brought about the global eradication of smallpox. Recent testing has shown that the current vaccine has retained adequate po-

The Nebraska court now embraces the "majority rule" that applies the comment k defense on a case-by-case basis, believing that societal interests in ensuring the marketing and development of prescription drugs will be adequately served without the need to resort to a rule of blanket immunity. *See, e.g.,* Tobin v. Astra Pharm. Prods., Inc., 993 F.2d 528 (6th Cir. 1993); Hill v. Searle Labs., 884 F.2d 1064 (8th Cir. 1989); Belle Bonfils Mem'l Blood Bank v. Hansen, 665 P.2d 118 (Colo. 1983) (superseded by statute in regard to blood banks, as recognized in *United Blood Servs. v. Quintana*, 827 P.2d 509 (Colo. 1992)); Ortho Pharm. Corp. v. Heath, 722 P.2d 410 (Colo. 1986), *overruled on other grounds by* Armentrout v. FMC Corp., 842 P.2d 175 (Colo. 1992); Toner v. Lederle Labs., 732 P.2d 297 (Ida. 1987); Feldman v. Lederle Labs, 479 A.2d 374 (N.J. 1984); Castrignano v. E.R. Squibb & Sons, Inc., 546 A.2d 775 (R.I. 1988).

50. The Third Restatement of Torts, Product Liability, §6 (c) holds that design defect claims can be brought against prescription drug and medical device manufacturers only if the drug provides no "net benefit" to any class of users.

51. Restatement (Third) of Torts: Products Liability, § 2 (b) provides that a product is defective if a "reasonable alternative" safer design was "unreasonably omitted".

tency during the extended storage period since its production.”⁵² But the FDA and others have called for development of alternatives to Dryvax. There are alternative vaccine design approaches which use recombinant technology,⁵³ a “defective” virus unable to reproduce,⁵⁴ or a weaker “attenuated” or “modified” strain, less likely to cause injury, particularly for children and immune compromised persons.⁵⁵

52. CTR. FOR DISEASE CONTROL, U.S. DEP’T OF HEALTH & HUMAN SERVICES, VACCINATION GUIDELINES FOR STATE AND LOCAL HEALTH AGENCIES: GUIDE B B-7 (June 16, 2002), *available at* <http://www.bt.cdc.gov/agent/smallpox/response-plan/files/guide-b-part1of3.pdf> (last visited Nov. 7, 2003).

53. Earl Patricia L; Americo Jeffrey L; Moss Bernard, Development and use of a vaccinia virus neutralization assay based on flow cytometric detection of green fluorescent protein, *J Virol* 2003 Oct; 77 (19): 10684-8. [A rapid and sensitive neutralization assay is required to evaluate alternative smallpox vaccines. Here we describe the development and use of a 96-well plate, semi-automated, flow cytometric assay that uses a recombinant vaccinia virus expressing enhanced green fluorescent protein and which would be applicable to other viruses.]

54. Ober B T, et al., Immunogenicity and safety of defective vaccinia virus lister: comparison with modified vaccinia virus Ankara, [“Potent and safe vaccinia virus vectors inducing cell-mediated immunity are needed for clinical use. Replicating vaccinia viruses generally induce strong cell-mediated immunity; however, they may have severe adverse effects. As a vector for clinical use, we assessed the defective vaccinia virus system, in which deletion of an essential gene blocks viral replication, resulting in an infectious virus that does not multiply in the host. The vaccinia virus Lister/Elstree strain, used during worldwide smallpox eradication, was chosen as the parental virus.”]

55. Andrew Pollack, Threats And Responses: Biological Defenses; Company Says It Will Test A Safer Smallpox Vaccine, *New York Times*, December 16, 2002, Section A; Page 16. [“A California biotechnology company said yesterday that it had acquired the American rights to a Japanese smallpox vaccine it says is safer than the one the Bush administration plans to use...The company, Vax-Gen, said it hoped to begin clinical trials early next year and to win approval from the Food and Drug Administration to begin sales in 2004. If the vaccine is approved, the company plans to market it

A products liability test focused on the prevention of avoidable harm would argue that if there is a safer design available which would be effective in creating immunity at less risk to the patient or contacts of the patient. Here, lower-strength vaccines such as those available in Japan (but not yet here) would be cited as examples to demonstrate such an alternative. Although the product-by-product comparison approach to design defect litigation has been rejected by some courts, a majority of the courts that have addressed the issue embraces such a case by case rule.⁵⁶ Failure to develop and deploy such technology could be deemed unreasonable – and therefore lead to a verdict on design defect..

It is worth noting that in the United Kingdom tardiness by the National Blood Authority into implement an effective screening test for Hepatitis C with reasonable promptness rendered the blood product defective. Liability would be imposed in favor of those infected with the virus after a date determined by the court to have been a reasonable date for screening program implementation.⁵⁷ Claims by vaccinees or infected contacts against hospitals and public health

commercially, hoping it will appeal to millions of consumers who want some protection against bioterrorism but fear the side effects of the existing vaccine.”] See also www.vaxgen.com. [last visited February 16, 2004.]

56. See George W. Conk, *Is There a Design Defect in the Restatement of Torts: Products Liability?*, 109 YALE L.J. 1087 (2000), and George W. Conk, *The True Test: Alternative Safer Designs for Drugs and Medical Devices in a Patent-Constrained Market*, 49 UCLA L. REV. 737 (2002) (arguing that drugs, vaccines, blood products, and medical devices are amenable to the alternative safer design test of product defect embraced by Section 2 of the Products Liability Restatement, and rejecting the Restatement’s Section 6(c) which rejected such a comparative test, permitting liability findings only where the sum of the harms done by the product exceed its benefits for every class of user); *but see* James A. Henderson, Jr., and Aaron D. Twerski, *Drug Designs Are Different*, 111 YALE L.J. 151 (2001) (acknowledging the aptness of testing by alternative designs, but limiting the comparison to products already approved by the U.S. Food and Drug Administration and actually available on the market at the time of sale of the challenged product).

57. See *A. and others v. National Blood Authority*, Queens Bench Division, 3 All E.R. 289 (Q.B. 2001).

authorities for failure to employ a new, safer smallpox vaccine once it becomes available, are possible. However, given the close attention being paid to the smallpox vaccination program, there is little chance that a safer alternative would long languish unused.

Another possibility is an action for medical malpractice. An action against the doctor, health worker, or employing hospital by a co-worker would, of course, be subject to the workers' compensation bar. An action by a hospital patient or contact to whom the vaccinia virus was inadvertently transmitted would be a more likely cause of action. Failure to follow appropriate precautions such as washing hands, maintaining protective bandages, or carelessly exposing immune-compromised persons to recently inoculated individuals are all potentially viable causes of action, grounded on the negligent failure to adhere to protocols recommended by the CDC and others.⁵⁸ Similarly, actions could be grounded on failure to recognize and effectively treat adverse reactions to smallpox.

Alternatives to Tort Claims

Workers' Compensation as a Remedy

Most persons injured through vaccinia vaccination will not have a viable cause of action in tort. They will have to look to workers' compensation laws. Though there are significant state variations, workers' compensation generally provides benefits for workers who suffer injury or disease that "arises out of and in the course of their employment."⁵⁹ Accordingly, there must be a causal relationship between employment and disease that is characteristic of the employment, not simply an unrelated event, which occurs while at work (such as a seizure, or, for that matter, a terrorist attack). Here, a seri-

58. See CTR. FOR DISEASE CONTROL, VACCINATION GUIDELINES FOR STATE AND LOCAL HEALTH AGENCIES, *supra* note 40 (recommending smallpox/vaccinia vaccination protocols); CTR. FOR DISEASE CONTROL, *Smallpox Vaccination and Adverse Reactions: Guidance for Clinicians*, 52 No. RR04 MORBIDITY & MORTALITY WEEKLY REPORT 1 (Feb. 21, 2003), available at <http://www.cdc.gov/mmwr/PDF/RR/RR5204.pdf> (discussing adverse reactions, recognizing transmission, preventing contract transmission, and available treatments) (last visited Nov. 7, 2003).

59. LARSON'S, *supra* note 45.

ous question exists as to whether adverse events associated with voluntary vaccinia vaccination "arise" out of employment.

Workers' compensation benefits characteristically include temporary disability benefits (after a one-week waiting period and subject to a statutory cap), permanent, partial, or total disability benefits, medical benefits, and death benefits.⁶⁰ The limitations on these benefits - the quid pro quo of which Professor Larson speaks, are largely what prompted the Waxman bill, H.R. 865, and the Administration proposal, to be sponsored by Senator Judd Gregg, which is discussed below.

As of this writing, there have been few adverse events reported, and no claims have yet been adjudicated or even made. Only one case of severe reaction (suspected generalized vaccinia), and 23 non-serious adverse events (fatigue, headache, fever, chills, myalgia, nausea) have been reported among the 7,354 civilian public health and health care workers vaccinated from January 24 to February 21, 2003.⁶¹

The AFL-CIO reports that 12 states have confirmed that they will offer workers' compensation benefits for those who suffer vaccine-related illnesses.⁶² In New Jersey, employers and their insurers make such decisions on a case-by-case basis, and the Division of Workers' Compensation does not issue advisory opinions. In New York, the State Department of Health is preparing a letter from Commissioner Antonia Novello, affirming her view that workers who fall ill from vaccinia vaccine will be entitled to workers' compensation benefits. Although her office has consulted with the State Insurance Fund and the Workers' Compensation Board, they are not expected to sign or formally endorse the Commissioner's statement.⁶³

60. *See id.*

61. CTR. FOR DISEASE CONTROL, U.S. DEP'T OF HEALTH & HUMAN SERVICES, *Smallpox Vaccine Adverse Events Among Civilians - United States, February 18-24, 2003*, 52 No. 8 MORBIDITY & MORTALITY WEEKLY REPORT 156 (Feb. 28, 2003).

62. Robert Pear, *Threats and Responses: Biological Defense; Officials Seek Smallpox Compensation Fund*, N.Y. TIMES, Mar. 7, 2003, at A25.

63. Telephone Interview with Christine Hoffman, Senior Attorney for Bioterrorism Preparedness, New York State Department of Health (Mar. 7, 2003).

The difficulty in predicting whether workers' compensation benefits will be available is that occupational diseases such as asbestosis, and risks like being robbed on the highway while traveling, are inherent in certain types of work. Some jobs carry increased risks that "arise" from the employment itself. Smallpox vaccination is voluntary and the adverse effects of the prophylactic measure do not inhere in the employment in the same way that carpal tunnel syndrome inheres in the work of seamstresses, or silicosis in the work of granite cutters and coal miners.⁶⁴ The New York statute illustrates the problem:

"Injury" and "personal injury" mean only accidental injuries arising out of and in the course of employment and such disease or infection as may naturally and unavoidably result.⁶⁵

The risk of vaccinia infection does not "naturally and unavoidably"⁶⁶ result from work as an Emergency Room physician, nurse, or orderly. The vaccination is a voluntary means of prophylaxis, encouraged by the authorities, and perhaps, the employer. The attendant risk of infection is an avoidable risk, taken in anticipation of an unprecedented event. Clearly, the legislature did not contemplate such a set of circumstances when it passed the Workman's Compensation Statute. But that, of course, is not the end of the matter. As the New Jersey Supreme Court observed in another workers' compensation case regarding occupational heart disease claims for which the statute was similarly unhelpful:

That omission leads us to "the land of mystery," see Benjamin N. Cardozo, *The Nature of the Judicial Process* 18 (Yale Univ. Press 1979), where the legislation is silent. In the absence of specific guidance, our task is to discern the intent of the Legislature not only from the terms of the Act, but also from its structure, history and purpose.⁶⁷

64. See DAVID ROSNER & ROBERT MARKOWITZ, *DUST AND DISEASE: SILICOSIS AND THE POLITICS OF OCCUPATIONAL HEALTH* (1991). See also Black Lung Benefits Act, 30 U.S.C. §§ 901-945 (2003) (establishing no-fault scheme of compensation for coal miners' silicosis claims).

65. N.Y. Worker's Compensation §2(7) (2003).

66. *Id.*

67. *Fiore v. Consol. Freightways, Inc.*, 140 N.J. 452 (N.J. 1995) (citation omitted).

Reference to other jurisdictions yields mixed results. Professor Larson observes that

When inoculation is occasioned by the particular conditions of employment, injury resulting from the inoculation should be deemed to have occurred in the course of employment. If there is an element of actual compulsion emanating from the employer, the work connection is beyond question, as when the company requires the employee to submit to vaccination by the company's doctor as soon as the employee is hired, or during an epidemic tells the workers that unless they are vaccinated they cannot work until the epidemic is over. By equal logic, just as an employee on an overseas assignment is entitled to associate the contraction of malaria or polio or tuberculosis with the nature of the work, so any harm stemming from inoculations undertaken to protect against the risks of overseas diseases, whether the inoculations were strictly required or not, should be viewed as flowing directly from the employment.⁶⁸

Here we find no compulsion to participate in the federal program, which is entirely voluntary, both for the individual and the institution. Unlike HIV or hepatitis C (which are blood-borne, and thus create risks for health workers) or tuberculosis (which is transmitted by aerosol), smallpox infection is not an inherent risk of employment, especially since it was globally eradicated, and there is no quantifiable, or even identifiable risk of bioterrorist attack.

Some courts have ruled in smallpox vaccination cases, with mixed results. In Connecticut, it was long ago held that an employee's vaccine-related injuries would not be compensable under the following circumstances: 1) where a board of health recommends but does not direct that the employees of an employer be vaccinated in an effort to prevent a threatened epidemic, and 2) the employer makes available the facilities for the vaccination without cost to his employees, but 3) leaves the choice of whether to be vaccinated up to the individual employee. The court reasoned that in such a situation, vaccination is recommended not for the benefit of the employer, but pri-

68. See LARSON'S, *supra* note 45, at § 27.03 [2] (heading of this Section is Acts Benefiting the Claimant).

marily for the benefit and protection of the employee and the public generally.⁶⁹

In *Saintsing v. Steinbach Company*,⁷⁰ an Asbury Park department store provided the vaccine free of charge, and “strongly urged” employees to be vaccinated during a 1947 smallpox scare. Each employee consented and released the employer from liability. *Saintsing* became seriously ill. The New Jersey appellate court found a mutual benefit, and therefore an employment relationship:

[I]nsofar as it aided in the prevention of smallpox within the employee group it protected the employer against possibly disastrous business consequences...While his efforts were highly commendable ... it would be unrealistic to find that they were for the exclusive benefit of the employees and not additionally designed to further a sound employer-employee relationship and safeguard the employer against the serious effects of a case of smallpox amongst its employees.⁷¹

In *King v. J.N. Arthur*,⁷² the North Carolina court held that where a board of health compelled dairy employees to submit to periodic blood tests, the risk of infection or other injury did not arise out of the employment and the injury was not compensable.⁷³

In *Suniland Toys v. Karns*,⁷⁴ an employee was vaccinated at employer expense during work hours after a hurricane contaminated the local water supply, creating a risk of typhoid fever. The Florida Supreme Court found the employee’s allergic reaction to the vaccine to be compensable, saying that the vaccination was “of ‘benefit’ and ‘mutually advantageous’ to employer [and employee].”⁷⁵ This finding, we think, is necessarily based on the fact that under the particular circumstances the inoculation was calculated to reduce the risk of compensable disability.⁷⁶ The Florida court embraced the mutual benefit doctrine, and thereby negated the defense that a measure in-

69. *See Smith v. The Seamless Rubber Co.*, 150 A. 110 (Conn. 1930).

70. 64 A.2d 99 (App. Div. 1949), *aff’d* 66 A. 2d 158 (N.J. 1949).

71. *Id.*

72. 96 S.E.2d 846 (N.C. 1957).

73. *See id.*

74. 148 So. 2d 523 (Fla. 1963).

75. *Id.*

76. *Id.*

tended for the worker's own benefit does not create a risk arising from the employment. The facts in *Suniland Toys*, however, are distinguishable because an identifiable danger of illness contracted on the job is present, and thus, avoided by the typhoid vaccination.⁷⁷

In *City of Littleton v. Schum*,⁷⁸ a fireman was required to be vaccinated for hepatitis because a fellow firefighter had developed the disease. The Colorado Court of Appeals rejected the vaccinee's workers' compensation petition, saying that "exposure to infectious hepatitis is not indigenous solely to the work of firemen, but exists equally outside of that employment, as evidenced here by claimant's advising his doctor that he was exposed at a banquet."⁷⁹ It could, therefore, be argued that potential first responders who are being vaccinated today simply share in a risk that faces the general public.

Perhaps closest to the mark is *City of Austin v. Smith*.⁸⁰ The court states the issue:

At the time of Smith's alleged injury of October 19, 1976 he was a firefighter employed by the City of Austin. The injury, so called, was or resulted by reason of a "swine flu inoculation," the ingredients for which were provided by the federal government and administered by the city through its agents and employees.

While receipt of the inoculation was voluntary in that Smith was at liberty to refuse it, the jury was entitled to believe that the City desired that he receive it for its own welfare (in that greater assurance of ability of Smith to perform the duties of his employment would be provided). The record shows that Smith desired to receive it for his individual protection.⁸¹

The Texas Court of Civil Appeals, further embraces the *Saintsing* decision, relying in part on the following support from a widely-cited treatise:

Injury through inoculation should be covered "if there is a combination of strong urging by the employer and some element of mutual benefit...." Larson, *Workmen's*

77. *See id.*

78. 553 P.2d 399 (Co. App. 1976).

79. *Id.*

80. 579 S.W.2d 84, 85 (Tex. Civ. App. 1979).

81. *Id.*

Compensation Law § 27.32 (1978), "Inoculations and employment health tests."⁸²

The argument favoring compensability seems likely to prevail, despite the voluntary nature of the program, and that it is for the general public benefit, rather than the employer's. The inoculation is a qualification for membership in a smallpox response team, which the nation's highest public health authorities, acting to protect the general welfare, have called upon states, local government, health care providers, and emergency response forces to undertake. A worker's response to the urging of his employer to take risks for such purposes is of mutual benefit - to himself, to the employer, and to the nation. That such an employee is doing his patriotic duty is also a factor that should not be ignored in the calculus.

Other No-fault Compensation Options

Workers' compensation programs are not the only no-fault compensation schemes that have ever been enacted. In a quasi-elective system, Congress enacted the National Childhood Vaccine Injury Act of 1986 (NCVIA), which in turn established the National Childhood Vaccine Injury Compensation Program.⁸³ In essence, the system creates a no-fault administrative remedy that must be exhausted before a common law tort claim can be brought. Financed by an excise tax on vaccines, the scheme immunizes manufacturers from suit, while providing for and assuring compensation to those suffering injuries caused by childhood vaccines.⁸⁴

This compensation scheme recognizes both, the special public interest in a comprehensive program of childhood immunization, and the essentially involuntary character of the risk of vaccine-related injury. A century ago, in *Jacobson v. Massachusetts*, the United States Supreme Court upheld the right of a state to compel immunization of children as a public health measure.⁸⁵ In such a mandatory immunization environment, pressure grew for a system that would compensate children injured by vaccinations to which they had no choice but to submit. From a public health standpoint, compensation was preferable to granting a parental right of refusal, such as had

82. *Id.*

83. 42 U.S.C. §§ 300aa-10 - 300aa-34 (2000).

84. 42 U.S.C. § 300aa-12(e).

85. 197 U.S. 11 (1905).

been implied by judgments requiring individualized warnings of the small risk of serious injury. Allowing children to opt out would hinder the vaccination program from achieving the degree of compliance critical to disease control and eradication.⁸⁶ These concerns coupled with the alarm of vaccine manufacturers at the unpredictability of the liability awards they faced for claims such as those arising from injuries ostensibly due to DPT vaccine, led to Congressional action.⁸⁷

86. *See, e.g.,* *Reyes v. Wyeth Labs.*, 498 F.2d 1264 (5th Cir. 1974) (upholding verdict for child injured by Sabin live virus polio vaccine whose mother did not receive warning of the risk of vaccine-induced paralytic polio when child was vaccinated in mass-inoculation program).

87. *See* *Reitze, supra* note 41 at 193-94. Surveying some of the DPT cases:

In *Holcomb v. United States*, No. 79-2376 (S.D. W. Va. Feb. 15, 1982), the plaintiff received a series of DPT shots in army clinics and then suffered encephalopathy. The parents brought suit against the United States under the Federal Tort Claims Act and against Richard-Merrell, the vaccine manufacturer. The government settled for \$390,000, Richard-Merrell contributed \$210,000. *Id.*

In *Wilson v. United States*, No. C80-1325A (N.D. Ga. July 9, 1982), Air Force physicians gave a DPT shot to a child who had severe reactions to previous DPT inoculations. The adverse reaction left the child permanently, severely retarded. The suit was brought under the FTCA and the plaintiff agreed to a structured settlement with a present value of \$2,299,948. *Id.*

In *Piefer v. Devitt*, No. 590-343 (Mil. Co. Cir. Ct. Feb. 1, 1984), a pediatrician gave a third DPT shot to a child who had adverse reactions to the first and second shots. The plaintiff suffered febrile reactions and convulsions that left the child mentally retarded, requiring 24 hour [sic] care. A jury awarded the plaintiff \$3.05 million. *Id.*

In *Toner v. Lederle Labs.*, 732 P.2d 297 (Idaho 1987), *aff'd* 828 F.2d 510 (9th Cir. 1987), a jury in Boise, Idaho awarded nearly \$1.2 million to the parents of a child who developed transverse myelitis, allegedly as a result of a DPT shot. According to the plaintiff's lawyer, the case turned on whether Lederle's vaccine was as safe as another vaccine, Tri-Solgen, which was manufactured by Eli Lilly. *Id.*

The NCVIA provides awards for (1) pain and suffering, approving an award even though the injured person may be incapable of conscious suffering but imposing a statutory cap of \$250,000 (2) lost wages or earnings (3) expenses of medical care and necessary diagnostic services (4) expenses of required care, therapy, assistance, or special education (5) expenses for adaptive living or architectural alterations to the homes of petitioners to enable them to continue living at home (6) under certain circumstances, premiums for health insurance (7) a \$250,000 death benefit, and (8) attorneys fees and costs or expenses incurred in the litigation.⁸⁸ Contested claims are litigated before a special master of the Court of Federal Claims to which appeals are taken, and are ultimately subject to review by the United States Court of Appeals for the Federal Circuit.⁸⁹

It would be a perilous decision for a child (or their parent) to risk an offer that's only inadequacy is in the amount of pain and suffering. As a result, the right to file a common law tort action is maintained, but there seems to be little vitality in that option given the efficiency and reliability of the administrative remedy.

The Institute of Medicine, in its letter report on the CDC proposal, urged that the smallpox vaccination program "clarify" each state's position on workers' compensation benefits, and that the CDC and Department of Health and Human Services be "bold and creative" to bring the "issue of smallpox adverse reactions - including those that occur despite non-negligent manufacture and administration of the

In *Morris v. Parke, Davis & Co.*, 573 F. Supp. 1324 (C.D. Cal. 1983), the plaintiff suffered irreversible brain damage as a result of a DPT shot. Since the plaintiff was unable to identify the specific manufacturer of the vaccine, the suit was brought against five pharmaceutical companies [that] produced a substantial share of the DPT vaccine marketed in 1965 on a market share theory of liability. Ruling on a pretrial motion, the court held that, if the plaintiffs proved causation and could show that one or more of the defendants marketed the drug with conscious disregard for the health of consumers, then the plaintiffs will be entitled to recover punitive damages from each defendant. *Id.*

88. 42 U.S.C. § 300aa-15.

89. *See id.* at aa-12.

vaccine - to speedy resolution.”⁹⁰ The Waxman Bill, as discussed below, is a step toward that speedy resolution.

The Waxman Bill – H.R. 865

Representative Henry Waxman has introduced in the 108th Congress H.R. 865, the “Smallpox Vaccine Compensation and Safety Act of 2003.”⁹¹ The bill would establish a federally funded, state-implemented education program:

[T]o provide to each individual to whom a covered countermeasure against smallpox is proposed to be administered an explanation of (i) the screening and medical surveillance and evaluation programs available...(ii) the risks and benefits from administration of such countermeasure for such individuals and those individuals with whom they have close contact; (iii) the availability of the compensation program [created under the bill]; (iv) the eligibility of the individual to receive health care benefits; (v) the right of the individual to refuse the administration of any covered countermeasure against smallpox; (vi) the right of an individual who [declines to be vaccinated] to be protected from disciplinary action or wage reduction; and (vii) the general functions and duties that such individual may be expected to carry out if there is a smallpox outbreak.

Freedom of Choice

H.R. 865 is designed to assure that informed consent is genuinely informed, that the states are relieved of much of the burden of the federal program, and that the choice to be vaccinated is truly voluntary. These are rights of individual autonomy which are widely recognized in the law, but which are likely to be eroded by peer pressure and employer influence without such Congressional support for their exercise and protection from their violation. It is often said that we have to sacrifice some of our freedoms for greater security, but

90. IOM *Letter Report #1*, *supra* note 27, at 35, Summary of Recommendations.

91. Smallpox Vaccine Compensation and Safety Act of 2003, H.R. 865, 108th Cong. (2003).

surely we should not ask only some to sacrifice their personal freedoms without ensuring that their choice to do so is fully informed. It is only right to insist that those whom we ask to subject themselves to the risk of disease, on our behalf, make genuinely free choices to do so.

Medical Leave

Workers' compensation laws generally provide wage loss benefits only if one is out of work one week or more. Filling the gap of 5 days common in workers' compensation laws, H.R. 865 would amend the Fair Labor Standards Act of 1938 and the Family Leave Act, to provide that a worker "shall be entitled to a total of not more than 4 workdays of paid leave because of a health condition that makes the employee unable to perform the functions of the position of such employee that arose as a result of the employee having received (smallpox vaccine) or come into close contact with (a vaccinated) individual." The measure would provide for full pay, and "shall apply to all employers regardless of size." It is enough to ask someone to subject herself to the vaccinia live virus vaccine, without quibbling over the time that is necessary to recover from its adverse effects, whether mild or severe.

Medical Surveillance and Evaluation Program

H.R. 865 would fund in HHS "an ongoing active medical surveillance and evaluation program [for] all individuals [vaccinated for smallpox] and [their close contacts]." As the IOM has urged, this is an active surveillance system, unlike the passive surveillance systems (e.g. VAERS) currently in place. The IOM, which urges a go-slow approach to smallpox vaccination, has urged that the CDC "develop and communicate the criteria (i.e. types and rates of adverse reactions) that would trigger a reconsideration" of the current vaccination plans. The IOM seeks a pause between Phase I (in which 500,000 public health and health care workers would be vaccinated, and Phase II (in which 10 million health care, public health, and other emergency response workers would be vaccinated).⁹² The active surveillance measures of H.R. 865 would provide a firm foundation of data, with which to assess the risks of the much larger Phase

92. *See id.*

II vaccination contemplated by the CDC. This is a prudent measure as we seek to minimize harm, where the benefits are uncertain; benefits could be nonexistent if there is no attack or very great if there is an attack.

Health Care Benefits

H.R. 865 would reimburse states for providing “such medical care as may be medically necessary” to any “health care worker or first responder” who has suffered any adverse reaction or complication, and to any individual who “has suffered any adverse reaction or complication as a result of contact with another person who received (smallpox vaccine).” The bill’s benefits are only for medical costs that are not covered by insurance or contractual reimbursement obligation. Health insurers would be obligated in every group health plan “to provide coverage of the side effects” of smallpox vaccination. These measures wisely provide compensation to those who were neither asked to volunteer to take the risk of vaccination, nor have the assurance that most workers will have of health insurance or workers’ compensation benefits.

National Smallpox Vaccination Injury Compensation Program

H.R. 865 would amend the Homeland Security Act’s exclusive tort remedy (which extends the protection from liability afforded Public Health Service officers)⁹³ by providing that claims for smallpox vaccine -related injuries be brought under the National Vaccine Injury Compensation Program.⁹⁴ Claimants would first have to exhaust the administrative petition for compensation under the Smallpox Program as established by the legislation. The bill would extend the benefit to those who were injured “as a result of contact” with a person who received the smallpox vaccine. Claimants would be exempt from the vaccine program’s requirement that the claimant prove death, residual effects for more than 6 months, or in-patient hospitalization and surgical intervention. The death benefit would “include an award for the estate of the deceased of \$850,000, in addition to any other compensation to which the petitioner is entitled.”

93. See 42 U.S.C. § 233 (2003).

94. 42 U.S.C. § 300aa-10 (2000).

Easing the burden of proof in the manner of the Childhood Vaccine Act, the Vaccine Injury Table would be amended by statute to include a presumption that the common adverse effects and complications of vaccinia vaccination are causally related to the vaccine itself. Compensation, however, would be barred for “minor scarring or minor local reaction.”⁹⁵ This comprehensive program would incorporate into the National Vaccine Compensation Program a new set of injuries due to a new set of risks undertaken. Though the number of persons at risk is small, our commitment to those from whom special commitment is asked (EMT crews, firemen, policemen, and rescue and recovery workers) is warranted. Their necessity and selflessness was demonstrated as they rushed towards the towers and the ruins of Ground Zero, on September 11, 2001; the day that New York and Washington became the first battlefields of a century of war anywhere, anytime. Learning from these exemplars of hero-

95. Proposed amendments to Vaccine Injury Table, 42 U.S.C. § 300aa-14:

Adverse event:

Time period for first symptom or manifestation of onset or of significant aggravation after administration of vaccinia virus or other substance or medication administered for the purpose of preventing or treating smallpox (including a covered countermeasure against smallpox):

- A. Anaphylaxis or anaphylactic shock 0-4 hours
- B. Eczema vaccinatum (including in a contact case) any
- C. Accidental inoculation (including in a contact case).... any
- D. Progressive vaccinia any
- E. Encephalopathy (or encephalitis)..... 0-21 days
- F. Stevens-Johnsonsyndrome 3-21 days
- G. Generalized vaccinia 0-60 days

ism, whom must never be forgotten, provides cogent support for reform.

The Administration Proposal

After several months of silence, the Bush administration on March 5, 2003 outlined a limited program of compensation. Rather than incorporate the program into the National Vaccine Injury Program (NVCIP), the Administration's initiative is modeled on the Public Service Officers Benefit Act (PSOBA), which provides a death and total and permanent disability benefit, with a COLA-adjusted cap.⁹⁶

The measure has not yet been introduced in Congress. The expected sponsor, Senator Judd Gregg (Rep. N.H.), explains that the benefits would be administered by the Department of Health and Human Services and be retroactive to cover those who already have been vaccinated under the program. The four elements of the plan, according to Senator Gregg,⁹⁷ include:

Permanent and total disability benefit: HHS would create a benefit modeled on the PSOBA to offer a \$262,100 permanent and total disability benefit for disability caused by the administration of the vaccine. This benefit would be paid regardless of other death benefits available to the individual.

Death benefit: HHS would create a benefit modeled on the PSOB to offer a \$262,100 death benefit for deaths caused by administration of the vaccine. This benefit would be paid regardless of other death benefits available to the individual (except the approximately one-third of first responders who are already covered by the PSOBA).

Temporary or partial disability benefit: HHS would compensate individuals for two-thirds of lost wages after the fifth day from work, up to a maximum of \$50,000.

96. 42 U.S.C. § 3796 (2003).

97. Press Release, Judd Gregg, Senator Gregg to Move Smallpox Compensation Legislation Through Senate (Mar. 6, 2003), *available at* <http://gregg.senate.gov/press/press030603a.pdf>.

Health care benefit: HHS would compensate individuals above for their reasonable out-of-pocket medical expenses. This benefit would be secondary to any health insurance benefit that might be available to the individual.

Additionally, says Gregg, HHS would compensate third parties contracting vaccinia from public health and medical response team workers who have been vaccinated.⁹⁸ Attorneys' fees are not included in the PSOB program and no mention is made of them in the Gregg/HHS proposal. It is also noteworthy that there is no award for permanent partial disability, such as disfiguring scarring due to eczema vaccinatum, or other long-term effects of vaccine-induced vaccinia.

The Gregg/HHS proposal is far less generous than the Waxman bill. The death benefit is much higher in the Waxman measure. Perhaps more important from a public health point of view, the education and surveillance programs provided by H.R. 865 are not mentioned in the Gregg/HHS announcements. These elements serve to minimize the risks we impose on our health care workers, and increase our confidence that a health care worker's choice to be vaccinated is really informed and really voluntary. The Gregg/HHS proposal is, nonetheless, a step forward because it marks the entry into the Congressional majority's and the Administration's discussion. The Waxman bill, H.R. 865, is a highly desirable set of measures to address the goals of protecting public health with maximum effectiveness, and at minimum cost in human suffering due to vaccine-related disease.

IV. POSTSCRIPT: FALSE ALARM? PREPAREDNESS, BIOTERRORISM, AND ADVERSE EVENT EXPERIENCE AMONG CIVILIAN AND MILITARY SMALLPOX VACCINEES

Following this paper's first presentation, the United States won a war in Iraq. Before the war began, President Bush advised us that our defense included "inoculating troops and first responders against smallpox" and that a "major research and production effort to guard our people against bioterrorism, called Project Bioshield" had be-

98. *Id.*

gun.⁹⁹ Invoking September 11, 2001, the President asked us to “imagine those 19 hijackers with other weapons and other plans - this time armed by Saddam Hussein. It would take one vial, one canister, one crate slipped into this country to bring a day of horror like none we have ever known.”¹⁰⁰

A week later, Secretary of State Colin Powell, speaking before the United Nations Security Council, declared that “Saddam Hussein has investigated dozens of biological agents, causing diseases such as gas gangrene, plague, typhus, tetanus, cholera, camel pox and hemorrhagic fever. And he also has the wherewithal to develop smallpox. The Iraqi regime has also developed ways to disperse lethal biological agents widely, indiscriminately, into the water supply, into the air.”¹⁰¹ The war, however, has yet to yield evidence of biological weapons, much less mobile laboratories capable of producing large amounts of infectious agents, as had been alleged.¹⁰²

99. Later introduced as H.R. 2122, the Project Bioshield Act of 2003 is described by its sponsor as an act “to enhance research, development, procurement, and use of biomedical countermeasures to respond to public health threats affecting national security to enhance research, development, procurement, and use of biomedical countermeasures to respond to public health threats affecting national security”. H.R. 2122, 108th Cong. (2003).

100. Press Release, Office of the Press Secretary, Remarks by the President on Smallpox Vaccination (Dec. 13, 2002) (on file with the Fordham Environmental Law Journal).

101. *Threats and Responses; Powell’s Address, Presenting ‘Deeply Troubling’ Evidence on Iraq*, N.Y. TIMES, Feb. 6, 2003 at A18.

102. According to Secretary Powell at the UN:

The trucks and train cars are easily moved and are designed to evade detection by inspectors. In a matter of months, they can produce a quantity of biological poison equal to the entire amount that Iraq claimed to have produced in the years prior to the gulf war. Although Iraq’s mobile production program began in the mid-1990’s, U.N. inspectors at the time only had vague hints of such programs. *Id.*

But the speculation was not confirmed. David Kay, the Central Intelligence Agency’s leader in the search for illegal weapons in Iraq has testified:

The short-term impact on the civilian smallpox vaccination program has been plain. Despite initial enthusiasm, in which half of Americans polled said they would get the vaccine if offered,¹⁰³ few civilians stepped forward as the biological warfare threat failed to materialize, and wide publicity highlighted the cases of those who suffered illness after inoculation with the Dryvax vaccinia vaccine.¹⁰⁴

We have not yet found stocks of weapons. . . With regard to biological warfare activities, which has been one of our two initial areas of focus, ISG teams are uncovering significant information. All of this suggests Iraq after 1996 further compartmentalized its program and focused on maintaining smaller, covert capabilities that could be activated quickly to surge the production of BW agents. . . . We have not yet been able to corroborate the existence of a mobile BW production effort. Investigation into the origin of and intended use for the two trailers found in northern Iraq in April has yielded a number of explanations, including hydrogen, missile propellant, and BW production, but technical limitations would prevent any of these processes from being ideally suited to these trailers. That said, nothing we have discovered rules out their potential use in BW production.

The Interim Progress Report on the Activities of the Iraq Survey Group (ISG) Before the House Permanent Select Comm. on Intelligence, the House Comm. on Appropriations, the Subcomm. on Defense, and the Senate Select Comm. on Intelligence (Oct. 2, 2003) (statement of David Kay, Central Intelligence Agency), at http://www.cia.gov/cia/public_affairs/speeches/2003/david_kay_10022003.html (last visited Oct. 25, 2003).

103. See REUTERS HEALTH, GALLOP POLL (Feb. 11, 2003).

104. McNeil, *supra* note 21 (“President Bush’s plan to vaccinate 500,000 health care workers against smallpox is getting off to an unexpectedly slow start as hundreds of hospitals and thousands of nurses across the country say that they will not participate.”).

Adverse Event Surveillance and Reporting

The IOM's request for a pause to study adverse effects, after the first stage of civilian inoculations, was not heeded.¹⁰⁵ However,

105. In its first letter report, the IOM had urged a cautious approach:

Based on the administration's statement that the risk of a smallpox attack is indeterminate (not zero but currently assumed to be very low) (White House, 2002), the benefit of the vaccination program to the public also is not zero but is assumed to be very low. The benefit to any individual might indeed be zero if the individual never encounters the smallpox virus. However, in the event of exposure to smallpox virus, the benefit to individuals may be very high. Given this profile of high vaccination risk and likely very low to zero benefit, the administration's policy to offer vaccination to public health, medical, and emergency workers must be implemented in a most prudent and cautious manner.

IOM Letter Report #1, supra note 27, at 5.

Two months later, the IOM was suggesting a pause - though the inconsistent implementation of the program had prevented the clean break that had been expected between phase I (first responders) and phase II (health care and other workers):

Plans for implementation of the vaccination program have evolved in a way that precludes the firm demarcation between what were initially intended as two distinct phases or stages of the program. The committee hopes that this turn of events will not impair efforts to ensure the safest vaccination program possible, but steps must be taken to (1) define and progress toward smallpox preparedness, and (2) evaluate the effectiveness of implementation and the safe use of the vaccine as extensively as the mandates and realities of the vaccination program will allow. Thus, evaluation at the national level might not take place before the program progresses (although some state and local jurisdictions may be able to pause for evaluation before expanding their program activities) but at

skeptical response from hospitals and health workers may have accomplished a functional equivalent. Rather than the 500,000 first responders who were expected to receive inoculation quickly, only 38,062 had been voluntarily vaccinated by August 29, 2003, at which point the civilian program was nearly at a halt.¹⁰⁶ While the 10 million health and emergency workers projected to be vaccinated apparently never will be inoculated, the Department of Defense carried out about 500,000 mandatory vaccinations of troops and military healthcare workers.¹⁰⁷ Their experience provides a basis on which to gauge the risks and wisdom of smallpox vaccination.

Because smallpox vaccination had been universal until 1972, when civilian vaccination ended, there was a large database available as vaccinations resumed. Relying extensively on the classic epidemiological reports of Professor J. Michael Lane, who had studied smallpox vaccination programs for 50 years, the Advisory Committee on Immunization Policy (ACIP) recommended in June of 2001 that smallpox vaccination need only resume when an actual terrorist release of the virus was reported.¹⁰⁸ Citing the risks of vaccine-related illness, the ACIP also recommended development of a new, safer smallpox vaccine.¹⁰⁹ Reviewing the reported complications associated with first-time vaccinia vaccination, the ACIP saw the principal risks to be 1) accidental inoculation (spread from one part of the vaccinee's body to another, or one person to another) 529.2/million, 2) generalized vaccinia (systemic illness due to the

least should occur simultaneously, to ensure that lessons are learned from phase I even in the face of a rapid expansion.

106. See CTR. FOR DISEASE CONTROL, U.S. DEP'T OF HEALTH & HUMAN SERVICES, *Smallpox Vaccination Program Status by State*, at www.cdc.gov/od/oc/media/spvaccin.htm (last visited Nov. 7, 2003). Through July 31, 2003 38,062 civilians had been vaccinated. *Id.* In the month of August only 315 were vaccinated. *Id.* The civilian total has thus reached only 38,377. *Id.*

107. See DEP'T OF DEF., *DoD Smallpox Vaccination Program Safety Summary, as of June 25, 2003*, at <http://www.smallpox.army.mil/event/SPSafetySum.asp> (last visited Nov. 7, 2003).

108. See ACIP Recommendations, *supra* note 13, at 18-21 (recommending vaccination for laboratory and medical workers working with non-attenuated orthopoxes).

109. See *id.*

vaccinia virus) 241.5/million, 3) eczema vaccinatum (skin rashes among those with eczema history) 38.5/million, 4) progressive vaccinia (severe necrosis at the vaccination site) 12.3/million, and 5) postvaccinial encephalitis 12.3/million.¹¹⁰ The last two were considered potentially fatal.¹¹¹

The ACIP's assessment was shared by scientists at the FDA, who urged the development of new, safer vaccines, and addressed the possibility of regulatory pre-market approvals gained without human studies of efficacy. Like the ACIP, they relied on the historic work of Lane and others. Unlike the ACIP, they took note of the rare case reports of acute pericarditis after smallpox vaccination.¹¹²

As the government moved toward large-scale vaccination, Dr. Lane himself took a cautious approach.¹¹³ Lane urged that vaccination should be limited to the "small numbers of first responders and personnel who might be involved in the investigation and control of possible smallpox outbreaks" because of the risk of vaccine-associated disease, because smallpox spreads slowly, and because vaccination within the first 2 to 3 days of contraction "generally aborts the disease."¹¹⁴ Following the conventional historical epidemiology, he identified as major adverse events after vaccination only postvaccinial central nervous system disease, progressive vaccinia, eczema vaccinatum, and fetal vaccinia.¹¹⁵ Lane's approach did not change the Administration's policy - seeking vaccination of millions - but the concerns he identified can explain the low rate of voluntary civilian vaccinations.

110. *See id.*

111. *See id.*

112. Steven R. Rosenthal, Michael Merchlinsky, Cynthia Klepinger & Karen L. Goldenthal, *Developing New Smallpox Vaccines*, 7 *Emerging Infectious Diseases* 6, 920-24 (Nov.-Dec. 2001).

113. *See* J. Michael Lane & Joel Goldstein, *Evaluation of 21st-Century Risks of Smallpox Vaccination and Policy Options*, 138 *ANNALS INTERNAL MED.* 6, 488-93 (2003).

114. *Id.*

115. *See id.*

Assessing the Recent Civilian and Military Vaccinia (Smallpox)
Vaccination Experience

The civilian rates of life-threatening complications have been low, compared to historical rates. Historically, generalized vaccinia - the disease caused by the live virus with which we now inoculate for smallpox - occurred among first-time vaccinees at the rate of 241/million. To date, only 3 cases have been reported among the 38,000 civilian vaccinees - a rate of only 78/million. There have been no cases of postvaccinial encephalitis (historically 12/million), and no cases of eczema vaccinatum (historically 38/million).¹¹⁶

These low rates were a surprise since the surveillance has been far more active than the usual passive Vaccine Adverse Event Reporting System (VAERS). The IOM had expected that the adverse reaction rates would be higher than the historical record because vaccination had ended in 1972 and persons are more susceptible to injury on first vaccination. Also, immune-compromised persons are a larger fraction of the population than in the past. However, as the IOM suggested, careful selection (and perhaps, low volunteer rates of self-selection) might have reduced the rate of adverse effects.¹¹⁷

116. For historic rates *see* ACIP Recommendations, *supra* note 13, at 8. For contemporary rates of injury *see* CTR. FOR DISEASE CONTROL, U.S. DEP'T OF HEALTH & HUMAN SERVICES, *Smallpox Vaccination and Adverse Reactions: Guidance for Clinicians*, 52 No. RR04 MORBIDITY & MORTALITY WEEKLY REPORT 1 (Feb. 21, 2003).

117. *See* IOM Letter Report #1, *supra* note 27.

Although the vaccine to be used in the first two phases of the program is the same calf lymph-derived vaccine stored since the 1970s, the host characteristics on a population level have changed significantly. First, a high proportion of the population has not been immunized against smallpox, and there is evidence that primary vaccinees are more likely to experience serious adverse reactions compared to those being revaccinated (Lane et al., 1969). The vaccine also carries significant risks for some members of the population—those with various types of immune suppression, such as HIV infection or due to cancer chemotherapy, those with certain diseases such as eczema and atopic dermatitis, and close personal contacts of vac-

From Passive to Active Surveillance

The high degree of public attention given to the program, the concerns of the IOM, and the lobbying pressure of trade unions and others may be responsible for the active reporting system adopted by the CDC. The VAERS is a post-marketing safety surveillance program created as an outgrowth of the National Childhood Vaccine Injury Act of 1986 (NCVIA), and is administered by the FDA and the CDC. The government does not actively survey as part of this system. Reporting by medical providers is not mandatory. The FDA explains that "when the event occurs soon after vaccination ... [d]octors and other vaccine providers are encouraged to report adverse events, whether or not they believe that the vaccination was the cause. If the VAERS data suggest a possible link between an adverse event and vaccination, the relationship may be further studied in a controlled fashion."¹¹⁸ In contrast, the smallpox adverse event reporting system is pro-active. Doctors and others are given far more direct advice to report possible vaccine-caused injury. The CDC has instructed practitioners:

Providers are strongly encouraged to report serious adverse events to VAERS after the administration of the smallpox vaccine.* VAERS is a passive reporting system for safety monitoring of all vaccines licensed in the United States, and is jointly managed by CDC and FDA. CDC and FDA will monitor smallpox vaccine-related ad-

cinees who have such contraindications. The U.S. population has many more people at high risk for serious adverse reactions now compared to the 1960s, when most data concerning the safety profile of the vaccine was collected. Furthermore, it is assumed that with rigorous efforts at screening those at risk and with intensive efforts at educating vaccinees about caring for the vaccination site, accidental inoculation of high-risk contacts of vaccinees can be minimized. However, the actual risks will only be known after the vaccination program is operative.

Id.

118. CTR. FOR BIOLOGICS EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., *Vaccine Adverse Event Reporting System (VAERS) Overview*, at <http://www.fda.gov/cber/vaers/what.htm> (last updated Apr. 17, 2003).

verse event reports daily, and will provide enhanced surveillance of adverse events after administration of the smallpox vaccine. However, adverse events that are judged to be serious or unexpected and which require CDC consultation or IND therapies (VIG or cidofovir) should not be solely reported to VAERS. These cases should instead be immediately reported by phone to the appropriate state health department officials and CDC, who will assist the reporting provider with completion of a VAERS form. All other smallpox vaccine adverse events that are serious, but do not require CDC consultation or administration of IND therapies, should be reported directly to VAERS within 48 hours of recognition. All other adverse events should be directly reported to VAERS within 1 week.¹¹⁹

*phone, fax, and other contact information omitted.

This active system of monitoring and follow-up by CDC produced a headline-making, and surprising observation - an unexpectedly high rate of myocarditis/pericarditis and inflammation of the heart/membrane-¹²⁰ conditions which may range in severity from mild to life threatening. The CDC recorded 10 cases of cardiac adverse events among civilian vaccinees in the period January 24 -

119. Joanne Cono, Christine G. Casey & David M. Bell, *Smallpox Vaccination and Adverse Reactions*, 52 No. RR04 MORBIDITY & MORTALITY WEEKLY REPORT 26 (Feb. 21, 2003); *see also*, CTR. FOR DISEASE CONTROL, U.S. DEP'T OF HEALTH & HUMAN SERVS., HOSPITAL SMALLPOX VACCINATION MONITORING SYSTEM (HSVMS), *at* <http://www.bt.cdc.gov/agent/smallpox/vaccination/hsvms/index.asp> (last modified May 13, 2003). "A voluntary, web-based component developed to assist hospitals or other vaccine monitoring sites in real-time monitoring and tracking of healthcare workers who receive smallpox vaccine. HSVMS can be used to record the daily assessment of the vaccination site, symptoms reported by the vaccinee, vaccine take, determination of fitness for duty, and work days lost." *Id.*

120. *See* CTR. FOR DISEASE CONTROL, U.S. DEP'T OF HEALTH & HUMAN SERVICES, *Update: Adverse Events Following Smallpox Vaccination - United States, 2003, Previous Civilian Cardiac Adverse Events*, 52 No. 13 MORBIDITY & MORTALITY WEEKLY REPORT 278 (Apr. 4, 2003).

March 30, 2003.¹²¹ Four cases of myocarditis or myopericarditis were reported in civilians aged 32, 45 (2), and 56 years of age.¹²² Historically, pericarditis and myocarditis had not been recognized as a smallpox-related complication.

During the military vaccination program, through March 31, 2003, fourteen cases of myocarditis and/or pericarditis were identified among 250,000 personnel who received smallpox vaccination for the first time.¹²³ No cases were reported among revaccinees.¹²⁴ Most surprising was the age of the patients, which ranged from 21 to 33 years.¹²⁵ Severity ranged from mild to severe (congestive heart failure), however there were no fatalities.¹²⁶

The ACIP quickly met and issued an advisory that those with known heart disease should not be vaccinated.¹²⁷ The ACIP found the data to be “consistent with a causal relation between myocarditis/pericarditis and smallpox vaccination, but no causal association between the ischemic cardiac events and smallpox vaccination has been identified.”¹²⁸ Nonetheless, the data was sufficiently alarming that ACIP urged new precautions. Vaccinees should be “informed that myopericarditis is a potential complication of receiving smallpox vaccine.”¹²⁹ The ACIP further recommended exclusion from the program of persons who:

... have known underlying heart disease, with or without symptoms, or who have three or more known major cardiac risk factors (i.e. hypertension, diabetes, hypercholes-

121. *See id.*

122. *See id.*

123. *See id.*

124. *See id.*

125. *See id.*

126. *See id.*

127. *See* CTR. FOR DISEASE CONTROL, U.S. DEP'T OF HEALTH & HUMAN SERVICES, *Supplemental Recommendations on Adverse Events Following Smallpox Vaccine in the Pre-Event Vaccination Program: Recommendations of the Advisory Committee on Immunization Practices*, 52 No. 13 MORBIDITY & MORTALITY WEEKLY REPORT 282 (Apr. 4, 2003).

128. *Id.*

129. *Id.*

teremia, heart disease at age 50 years in a first degree relative, and smoking).¹³⁰

Myopericarditis (an inflammation of the muscular wall of the heart and the enveloping pericardium) proved to be the most common of the serious possible sequellae reported.¹³¹ Determination of whether the incidence of that illness among adult vaccinees is coincidental or causally related may be the subject of study and disagreement for some time. The active monitoring by CDC of vaccine adverse health effects and its prompt advice to practitioners was an exemplary precautionary approach by public health authorities who have the benefit of military data. However, the military experience also shows that the CDC/ACIP continued to underestimate the risk of myopericarditis, and that its exclusions may have been too cautiously stated.

Military surveillance has yielded the most instructive data. Its success yields lessons for those concerned with the effectiveness of the haphazard reporting that characterize the VAERS. The military experience may also yield lessons for the post-market reporting the FDA requires of manufacturers of drugs and biologic products.¹³² The military experience is especially valuable because of the large

130. *Id.*

131. CTR. FOR DISEASE CONTROL, U.S. DEP'T OF HEALTH & HUMAN SERVICES, *Adverse Events Associated with Smallpox Vaccination Among Civilians*, at <http://www.cdc.gov/od/oc/media/spcivil.htm> (last updated Sept. 25, 2003).

132. See U.S. FOOD & DRUG ADMIN., *Guidance for Industry, Post-marketing Adverse Experience Report for Human Drug and Licensed Biological Products: Clarification of What to Report*, at <http://www.fda.gov/cber/guidelines.htm> (Aug. 27, 1997). Biologic product manufacturers must submit postmarketing safety reports to the FDA (21 C.F.R. §§ 600.80 – .81). *Id.* Drug manufacturers, packers and distributors have postmarket safety reporting responsibilities under 21 C.F.R. § 310.305, 314.80, 314.98 and 600.80. *Id.* They are required to report reports of serious and unexpected adverse events from all sources. *Id.* Postmarketing study reports of adverse experiences must be reported if the applicant/licensee “believes that there is a reasonable possibility that the drug or biological product caused the adverse experience.” U.S. FOOD & DRUG ADMIN., *Draft Guidance for Industry, Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines*, at <http://www.fda.gov/cber/guidelines.htm> (Mar. 12, 2001).

number of vaccinees, and the Defense Department's well-conducted surveillance of health effects. These studies were the careful evaluation of the health effects of smallpox/vaccinia inoculation, for which the IOM had hoped. The study results, though containing some surprises, were generally reassuring, yielding somewhat lower than historical rates of adverse effects, and illuminating historically underappreciated risks, principally cardiac in nature.

The results of the military program have been reported in the *Journal of the American Medical Association (JAMA)*. The record is summarized in a report by John D. Grabenstein of the Military Vaccine Agency and William Winkenwerder, Jr., Assistant Secretary of Defense for Health Affairs.¹³³ They reported that adverse events were below historical rates, that all patients recovered and returned to duty, and that mass smallpox vaccinations can be conducted safely with lower than historically recognized rates of vaccine-related illness.¹³⁴ The Defense Department's reports in *JAMA* were lauded by the Director of the National Institute of Allergy and Infectious disease for "highlight[ing] the ongoing challenge to clinicians to be mindful of the old while being vigilant for the new" and for providing a "model" which "provided the civilian population with critical information pertaining to an important general public health issue."¹³⁵

Particularly impressive as a model for the study of the health effects by public health authorities and pharmaceutical manufacturers is the military surveillance program, which is aided by a powerful relational database known as the Defense Medical Surveillance System.

This system integrates data from sources worldwide in a continuously expanding relational database that documents the military and medical experiences of service members throughout their careers. The DMSS allows nearly instantaneous assessments of the morbidity experi-

133. John D. Grabenstein & William Winkenwerder, Jr., *US Military Smallpox Vaccination Program Experience*, 289 *JAMA* 3278, 3280-81 (2003).

134. *See id.* at 3280, Table 3.

135. Mary E. Wright & Anthony S. Fauci, *Smallpox Immunization in the 21st Century: The Old and the New*, 289 *JAMA* 3306, 3307-08 (2003).

ences of service members who share common characteristics, such as vaccination.¹³⁶

The successes of the Department of Defense surveillance of smallpox vaccination demonstrates the limitations of the ordinary system for reporting health effects from pharmaceutical and other medical products. The latter characterized as a passive system in which FDA marketing approval decisions are “rarely” reversed.¹³⁷ Similarly, like the pro-active CDC surveillance program, the Department of Defense program is markedly superior to the Vaccine Adverse Event Reporting System created by the National Childhood Vaccine Compensation Act (VAERS).¹³⁸

The system’s principal success is the recognition of myopericarditis as a complication of smallpox vaccination in young men who have not previously been vaccinated for smallpox. Halsell et al. report in *JAMA* that although vaccinia virus has long been associated with myopericarditis, “only 1 previous report has described the pathological characteristics of myopericarditis following smallpox vaccination.”¹³⁹ Yet, the authors of the study of the disease’s incidence among U.S. military vaccinees revealed the occurrence rate was 78/million in a 30 day observation period, while the background rate was only 21.6/million.¹⁴⁰ Such result represents a relative risk for vaccinees of 3.61 times of that which is considered normal. Most notably, all military myopericarditis cases were:

136. Mark V. Rubertone & John F. Brundage, *The Defense Medical Surveillance System and the Department of Defense Serum Repository: Glimpses of the Future of Public Health Surveillance*, 92 *AM. J. PUB. HEALTH* 1900 (2002).

137. U.S. DEP’T OF HEALTH & HUMAN SERVS., TASK FORCE ON RISK MGMT., *Managing the Risks from Medical Product Use - Creating a Risk Management Framework*, May 1999, at <http://www.fda.gov/oc/tfrm/riskmanagement.html> [hereinafter *Managing the Risks*].

138. See Weiging Zhou et al., *Surveillance for Safety After Immunization: Vaccine Adverse Event Reporting System (VAERS) - United States, 1991-2001*, 52 No. ss01 *MORBIDITY & MORTALITY WEEKLY REPORT* 1 (Jan. 24, 2003).

139. Jeffrey S. Halsell et al., *Myopericarditis Following Smallpox Vaccination Among Vaccinia-Naïve Military Personnel*, 289 *JAMA* 3283, 3287 (2003).

140. See *id.*

white (73% of total vaccinees), men (78% of total vaccinees), aged 21 years to 33 years (mean age 26.5 years; 59.5% of total vaccinees were 21-25 years), with disease onset 7 to 19 days post-vaccination.¹⁴¹

These results are remarkable because this markedly elevated rate of significant heart disease occurred among the young, and presumably physically fit, male soldiers, sailors, and airmen.

The hypotheses that rates have either been historically under-reported, or that we have lost the herd immunity to smallpox existing when the virus was endemic, warrant further study. Other recently released evidence is either equivocal or negative, on the likelihood of a causal relationship between smallpox vaccination and myopericarditis.¹⁴² Although the rate of myopericarditis among civilian vaccinees was higher than in the military (1/1,700 vaccinees vs. 1/12,000 military vaccinees), 19 of the 21 civilian myopericarditis cases reported through May 9, 2003 were revaccinees (who were expected to suffer lower rates of injury than first-time vaccinees).¹⁴³ The median age was 48 years and 67% had prior histories of heart attack, angina, or exertional chest pain.¹⁴⁴

Similarly, a recent review of death certificates shows no identifiable increase in cardiac deaths following the mass vaccination of millions of people in New York City in 1947.¹⁴⁵ In a mass inoculation program reaching 80% percent of the residents of New York City, 6.4 million were vaccinated "during April 4 -May 2, 1947 (Figure 1), including an estimated 500,000-1,000,000 persons each day during the peak 5 days of the vaccination campaign (April 17-21). The putative high-risk period for cardiac death was an estimated 4-17 days after vaccination, corresponding to the range of

141. *Id.*

142. CTR. FOR DISEASE CONTROL, U.S. DEP'T OF HEALTH & HUMAN SERVICES, *Update: Cardiac-Related Events During the Civilian Smallpox Vaccination Program - United States, 2003*, 52 No. 21 MORBIDITY & MORTALITY WEEKLY REPORT 492 (May 30, 2003).

143. *See id.*

144. *See id.*

145. CTR. FOR DISEASE CONTROL, U.S. DEP'T OF HEALTH & HUMAN SERVICES, *Cardiac Deaths After a Mass Smallpox Vaccination Campaign - New York City, 1947*, 52 No. 39 MORBIDITY & MORTALITY WEEKLY REPORT 933 (Oct. 3, 2003).

onset dates of cardiac events observed during the 2003 campaign.”¹⁴⁶ No increase in cardiac or all-cause death rates was detected.¹⁴⁷

This data has not rebutted the conclusion of the Smallpox Vaccine Safety Working Group of the ACIP. That group, the IOM reports, was asked about causal relationship between smallpox vaccination and inflammatory cardiac disease. Specific to the myo/pericarditis cases:

[t]he working group concluded, “DoD data support a risk for myocarditis after smallpox vaccination that is significantly higher than background rate, and suggest that a causal association is highly likely.”¹⁴⁸

The link between myo/pericarditis and the vaccinia vaccine is more than merely “suspected.” It is probable that first-time live-virus vaccinees are at significant risk of cardiac injury. The IOM notes that 10 of 12 members of the working group urged “careful screening” of health workers for cardiac risk factors and “no member favors beginning phase 2 of the vaccination program.”¹⁴⁹ Similarly, the National Vaccine Advisory Committee has urged the DHHS Office of Public Health Emergency Preparedness that “further smallpox vaccinations, beyond those of public health response and vaccination teams, should be delayed until a national consensus is developed on appropriate next steps.”¹⁵⁰ The ACIP itself unanimously

approved a draft resolution and later released a final statement recommending to CDC that it would be “unwise to expand beyond its current, pre-event smallpox vaccination recommendations because of the new and unanticipated safety concerns, i.e. myo/pericarditis, whose extent and severity, particularly of long term sequelae, are not yet known. Any smallpox vaccination that occurs should be carried out only within the context

146. *Id.*

147. *See id.*

148. COMM. ON SMALLPOX VACCINATION PROGRAM IMPLEMENTATION, INST. OF MED. OF THE NAT’L ACADS., *Review of the Centers for Disease Control and Prevention’s Smallpox Vaccination Program Implementation, Letter Report #4*, at http://books.nap.edu/html/smallpox_vac/letter_report4.pdf (Aug. 12, 2003) [hereinafter *IOM Letter Report #4*].

149. *Id.* at 27-28.

150. *Id.* at 28, n4.

of the currently recommended response teams and state and local response plans, and should be administered according to currently recommended vaccination procedures and protocols ...¹⁵¹

Significant evidence indicates that there may be long-term adverse consequences for vaccinees who suffered from myocarditis.¹⁵² Although all vaccinees recovered from the inflammatory condition, the IOM urges that “there is a general need for longer follow-up in some of the vaccine studies. Particularly there is a need to follow those who experienced serious adverse events in order to learned long-term outcomes, especially for those who experienced cardiac events.”¹⁵³

The discovery of cardiac complications among military vaccinees leads one to readily concur with National Institute for Allergy and Infectious Disease Director Anthony S. Fauci’s conclusion that the effort was a “model for how military and civilian cooperation can effectively serve the public health of the entire nation.”¹⁵⁴ There is

151. *Id.* (citing ACIP, *Statement on Smallpox Preparedness and Vaccination*, at <http://www.bt.cdc.gov/agent/smallpox/vaccination/pdf/acipjun2003.pdf> (last visited July 17, 2003)).

152. *See IOM Letter Report # 4*, *supra* note 141, at 32.

Research in non-smallpox vaccine settings suggests that some people who experience myocarditis may develop long-term sequelae such as left ventricular dysfunction (Hiroe et al, 1985) and cardiomyopathy (Hayakawa et al, 1984; Das et al, 1985; Drucker and Newburger, 1997). As of June 20, 2003, two cases of dilated cardiomyopathy were diagnosed in civilian smallpox vaccinees three months after vaccination (CDC, 2003n). CDC is now advising, “Because smallpox vaccination appears to be associated causally with myocarditis, which can cause [dilated cardiomyopathy], further evaluation is warranted” (CDC, 2003n). In one study, one fourth of patients reporting to a major medical center with symptomatic dilated cardiomyopathy died within a year, and half died within five years.

153. *Id.* at 30.

154. Mary E. Wright & Anthony S. Fauci, *Smallpox Immunization in the 21st Century: The Old and the New*, 289 JAMA 3306, 3308 (2003).

less reason for sanguinity, however, about the conclusions to be drawn from Drs. Grabenstein and Winkenwerder's finding that "mass smallpox vaccinations can be conducted safely with very low rates of serious adverse events" among soldiers.¹⁵⁵ The military data does not support the conclusion that the civilian campaign was wise. It appears that we were fortunate to have met with such low public response. Had many more volunteered, there would likely have been more vaccine-caused illness. The "healthy worker effect" is a recognized bias in epidemiological work.¹⁵⁶ Workers are healthier than the rest of the population. They are better able to resist pathogens. That may be true in spades for soldiers girding for war. Had more civilians heeded the government's call, we would doubtless have experienced substantially higher rates and severity of illness among those whose age exceeds, and whose fitness levels fall below, those of the soldiers and sailors who experienced significant rates of cardiac disease as a result of smallpox vaccination.

"Pre-event vaccination" has proven to cause illness, but the benefit of this program remains unascertainable. There remains a dearth of evidence to support the alarms our leaders sounded. We must consider that one effect of 9/11 is an excess of fear. Ordinary prudence, one may argue, dictates that where harm is certain and the benefit unknowable, one should keep risk to an absolute minimum.

We currently have a substantial corps of military medical personnel who have been vaccinated, and teams of health professionals who have successfully carried out a mass immunization. This large cadre is now immune from smallpox. In the event of an actual use of the smallpox virus by criminal elements, these military personnel are available as key responders for our defense. If we carefully marshal and identify our human resources, they can lead and implement the measures necessary to deal with an outbreak of the disease of smallpox - a virus existing in secure and controlled environments accessible only to a small number of authorized personnel. Thus, it

155. *See supra*, note 123.

156. *See* CHARLES H. HENNEKENS & JULIE E. BURING, *EPIDEMIOLOGY IN MEDICINE* 160 (Sherry L. Mayrent ed., Little, Brown & Co. 1987). "[P]eople who are employed are, on average, healthier than those who are not...The effect of this phenomenon, termed the 'healthy worker effect' is that any excess risk associated with a particular occupation will again tend to be underestimate by a comparison with the general population." *Id.*

is time to put an end to the current vaccinia vaccination program. Such conclusions are firmly supported by the most recent report of the Institute of Medicine.

Lessons of the Smallpox Vaccination Program

As few civilians were vaccinated recently, few became ill. The rates of vaccine-related injury in the past had been stated in cases per million, because vaccination was the norm and because in case of outbreaks – such as in New York City in 1947 – millions had been vaccinated in emergency campaigns. There will be no such statistics for the vaccinia vaccine epidemic, and few claims filed under the Smallpox Emergency Personnel Protection Act of 2003,¹⁵⁷ enacted April 30, 2003, after a short but intense pre-war debate.¹⁵⁸

The IOM has voiced the need for a broad view of the issue of preparedness for microbial outbreaks. SARS, the anthrax attacks, and the fear of more incidents of bio-terror lead the IOM to the conclusion that our goal should be to “protect against acts of bioterrorism and improve the U.S. public health response to all microbial threats.”¹⁵⁹ Vaccination, the IOM observes, is “only one component of smallpox preparedness” and smallpox preparedness is only one component of overall public health preparedness.¹⁶⁰ In the IOM’s

157. 42 U.S.C. §§ 239a-h (2003).

158. The Republicans decided to suspend the rules and offer for approval H.R. 1463, the Smallpox Emergency Personnel Protection Act of 2003, as a proposed amendment to the Public Health Service Act, 42 U.S.C. § 202. *See* 149 CONG. REC. 51, H2476-78 (daily ed. Mar. 31, 2003). As this proposal was presented under a rule used for non-controversial measures requiring 2/3 approval, a short but sharp debate ensued - principally over the failure to guarantee funding and the inadequacy of compensation asserted by organizations of health workers, public employee unions, and the American Public Health Association. The opposition cited inadequate funding and the asserted inadequacy of the proposed terms of compensation. In the face of this opposition, the proceedings were postponed. *See* 149 CONG. REC. H2476 -94 (daily ed. Mar. 31, 2003). One month later, a substantially similar bill, HR 1770, was enacted. 149 CONG. REC. 62, H3448 (daily ed. Apr. 29, 2003).

159. IOM *Letter Report #4*, *supra* note 141.

160. *Id.*

view, preparedness begins with the identification and training of key responders - public health teams equipped to respond quickly in a crisis, and ready to take measures, such as mass vaccination and education to protect the public.¹⁶¹

Rather than the attention to numerical goals that initially characterized CDC efforts, defining a “baseline level or minimum standard of preparedness” is a key task of the CDC as a national leader in preparedness planning.¹⁶² As the IOM urges, we should seek to minimize the number of people vaccinated.¹⁶³ The Virginia Commonwealth University Health System is offered as a model of an approach to preparedness without vaccination.¹⁶⁴

161. *See id.* at 2-3.

The national smallpox vaccination program may well be the first disease-specific test of implementing public health preparedness in a systematic and comprehensive manner, and with some public visibility. The smallpox vaccination program has taken the notion of preparedness beyond the realm of public health professionals and academics and has brought it to the attention of a broader audience of health care workers, emergency responders, and even the general public.

Implementing the smallpox vaccination program, however, has also highlighted the need to integrate smallpox preparedness into readiness to respond to a vast range of public health challenges, including bioterror agents and other weapons of mass destruction, emerging or reemerging infectious diseases, natural disasters, and the insidious and growing threat of chronic diseases and their predisposing conditions (e.g., obesity). Smallpox is just one of a multitude of actual and potential threats to the public's health. *Id.*

162. *Id.*

163. *See id.*

164. *See id.* at 5.

Attaining a high level of preparedness may well be possible without vaccinating any personnel pre-event. For example, Virginia Commonwealth University Health System, that presented its hospital preparedness plans to the committee at the May 1, 2003 meeting, has chosen not to

A day may come when mass vaccination will be warranted. Rather than simply prepare for one form of outbreak - smallpox - vaccination clinics should be established to “distribute other vaccines or countermeasures, and provide other services in response to an outbreak or other threat.”¹⁶⁵ Members of the general public who seek vaccination should be steered into controlled studies, perhaps as part of clinical trials for the safer vaccines that the FDA has urged be developed.¹⁶⁶

The IOM’s broad approach to preparedness integrates quite smoothly the horrific jolt of 9/11, the vulnerability which the anthrax assailant exploited, the rapid international spread of SARS, and the experience of the civilian and military smallpox vaccination programs. Its level-headedness and practicality make their contribution a particularly welcome addition to the discussion.

The Smallpox Emergency Personnel Protection Act of 2003

The legislative majority prevailed in the end. Rather than the proposals of Reps. Henry Waxman and Lois Capps (a public health nurse before entering Congress), which would track the National

have health care workers vaccinated pre-event (Edmond, 2003). The health system’s decision was based on considerations of hospital patient safety. Although no vaccinated teams of responders were formed, a policy on smallpox vaccination was developed, with plans to revisit the policy as needed. Furthermore, a working group on smallpox preparedness was established, facilities were modified in accordance with requirements for treating smallpox victims, training on smallpox diagnosis, treatment, and infection control measures was conducted, and plans were put in place to rapidly vaccinate hospital staff in a post-event scenario. The committee believes that Virginia Commonwealth University Health System’s smallpox preparedness activities provide a good example of how an organization or jurisdiction can be well-prepared to respond to a smallpox attack without necessarily having workers vaccinated pre-event. *Id.*

165. *Id.* at 10.

166. *See id.* at 17.

Vaccine Injury Compensation Act and¹⁶⁷ add smallpox-vaccine related injury to those injuries due compensation,¹⁶⁸ the final administration bill, H.R. 1770,¹⁶⁹ tracks the Public Safety Officers Benefit program administered by the Department of Justice.¹⁷⁰ This Act is far less generous in compensation than the Vaccine Injury Act, and—remarkably, bars judicial review by any court of the Secretary of Health’s actions.

H.R. 1770 covers volunteers and their contacts for vaccinations carried out under the Secretary of Health’s Declaration Regarding Administration of Smallpox Countermeasures.¹⁷¹ Benefits, which are secondary to any other coverage, are to be determined based on a smallpox vaccine injury table, which will define the class of “adverse effects ... that shall be presumed to the administration of (or exposure to) a smallpox vaccine, and the time period” in which symptoms “must manifest in order for the presumption to apply.”¹⁷² Claims under the Act are administered by the Secretary of Health, whose determinations “[n]o court of the United States ... shall have subject matter jurisdiction to review.”¹⁷³ The statute of limitation is one year from administration for persons receiving the vaccine, and two years from the date of the first symptom in the case of accidental inoculation.¹⁷⁴

The benefits are limited. No provision is made for pain and suffering, unlike the National Childhood Vaccine Injury Compensation program, which provides for non-economic damages of up to

167. 42 U.S.C. §§ 300aa (2000).

168. *See* 42 U.S.C. § 300aa-13.

169. *See* 42 U.S.C. § 239 (2003).

170. 42 U.S.C. § 3796 (2003) (providing supplemental benefits in case of death or permanent and total disability of a public safety officer due to personal injuries sustained in the line of duty).

171. Declaration Regarding Administration of Smallpox Countermeasures, Department of Health and Human Services (HHS), Office of the Secretary of Health and Human Services, 68 Fed.Reg. 4212 (Jan. 28, 2003).

172. 42 U.S.C. § 239b(a)(1). A retroactivity provision permits claims to be filed within one year of addition of an adverse effect to the table for vaccinees, and within two years for persons accidentally inoculated. *See* 42 U.S.C. § 239b(a)(2).

173. 42 U.S.C. § 239a(f)(2).

174. *See* 42 U.S.C. § 239a(d).

\$250,000.¹⁷⁵ Medical benefits are secondary to all other coverages,¹⁷⁶ wage loss is compensated at 66 2/3% of “loss of employment income,” but is limited to \$50,000 per year, capped by the amount payable under the Public Safety Officers Benefit Program,¹⁷⁷ except in the case of permanent and total disability. Wage loss benefits under the Act cease at age 65.¹⁷⁸ A death benefit is provided, tracking that of the PSOB program, which is adjusted yearly. Any payments for lost income are deducted from the death benefit.¹⁷⁹

The volunteers were so few, and those injured correspondingly few, that the inadequacies of the compensation program are unlikely to affect many. The most troubling aspects of the Smallpox Emergency Personnel Protection Act may also never be challenged. The two most troubling aspects being the exclusion of Secretary of Health and Human Services determinations from judicial review, and a statute of limitation incapable of relaxation even where vaccine related problems do not manifest themselves in vaccinees until more than one year after administration, a distinct possibility in the IOM’s view.

V. CONCLUSION

As the IOM concludes, smallpox is not the only threat to the nation’s public health and vaccination is not our only defense. We were driven to implement the smallpox vaccination program by a uniquely prompted sense of alarm. Regardless of whether the program was justified in hindsight - and there appears to be little sup-

175. 42 U.S.C. § 300aa-15.

176. 42 U.S.C. § 239c.

177. 42 U.S.C. § 3796 (2003).

178. 42 U.S.C. § 239d. These benefits too are secondary to all other benefits and may be paid in a lump sum or over “multiple years.” *Cf.* NCVIA, 42 U.S.C. § 300aa-15 (affording compensation for all “actual and anticipated loss of earnings determined in accordance with generally recognized actuarial principles and projections”).

179. *See* 42 U.S.C. § 3796 (2003); *see also* BUREAU OF JUSTICE ASSISTANCE, *Public Safety Officers’ Benefits (PSOB) Program*, at <http://www.ojp.usdoj.gov/BJA/topics/PSOBProgram.html> (last visited Nov. 7, 2003) (setting benefit limit at \$262,100).

port for justification - we have learned much from the civilian and military campaigns. A broad approach to preparedness can yield broad public health advances against natural and intentional outbreaks of disease. Active surveillance and streamlined, active data collection (like that of the Defense Medical Surveillance System) may reveal benefits in observing previously unsuspected health effects.

Cautious approaches to potentially dangerous mass vaccination programs, attention to prioritizing research goals, and emphasis on preparedness against all forms of microbial threats can increase the public's sense of security and accordingly improve public health. In the event that we enlist citizens in essentially experimental defensive efforts such as the smallpox vaccination program, we should not limit the nature of compensation afforded, nor should the usual right of judicial review to those seeking such compensation be denied.