

The Threat of Smallpox: Eradicated But Not Erased

A Review of the Fiscal, Logistical, and Legal Obstacles Impacting the Phase I Vaccination Program

Holly Myers, Elin Gursky, Georges Benjamin, Christopher Gozdor, and Michael Greenberger

February 2004

Holly Myers is a third-year law student at the University of Maryland and former research assistant at the ANSER Institute for Homeland Security. Elin Gursky, Sc.D., is Senior Fellow for Biodefense and Public Health at the ANSER Institute for Homeland Security. Georges Benjamin, M.D., is Executive Director of the American Public Health Association. Christopher Gozdor, J.D., is a Law Fellow at the University of Maryland Center for Health and Homeland Security, where Michael Greenberger, J.D., is Director as well as Professor at the School of Law.

Introduction

Smallpox, one of the most virulent and deadly diseases that ever plagued humankind, has not afflicted a single person since the World Health Organization (WHO) declared that the disease had been eradicated in 1980 following an intensive, worldwide vaccination program.¹ Although WHO subsequently allowed the United States and the Soviet Union to retain samples of variola,² the etiological agent of smallpox, the disease began fading from the memories of most Americans.

Nearly a quarter century later, the disease has entered U.S. consciousness once again as intelligence suggests that other countries besides the two depository nations have retained or obtained variola.³ The fall of the Soviet Union and the resulting economic chaos have displaced many of the Soviet germ weapons experts from their jobs, leaving them vulnerable to the monetary enticements of terrorists and of nations interested in obtaining smallpox.⁴ Moreover, while the existence of international treaties prohibiting the development, production, stockpiling, acquisition, and use of biological weapons may prevent a signatory from using weaponized smallpox,^{5, 6} the treaties certainly do not bind subnational actors such as terrorists. Nor are these elusive terrorist organizations likely to fear the sort of retaliation that might deter a nation from deploying weaponized smallpox.

The probability of a smallpox bioterrorist event remains unknown, but the level of vulnerability of the United States population makes the threat too great to ignore. The U.S. smallpox vaccination program ended in 1972, leaving 119 million Americans fully susceptible to the disease in 2003.⁷ The 157 million U.S. citizens vaccinated before that time likely have little or no protection left.⁸ Accordingly, on 24 January 2003, the U.S. government began Phase I of a proposed multiphase smallpox vaccination program by targeting approximately 500,000 frontline health workers throughout the country. A year later, however, fewer than 10% of the original goal of civilian healthcare workers—only 39,353—volunteered to receive vaccinations.⁹

Given the lofty goals of this program and the putative bioterrorist threat, in this article we seek to discover the reasons the Phase I program did not achieve its initial vaccination goals. After a general introduction to smallpox, its use as a weapon, and the rationale behind implementing Phase I, we investigate the federal smallpox vaccine compensation and liability protections, as well as the program funding strategies and volunteer recruitment tactics that contributed to, or detracted from, the goals of the smallpox vaccination program.

Study Methodology

Twenty states were selected for participation in this study by calculating the ratio of persons vaccinated to the number of anticipated vaccination volunteers. The surrogate for volunteers was the number of doses of vaccine ordered from the U.S. Centers for Disease Control and Prevention (CDC). The states were divided into two groups for comparison purposes: "high yield" and "low yield." The states with the ten highest ratios were determined to be the high-yield states, while the states with the ten lowest ratios were determined to be the low-yield states. Data used to calculate the total number of vaccinations administered were taken from the CDC's "Smallpox Vaccination Report Status and Adverse Events," 21 March 2003.¹⁰ Calculations for anticipated numbers of vaccinations were based upon the CDC report "Smallpox Vaccination Program Vaccine Doses Shipped and Released for Use."¹¹

The study engaged the public health perspective by interviewing state health department bioterrorism coordinators or, in some cases, a specific smallpox program coordinator for each of the 20 selected states that were invited to participate. These individuals were selected because they worked in conjunction with the state epidemiologists, immunization program managers, and health officials and because they were responsible for crafting a plan within the framework of the CDC's "Interim Smallpox Response Plan and Guidelines."¹² The initial invitation to participate in the study was made via a formal letter. A follow-up phone call was placed to confirm interest and to schedule a time for the telephone interview. A pilot-tested questionnaire guided the 30-minute interview process. Interviewees were assured that their responses were not for attribution. All 20 interviews were conducted 20–30 May 2003.

This study was supported by the ANSER Corporation on behalf of the ANSER Institute for Homeland Security.

Background: Smallpox—A Cycle of Threat

The elimination of naturally occurring smallpox stands as one of the most significant victories of humans over disease. Variola virus plagued humankind as far back as 1350 BC, killing 300 million in the 20th century alone¹³ and scarring and blinding millions more.¹⁴ The continued devastation of populations from the variola virus led WHO member states¹⁵ to set aside a malaria eradication campaign in favor of a smallpox eradication program. WHO initiated this effort, called the Intensified Smallpox Eradication Programme, in 1967 and achieved victory by 1980 when it formally announced that the disease had been eradicated.¹⁶

After the Intensified Smallpox Eradication Programme's successful conclusion, WHO began the Consultation on the Worldwide Certification of Smallpox Eradication to decrease the number of laboratories preserving variola virus stocks.¹⁷ WHO

permitted the remaining smallpox virus to be officially stored in two high-containment laboratories: the Research Institute for Viral Preparations in Moscow and the CDC in Atlanta.¹⁸ Member states were asked to guarantee that no other labs besides the two authorized facilities contained stocks of variola virus and that they had destroyed any remaining antigen used during the Smallpox Eradication Programme.¹⁹ In 1994 the Russian government, growing concerned over security at the Moscow facility, moved its cache of variola to the Russian State Research Center of Virology and Biotechnology (Vector), a Siberian facility near Novosibirsk, without notification to or permission from the international community.^{20, 21} The Russian smallpox stock remains housed at Vector today after the facility gained final WHO approval in 1997.²²

Despite these assurances, mounting evidence suggests that the smallpox virus—once an essential chapter in infectious-disease textbooks, but ultimately relegated to academic history and the memories of old-time medical and public health practitioners—has returned as a terrible threat. Early concerns about smallpox bioterrorism stemmed from the prevailing worries that Russian scientists, in dire economic straits after the fall of the Iron Curtain, may have sold their expertise, the virus, and the necessary technology to terrorists or hostile regimes.²³ Furthermore, it is possible that other nations have illegally maintained stocks of smallpox.²⁴

In a December 2002 speech announcing the vaccination program, President Bush stated, "Since our country was attacked 15 months ago, Americans have been forced to prepare for a variety of threats ... One potential danger to America is the use of the smallpox virus as a weapon of terror.... We know ... that the smallpox virus still exists in laboratories, and we believe that regimes hostile to the United States may possess this dangerous virus."²⁵ The President conceded, however, that vaccinations would be a precaution only and that an attack using smallpox was not an imminent danger.

Echoing the President's remarks linking the vaccination program to the pervasive terrorist concern, CDC Director Julie Gerberding testified in early 2003 that the "stockpiling of smallpox vaccine was an important priority before September 11, 2001, and smallpox vaccine was already in production at that time. The events of the fall of 2001 heightened concern that terrorists may have access to the virus and attempt to use it against the American public."²⁶

The looming war with Iraq, a country with suspected biowarfare capabilities,²⁷ promoted a new sense of urgency for a smallpox program. In the minds of many Americans, the initiation of the smallpox vaccination program was linked to the growing threat of war.²⁸ However, despite earlier evidence that Iraq possessed weapons of mass destruction, such weapons have not been uncovered in Iraq subsequent to Operation Iraqi Freedom.²⁹

The probability of smallpox being an "imminent threat" is unknown, but the level of vulnerability of the U.S. population is decidedly high. Few persons born after 1972 have been vaccinated, with the exception of some scientists and members of the military. U.S. military personnel were vaccinated when enlisting and were revaccinated every five years until the early 1990s to preserve the pool of vaccinia immune globulin.³⁰ Although recent research suggests that residual immunity may last longer and be more powerful than once thought,³¹ the issue remains unresolved,

and most Americans, including emergency medical personnel, may be susceptible to the virus.³²

On 13 December 2002, President Bush announced a plan to begin vaccinating volunteer health care workers drawn from the medical community in all states: individuals who would be exposed to the virus by virtue of being first on the scene if an attack were to occur.³³ In the event of a smallpox attack, teams of protected medical and public health “first responders,” termed Smallpox Response Teams, would be able to vaccinate, treat, and investigate suspected cases to reduce the epidemic proportions of such an event.³⁴ The CDC’s containment strategy, known as “ring vaccination,” involves isolating initial smallpox cases and vaccinating close contacts to create an immune human buffer-zone around localized outbreaks. A large and coordinated cohort of immunized first responders and other healthcare providers would be an essential component of such a response.³⁵ The President’s statement followed a review by the Department of Health and Human Services (HHS) of the states’ preliminary smallpox response plans, which revealed that the states, in total, planned to offer vaccinations to about 450,000 individuals.³⁶ This number was consistent with recommendations made by the Advisory Committee on Immunization Practices in October 2000. By estimating that each of the 5,100 acute-care hospitals in the nation would require a team of 100 healthcare workers with a range of specialties to respond to a smallpox outbreak, the committee recommended that 510,000 healthcare workers nationally be immunized. This recommendation amended an earlier recommendation to immunize 10,000 to 20,000 healthcare workers nationally after members agreed that the healthcare system would require far more preparation for smallpox.³⁷

The civilian smallpox countermeasures were authorized by Section 304 of the Homeland Security Act of 2002, which allowed the Secretary of Health and Human Services to issue a declaration that an “actual or potential bioterrorist incident ... makes advisable the administration of a [smallpox] countermeasure.”³⁸ This declaration also announced the scope of the federal government’s liability in time and coverage for injury or death caused by the vaccination program.³⁹ (However, it was not until April 2003 that Congress created a no-fault compensation regime.) Secretary Thompson’s declaration called for the voluntary smallpox vaccination of four categories of people: members of smallpox response teams, public safety personnel, “persons associated with certain U.S. Government facilities abroad,” and healthcare workers who may be called on to “monitor or treat” persons in the other three categories.⁴⁰ Vaccination teams—typically a duty largely relegated to the public health sector—required that healthcare workers and essential hospital support staff be protected to retain the ability to treat patients exposed to smallpox within 7 to 10 days of an attack.

The Phase I Smallpox Vaccination Plan was launched on 24 January 2003, when the first healthcare worker was vaccinated in Connecticut,⁴¹ after Secretary Thompson delivered his declaration.⁴² As of 31 January 2004, only 39,353 had been vaccinated—far short of the 500,000 goal. The Secretary has extended the vaccination plan through 23 January 2005.⁴³

Study Findings

Finding I: The Phase I Smallpox Vaccination Program Strained Already Burdened Public Health and Hospital Resources

The smallpox vaccination campaign fell on a public health system bereft of infrastructure and resources. Long struggling to meet the needs of emerging microbial threats like West Nile virus, multidrug-resistant tuberculosis, and hemorrhagic *E. coli*⁴⁴ and tasked to counter the increasing prevalence of chronic diseases such as hypertension, obesity, diabetes, and generalized health disparities, state and local public health departments had little capacity to take on the specter of bioterrorism. The hospital and healthcare delivery sector was equally constrained by a climate of increased regulatory burdens, revenue shortfalls, cost-cutting strategies, reduced bed capacity, reduced on-demand purchases of consumable supplies, and waning ranks of nurses, food handlers, and technicians.⁴⁵

Shrinking capacity and resources were exacerbated by a limited knowledge of smallpox disease and vaccination, presenting an educational challenge to public health and hospital personnel. The United States discontinued routine smallpox vaccinations over 30 years ago:⁴⁶ most currently practicing medical professionals had never administered a smallpox vaccination. To meet the goals of the Phase I Program, physicians and nurses had to learn the basics. This included mastering the use of the bifurcated needle and acquiring the precision needed to administer fifteen “jabs” in the upper arm to maximize the probability of a vaccine “take”; screening for medical contraindications; using a perishable vaccine (once reconstituted) efficiently; and explaining to vaccinees the importance of post-immunization precautions to avoid transferring live virus to susceptible patients and housemates.⁴⁷

Beyond these specialized skills there was, going into the Phase I Program, a dearth of knowledge about smallpox in the medical and public health communities. For example, a nationwide survey of 2,661 practicing nurses revealed that most lacked a basic understanding of the disease, transmission, and vaccine: only 1 of 5 was aware that immunization given within a few days of initial exposure will prevent the disease.⁴⁸

The ANSER study indicates that when the interviewees were confronted with the challenge of developing strategies to implement Phase I, they did so with very little personal or clinical knowledge of administering the vaccine, evaluating contraindications, and implementing adequate post-vaccination surveillance. Study participants, facing a steep learning curve in bioterrorist agents and bioterrorism in general, confronted a specific “new” disease requiring different business practices and systems. The implementation of new skills and operations was afforded little start-up time in an atmosphere exhibiting “very hyped up demand” and a “sense of urgency.” Additionally, many of the interviewees indicated that they were caught unaware by the perceived “detour” from the original biodefense preparedness core focus areas—planning and readiness assessment, surveillance and epidemiology capacity, laboratory capacity, communications and information technology, risk communications and health information, and education and training—described in the DHHS/CDC Bioterrorism Cooperative Agreement Guidance Document of 2002.⁴⁹ None of these six focus areas specifically addressed smallpox planning.

The Phase I Smallpox Program loomed large as a logistical, technical, and financial conundrum. On 22 November 2002, the CDC requested "pre-attack" vaccination plans containing information on the size of each Smallpox Response Team, the location of each vaccination site, the number of healthcare facilities identified to participate, and the number of clinics needed to support this effort. The CDC also asked states to address vaccine logistics and security, vaccine safety monitoring, training and education, data management, and communications in their plans.⁵⁰ The states were notified that these plans were due by 9 December 2002 and that they should utilize and redirect already released fiscal year 2002 preparedness funds to support this effort.⁵¹

At the inception of the Phase I program, however, many states had already encumbered bioterrorism preparedness funds for other programs and purchases. Although bioterrorism preparedness and response had emerged as a key agenda item of the federal government moving into this new century,^{52, 53, 54, 55} there simply were inadequate federal dollars targeted toward a smallpox vaccination program. This lack of federal funding presented a hardship, especially for the low-yield states. Furthermore, as one low-yield state official noted, "vaccination was never a priority" in the state because there were other pressing public health issues.

In March 2003, Secretary Thompson released to the states an initial 20%, or \$280 million, of the \$1.4 billion that had been appropriated in fiscal year 2003 for public health and hospital preparedness. The remaining 80% would be distributed once state preparedness plans were created and approved. In a statement announcing the release of these initial funds, the Secretary urged states to use these monies to support smallpox vaccination activities, which had begun two months earlier, and all other preparedness activities already in progress.⁵⁶ The administration released another \$100 million not included in fiscal year 2003 appropriations to the states in May 2003 for the same general purposes.⁵⁷ HHS did not begin to release the remaining 80% of each state's share of the 2003 appropriations until September 2003.⁵⁸

The lack of smallpox-specific funding at the planning and initiation stages presented a hardship to all the participants in this study. However, the ANSER study demonstrated that high-yield states (n=6) were more likely than their low-yield counterparts (n=2) to draw from state health department budgets and existing funds to implement the Phase I Smallpox Program. One official from a high-yield state characterized the use of state and local health department budgets as necessitating "putting [other] work aside to do vaccination clinics." Another underscored public health's role in preparedness and "national security" efforts, noting that the state requested "redirection" of the bioterrorism preparedness grant to cover the smallpox vaccination activities. A third state made a "good faith" assumption that the smallpox vaccination program would be "within the scope of the CDC biopreparedness grant" and proceeded accordingly.

Despite the best of efforts, the lack of specifically awarded smallpox vaccination funding was an impediment to the Phase I program. Some viewed the vaccination initiative as a federally imposed program without the benefit of federal funding, or, as one state official noted, "an unfunded mandate eating the [state] money."⁵⁹ By having to subtract money from general public health budgets, the states had to decrease spending on routine public health activities such as childhood immunizations and redirect staff from other disciplines across public health agencies.

Even after the federal government dispensed funds that could be used to implement Phase I, volunteer participation in the program remains below 10% of the President's goal of 500,000 smallpox vaccinees.⁶⁰ While this may spawn debate over whether the initial funding was adequate, other considerations on a personal level and a public health policy level also helped determine the Phase I outcome.

Finding II: Perceptions of Vaccination Risk and Smallpox Threat Contributed to Low Vaccination Volunteer Rates

Early in the program, states needed to calculate the number of volunteers and vaccine doses that would make up their Phase I goal. States did receive some guidance from the CDC about the criteria to use for estimating how many doses would be necessary,⁶¹ but it was described as "vague." Most states arrived at their final figure based on the number of acute care hospitals within the state, the number of Emergency Response Teams, and the personnel needed for each team.⁶² Adjustments were imposed upon these calculations by estimating the numbers of volunteers who might be screened out given the prevalence of medical contraindications. Yet, when it came down to the precise number of volunteers, states noted that they "just had to guess" or give a "ballpark estimate."

States adopted differing tactics to cope with the guesswork. As this study revealed, some states slightly inflated the number of doses of vaccine they would require in anticipation of vaccine waste. Some states ordered extra vaccine to save for future use. Others ordered extra recognizing that they could not use all hundred doses before vials of reconstituted vaccine expired. There were states that decided against a "fudge factor" and determined, instead, that they would rely upon the Strategic National Stockpile should the need for more vaccine arise. The complexities of calculating vaccine quantity reflected the difficulty of forecasting participation.

Once Bioterrorism Coordinators determined the potential *number* of volunteers and doses of vaccine, they faced the problem of how to actually *recruit* volunteers. Because the Phase I Program was voluntary, states needed to address the risk-benefit analysis that potential volunteers were likely conducting on a personal level before deciding to be vaccinated. In times when variola ran rampant in the world, the risks associated with vaccinia were immediate but seemed negligible in contrast with the very real probability of coming into contact with the virus and dying from it. Historically, the smallpox virus killed up to 30% of those infected,⁶³ and it hideously disfigured its survivors.⁶⁴ The benefits of vaccination were immediate and invaluable in terms of lives saved. In today's world, where naturally occurring smallpox has been eradicated and the threat of smallpox-related bioterrorism is unquantifiable, vaccine-related side effects, contraindications, and rare (but potentially increased) risk of mortality could weigh more heavily in the minds of those making a personal risk-benefit assessment.⁶⁵ The benefits may never materialize (although some speculate that vaccination has an immediate deterrent effect for bioterrorists),⁶⁶ but the risks are immediate and may seem comparatively large to a potential volunteer. The ANSER study indicated that states tackled this concern using a fairly uniform approach: offer no incentive; just educate potential volunteers so that they can make an informed decision.

Program planners began volunteer recruitment by identifying a target group of people who met the definition of "first responder." Some states used a committee process to determine strategies for identifying and recruiting volunteers. Most of the

interviewees stated that they had not thought to use “perks” or rewards, such as time off or bonuses, to encourage participation. Other participants noted that they thought of, but rejected these strategies. One interviewee stated, “We tried to minimize disincentives, but [offer] no incentives.”

Another participant echoed these sentiments in efforts to “stop physicians from discouraging if not encouraging participation.” Other states echoed the sentiment of “no carrots” and “no push,” and just a “simple request.”

Instead of incentives, states mounted vast education and advertising campaigns. They assembled information to describe the federal program, provide education about the smallpox vaccine, and explain vaccination-screening criteria. State bioterrorism coordinators attempted to hold multiple meetings with hospital staff and healthcare workers and other potential volunteers. Some sent briefing packets to hospital associations, physicians, and nurses.

A review of the recruitment strategies used in states participating in the ANSER study (see [Table 1](#) for a comparison of educational initiatives used by high- and low-yield states to recruit volunteers) indicated that high-yield states incorporated more intensive and multiple outreach efforts with target volunteer populations than did low-yield states. One participant described a state’s repeated contact with acute care practitioners as “beat[ing] them over the head.” Additionally, it was not just the tenacity of contact but also the novelty of approach that led to success. One state developed a 30-minute informational videotape, which it aired on cable channels in two major cities and provided as video streams via webcast. This state also used one-on-one meetings and small group breakout sessions. Statewide teleconferences were useful educational strategies to recruit volunteers, as were individual meetings with all hospital CEOs. While interviewees in the majority of high-yield states felt that participation in the program was less a matter of “their own volition,” only one of the ten low-yield states had engaged in education and outreach to the extent that the majority of their high-yield counterparts had.

Outreach by the public health community was not the only source of encouragement for potential vaccinees. Operation Iraqi Freedom was a powerful motivator for the Phase I vaccination program: some states acknowledged that the climate of “war and politics” increased the perception of threat and resulted in a surge of volunteers. Other states were less convinced.

One study participant noted, “We were given no information of a threat so it was hard to say ‘take this’ [vaccination] when we weren’t informed of the risk.”

Another participant stated, “It was controversial from the outset whether risk of vaccine outweighed risk of an attack.”

Others felt that the risk “wasn’t well-articulated” or that concerns of threats were misplaced —“What’s a smallpox vaccination going to do if someone blows up my house.”

War and smallpox became a conjoined issue. One study participant commented, “People in their minds really connected war with smallpox. [It was] very frightening before the war happened.” Some states were willing to *use* this as an incentive for vaccination; other states chose to *avoid* making these issues one and the same. But

while events in the Iraqi theater may have helped support the Phase I campaign, once the war was declared over, 17 of the 20 states that participated in this study reported that interest in smallpox vaccination dropped "precipitously."

"When the war ended and no smallpox had been found, it became especially difficult to justify a vaccination program based on a potential threat," noted one participant. Both high- and low-yield states felt the increased strain to weigh the threat of attack against the possibility of adverse vaccine-associated side effects. However, while the majority of states interviewed for this study agreed that the perception of reduced threat instigated a steep decrease in vaccinations, a few acknowledged the continuing threat of smallpox attacks from countries other than Iraq.

Swelling and ebbing vaccination participation was not only a reflection of the war's outcome and failed efforts to locate weapons of mass destruction, but also the discovery of cardiac-related vaccine side effects among some recipients. By late June 2003, 21 cases of myo/pericarditis had been reported among civilian vaccine recipients. Eight cases of ischemic heart disease had also been reported, including five cases of myocardial infarction and three cases of angina. Two cases of cardiomyopathy were identified three months after smallpox vaccination in persons lacking any previous history of heart disease. Evidence suggests that the cases of myocarditis and pericarditis might be causally linked with vaccination, but other adverse events, including cardiomyopathy, not previously linked to smallpox vaccination, have not clearly been associated with the vaccinations.⁶⁷ Many of the individuals interviewed for this study indicated that they had to modify their strategies and decrease their expected numbers of volunteers because fewer people would meet the more rigorous screening standards.⁶⁸ A few high-yield states indicated that they did not have to modify their Phase I plans because they began early and finished quickly, completing their efforts "before the cardiac problems emerged."

Logistical, recruitment, and screening challenges associated with the Phase I program contributed to lower-than-anticipated numbers of vaccinees, but the efforts were not without benefit. A number of study participants recognized that the planning initiatives contributed to overall preparedness efforts and some improved relationships with the hospital community. As one participant noted, "[This] is giving us luxury of having to prepare a team to be effective rather than having to learn on the run."

Table 1: Educational Initiatives Engaged in by High- and Low-Yield States During the Phase I Smallpox Vaccination Program

	Frequency in high-yield states	Frequency in low-yield states
Meeting with hospital CEOs or hospital organizations	6	2
Meeting with local health departments	5	2
Briefing packets	9	6
Presentations	4	2
Videos	1	0
Letters	2	2
Breakout sessions	2	1
Teleconferences	2	1
Minimizing disincentives	2	0
Offering a “no push” environment	1	4

Finding III: Liability and Compensation Concerns Curbed Participation in the Phase I Smallpox Initiative

The smallpox vaccination introduces live vaccinia virus to the human host; it can prevent the occurrence of disease if administered up to four days after exposure to an infectious case. However, vaccinia comes with certain well-established risks that must be weighed against the likelihood of ever contracting the disease. The vaccine carries a broad range of sequelae, including mild side effects such as fever, headache, body ache, and fatigue (1,000 out of every 1 million vaccinated) and more serious life-threatening side effects such as encephalitis (14 to 52 people out of 1 million vaccinated).⁶⁹ The vaccine is fatal for one or two people out of every million vaccinated.⁷⁰ Among previously vaccinated individuals, the rates of vaccine-related adverse reactions may be lower.⁷¹ Contraindications to the vaccine include dermatologic conditions such as eczema and severe acne, pregnancy, chronic viral illnesses like herpes, a history of chemotherapy, immune system disorders such as HIV-AIDS, and cardiac disease such as myocardial infarction, angina, congestive heart failure, or cardiomyopathy.⁷² Additionally, the vaccinia virus can be “shed” for up to three weeks subsequent to vaccination,⁷³ posing an unconsented risk for vulnerable individuals who are exposed to a recently vaccinated person. During the military smallpox vaccination program, health workers and military personnel were successful in preventing vaccinia contact transmission to patients, vaccinating over 450,000 individuals and logging over 19,000 worker-months of patient interactions without infecting any contacts.⁷⁴ (However, 30 cases of contact transmission reportedly occurred between vaccinees and household or intimate contacts outside of the workplace.⁷⁵) Screening recommendations from the CDC attempt to limit contact transmission of vaccinia, but the prevalence in the U.S. civilian population of the contraindications mentioned above may exceed 10 million individuals, or nearly 4% of the population today, a large at-risk contact group.⁷⁶ Understandably, many involved with the administration of the vaccine had legitimate liability concerns in connection with the Phase I program.

Interviewees for the ANSER study confirmed that public health officials had early concerns regarding compensation and liability, even, as one noted, “before the first person was inoculated.” For some states, the full extent of concerns regarding liability did not arise until the actual release of Section 304 (the federal liability regime for Phase I smallpox vaccinations) in November 2002. But many also underscored that it was the reaction of hospitals that led to grave concerns regarding how little protection Section 304 afforded. Although the media, and to some extent the unions, highlighted strong reservations about the risks associated with the vaccination program, it was the hospital associations and their attorneys that triggered the fullest measure of disharmony over the program. There was a consensus that the media reported the issue but “were hearing it from the hospitals.” One study participant indicated that larger hospitals stifled the start of the program by “voicing concern and withdrawing support.” One state blamed its lower numbers on “hospitals balking.” Some states admitted that hospitals felt cheated from the outset by the program because they had the most to lose in terms of liability, but they were omitted from the “table of decision-making.” They felt “blindsided” by a program that was “targeted” toward them. A review of the study data indicated that high-yield states, more so than low-yield states, engaged hospitals’ participation in the earlier stages of smallpox vaccination planning.

Discussions with interviewees for this study reflected the different climate of legal vulnerabilities between the public health and hospital sectors. The public health community acknowledged that it operated under the protections afforded them from sovereign immunity—the absolute immunity of a sovereign government (as a state) from being sued. “Hospitals,” as one participant noted, “had a different environment for liability.” While public health officials felt they had no choice but to support the federal Phase I Smallpox Program, hospitals felt they could opt out if they so desired. When one state hospital association hired an outside consultant to write an opinion as to why the vaccine was not a compensable injury, that state’s bioterrorism coordinator answered with countering legal opinions. Of the 20 study participants, 14 ranked liability as a strong factor and 15 ranked compensation as the strongest factor adversely affecting their implementation. The ways in which the states managed these two concerns possibly made a difference in their relative high and low yields.

A majority of study participants noted that it was a substantial and largely unsuccessful effort to overcome the lack of federal liability and compensation protections and maintain momentum to achieve their vaccination goals. A comparison of strategies used by high- and low-yield states to manage concerns about compensation and liability can be found in [Table 2](#). Twelve of twenty reported that they approached state workers’ compensation programs to negotiate having smallpox protected as a “within scope of employment” activity. Some workers’ compensation programs provided compensation under the rubric of “on-the-job-related injuries” even though smallpox was not specifically listed. Other states provided compensation case by case. The legislature of one high-yield state introduced its own compensation and liability bill instead of waiting on a federal amendment augmenting the coverage in Section 304. Other states assumed that there was adequate coverage through existing legal system remedies that could, if needed, augment the coverage provided through Section 304. The combination of adopting a favorable interpretation of Section 304 for liability and maintaining open lines of communication with hospital CEOs made clear contributions to the large numbers of vaccinated volunteers in the high-yield states.

One of the state public health department's strongest roles was to keep the hospitals and volunteers informed and connected to the program. Ten of the twenty study participants spoke of their outreach to hospitals. Meetings between public health and hospital officials improved the transparency of the vaccination program, created a venue from which to consider program options, and helped coordinate efforts to track the progress of proposed legislation. Public health served as an interpreter of the law for those seeking answers as a prerequisite to participating. Although the states could not control how quickly and effectively the federal government resolved concerns, some states stayed "side-by-side" with the issue to keep stakeholders and first responders well informed. One state noted, "We would share as quickly as we could any draft in Congress, [and] any interpretation released."

Another noted, "We kept [first responders] well-apprised of federal efforts to allay concerns." Having a full-time attorney assigned by one state's health commissioner to the smallpox initiative, available at any time to public health officials, facilitated dealing with problems as they arose. While several of the low-yield states acknowledged the importance of keeping all parties informed, only three of these states reported initiating meetings with hospitals and stakeholders or implementing efforts to keep lines of communication open.

Absent adequate compensation and liability assurances, states resorted to instituting more stringent guidelines for vaccination eligibility. However, while this may have been a useful tactic to reduce employer risk, it also resulted in reducing the absolute numbers of people who were vaccinated. Six of the ten low-yield states either imposed or exceeded the most restrictive screening guidance provided by the CDC. In contrast, only two of the ten high-yield states reported following a similar approach. One low-yield state noted that even though it had instituted a conservative approach from the beginning, it added further restrictions not listed by the CDC, even prior to the incidence of cardiac-related outcomes. This distinction is clearly illustrated by the difference in responses between high- and low-yield states to the concerns that injuries resulting from secondary transmissions were not protected under Section 304 (the federal liability regime for Phase I smallpox vaccinations). One low-yield state's solution was to screen out potential vaccine recipients with any household contacts who had contraindications. In contrast, one high-yield state allayed concerns by distributing Baggies with bandages to staff members to decrease the likelihood of secondary transmission.

Two of the low-yield states did not use any of the above-mentioned strategies. Study participants from these states expressed the belief that there was nothing within their power to manage liability concerns. Both assumed this issue to be entirely the federal government's responsibility to resolve. One participant justified his lack of efforts toward Section 304: "[We] couldn't sell it because it was indefensible."

Table 2: Strategies Engaged to Manage Concerns About Liability and Compensation

	Frequency in high-yield states	Frequency in low-yield states
Assumed that Section 304 covered liability	6	2
Approached state workers' compensation programs	7	5
Used existing legal remedies to augment Section 304	2	0
Implemented regular meetings with key stakeholders	7	3
Imposed tougher screening process for contraindications	2	6
Relied entirely upon federal resolution	0	2

Study participants believed that compensation and liability were the two most important factors influencing achievement of Phase I Smallpox Program goals (see Table 3 for participants' ratings regarding the relative impact of factors).

Table 3: Relative Impact of Factors on the Phase I Smallpox Vaccination Program

	Study Participant Ratings		
	Not at all/Slight	Moderate	Strong
Offering incentives to vaccine recipients (for example, days off work)	19/20	1/20	0/20
Concerns by people in charge of the program about liability* (for example, hospitals)	2/20	4/20	14/20
Concerns by vaccine recipients about compensation for post-vaccination side effects	2/20	3/20	15/20
Ability to locate suitable vaccination sites	17/20	2/20	1/20
Perceptions of vulnerability to smallpox attack or risk	7/20	5/20	8/20
Delay in receiving vaccine and needles	17/20	3/20†	0/20
Attracting attention from the media	2/18	1/18	5/18

*Some indicated that their answers depended on the fact that liability was a more prominent concern among hospitals than in public health.

†One of these respondents noted a delay in the arrival of needles for training, but not a delay in the program itself.

Discussion

Study participants affirmed that their Phase I vaccination efforts often were the casualty of a rapidly launched program that placed logistical and resource challenges upon an already weakened public health infrastructure, limited budgets, and finite numbers of personnel. Despite these obstacles, in many instances the high-yield states' outcomes were commensurate with a greater investment of efforts to redirect personnel and funds and to educate and ultimately recruit volunteers than were their low-yield counterparts (although the numbers are too small to test statistical significance).

By exacerbating the perceived threat environment, the war in Iraq initially provided a powerful and motivating backdrop for volunteer recruitment. However, with the

war's conclusion, interest in the smallpox vaccination campaign by both potential recruits and, to some extent, their vaccinators, diminished. Ultimately, the risk of the vaccine exceeded the perception of threat from a smallpox attack.

Unlike other pre-exposure mass-immunization programs with which the public health sector has significant experience, the Phase I program involved an unfamiliar antigen, a unique and unpracticed vaccine delivery method, and complex operational and administrative strategies. Moreover, success demanded a strong—but generally absent—partnership between the public health and hospital sectors to support the joint planning and shared consensus and strategy required to construct a solidified Phase I program initiative. Although some states saw the smallpox planning efforts as contributing to improved relationships between the hospital and public health sectors, in other instances the Phase I plan contributed to further strain.

We ultimately conclude that Section 304 of the Homeland Security Act of 2002 and the Smallpox Emergency Personnel Protection Act of 2003, which ineffectively addressed smallpox vaccine compensation and liability issues, were perceived as the most significant factors in failure to achieve initial Phase I vaccination goals. To that end, we have undertaken a review of relevant liability and compensation legislation to provide an understanding of the limitations facing potential Phase I participants.

Liability and Compensation Generally

There are two closely linked legal issues germane to the smallpox vaccination program: liability and compensation. In the vaccine context, liability focuses on who will be held legally responsible for a vaccine's adverse effects. Compensation concerns the reimbursement that the injured person or the person's family receives for injuries or death. These issues, as they pertain to vaccinations, are not unique to Phase I, and in fact have been addressed statutorily by Congress in two other public health contexts: the National Swine Flu Immunization Program of 1976⁷⁷ and the National Childhood Vaccination Injury Compensation Act of 1986.⁷⁸ As shown below, the two previous programs' compensation and liability provisions were more generous than the program that Congress created to address liability resulting from the administration of smallpox countermeasures.

Congress Sets Phase I's Legal Framework

In November 2002, Congress enacted Section 304 of the Homeland Security Act to provide liability protection for injury or death caused by the administration of the smallpox countermeasures at issue. This liability coverage extended to those engaged in the physical act of administering countermeasures, as well as others in the chain of countermeasure distribution.⁷⁹ However, this universe of covered persons seemed to leave those responsible for other sources of vaccine-related injury or death, such as contraindication screening or patient monitoring, fully exposed to liability for smallpox countermeasures.⁸⁰

Unlike previous vaccine liability and compensation legislation, Section 304 did not establish a no-fault compensation system that allowed a vaccinee to be reimbursed for adverse effects without showing that someone did something wrong. Under the National Swine Flu Immunization Program of 1976 and the National Childhood Vaccination Injury Compensation Act, injured persons needed only to show that their injuries stemmed from the vaccine.⁸¹ If an adverse reaction resulted from the

administration of a smallpox countermeasure, Section 304 required the United States to assume liability only for the *negligent* conduct that caused the injury or death.⁸² Section 304's standard of negligence made it much more difficult and highly unlikely that an injured person would recover any money for injuries arising from smallpox countermeasures. For example, if a nurse administered a properly manufactured smallpox vaccination according to guidelines, a person injured by the vaccine could not be compensated, regardless of the vaccine's inherent risks, because neither the nurse nor the manufacturer had been negligent.⁸³ The federal government was aware of Section 304's limited prospects for recompense, but assumed that other programs, such as state workers' compensation plans, would provide any needed compensation for injury or death arising from Phase I.⁸⁴ In other words, even if first responders did not receive any compensation for an injury under Section 304, the federal government believed that state workers' compensation would readily compensate them for their injuries.

However, there was substantial doubt in the first responder community that state workers' compensation funds could in fact legally cover these costs.⁸⁵ Many public health officials, unions, and attorneys explained that a high degree of uncertainty existed concerning recovery from state workers' compensation, because the scope and quality of workers' compensation plans varied greatly among the states.⁸⁶ Additionally, it was nearly uniformly true that patients or family members who were injured by coming in contact with a recently vaccinated person would not be covered under most state workers' compensation laws.⁸⁷ This confusing state of affairs left many potential Phase I volunteers wondering if the risk of injury posed to them and their families was worth the benefit of receiving the smallpox vaccine. Furthermore, the thought of workers' compensation coverage for Phase I injuries distressed volunteers' employers because of the specter of higher insurance premiums,⁸⁸ which Section 304 did not cover.^{89, 90}

Section 304 had structural flaws from the outset. At the bare minimum, Section 304 did not clearly define its scope of liability coverage, and in the worst-case scenario, it left those performing vaccination-related activities completely open to liability for injuries and fatalities related to smallpox countermeasures. In addition, Section 304's negligence standard left vaccinees and their families little hope of being compensated for Phase I injuries and deaths. While workers' compensation programs might have provided coverage, this was far from clear and, therefore, uncertain enough to discourage potential vaccinees. The public health, hospital, and first responder communities saw great risk in administering and receiving smallpox vaccinations without plainly defined liability provisions or strong assurances of compensation for adverse reactions.

Department of Health and Human Services Attempts to Address Fears

Faced with the growing unease among those responsible for administering smallpox countermeasures over what was perceived to be the narrow scope of liability coverage, Secretary Thompson hoped to calm those fears through the declaration he was required to issue under Section 304.⁹¹ On 28 January 2003, he published the statutorily required declaration in which he tried to broaden Section 304's liability umbrella by, *inter alia*, including activities peripheral to the actual vaccination.⁹² Rather than quell concerns, the declaration only added to program participants' worries, because the purportedly expanded liability coverage was deemed to be

legally questionable—that is, it was viewed as being in excess of the authority granted the Secretary under Section 304.⁹³

Because of the confusion over liability and compensation, the American Federation of State, County, and Municipal Employees, an important union representing, *inter alia*, 350,000 healthcare workers, requested that President Bush postpone the smallpox vaccination program just as Secretary Thompson was about to launch Phase I in January 2003.⁹⁴ The Massachusetts Nurses Association specifically requested that nurses in Massachusetts refuse the vaccine until the government resolved compensation concerns, as well as other safety considerations.⁹⁵ By March 2003, other prominent organizations, including the American Public Health Association, the Association of State and Territorial Health Officials, and the National Association of County and City Health Officials, requested the swift passage by Congress of new legislation to close the gaps in Section 304 by clarifying the ambiguities over liability coverage and by providing an “easily accessible” compensation regime.⁹⁶ By mid-April 2003, the nascent Phase I program found itself floundering, with only 33,444 out of 500,000 volunteers having been vaccinated.⁹⁷

Congress Extends Liability Coverage and Provides a Federal No-Fault Compensation Package

A legislative response came on 30 April 2003—three months after the first inoculation under Phase I. Congress enacted the Smallpox Emergency Protection Personnel Act of 2003 (SEPPA),⁹⁸ which clarified and extended Section 304’s liability provisions by legally providing coverage to those involved in important vaccination support activities.⁹⁹ Just as important, SEPPA created a no-fault compensation regime,¹⁰⁰ which would be administered through an agency proceeding rather than a court action.¹⁰¹ Accordingly, there was no need to show negligence under SEPPA. SEPPA also supplied medical, death, and lost-income benefits for covered injuries¹⁰² resulting from countermeasures administered to those volunteering before the discovery of a confirmed active case of smallpox anywhere in the world.¹⁰³ Despite the statutory improvements, SEPPA raised new issues of concern to the public health and first responder communities.

SEPPA benefits were made secondary to all other sources of compensation,¹⁰⁴ meaning that benefits from other sources of compensation, for example workers’ compensation, would be subtracted from any potential award under SEPPA. Therefore, the ambiguity of workers’ compensation coverage for Phase I injuries remained a factor in deciding whether to be vaccinated. Injured vaccinees would still need to wrestle with each individual state workers’ compensation regime before understanding whether they would be compensated by SEPPA. Moreover, SEPPA did little to alleviate the concerns of employers. For example, the legislation failed to address concerns over increased workers’ compensation premiums, which meant employers would potentially need to self-finance a portion of an injured employee’s smallpox vaccine-related injuries.

Besides the problems mentioned above, even when an injured person was entitled to recovery under SEPPA, that legislation imposed caps on awards, caps that were more stringent than previous federal vaccine compensation and liability laws. For example, the National Swine Flu Immunization Program of 1976 did not limit awards,¹⁰⁵ and the National Childhood Vaccination Injury Compensation Act’s caps, when taking cost-of-living increases into account, were by and large considerably more generous

than SEPPA.¹⁰⁶ Moreover, in order to receive full compensation for lost wages under SEPPA, an individual needed to miss at least 10 days of work.¹⁰⁷ Even when the statutory benefits became available, SEPPA limited compensation for lost employment income to two-thirds of the vaccinee's income, providing an additional 8.3% of the income if the person had one or more dependents.¹⁰⁸ The act further limited this benefit to a maximum of \$50,000 per year and a lifetime total of \$262,100, if injuries were not permanently disabling.¹⁰⁹ Finally, these benefits ceased to be payable if the injured person died from the countermeasure and the survivors collected death benefits,¹¹⁰ which in turn were limited to a lump sum of \$262,100 or a maximum annual payment of \$50,000 until the deceased's youngest dependent reached 18 years of age.¹¹¹ As a result, a seriously injured, but not permanently disabled, first responder such as an emergency room doctor who hypothetically made \$100,000 per year could see his or her annual salary halved, and that salary would last for only five years—an especially troublesome prospect if the doctor had a young family. Any claimant not satisfied with an administrative award had the daunting task of litigating under Section 304,¹¹² thereby placing the injured vaccinee or survivors under the original Section 304 regime that SEPPA was designed to reform.

The unsatisfactory nature of the remedies provided by SEPPA may be measured by the fact that as of 31 January 2004, only 39,353 had been vaccinated for smallpox,¹¹³ meaning that in the nine months following SEPPA, only an additional 5,909 people had chosen to be vaccinated against smallpox.

Concluding Remarks

The study assembled insights from low- and high-yield states regarding factors that contributed to or distracted from their initial Phase I smallpox vaccination goals. We hope that the information provided will offer guidance to key decision makers, administrators, clinicians, and others who bear the responsibility for determining whether a smallpox vaccination program should be reinvigorated (although supporting or refuting efforts to revitalize the smallpox program was not specifically the object of this article). This information may inform strategy for other initiatives to protect America's citizens from the ongoing threat of bioterrorism.

This study engaged a relatively small sample of states (n=20). Although an analysis of factors *between* low- and high-yield states does not lend itself to statistical comparison, this study *in aggregate* does support the importance of fiscal support, communication, resource allocation and planning, and a sound legal framework as being critical to the successful formulation and outcome of a pre-event vaccination program.

Funding

A vaccination program carried out under federal mandate or for homeland security requires adequate resources. Phase I's slow start can, in part, be attributed to insufficient funding. Certainly skeptics will point to the fiscal year 2002 biopreparedness funding totaling approximately \$1 billion and query why the states could not carve out a little to accomplish Phase I for 500,000 people. Several issues must be taken into consideration in evaluating the fiscal support for the Phase I vaccination program.

Over the past few decades, the public health sector has been deprived of the resources necessary to fulfill its basic population health responsibilities and to respond to growing chronic health issues, emerging infections, and other mission-critical concerns. There are no financial cushions within public health departments or their local and state governments to assume new responsibilities in the absence of sufficient and frontloaded funding—especially given dismal state economic shortfalls.¹¹⁴

The administration charged state and local health agencies with preparing for the smallpox vaccination program in the fall of 2002, but released no funds earmarked for the endeavor until March of the following year. Instead, if states wanted to apply federal funds toward this mandate, they would have to use or redirect the remains of their fiscal year 2002 bioterrorism preparedness funds. Unfortunately, the development of state and local preparedness spending plans had already presented a considerable hardship,¹¹⁵ and states had very little left of the 2002 funds to spend.^{116, 117} Consequently, as this study demonstrated, some states contributed their own money to implement Phase I, but in most cases this resulted in a diversion from routine public health responsibilities.

The sense of urgency expressed by federal authorities for initiating the smallpox vaccination program was inconsistent with the limited resources and legal protections made available at the inception of the plan. Additionally, quick implementation of the plan required public health departments to cast aside responsibility for other bioterrorism preparedness initiatives as well as routine and traditional functions in order to concentrate on smallpox; they did not have the fiscal or human resources to simultaneously handle all of these activities.

Moreover, recreating the infrastructure to deliver and monitor a vaccine that has not been used in this country in over 30 years required tremendous resources, much more than originally anticipated. Early estimates projected that the program would cost \$85 per vaccinee,¹¹⁸ but the latest data show that costs incurred by local public health agencies' smallpox vaccination ranged from \$154 to \$284 per vaccinee, with an average of \$204.¹¹⁹ As a result, the \$1.4 billion given to states in 2002 for general biopreparedness *and* the smallpox vaccination program was insufficient.

The fiscal burden of the Phase I program encompassed many components. Within the cost equation are factors that included time for personnel training, program planning, clinic setup and administration, vaccination tracking and monitoring, and the vast amount of hours that were subtracted from the delivery of routine and vital public health services.¹²⁰ These costs—in light of the relatively paltry response from volunteers—are further amplified by the estimates of vaccine wastage. Nationwide the CDC shipped 291,400 vaccine doses, but only 13% were used.¹²¹ Thousands of doses of vaccine had to be discarded in instances where vials of antigen were reconstituted, but not completely used.¹²²

Planning

Throughout the last half century there has been a well-documented schism between medicine and public health. Medicine has focused on the delivery of illness intervention to *individuals*, while public health has focused on efforts to promote and protect the health of *populations*. The two sectors have diverged greatly and have come to operate more or less independently with little communication.¹²³

Through interviews with public health officials, this study indicated that some hospitals were frustrated that they had not been sufficiently included in the smallpox vaccination planning processes, both at the strategic and tactical stages. In fact, in some circumstances, the apparent clash over legal protections and responsibilities worked against other ongoing bioterrorism planning initiatives that had had hopes of bridging the chasm between public health and medicine.

A critical challenge facing the nation's public health system's bioterrorism preparedness efforts is to build an infrastructure capable of rapidly implementing mass immunization services. To achieve this goal, public health will be required to identify the risk groups, screen out individuals, and monitor and track cohorts who are vaccinated, infected, and exposed, but not ill. These decisions and actions demand seamless and reciprocal relationships between the public health sector and the medical and healthcare delivery communities. The threats associated with emerging microbial pathogens and deliberate biological attacks will place the public health sector in the lead role for initiating and administering pre- and post-event vaccination efforts. Greater integration and coalescence between the public health and medical communities should be a critical objective.

To a large degree, the outcome of the Phase I program represents a failure to convince many potential vaccinees that smallpox presented a personal and national security threat. Although the federal government planned for smallpox vaccinations prior to the most recent war in Iraq, the war certainly accelerated implementation. This sense of urgency cast over the vaccinations faded after the war ended and the United States found no evidence of an active Iraqi bioweapons program. In the minds of the public, and many within the medical and public health sectors, the federal government cried wolf and lost credibility. Trust—among vaccine recipients as well as vaccinators—must be rebuilt if the smallpox program and other preparedness measures are to succeed. That trust can come from careful articulation of the global threats we face. It can come in the form of more careful, deliberate planning and adequate funding should subsequent mass pre-event vaccination programs be conceived. Whatever form a vaccination program ultimately takes, trust is crucial to inspiring the states to pursue vaccination objectives vigorously. If the states are not behind the vaccination plan, they will be less likely to seek ways to implement it creatively. Just as important, states will receive plans for future voluntary biodefense vaccination programs with skepticism, rather than optimism, if the federal government fails to regain their trust.

Liability

The results of this study indicate that the lack of an adequate smallpox vaccine liability and compensation scheme was one of the largest obstacles to the United States' achieving its goal of vaccinating 500,000 first responders. A comprehensive liability and compensation package was especially necessary for Phase I, because it was a pre-event vaccination of first responders, where the risks and benefits are necessarily balanced much differently than in a post-event vaccination. Without an active case of smallpox, potential vaccinees will likely not assume the current smallpox vaccine's risks without reassurance from the government that they will be reasonably compensated, and those potentially involved with administering the vaccine will not do so without assurance that the United States will, within reason, assume their liability. A post-event mass vaccination of Americans would likely shift the personal risk-benefit analysis towards receiving the vaccine, even without

adequate compensation, because the risk of being harmed by the vaccine is much less than the disastrous consequences of contracting smallpox.

When Congress belatedly assembled its final liability and compensation plan for the smallpox vaccination effort—three months after the beginning of Phase I—it offered protection and benefits less generous than the National Swine Flu Immunization Program of 1976 or the National Childhood Vaccination Injury Compensation Act. Congress was most likely reacting to concerns that the two previous vaccination programs were considered too costly to the federal government in terms of awards. However, the cost of more generous liability coverage and compensation benefits for the smallpox vaccination program or any pre-event campaign must be considered contextually.¹²⁴ For example, the Phase I smallpox program has about 500,000 vaccinees, plus a smaller potential subset of individuals who might become infected by those who are vaccinated, for which the United States could potentially be liable, rather than the continuously growing pool of child vaccinees under the National Childhood Vaccination Injury Compensation Act, or the 40 million people vaccinated in the National Swine Flu Immunization Program. Not only must the more modest cost of compensating the fewer potential claims¹²⁵ under Phase I be considered, but lawmakers need to balance that cost against the enormous benefit of having a first responder network in place to conduct post-event mass smallpox vaccinations of the public.¹²⁶

To be sure, the liability and compensation issues are complex, and they need a more rigorous analysis than space permits here. For now, suffice it to say that we believe that the additional liability and compensation protections offered by SEPPA were inadequate. Public health institutions, academics, Congress, and the Executive Branch must focus and create a better solution. In this regard, we are developing a more probing and comprehensive analysis of a compensation and liability scheme for pre-event biodefense vaccinations, which will be published in the near future.

Final Thoughts

Anecdotal information, reports, and even the comments of public health officials interviewed for this study would suggest that the Phase I program was a failure, as it fell far short of its initial goal of vaccinating 500,000 responders. However, the program provided many opportunities to rethink the relationships, systems, and resources critical to improving the nation's homeland security. We must invest now in strategies for planning and financing pre- and post-event vaccination programs and in developing a legal framework to support their implementation. If this administration and future administrations are serious about making a volunteer vaccination program work, they must address the concerns of administrators and potential vaccinees. We seek to provide a suitable framework.

References

Click on an end note number to return to the article.

¹ See David A. Koplow, "That Wonderful Year: Smallpox, Genetic Engineering, and Bio-Terrorism," *Maryland Law Review*, vol. 62, no. 3, 2003, pp. 417, 433-436 (describing the smallpox eradication campaign).

- [2.](#) Jonathan B. Tucker, *Scourge: The Once and Future Threat of Smallpox* (New York: Atlantic Monthly Press, 2001), p. 135.
- [3.](#) Barton Gellman, "Four Nations Thought to Possess Smallpox: Iraq, North Korea Named, Two Officials Say," *Washington Post*, 5 Nov. 2002.
- [4.](#) Scott Parrish and Tamara Robinson, "[Efforts to Strengthen Export Controls and Combat Illicit Trafficking and Brain Drain](#)," *Nonproliferation Review*, vol. 7, no. 1, spring 2000, p. 112.
- [5.](#) The [Geneva Protocol of 1925](#), Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare. Opened for signature 17 June 1925; entered into force 8 Feb. 1928.
- [6.](#) [Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological \(Biological\) and Toxin Weapons and on Their Destruction](#), opened for signature 10 April 1972, 26 U.S.T. 583, 1015 U.N.T.S. 163. Signatories include many countries of concern to the United States, such as Iraq, Iran, and North Korea. [Fifth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological \(Biological\) and Toxin Weapons and on Their Destruction](#), 2002.
- [7.](#) William J. Bicknell, "[The Case for Voluntary Smallpox Vaccination](#)," *New England Journal of Medicine*, vol. 346, no. 17, 25 April 2002, pp. 1323–1325.
- [8.](#) Ibid.
- [9.](#) Centers for Disease Control, "[Smallpox Vaccination Program Status by State](#)." (This page is updated weekly.) See note 13.
- [10.](#) Ibid.
- [11.](#) Centers for Disease Control, "[Smallpox Vaccination Program Vaccine Doses Shipped and Released for Use](#)."
- [12.](#) Centers for Disease Control, "[Smallpox Response Plan and Guidelines](#)" (version 3.0), 26 Nov. 2002.
- [13.](#) Colette Flight, "[Smallpox: Eradicating the Scourge](#)," BBC History page, 1 Feb. 2002.
- [14.](#) Gro Harlem Brundtland, "[Smallpox Revisited](#)," *Journal of the American Medical Association*, vol. 287, no. 9, 6 March 2002, p. 1104.
- [15.](#) All members of the United Nations as of 1967, except for South Africa, which no longer participated in WHO. Reference F. Fenner, D. A. Henderson, I. Arita, Z. Jezek, and I. D. Ladnyi, "[Smallpox and Its Eradication](#)," World Health Organization, 1988.
- [16.](#) See David A. Koplow, pp. 433–436 (describing the smallpox eradication campaign).
- [17.](#) F. Fenner et al., "Reduction in the Number of Laboratories Retaining Variola Virus," in "Potential Sources for a Return of Smallpox," [chap. 30](#) of *Smallpox and Its Eradication*, p. 1338.
- [18.](#) Jonathan B. Tucker, p. 135.
- [19.](#) Ibid., p. 136.
- [20.](#) Judith Miller, Stephen Engelberg, and William Broad, *Germs: Biological Weapons and America's Secret War* (New York: Simon & Schuster, 2002), pp. 169–70.
- [21.](#) David A. Koplow, pp. 439–440.
- [22.](#) Ibid., p. 440, note 143.

[23.](#) Ken Alibek, testimony before the House Committee on Government Reform, Subcommittee on National Security, Veterans Affairs, and International Relations, 12 Oct. 2001.

[24.](#) Barton Gellman.

[25.](#) President George W. Bush, [remarks on smallpox vaccination](#), 13 Dec. 2002.

[26.](#) CDC Director Julie L. Gerberding, M.D., M.P.H., [testimony](#) before the Senate Committee on Health, Education, Labor, and Pensions on CDC efforts in implementing a smallpox vaccination program, 30 Jan. 2003.

[27.](#) For example, a 1995 United Nations Special Commission inspection revealed a freeze drier labeled "smallpox" in the State Establishment for Medical Appliances near Baghdad. A spring 2002 report from the Weapon's Intelligence Nonproliferation and Arms Control Center stated that a Soviet scientist admitted that his country gave smallpox technology to Iraq in the early 1990s. The Armed Forces Medical Intelligence Center reported that 8 of 69 Iraqi prisoners of war who received blood tests in 1991 showed immunity to smallpox even though the virus had not occurred naturally in Iraq for 20 years. See Barton Gellman.

[28.](#) Associated Press, "[Bush Favors Dual Smallpox Plans](#)," 14 Nov. 2002.

[29.](#) CNN, "[Transcript: David Kay at Senate Hearing](#)," 28 Jan. 2004.

[30.](#) Jonathan B. Tucker, p. 138.

[31.](#) E. Hammarlund et al., "Duration of Antiviral Immunity After Smallpox Vaccination," comment in *Nature Medicine*, vol. 9, no. 9, Sep. 2003, p. 1131.

[32.](#) Jennifer M. Lofquist, Nicole A. Weimert, and Mary S. Hayney, "[Smallpox: A Review of Clinical Disease and Vaccination](#)," *American Journal of Health-System Pharmacy*, vol. 60, no. 8, 29 April 2003, pp. 749–756.

[33.](#) "[Protecting Americans: Smallpox Vaccination Program](#)," White House press release, 13 Dec. 2002.

[34.](#) Ibid.

[35.](#) An initial CDC estimate was "based on the number of hospitals ... [and the] average number of people per hospital and the proportion of hospitals that would participate" ("[Smallpox Vaccine Adverse Events Monitoring and Response System](#)," CDC Telebriefing Transcript, 6 Feb. 2003).

[36.](#) "[CDC Initial Review of State Smallpox Vaccination Plans Complete](#)," CDC press release, 12 Dec. 2002.

[37.](#) Robert Roos, "[ACIP \[Advisory Committee on Immunization Practices\] Suggests Which Hospital Workers Need Smallpox Shots: Total Could Reach 500,000](#)," *CIDRAP* (Center for Infectious Disease Research and Policy) *News*, 18 Oct. 2002.

[38.](#) [Homeland Security Act of 2002](#), Public Law no. 107-296, § 304(c), 116 Stat. 2135, 2165 (codified at 42 U.S.C., § 233(p) (2)).

[39.](#) Secretary of Health and Human Services, [Declaration Regarding Administration of Smallpox Countermeasures](#), 24 Jan. 2003, *Federal Register*, vol. 68, no. 18, 28 Jan. 2003, p. 4212.

[40.](#) Ibid.

[41.](#) Pamela Ferdinand and Ceci Connolly, "Turnout Low at Launch of Domestic War on Smallpox; Conn. First State to Carry Out Bush's Immunization Campaign," *Washington Post*, 25 Jan. 2003.

[42.](#) Secretary of Health and Human Services, Declaration Regarding Administration of Smallpox Countermeasures.

[43.](#) Secretary of Health and Human Services, [Amendment to Extend January 24, 2003 Declaration Regarding Administration of Smallpox Countermeasures](#), 21 Jan. 2004.

44. For information on emerging microbial threats and factors of emergence, see Mark S. Smolinski, Margaret A. Hamburg, and Joshua Lederberg, editors, Committee on Emerging Microbial Threats to Health in the 21st Century, Board on Global Health, *Microbial Threats to Health: Emergence, Detection, and Response* (Washington, DC: National Academies Press, 2003).

45. Monica Schoch-Spana, "Hospitals Buckle During Normal Flu Season: Implications for Bioterrorism Response," *Biodefense Quarterly*, March 2000.

46. Jonathan B. Tucker, p. 138.

47. Jennifer M. Lofquist, Nicole A. Weimert, and Mary S. Hayney, "[Smallpox: A Review of Clinical Disease and Vaccination](#)," *American Journal of Health-System Pharmacy*, vol. 60, no. 8, 29 April 2003, pp. 749–756.

48. Ceci Connolly, "Many Nurses Lack Understanding of Smallpox, Poll Says," *Washington Post*, 23 Jan. 2003. The public was even less educated. A Harvard School of Public Health Survey found that 30% of those surveyed believe there has been a smallpox case in the United States in the past five years, when in fact the last case was in 1949 (Robert J. Blendon et al., "[The Public and the Smallpox Threat](#)," *New England Journal of Medicine*, vol. 348, no. 5, 30 Jan. 2003, pp. 426, 427). Moreover, only 16% believed that the country has enough vaccine to give everyone in the event of an attack, when actually the government has taken aggressive steps to ensure sufficient vaccine for everyone (p. 429).

49. CDC, [Notice of Cooperative Agreement Award, Guidance for Fiscal Year 2002 Supplemental Funds for Public Health Preparedness and Response for Bioterrorism](#), 15 Feb. 2002.

50. CDC Director Julie L. Gerberding.

51. "[Smallpox Vaccination: Implementation of National Program Faces Challenges](#)," U.S. General Accounting Office, report (GAO 03-578) to the Chairman of the Senate Committee on Governmental Affairs, April 2003, pp. 10–11.

52. From fiscal years 1997 through 2001, 97 U.S. cities received funds from the Office of Emergency Preparedness for Metropolitan Emergency Bioterrorism Preparedness to develop the Metropolitan Medical Response System called for by the Nunn-Lugar-Domenici Act (Alexandra Kobishyn et al., [Bioterrorism: Preparedness and Response](#) [Princeton, NJ: Princeton University, Woodrow Wilson School of Public and International Affairs]).

53. The CDC issued a Bioterrorism Cooperative Agreement in August 1999 to support state and local public health departments' initiatives for planning responses to bioterrorism, other infectious disease outbreaks, and other public health crises. For fiscal year 2002, the Cooperative Agreement provided \$135 million in grants to the state health departments (U.S. Dept. of Health and Human Services, Health Resources and Services Administration, [Bioterrorism Hospital Preparedness Program](#)).

54. On 12 June 2002, the President signed the Public Health Security and Bioterrorism Preparedness and Response Act, which authorized \$1.6 billion to fund additional bioterrorism preparedness activities, \$175 million of which went to state and local efforts (Beth Daley, "US Plan to Fight Smallpox Faulted," *Boston Globe*, 28 Nov. 2001).

55. In fiscal year 2002, the states were allocated \$1 billion in bioterrorism funding to be used specifically for strengthening state and local public health and medical care infrastructures for bioterror events ("[HHS Announces States' Shares of Bioterrorism Preparedness Funds](#)," *CIDRAP News*, 1 Feb. 2002). All in all, states received approximately \$1.8 billion for bioterrorism preparedness efforts in fiscal year 2002. For fiscal year 2003, \$1.4 billion was disbursed to state and local health departments ("[Secretary Thompson to Release \\$100 Million to Assist States With Smallpox](#)," U.S. Newswire, 10 May 2003).

56. "[HHS Announces Bioterrorism Aid for States, Including Special Opportunity for Advance Funding](#)," HHS press release, 20 March 2003.

57. "Secretary Thompson to Release \$100 Million to Assist States With Smallpox."

58. "[HHS Provides \\$1.4 Billion More to States and Hospitals for Terrorism Preparedness](#)," HHS press release, 2 Sept. 2003.

59. Although the Unfunded Mandate Reform Act of 1995 exempts regulations or legislation that is "necessary for the National Security" (2 U.S.C. § 1503 (5)), Secretary Thompson's declaration of 24 Jan. 2003 states that at this time it is only "advisable to administer [smallpox vaccinations] on a voluntary basis" (Declaration Regarding Administration of Smallpox Countermeasures [emphasis added]).

60. CDC, Smallpox Vaccination Program Status by State. As of 31 January 2004, the CDC reported that only 39,353 persons had been vaccinated against smallpox.

61. CDC, Smallpox Vaccine Adverse Events Monitoring and Response System.

62. Ibid.

63. D. A. Henderson, T. V. Inglesby, J. G. Bartlett, et al., "Smallpox as a Biological Weapon: Medical and Public Health Management," *Journal of the American Medical Association*, vol. 281, no. 22, 9 June 1999, pp. 2127–2137.

64. David A. Koplow, p. 423.

65. Cf. Judith Miller et al., p. 270 (explaining in relation to mandatory U.S. military anthrax vaccinations that "an otherwise healthy group of men and women received shots to protect against a health threat that might well never materialize").

66. William J. Bicknell, p. 1323.

67. CDC, "Update: Cardiac and Other Adverse Events Following Civilian Smallpox Vaccination—United States, 2003," *Morbidity and Mortality Weekly Report*, vol. 52, no. 27, 11 July 2003, pp. 639–642.

68. The Advisory Committee on Immunization Practices recommended the following in 2001: "Smallpox vaccination is contraindicated for persons with a history or presence of eczema or atopic dermatitis; who have other acute, chronic, or exfoliative skin conditions; who have conditions associated with immunosuppression; are aged <1 year; who have a serious allergy to any component of the vaccine; or who are pregnant or breastfeeding. ACIP does not recommend smallpox vaccination for children and adolescents aged <18 years during the pre-event vaccination program. Pre-event vaccination also is contraindicated among persons with household contacts who have a history or presence of eczema or atopic dermatitis; who have other acute, chronic, or exfoliative skin conditions; who have conditions associated with immunosuppression; or who are pregnant.... Persons with inflammatory eye disease might be at increased risk for inadvertent inoculation as a result of touching or rubbing the eye. Therefore, deferring vaccination is prudent for persons with inflammatory eye diseases requiring steroid treatment until the condition resolves and the course of therapy is complete" (CDC, "Vaccinia [Smallpox] Vaccine: Recommendations of the Advisory Committee on Immunization Practices [ACIP], 2001," *Morbidity and Mortality Weekly Report*, vol. 50, no. RR-10, 22 June 2001, pp. 1–25). Since those recommendations the CDC has added breastfeeding and heart disease to the list of contraindications (CDC, "Smallpox [Vaccinia] Vaccine Contraindications," 28 March 2003).

69. NIH Director Anthony S. Fauci, "NIH's Role in Implementing a Smallpox Vaccination Program," testimony before the Senate Appropriations Committee, Subcommittee on Labor, HHS, Education and Related Agencies, 108th Cong., 29 Jan. 2003.

70. Ibid.

71. CDC, "Smallpox Vaccinations and Adverse Reactions: Guidance for Clinicians," *Morbidity and Mortality Weekly Report*, vol. 52, no. RR-4, 21 Feb. 2003, pp. 1–28.

72. CDC, [Smallpox \(Vaccinia\) Vaccine Contraindications](#), 28 March 2003.

73. CDC, "Smallpox Fact Sheet: What to Do After You've Gotten the Smallpox Vaccine," 14 Jan. 2003.

74. Robert G. Darling, et al., "Removing Health Care Workers From Clinical Duties After Smallpox Vaccination: Is It Really Necessary?" *Annals of Emergency Medicine*, vol. 42, no. 5, Nov. 2003, pp. 665–680.

75. CDC, "Secondary and Tertiary Transfer of Vaccinia Virus Among U.S. Military Personnel—United States and Worldwide, 2002–2004," *Morbidity and Mortality Weekly Report*, vol. 53, no. 05, 13 Feb. 2004, pp. 103–105.

- [76.](#) Alex R. Kemper, Matthew M. Davis, and Gary L. Freed, "[Expected Adverse Events in a Mass Smallpox Vaccination Campaign](#)," *Effective Clinical Practice*, vol. 5, no. 2, March/April 2002, pp. 84–90.
- [77.](#) National Swine Flu Immunization Program of 1976, Public Law no. 94-380 § 2, 90 Stat. 1113.
- [78.](#) National Childhood Vaccination Injury Compensation Act, Public Law no. 99-660, 100 Stat. 3753.
- [79.](#) Homeland Security Act of 2002, § 304, 116 Stat. 2165. Congress afforded liability protection to manufacturers or distributors of covered smallpox countermeasures, health care entities such as clinics or hospitals that administer such countermeasures, people authorized to administer such countermeasures, or an "official, agent, or employee of a person described" in the first three categories (Homeland Security Act of 2002, § 304(c), 116 Stat. at 2168).
- [80.](#) Edward P. Richards and Katharine C. Rathbun, [Smallpox Vaccine Injury and Law Guide, 19 May 2003](#).
- [81.](#) Ibid.
- [82.](#) 42 USC § 233(p)(1). The statute states that a covered person is deemed an employee of the Public Health Service, which means that those seeking to hold a vaccine administrator liable must instead sue the United States through the Federal Tort Claims Act (Edward P. Richards and Katharine C. Rathbun). Section 304 also guarantees defendants that the government will "take their place" in the lawsuit and litigate on their behalf (the Homeland Security Act of 2002, § 304(c), 116 Stat. at 2165). However, the United States can seek reimbursement from the defendant if the defendant engaged in any "grossly negligent, reckless, or illegal conduct or willful misconduct" (the Homeland Security Act of 2002, § 304(c), 116 Stat. at 2167). Furthermore, if the party that the government is defending does not cooperate in the government's defense, then liability and the responsibility to defend can be transferred back to the allegedly negligent party (the Homeland Security Act of 2002, § 304(c), 116 Stat. at 2167).
- [83.](#) See Edward P. Richards and Katharine C. Rathbun.
- [84.](#) [A Biodefense Failure: The National Smallpox Vaccination Program One Year Later](#), prepared by the Democratic members of the House Select Committee on Homeland Security, Jan. 2004 (citing Tommy Thompson, HHS teleconference on smallpox policy, 14 Dec. 2002).
- [85.](#) Robin J. Strongin and Eileen Salinsky, "[Who Will Pay for the Adverse Events Resulting From Smallpox Vaccination? Liability and Compensation Issues](#)," National Health Policy Forum Issue Brief no. 788, 12 March 2003, pp. 8–10 (citing Assn. of State and Territorial Health Officials and Natl. Assn. of City and County Health Officials, "Smallpox Pre-event Vaccination: Liability and Compensation Concerns," unpublished issue brief, 2003).
- [86.](#) [A Biodefense Failure](#), pp. 13–14.
- [87.](#) "[National Public Health Associations Urge Legislative Action to Protect Smallpox Vaccine Volunteers](#)," American Public Health Association press release, 7 March 2003.
- [88.](#) See Robin J. Strongin and Eileen Salinsky, p. 10.
- [89.](#) Edward P. Richards and Katharine C. Rathbun.
- [90.](#) Wyeth Laboratories, Inc., [Package Insert: Dryvax \(Smallpox Vaccine, Dried, Calf Lymph Type\)](#).
- [91.](#) 42 U.S.C. § 233(p)(1).
- [92.](#) Declaration Regarding Administration of Smallpox Countermeasures.
- [93.](#) Edward P. Richards and Katharine C. Rathbun.
- [94.](#) Donald G. McNeil Jr., "Health Care Leaders Voice Doubts on Smallpox Inoculations," *New York Times*, 30 Jan. 2003.
- [95.](#) Ceci Connolly, "Many Nurses Lack Understanding of Smallpox, Poll Says."

[96.](#) "National Public Health Associations Urge Legislative Action to Protect Smallpox Vaccine Volunteers."

[97.](#) Julie Samia Mair and Michael Mair, "[Vaccine Liability in the Era of Bioterrorism](#)," *Biosecurity & Bioterrorism: Biodefense Strategy, Practice, and Science*, vol. 1, no. 3, 2003, p. 10.

[98.](#) Smallpox Emergency Personnel Protection Act of 2003 (SEPPA), Public Law no. 108-20, 117 Stat. 642. However, the Department of Health and Human Services did not issue regulations to implement SEPPA until December 2003 ([Smallpox Vaccine Injury Compensation Program: Administrative Implementation; Interim Final Rule](#), *Federal Register*, vol. 68, no. 241, 16 Dec. 2003, p. 70080, codified at 42 C.F.R. pt. 102).

[99.](#) SEPPA § 3, 117 Stat. at 647.

[100.](#) SEPPA § 263, 117 Stat. at 641.

[101.](#) SEPPA § 262, 117 Stat. at 640–641.

[102.](#) SEPPA § 261(a)(3), 117 Stat. at 638. The list of covered injuries may be found at 42 C.F.R. § 102.21 (2004). If an injury is not a covered injury, that person may still make a claim, but must establish that the injury was the result of a countermeasure administration during the Secretary's declaration (§ 102.20(d)).

[103.](#) SEPPA § 261(a)(2)(C), 117 Stat. at 638. Those vaccinated after such a discovery would receive no compensation (SEPPA § 261(a)(2)(C), 117 Stat. at 638).

[104.](#) SEPPA §§ 264(b), 265(c), 266(b)(3)(B), 117 Stat. at 641-42, 645. The section limiting medical benefits provides:

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

The sections of SEPPA limiting lost employment and death benefits are worded identically, differing only in reference to the benefit they limit.

[105.](#) National Swine Flu Immunization Program of 1976, Public Law no. 94-380, 90 Stat. 1113.

[106.](#) National Childhood Vaccination Injury Compensation Act, Public Law no. 99-660 § 2115, 100 Stat. 3753, 3767–3769.

[107.](#) SEPPA § 265(c)(4), 117 Stat. at 643.

[108.](#) SEPPA § 265(b), 117 Stat. at 642.

[109.](#) SEPPA § 265(c)(3)(A), 117 Stat. at 643. There is no lifetime total limit if the person is permanently disabled (SEPPA § 265(c)(3)(B), 117 Stat. at 643).

[110.](#) SEPPA § 265(c)(3)(B), 117 Stat. at 643.

[111.](#) Julie Samia Mair and Michael Mair, p. 11, citing 42 U.S.C.S. §§ 239e, 239d(c)(3)(ii) (2003).

[112.](#) *Ibid.*, citing 42 U.S.C. § 233(p)(3)(B) (2003); SEPPA § 266(b), 117 Stat. at 644.

[113.](#) CDC, Smallpox Vaccination Program Status by State.

[114.](#) See Natl. Governors Assn. and Natl. Assn. of State Budget Officers, "[The Fiscal Survey of States](#)" (noting that states have faced budget woes for the past two years and in fiscal year 2002 alone, 37 states collectively made \$12.6 billion in budget cuts), June 2003.

[115.](#) Elin Gursky, *Progress and Peril: Bioterrorism Preparedness Dollars and Public Health* (New York: Century Foundation, 2004).

[116.](#) "Smallpox Vaccination: Implementation of National Program Faces Challenges."

[117.](#) Patrick M. Libbey (Executive Director, National Association of County and City Health Officials), [testimony](#) before the Senate Appropriations Committee, Subcommittee on Labor, Health and Human Services, Education and Related Agencies, 29 Jan. 2003.

[118.](#) "National Public Health Associations Urge Legislative Action to Protect Smallpox Vaccine Volunteers."

[119.](#) National Association of County and City Health Officials, [letter](#) to Senator Evan Bayh regarding the Smallpox Vaccination Program, 2 April 2003.

[120.](#) Ceci Connolly, "Smallpox Campaign Taxing Health Resources," *Washington Post*, 10 March 2003.

[121.](#) CDC, [Smallpox Vaccination Adverse Events Report](#). This site is updated weekly to provide the most current figures. The number used in the above text is from the week ending 17 Oct. 2003.

[122.](#) Christopher Snowbeck, "[Thousands of Smallpox Shots Unused](#)," *Pittsburgh Post-Gazette*, 4 July 2003.

[123.](#) Laurie Larson, "Going Public: Do Medicine and Public Health Have a Future Together?" *Trustee* magazine, Nov./Dec. 1997, pp. 10-15.

[124.](#) The federal government has paid out over \$90 million to those who developed Guillain Barre syndrome linked to the swine flu vaccine (David Brown, "A Shot in the Dark: Swine Flu's Vaccine Lessons," *Washington Post*, 27 May 2002). Admittedly, the National Childhood Vaccination Injury Compensation Act has paid out even more in compensation awards: As of July 2003, the federal government had paid 3,509 claims totaling \$1.4 billion (Health Resources and Services Admin., National Vaccine Injury Compensation Program Monthly Statistics Report, 31 July 2003).

[125.](#) The administration has since shifted its goal of having 500,000 health care first responders vaccinated to being able to vaccinate the entire American population within ten days (David McGlinchey, "[HHS Secretary Says 'Vast Majority' of States Ready for Smallpox](#)," *Government Executive*, 29 Jan. 2004). Critics of that plan suggest that it, in fact, would require 1.25 million vaccinated health care workers, rather than 500,000 vaccinees.

[126.](#) Indeed, the figure of 10 million vaccinees projected for Phase II is comparatively small compared to the National Childhood Vaccination Injury Compensation Act or the National Swine Flu Immunization Program.