

**THE UNITED STATES SMALLPOX BIOTERRORISM
PREPAREDNESS PLAN: RATIONAL RESPONSE OR
POTEMKIN PLANNING?**

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I. INTRODUCTION

Smallpox is perhaps the most frightening bioterrorism agent because we do not need to imagine its effects. Smallpox killed and disfigured hundreds of thousands of people within living memory, even with the availability of effective vaccines. Before the vaccine age, smallpox was one of the great plagues, evolving with human civilization because it affects no other species. While malaria and tuberculosis are also great killers, they kill by stealth. Smallpox strikes terror because it kills quickly and horribly.

Smallpox was a major bogeyman after the terrorist attacks on September 11, 2001. The Bush administration launched a major smallpox vaccination campaign, and the Centers for Disease Control and Prevention (CDC) was directed to develop a national response plan for a smallpox bioterrorism attack. This article grows out of an article written in 2004 on the failure of that smallpox vaccination campaign in the civilian population and implications for the CDC's smallpox response plan.¹ Since the 2004 article, public health systems across the United States have lost key personnel and resources due to budget cuts, Hurricane Katrina showed the danger of relying on local emergency response, and the H1N1 vaccination campaign illustrated how hard it is to implement a new vaccination program.

The thesis of this article is that these events further undermine what was already a questionable smallpox response plan. But one more ineffective government response plan would hardly be news. Since the Duck and Cover films of the 1950s,² the federal Government has attempted to mollify the public with patently inadequate response plans for events that experts understand cannot be mitigated. The official U.S. nuclear war strategy was called Mutually Assured Destruction because it was assumed that there would be few survivors—making duck and cover little more than a cruel joke to frighten a generation of children.

The smallpox response plan is useful to study because the plan itself—unlike duck and cover—is based on good science and

1. See generally Edward P. Richards et al., *The Smallpox Vaccination Campaign of 2003: Why Did It Fail and What Are the Lessons for Bioterrorism Preparedness?*, 64 LA. L. REV. 851 (2004) (discussing the failures of the CDC's civilian smallpox vaccination campaign).

2. DUCK & COVER (Archer Productions 1952).

experience. It fails because the necessary public health infrastructure has been undermined, and because more than thirty years of politically expedient public health decisionmaking has made it impossible to deal with large scale threats when dealing with those threats has significant political costs.³ It is a Potemkin plan, which, like the villages in Potemkin's story, exists only to fool the eye.⁴ This article will show ways to recognize Potemkin planning, which is the first step to realistically facing risk.

II. BASELINE ASSUMPTIONS ON BIOTERRORISM

If you study disasters, a natural part of that study is working on worst case scenarios. For natural disasters, these are somewhat constrained by laws of physics and the history of such events. For example, while Hurricane Katrina was a large storm, it was well within known parameters and was not as large as other known storms in the same area. Assume an analysis based on Hurricane Katrina hitting the Louisiana coast about one hundred miles farther west than its actual landfall. This would shift the major forces of the storm to New Orleans, rather than the Mississippi coast, which would overwhelm all existing and proposed protections and utterly destroy most of the city. This is a worst case, but one that arises from known and highly probable events.

We use the same sort of bounded assumptions about bioterrorism by basing our analysis on the known properties of existing bacterial and viral agents. The analysis in this article follows this principle for smallpox. This can lead to a pretty frightening worst case. However, if you are free to speculate about unproven bioengineering modifications of bioterrorism agents, all bounds are lost. Assume a disease is untreatable and without a vaccine, fast to develop, very contagious, and that people are infectious for a few days before they are obviously ill, and you have a disease that will kill the world pretty quickly. Such a disease can be used to justify whatever draconian powers the proponent would

3. Cf. *House of Cards* (CNBC television broadcast June 3, 2009) (discussing the government policies that enabled the housing bubble that contributed to the financial crisis of 2008).

4. The term Potemkin village "is taken from a Russian story that Potemkin once had impressive fake villages built along a route that Catherine the Great was to travel, and is defined as an imposing or pretentious facade or display designed to obscure or shield an unimposing or undesirable fact or condition." *Forest Guardians v. Thomas*, 967 F. Supp. 1536, 1561 n.22 (D. Ariz. 1997).

like to justify, even if such powers would be meaningless in actually controlling the disease. For the purpose of this article, it is clear that garden-variety smallpox is quite sufficient to challenge our best defenses. In this author's view, policy makers should not worry about fantasy bugs until they have solved the problems with known agents.

III. THE COURSE OF SMALLPOX INFECTION⁵

Smallpox is caused by a virus. It has a characteristic course, with the different stages varying in duration and severity in different individuals.⁶ When a person becomes infected, the virus grows silently for seven to seventeen days, without symptoms, and without posing a risk of infection to others. The variability of the length of this period means that when the first case of smallpox is identified, it will be at least a week before it is known with any certainty how many persons were infected by the attack.⁷ If a case of smallpox is detected, every person in contact with the case must be quarantined at least twenty-one days to assure that they are not infected.⁸ As discussed below, an individual exposed to smallpox who is vaccinated within a few days of exposure may escape infection, but will still have to be helped for the full quarantine period.

This is followed by the prodrome, two to four days of flu-like symptoms, usually with a high fever.⁹ The disease becomes contagious during the prodrome.¹⁰ While not as contagious as later in the infection, this period is very dangerous from a disease-control perspective because the disease is easily confused with other flu-like illnesses. If the health care providers are not specifically looking for smallpox—which would only be the case after an outbreak has been declared—it is unlikely that the disease would be identified until the characteristic rash develops in the next phase of the illness. The disease is likely to bring the person into an emergency room or urgent care center, potentially

5. Parts of this section are adapted from Richards et al., *supra* note 1.

6. See DEP'T OF HEALTH & HUMAN SERVS., CTRS. FOR DISEASE CONTROL AND PREVENTION, SMALLPOX FACT SHEET 2 (2004) [hereinafter CDC SMALLPOX SHEET] (describing different stages of smallpox infections).

7. *Id.* This, of course, assumes there is only a single introduction of the virus.

8. *Id.*

9. *Id.*

10. *Id.*

exposing others in the facility, including the health care workers, before the disease is identified. The risk is minimized to the extent that the disease keeps the infected person from carrying on normal activities.

The end of prodrome is defined by the emergence of a characteristic rash, starting as small red spots on the tongue and in the mouth.¹¹ These spots become sores which break down and shed virus.¹² When this begins, the person is the most infectious, and remains infectious as long as the unhealed sores remain.¹³ Over the next ten days, the rash spreads over the body, developing into pustules, which then begin to rupture.¹⁴ The severity of this pustular rash is related to the fatality of the disease. In the most severe cases, the pustules merge into a uniform pavement and large sections of the patient's skin sloughs off.

When the rash becomes pustular and widespread, it is easy to identify as smallpox, and in severe cases, it is impossible to confuse with any other disease. While the current literature on smallpox focuses on these very characteristic manifestations of the disease, the historical record provides ample evidence of persons with much milder—and thus more difficult to diagnose—cases. During a known outbreak, every rash will be assumed to be smallpox until proven otherwise. Mild cases could complicate the initial identification of the disease, and during an outbreak, would not incapacitate an infected individual, allowing that individual to evade detection. This is a real problem, because control strategies that depend on identifying and controlling infected individuals assume that individuals are too sick to evade detection.

Once the rash develops, the infected person will either die or begin to recover over the next two weeks. Recovery begins when the pustules began to scab over. The recovery may be prolonged, and the person remains contagious until all of the scabs have fallen off.¹⁵ In previous outbreaks, between 6.3% and 35.5% of infected persons died, depending upon the type of infection and whether the individual had been vaccinated.¹⁶ Those who survive are often

11. *Id.*

12. *Id.*

13. *Id.*

14. *Id.*

15. *Id.*

16. FRANK FENNER ET AL., SMALLPOX AND ITS ERADICATION 5 (1988). This is the definitive work on smallpox, compiled to “preserve for posterity” the story of the control of smallpox. See also WILLIAM H. MCNEILL, PLAGUES AND PEOPLES 206–09

terribly disfigured by the smallpox scars and many were blinded by the disease.¹⁷ Persons who recover from a smallpox infection have a long-lasting immunity.¹⁸ Antiviral drugs and intensive-care support for vital life functions both postdate the last smallpox outbreaks. This means that we have no data on whether smallpox would be as lethal with full access to modern treatments. We do know that it would be difficult to provide such treatments on a widespread basis during an epidemic.

IV. SMALLPOX TRANSMISSION

Smallpox is spread through close contact when infected persons cough out particles of the virus (*variola major*) from sores in their mouths and lungs.¹⁹ These particles can be inhaled, but are more commonly picked up as tiny dried droplets in the environment and inadvertently ingested or rubbed into the eyes.²⁰ The infectious period can begin during the prodrome of the disease and extends until the scabs fall off, a period of about three weeks.²¹ It is estimated that about half of those exposed to the virus, who are not immune to smallpox, develop the infection. This varies, based on the nature of the contacts and the contagiousness of the infected person.²²

Smallpox infects only human beings. It has no animal reservoirs and persists in the environment for only a short period, except when properly preserved in a laboratory.²³ Smallpox infections lead to no chronic carrier states—no individual is infectious for more than a few weeks, and there are no latent

(1976) (detailing how *disease* really subdued the Aztecs, not the Spanish).

17. FENNER ET AL., *supra* note 16, at 49–50.

18. *Id.* at 51–52.

19. See, e.g., Joel G. Breman & Donald A. Henderson, *Diagnosis and Management of Smallpox*, 346 NEW ENG. J. MED. 1300, 1302 (2002) (describing how one patient at a hospital managed to infect seventeen others patients on three different floors of the hospital simply by coughing).

20. *Id.* (noting that smallpox is spread “primarily through respiratory-droplet nuclei”).

21. *Id.* at 1300. The typical period is about ten days, but stretches out to three weeks if the rash is slow to heal. *Id.*; see also CDC SMALLPOX SHEET, *supra* note 6, at 2 (explaining that the infectious period begins during the prodrome phase and continues until the scabs fall off).

22. *Id.* The rate of secondary attacks among unvaccinated contacts is thirty-seven to eighty-eight percent. *Id.* at 1302. As previously noted, figuring how many people will be exposed is controversial.

23. Therefore, there is no risk that an ancient smallpox-infected blanket will turn up in a museum and trigger an outbreak.

infections to blossom later. Smallpox must spread from human to human in an unbroken chain or it dies out. Smallpox could not exist until the human population reached a high enough density that there were enough communities to allow the disease to circulate from community to community, often not returning until there was a new generation of children or young adults who were susceptible to the disease.²⁴

The lack of a chronic infected state and an animal host is fundamental to the control of a smallpox outbreak and, ultimately, to the eradication of smallpox.²⁵ Outbreaks are controlled by limiting the ability of an infected person to come into contact with persons who are susceptible to smallpox, i.e., persons who have not been previously infected or have not had a recent vaccination. This is done by a combination of isolating contagious individuals to limit their contacts, and quickly immunizing all identified contacts or potential contacts to limit the development of new cases.²⁶ It is like starving a fire of fuel. Once the fire runs out of fuel (susceptible persons), the fire burns out. The more effectively you can isolate every case from contacting susceptible individuals, the quicker the outbreak will be controlled. Outbreaks are ended when it has been three weeks from the last infection.

V. ERADICATION

The difficulties in storing and transporting vaccines made worldwide eradication of smallpox a distant hope until 1951, when Collier developed a freeze-dried smallpox vaccine that could be stored at room temperature and thus easily transported to remote locations.²⁷ A Western Hemisphere smallpox eradication program was started by the Pan American Sanitary Organization in 1950.²⁸ At the suggestion of the Soviet Union, the World Health Organization (WHO) began a worldwide eradication program in 1967.²⁹

The best description of the worldwide eradication program is

24. JONATHAN B. TUCKER, SCOURGE: THE ONCE AND FUTURE THREAT OF SMALLPOX 6 (2001).

25. While HIV does not have an animal host, infected persons remain infected for decades because there is no cure, making eradication impossible.

26. As discussed *infra* Parts XII-XIII, the trade-off between isolation and vaccination is the core controversy in smallpox control.

27. FENNER ET AL., *supra* note 16, at 287.

28. *Id.* at 388-89.

29. *Id.* at 387.

in the book, *Smallpox, The Death of a Disease*,³⁰ by Dr. D.A. Henderson, the U.S. scientist who was the administrative genius who kept the program on track. Putting the enormous administrative and political complications aside, the fundamental approach was the same as controlling a local outbreak: combine intensive case finding and contact tracing—looking for persons infected with or exposed to smallpox—with mandatory vaccinations and isolation for all exposed persons. While Dr. Henderson does not dwell on the individual rights issues, he does not attempt to rewrite history and claim that eradication was accomplished through full information and informed consent.

As all honest public health experts recognize, eradication demanded the ruthless suppression of the disease. Rewards were paid for finding cases, and individuals had no right to refuse isolation and vaccination. This is significant, because, as discussed later, the smallpox vaccine has real risks. The eradication campaign was carried out mostly in the developing world, and it is easy to assume that it was only for that reason that such single-minded methods were tolerated. It is impossible to say for certain that such methods would have been allowed in Europe or the United States in the 1970s, but they had clearly been accepted when smallpox was still in those countries.

On October 26, 1977, the last known naturally occurring smallpox case was recorded in Somalia. In 1980, the WHO declared that smallpox had been eradicated. The United States ended routine smallpox vaccinations in 1972, and they were not routinely given anywhere after 1983.

VI. ENABLING SMALLPOX BIOTERRORISM

The irony of smallpox bioterrorism is that it would have been impossible in 1970. By 1970, most of the developed world had been vaccinated, and much of the developing world was either vaccinated or had natural immunity from exposure to the disease. Introducing smallpox into a community could cause new infections and even deaths, but the public health community could and did bring new outbreaks under control very quickly. This was because a large part of the population was not at risk or was only at low risk of contracting the disease. Thus, if the tracking of contacts was not perfect, the probability was that a missed contact would not

30. D.A. HENDERSON, *SMALLPOX: THE DEATH OF A DISEASE* (2009).

become infected. While individuals were at risk of death, and an outbreak would be disruptive, it did not threaten the destabilization of the state.

It took many years after eradication and ending of routine smallpox vaccinations for the world to become immunologically susceptible to smallpox bioterrorism. Unlike the life-long immunity that accompanies surviving smallpox, immunity from the vaccine wears off, with the assumption that after thirty or more years, there is little residual immunity. In the developing world, with its faster population growth, most of the population was born after the last immunizations, and even in the developed world, the majority of the population has never been vaccinated. With the exception of a small number of individuals who survived a smallpox infection, the whole world is immunologically naïve for smallpox.

An immunologically naïve population poses special risks beyond the obvious one that there are a lot of people who can get infected. If the disease is fast moving, it means that a lot of people can get sick at the same time, which will cause social disorder and the breakdown of basic societal services. For example, measles alone does not kill a very high percentage of infected individuals. But when measles enters a naïve population, as it did when European explorers brought it to the new world, it has a high fatality rate. The disease is the same, but when everyone in a culture is infected at once, no one can care for the sick, find food and water, and carry out the necessary tasks of daily life.³¹ The social disorder potentiates the disease.

VII. THE POTENTIAL IMPACT OF SMALLPOX BIOTERRORISM

It is the potential impact of a smallpox bioterrorism event

31. See generally MCNEILL, *supra* note 16 (describing the impact of plagues on societies); J.V. Neel et al., *Notes on the Effect of Measles and Measles Vaccine in a Virgin-Soil Population of South American Indians*, 91 AM. J. EPIDEMIOLOGY 418, 418 (1970) (“The impact of measles on a primitive population is well-known. It seems to have been generally assumed that this is a result of a greater ‘constitutional’ susceptibility. However, in 1877, Squire (1), describing the collapse of village life during an epidemic of measles in Fiji, clearly presented a contrary view: ‘Excessive mortality resulted from terror at the mysterious seizure, and the want of commonest aids during illness; there were none to offer drink during the fever nor food on its subsidence. Thousands were carried off for want of nourishment and care as well as by dysentery and congestion of the lungs. We need to invoke no special susceptibility of race or peculiarity of constitution to explain great mortality.’”).

where the facts are few and the controversies large that is of particular concern. The heart of the controversy is how fast the epidemic would spread, both temporally and geographically. The most basic data is the number of persons who will be infected by a given contact. Our only information on this is basic because it was derived from populations with significant immunity.³² The limited data we do have suggests the vulnerability of unprotected societies could be both quite severe and difficult to predict or control.

For example, Fenner's comprehensive history of the eradication of smallpox gives a revealing illustration of the problem.³³ In 1970, a German hospital in Meschede admitted an electrician into its isolation ward ten days after his return from Pakistan with a "feverish illness . . . suspected to be typhoid fever."³⁴ Three days later, he developed a rash, confirmed, using an electron microscope, to the smallpox two days later.³⁵ At that time, after five days in the general hospital in full isolation, the patient was transferred to a specialized smallpox hospital.³⁶ Despite the "rigorous isolation of the patient" and "the vaccination of all of the patients and nurses in the general hospital," nineteen additional cases of smallpox resulted from the electrician's admission.³⁷ Several aspects of this event are quite chilling. The electrician was only on the first floor, yet persons on all three floors of the hospital developed smallpox. One person, case 8, visited the ground floor of the hospital only once, fourteen days after the electrician was admitted, for no more than fifteen minutes.³⁸ Smoke tests performed by investigators of the outbreak revealed that eleven cases were in rooms outside of the smoke's flow pattern; two cases upwind of the smoke pattern.³⁹ Case 17 developed twenty-one days after the electrician's admission and case 19 developed fourteen days after a visit to case 17.

Perhaps the most sobering aspect of the Meschede outbreak is

32. See generally Martin I. Meltzer et al., *Modeling Potential Responses to Smallpox as a Bioterrorist Weapon*, 7 EMERGING INFECTIOUS DISEASES J. 959 (2001) (discussing the probable durations of each disease stage). The base rate information used by Meltzer was from Fenner's study, which included populations with significant immunities. See generally FENNER ET AL., *supra* note 16.

33. See generally FENNER ET AL., *supra* note 16.

34. *Id.* at 192.

35. *Id.*

36. *Id.*

37. *Id.*

38. *Id.*

39. *Id.* at 193.

the contrast between the results of a fleeting exposure in an unprotected population with the results of prolonged exposure in a protected population. Fenner observed: “Especially in India, long-distance movements by train or bus of patients suffering from smallpox, with an overt rash, used to occur frequently, yet infection of casual fellow-travellers [sic] was rare indeed—so rare that instances of it were deemed unworthy of special report.”⁴⁰ Here, while contained in a controlled, isolated hospital room, one sick person infected nineteen more with smallpox, more than six times the 3:1 infection ratio assumed in the Meltzer model,⁴¹ which was developed by a CDC team and reflects the CDC assumptions about transmission.

Beyond the critical variable of how many people will be infected by a given carrier is the question of how far contacts can spread the disease if they are not identified and quarantined. For almost all of human history, the “natural” spread of human disease was essentially limited by how far a person could walk before he became too sick to travel. In an age when an infectious person can reach any spot on Earth in twenty-four hours, the geographic spread of a disease might also be much faster.⁴² If individual carriers can spread the disease to more than two or three people, and if some of those people can travel before being identified and quarantined, this could be sufficient to seed a global pandemic that would disrupt modern society.⁴³

The greatest fear with smallpox bioterrorism is that it would escape control and infect so many people that basic social order would break down. Modern society is very complex but not necessarily very robust. Grocery stores run out of food, and few people keep more than a day or two of food on hand at home. Water and power systems can fail. A failing police presence, combined with a desperate population, leads to the worse nightmare of smallpox response planners: an out-of-control

40. *Id.* at 191.

41. See Meltzer et al., *supra* note 32, at 961.

42. See FENNER ET AL., *supra* note 16, at 202, 1077–79 (describing how the modern transportation infrastructure has contributed enabled the rapid spread of smallpox and providing case studies of the disease’s importation into Europe).

43. See Tara O’Toole et al., *Shining Light on “Dark Winter,”* 34 CLINICAL INFECTIOUS DISEASES 972, 975 (2002) (describing how a war-game simulation of a smallpox outbreak in the United States used a transmission rate of 1:10, which the authors characterized as conservative estimate in part due to “the globalization of trade and travel, urban crowding, and deteriorating public health infrastructure”).

population would make disease control impossible, assuring the maximum spread and lethality of the disease. This would rapidly destabilize global markets and lead to a worldwide financial collapse.

Thus smallpox has the ultimate blowback—the risk of destruction of the party that started the pandemic. While blowback, in the form of mutually assured destruction (MAD), was the cornerstone of nuclear deterrence against the Soviet Union and China, it was based on each country's refusal to commit suicide to punish the others. In a world dominated by the NGO terrorist groups who use suicide as a tool and, at least for some of them, believe the rebirth of the earth can only come through destruction, biological MAD is not a reassuring concept.

VIII. IS SMALLPOX PREPAREDNESS REALLY NECESSARY?

There is no smallpox in the wild, nor do we need to worry about some dusty old museum exhibit or tomb reseeded the world. Unless carefully preserved, it is not a stable virus.⁴⁴ When smallpox was still an active disease threat, laboratories around the world maintained stocks of the virus for research purposes. After eradication, a laboratory accident that led to a smallpox death reminded the world that these laboratory stocks of virus had the potential to reintroduce smallpox into the world.⁴⁵ Political pressure finally persuaded all the labs to transfer their collections of smallpox virus subtypes to the CDC, or to destroy them. The CDC and the Soviet Union were designated the only labs that could retain the smallpox virus.

Many scientists believed that the smallpox virus retained by the CDC and the Soviet laboratory should be destroyed as a sign of good faith and to eliminate the possibility of an accident reseeded

44. If this were not so, we would never have been able to eradicate it. Infected persons shed a huge amount of virus into their environment, but once the active cases are healed, you do not see subsequent cases.

45. See FENNER ET AL., *supra* note 16, at 1097. The victim, a forty-year-old woman, was "a medical photographer in the Anatomy Department of the Medical School of the University of Birmingham . . . [who] became ill with fever, headache and muscular pains on 11 August [1978]." *Id.* She had last been vaccinated in 1966. *Id.* A rash developed on August 15, vesicles developed on August 24 (which "led to a suspicion of smallpox"), and she was placed in an isolation hospital later that day. *Id.* However, her health "deteriorated rapidly and she died on 11 September [1978]." *Id.* The specifics of this outbreak are in Chapter 23, "Smallpox in Non-endemic Countries." *Id.* at 1069–1101.

the virus into the world. There was further unease about the retained stocks when it was found that the Soviet Union moved its stocks without informing the world community. While this debate was going on, a defector who ran the Soviet Union's biological warfare operations claimed that the Soviet Union had produced thousands of pounds of smallpox virus in derogation of the Biological Warfare Treaty.⁴⁶

This defector, Ken Alibek, had been a high official at Biopreparat, the Soviet bioweapons research center. His specific claims have been impossible to verify, and there have been questions about whether his story was really about increasing his perceived value to the West. Unfortunately, with the breakup in the Soviet Union and the lack of cooperation of Russian authorities, it has been impossible to either verify or refute this claim. It is clear that the Soviets were violating the Biological Warfare Treaty, so it is credible that smallpox was made at the facility.⁴⁷

Thus we have to assume that smallpox is available as a bioterrorism weapon. But, because there is no way to determine a probability for a smallpox attack, the level of threat is an arbitrary determination subject to political manipulation. On the legislative side, Congress is easily frightened into passing bioterrorism response laws that provide immunity for the Government and private companies for vaccines and other bioterrorism response agents and practice. The arbitrariness of the risk makes the public suspicious of the Government's motives, and ties into the current anti-vaccination paranoia. Rather than confront these fears, the federal Government has avoided them in its response plan. In the view of this author, ignoring public fears and the public role in smallpox preparedness will greatly complicate response to a smallpox bioterrorism event and exacerbate the damages.

46. See *Terrorist & Intelligence Operations: Potential Impact on the U.S. Economy: Hearing Before the J. Economic Comm.*, 105th Cong. (1998) (statement of Dr. Kenneth Alibek, Program manager, Battelle Memorial Institute) (describing the role of smallpox in the Soviet Union's development of biological weapons).

47. See generally KEN ALIBEK, *BIOHAZARD* (1999) (telling the story of the Soviet bioterrorism enterprise). Dr. Henderson indicates that he believes enough of the story is true to paint a picture of a very dangerous Soviet bioterrorism program. HENDERSON, *supra* note 30, at 275.

IX. CONTROLLING A SMALLPOX OUTBREAK

The basic strategy for controlling all short-duration infectious diseases is the same: prevent infected persons from coming in contact with persons who are susceptible to the disease, and doing it until everyone who is infected either recovers or dies.⁴⁸ In the 1960s, the solution was universal smallpox vaccinations in the United States. While no universal system is 100% effective, it assured that most people who encountered a person infected with smallpox were immune. This limited the spread, which gave the public health authorities plenty of time to find and isolate contacts, and immunize anyone whose immunization was out of date. After 9/11, Vice President Cheney advocated beginning universal vaccination of the U.S. population.

If you apply the one-percent doctrine, as espoused by Vice President Cheney and others in the Bush administration,⁴⁹ universal vaccination makes sense. The Dark Winter simulation showed that it was possible for a smallpox outbreak to burn through a large part of the population, destroying the U.S. economy, and perhaps even leading to civil disorder and the breakdown of the state. While this is a low probability event, a pure national security analysis would argue that it would be worth avoiding at almost any cost, and the cost of universal immunization would be low compared to many other security measures that were taken post-9/11.⁵⁰ If it could be carried out, it would absolutely end the threat of smallpox bioterrorism in the United States, reducing it to an annoyance that might kill a few people and cost some time and money for eradication, but nothing that could not be handled by local public health.

This was strongly opposed by public health experts,

48. This cannot work for long-term infectious diseases such as HIV because individuals remain infectious for decades. For large outbreaks, it is only realistic for diseases with a short incubation period and a short infectious period, otherwise the logistics become impossible. For example, drug-resistant tuberculosis carriers may need to be isolated for long periods of time, but it is a hard disease to spread, so there are never more than a handful of cases at any one time.

49. See generally RON SUSKIND, *THE ONE PERCENT DOCTRINE: DEEP INSIDE AMERICA'S PURSUIT OF ITS ENEMIES SINCE 9/11* (2006) (describing the Bush administration's decision to treat the likelihood of a catastrophic event or terrorist attack as a certainty even though in reality it is closer to one percent).

50. The war in Iraq, for example, has cost more than \$1 trillion and was also a response to a low probability threat.

particularly Dr. D.A. Henderson.⁵¹ Risk analysis in public health is always about balancing risks, benefits, costs, and probabilities. Unlike national security, public health officials are always acutely aware of their limited political and financial support.⁵² The critical issue, medically and politically, is that the smallpox vaccine is dangerous to persons with impaired immune systems. Understanding these risks is critical to evaluating whether the opposition of Dr. Henderson and others is well-founded.

X. SMALLPOX VACCINATIONS

Vaccination for smallpox was one of the first effective public treatments. Drawing on folk traditions, the English physician Edward Jenner documented that dairymaids who had been infected with cowpox, a mild pustular infection, thereafter were immune to smallpox.⁵³ In 1796, Jenner intentionally infected a young man with cowpox, and the boy developed smallpox immunity.⁵⁴ The technique for inoculating individuals with cowpox spread quickly and became a standard public health intervention. This is a live virus vaccine, which works because the person develops a mild case of the disease, triggering the development of antibodies. Dead virus vaccine has been tried, but it does not work.⁵⁵

At the same time, it was a controversial intervention because the vaccination process was dangerous. This was long before the germ theory and notions of sanitation. The vaccine either came from a scab on the vaccination site of another person, or from the scabs on the belly of a calf who had been vaccinated by abrading its abdomen and rubbing in vaccine material. In both cases, there was a high probability of bacterial contamination of the vaccine, as well

51. See HENDERSON, *supra* note 30, at 293.

52. Cf. M. J. Rosenau, *The Uses of Fear in Preventive Medicine*, 162 BOSTON MED. & SURGICAL J. 305, 305–07 (1910), available at http://biotech.law.lsu.edu/cphl/history/articles/Rosenau_fear.htm (suggesting that the amount of public funding dedicated to a particular public health initiative corresponds with the level of fear a society has toward a particular disease).

53. See EDWARD JENNER, *THE THREE ORIGINAL PUBLICATIONS ON VACCINATION AGAINST SMALLPOX* (1798).

54. *Id.* at 258.

55. See E.R. Freed et al., *Vaccinia Necrosum and Its Relationship to Impaired Immunologic Responsiveness*, 52 AM. J. MED. 411 (1972). This article discusses the use of killed virus to screen for antibody response because it cannot cause infection. There is no other discussion of the use of killed virus in the modern literature.

as the transmission of blood-borne illness such as hepatitis or syphilis. A vaccination involved inserting a bit of scab or an elixir made from scabs into the skin of the individual being vaccinated, assuring that whatever accompanying infections would also be effectively introduced into the person's system. Add in that physicians and vaccine agents did not clean their instruments between patients, and it is clear that fears of complications from smallpox vaccination were well-founded.

When genetic analysis was developed, it was found that the virus used for inoculation was not really cowpox at all. It was a virus called vaccinia, which is not cowpox nor any other known pox virus.⁵⁶ It may be the now extinct horsepox or a hybrid of horsepox and cowpox. Vaccinia is so closely related to smallpox that a person who is infected with vaccinia develops immunity to smallpox. Because this vaccinia is not identical to smallpox, this immunity is not as long lasting. Persons who are vaccinated with vaccinia have to be revaccinated every five to ten years to keep up full immunity and need to be vaccinated again when exposed to smallpox.⁵⁷

The modern vaccine is called Dryvax, manufactured by Wyeth.⁵⁸ It was developed during World War II, and some of the current stockpile has been in storage for more than thirty years.⁵⁹ It is produced in a sanitary matter and is then freeze dried, which allows it to be stored for long periods. It is still a live virus vaccine containing vaccinia,⁶⁰ but it does not pose the risk of any other infections. There is a new way of manufacturing the vaccine using cell culture that produces a vaccine with less contamination than the process used for making Dryvax, but it poses the same risks because it uses the same live virus.⁶¹

56. TUCKER, *supra* note 24, at 37.

57. FENNER ET AL., *supra* note 16, at 175.

58. Press Release, Am. Home Prods. Corp., American Home Products Submits Plan to Produce Smallpox Vaccine (Oct. 26, 2001).

59. Wyeth-Ayerst Laboratories, a division of American Home Products Corporation, began manufacturing a vaccinia (smallpox) vaccine, Dryvax, in 1944. *Id.*

60. See Wyeth Laboratories, Inc., Package Insert Dryvax [hereinafter Dryvax Package Insert], *available at* <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142613.pdf> (listing vaccinia as one of the ingredients). The current label reflects the risk of myocarditis. *Id.* The original label is available at http://biotech.law.lsu.edu/blaw/bt/smallpox/DRYVAX_label.htm.

61. See Sharon E. Frey et al., *Dose-Related Effects of Smallpox Vaccine*, 346 NEW

To be effective, a smallpox vaccination must result in a small infected sore on the patient's arm. A drop of the vaccine is put between the prongs of a very small two-pronged needle, which is then punched into the patient's arm multiple times.⁶² Patients with normal immune system function will have a small sore at the vaccination site, which will form a scab, and then the scab will fall off as the sore heals. That sore and scab contain live vaccinia virus. The sore will not spread unless the person scratches it or it is spread by some other trauma.⁶³ If a person scratches the sore and then scratches his or her eye or nose, or an insect bite or scratch, the virus will form sores at the scratched location. As many as one-third of vaccinated persons suffer fever and malaise sufficient to interfere with work or recreation, but most recover quickly without permanent sequelae.⁶⁴

The recommendation for bandaging the sore and wearing long sleeves until the sore heals is to prevent the spread of the vaccinia to other sites on the vaccinated person and to others. The recommended bandage is a combination of gauze to absorb the

ENG. J. MED. 1275 (2002); Steven R. Rosenthal et al., *Developing New Smallpox Vaccines*, 7 EMERGING INFECTIOUS DISEASES 920, 922 (2001) (describing a new cell culture used to manufacture the vaccine, which still contains vaccinia).

62. See Dryvax Package Insert, *supra* note 60 (describing the administration of the vaccine). It was found during the smallpox eradication program that it was better to use fifteen jabs with the needle rather than package insert specified three jabs for a primary immunization. HENDERSON, *supra* note 30, at 294. This increased the chance that the vaccine would really get through the skin and had a much higher rate of successful vaccinations. *Id.* When the CDC was preparing recommendations for smallpox vaccinations for the 2002 vaccine campaign, the FDA prevented them from using the fifteen poke standard because it had never been approved by the FDA, even though it had been shown to be much more effective. *Id.*

63. Ctrs. for Disease Control and Prevention, *Smallpox Vaccination and Adverse Reactions: Guidance for Clinicians*, MORBIDITY & MORTALITY WKLY. REP., Jan. 24, 2003, available at <http://biotech.law.lsu.edu/blaw/bt/smallpox/di52cha1/di52cha1.htm>. This document was originally published as a Dispatch from the Centers for Disease Control and Prevention's (CDC) Morbidity and Mortality Weekly Report (MMWR). However, the CDC no longer maintains the original document. An updated version was published by the CDC as an MMWR Recommendations and Reports on February 21, 2003. Ctrs. for Disease Control and Prevention, *Smallpox Vaccination and Adverse Reactions: Guidance for Clinicians*, MORBIDITY & MORTALITY WKLY. REP. RECOMMENDATIONS AND REP. RR-04, Feb. 21, 2003, at 1, 1-28 [hereinafter CDC, *Guidance II*], available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5204a1.htm>.

64. See CDC, *Guidance II*, *supra* note 63 (describing the side effects resulting from the vaccine).

fluids from the vaccination sore and a covering that will keep these fluids and the virus they contain from getting out of the bandage.⁶⁵ Changing the bandage to keep the sore dry and healing increases the risk of spread to others. There was documented secondary spread among the military vaccinees.⁶⁶ This could be a more serious problem for recently vaccinated health care workers, since patient contact is a much more conducive environment for transmission.⁶⁷

XI. VACCINE COMPLICATIONS

All modern vaccines are very safe, yet the general public is still frightened of them.⁶⁸ Despite massive efforts by the CDC and state public health programs, it is estimated that only about twenty-five percent of the target population was willing to be vaccinated for H1N1.⁶⁹ Unfortunately, the smallpox vaccine is dangerous. A small number of persons suffer neurologic sequelae, which can be permanent or even fatal in a small percentage of cases.⁷⁰ Persons with eczema and related skin conditions are at risk for the spreading of the vaccination sore, leading to the development of sores on other parts of the body.⁷¹ While not usually life-threatening, this is a painful, difficult-to-treat complication that can leave the individual permanently scarred. When the virus spreads from the original vaccination sore, the risk of infecting others with

65. Dryvax Package Insert, *supra* note 60.

66. Ctrs. for Disease Control and Prevention, *Secondary and Tertiary Transfer of Vaccinia Virus Among U.S. Military Personnel—United States and Worldwide, 2002–2004*, 53 MORBIDITY & MORTALITY WKLY. REP. 97, 103 (2004).

67. *Id.*

68. There are many reasons for this fear, including long-term efforts by plaintiffs' attorneys to undermine confidence in vaccines to benefit their products liability cases. The best example are the autism cases, which were subject to comprehensive rejection in a recent series of cases: Snyder *ex rel.* Snyder v. Sec'y of Dep't of Health and Human Servs., No. 01-162V, 2009 WL 332044 (Fed. Cl. Feb 12, 2009), *appeal denied*, Snyder *ex rel.* Snyder v. Sec'y of Health and Human Servs., 88 Fed. Cl. 706 (Fed. Cl. 2009); Cedillo v. Sec'y of Health and Human Servs., No. 98-916V, 2009 WL 331968 (Fed. Cl. Feb 12, 2009), *aff'd*, Cedillo v. Sec'y of Health and Human Servs., 89 Fed. Cl. 158 (Fed. Cl. 2009); Hazlehurst v. Sec'y of Dep't of Health and Human Servs., No. 03-654V, 2009 WL 332306 (Fed. Cl. Feb 12, 2009), *aff'd*, Hazlehurst *ex rel.* Hazlehurst v. Sec'y Dep't of Health & Human Servs., 88 Fed. Cl. 473 (Fed. Cl. 2009).

69. *Only 1 in 4 Americans Got H1N1 Vaccine*, MEDLINE PLUS, Apr. 1, 2010, http://www.nlm.nih.gov/medlineplus/news/fullstory_97126.html.

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

71. *Id.* at 2134.

vaccinia through secondary spread is dramatically increased.⁷²

There is little reason to expect that the eczema and neurologic complications would occur at higher rates than they did in the 1960s when smallpox vaccinations were routine. The major change in risk factors since the 1960s is for immunosuppressed persons. Vaccinia creates a small sore because the vaccinated individual's immune system keeps the infection in check. If the individual's immune system does not function properly, the vaccinia virus grows unchecked and the sores spread over the entire body. This is called disseminated vaccinia.⁷³ The virus spreads as a whole body illness, creating sores that look very much like smallpox. Disseminated vaccinia is often fatal. It was very rare in the 1960s and early 1970s when the last smallpox vaccinations were done in the United States, accounting for about one death per million immunizations.⁷⁴

Studies at the time found that such cases could usually be traced to persons with defective immune systems. More importantly, the leading study determined that persons with defective cellular immunity were usually killed by the vaccine.⁷⁵ The only specific treatment for disseminated vaccinia is human vaccine immunoglobulin (VIG) which is made from the serum of persons recently vaccinated with smallpox vaccine.⁷⁶ There was very little VIG available when the smallpox vaccination campaign was announced in 2002, and it is unlikely that there is nearly enough VIG to treat the expected complications from vaccinating millions of persons over a few months.⁷⁷ The amount of available VIG has never been revealed to the general public. While there are no antiviral drugs that are known to treat vaccinia, there are drugs that are effective against other pox viruses, and it is hoped these will help cure vaccinia reactions.

When smallpox vaccinations were routinely given in the United States, there were very few persons with chronic immune

72. Such persons must be managed much as a smallpox case is managed so they do not spread vaccinia to unvaccinated persons or persons at risk of vaccine complications.

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

74. Steven M. Gordon, *Pre-Event Smallpox Vaccination: Unresolved Issues*, 70 CLEVELAND CLINIC J. MED. 80, 81 (2003).

75. Freed et al., *supra* note 55.

76. Henderson et al., *supra* note 70, at 2132.

77. *Id.*

system defects. Children with genetic defects in their immune systems usually died shortly after birth because they could not fight off any infections. There were some persons with cancer, and some whose cancer was not yet diagnosed, who were inadvertently vaccinated. Immunosuppression was so rare that it was a major clinical research triumph when scientists were able to keep a completely immune suppressed baby alive in a germ-free environment.⁷⁸ Since 1972, the use of powerful cancer drugs, arthritis drugs, and transplant drugs, plus the emergence of HIV/AIDS, has increased the number of immunosuppressed persons. There are at least one hundred times as many immunosuppressed people in the United States today as in 1972 and perhaps one thousand times as many.⁷⁹

Since routine smallpox immunizations were stopped before immunosuppression secondary to drug treatment or HIV was a risk, the consequences of immunizing such persons have to be extrapolated from limited data and from the susceptibility of immunosuppressed persons to other viral illnesses. There is one case reported in the literature where a person with HIV was immunized with smallpox vaccine.⁸⁰ The victim was a healthy nineteen-year-old soldier who had been tested and found to have normal blood work before immunization.⁸¹ This was before all military personnel were routinely screened for HIV, which began after this case. Within three weeks of vaccination, the soldier developed disseminated vaccinia.⁸² Despite intensive treatment, including many injections with VIG, he died after a prolonged illness, although his vaccinia appeared to resolve before this death.⁸³ The vaccinia virus triggered a rapidly progressive case of AIDS.⁸⁴ Given the lack of knowledge about AIDS and HIV at the time, and the unavailability of modern anti-HIV drugs, it is unknown whether he would have had the same course with modern aggressive treatment.

78. Probably the best-known case of Severe Combined Immunity Deficiency Syndrome was David Vetter, the "bubble boy," who died in 1984 at the age of thirteen. See Steve McVicker, *Bursting the Bubble*, HOUSTON PRESS, Apr. 10, 1997, at 10–20.

79. Gordon, *supra* note 74, at 81–82.

80. R.R. Redfield et al., *Disseminated Vaccinia in a Military Recruit With Human Immunodeficiency Virus (HIV) Disease*, 316 NEW ENG. J. MED. 673, 673 (1987).

81. *Id.*

82. *Id.* at 674.

83. *Id.*

84. *Id.*

In the 2002 vaccination campaign, it was discovered that several vaccinees suffered symptoms of cardiac disease, and three died.⁸⁵ This unexpected complication, occurring in a relatively small population of civilian vaccinees, marked the end of the Government's active support of the vaccination of civilian volunteers. Subsequent studies confirmed an excess occurrence of myopericarditis in military vaccinees, at a rate of about 140 cases per million vaccinations.⁸⁶ While a retrospective study of cardiac deaths in New York City during the last mass vaccination program for smallpox in 1947 showed no excess cardiac deaths,⁸⁷ myopericarditis does appear to be a risk of smallpox vaccinations in contemporary populations.

XII. RISKS OF A MASS IMMUNIZATION PROGRAM

The CDC estimated that about 1.1 million persons were infected with HIV in 2006, with about twenty-one percent undiagnosed.⁸⁸ It is estimated that there are more than 50,000 new cases each year.⁸⁹ About 12,000 people die each year from HIV-related illness,⁹⁰ so there is a net increase of about 38,000 cases a year.⁹¹ The CDC estimates are very likely on the low side so these will be minimum estimates of HIV prevalence, so a working estimate in 2010 would be at least 1.2 million cases. There are probably more than 300,000 solid organ transplant patients living and on long-term immunosuppressive therapy. There is no good data on patients on immunosuppressive chemotherapy for cancer, arthritis, and other diseases, or persons on short-term and long-

85. Ctrs. for Disease Control and Prevention, *Update: Cardiac and Other Adverse Events Following Civilian Smallpox Vaccination—United States, 2003*, 52 MORBIDITY & MORTALITY WKLY. REP. 629, 639 (2003).

86. Mark K. Arness et al., *Myopericarditis Following Smallpox Vaccination*, 160 AM. J. OF EPIDEMIOLOGY 642, 642 (2004).

87. Ctrs. for Disease Control and Prevention, *Cardiac Deaths After a Mass Smallpox Vaccination Campaign—New York City, 1947*, 52 MORBIDITY & MORTALITY WKLY. REP. 933, 933 (2003) [hereinafter CDC, *Cardiac Deaths*].

88. Ctrs. for Disease Control and Prevention, *HIV Prevalence Estimates—United States, 2006*, 57 MORBIDITY & MORTALITY WKLY. REP. 1069, 1073 (2008).

89. H. Irene Hall et al., *Estimation of HIV Incidence in the United States*, 300 JAMA 520, 520 (2008).

90. CTRS. FOR DISEASE CONTROL AND PREVENTION, *HIV/AIDS SURVEILLANCE REPORT 2007*, at 19 (2009).

91. Whether the low death rate will continue depends on the race between scientists developing new anti-HIV drugs and the ability of the virus to mutate to forms that are resistant to the drugs. In the early 1990s, the death rate was about 50,000 per year.

term steroid therapy, which is immunosuppressive. A rational working number might be that one percent of the population is at significant risk of serious or fatal complications from a smallpox vaccination. This is orders of magnitude higher than the baseline in 1970.⁹²

These numbers mean that a mass immunization program that indiscriminately vaccinated individuals without regard to risk status could lead to thousands of serious reactions and hundreds of deaths per million persons vaccinated. HIV is also disproportionately concentrated in the minority populations, with blacks having seven times the risk for HIV infection as whites, and risk factors for Hispanics falling somewhere between the two ethnic groups. This would make vaccine complications strongly race-related. The complications would overload local health care resources, further raising the death rate. People would need to be carefully screened for immunological status, which would need to include an HIV test. There would also be the question of providing economic support for treating the patients and for compensating injured persons.

While Dr. Henderson and others were successful in persuading the Bush administration to not roll out a national smallpox vaccination campaign, the Bush administration did start a more limited campaign in the fall of 2002 to vaccinate military personnel (before the Iraq war) and civilian health care providers and first responders.⁹³ The results of this campaign were detailed in a previous paper, and will only be summarized here.⁹⁴ Approximately 500,000 vaccinations were given to military

92. More generally, we have many more persons at medical risk in the population today than in 1970. Advances in treatment have dramatically increased the life expectancy for diseases such as Type I diabetes, chronic pulmonary disease, and cystic fibrosis, among many others. These individuals are medically fragile, so that any medical risk will affect them much more severely than it will the general population.

93. In previous smallpox epidemic, hospital-based spread was very important. Mathematical modeling of smallpox control strategies first published at the time of the roll out of the smallpox vaccine campaign showed that the most efficient control strategy was a combination of vaccinating hospital workers before an outbreak, and then aggressively vaccinating contacts after an outbreak. This would quench the epidemic more quickly with the smallest number of vaccinations, and thus the least risk of vaccine complications. Joshua M. Epstein et al., *Toward a Containment Strategy for Smallpox Bioterror: An Individual-Based Computational Approach* 15 (Ctr. on Soc. and Econ. Dynamics, Working Paper No. 31, Dec. 2002).

94. Richards et al., *supra* note 1.

personnel, and another 500,000 have been given to military personnel since then, with relatively few complications, other than the cardiac complications noted above. This is not surprising—military personnel are screened for HIV on a regular basis and are separated from the service if infected. They are also separated for most other conditions that would put them at risk for immunosuppression. As importantly, every soldier's medical history is known by the military and there are no privacy issues involved in screening them for risk factors.

The civilian side of the campaign was less successful, but provides useful insights into the problems that would be posed by a more widespread civilian immunization campaign. The goal was to vaccinate 500,000 volunteer health care workers and first responders who would be available to manage smallpox cases if there was an outbreak. When the program was cancelled due to cardiac complications, only 39,213 were vaccinated, fewer than ten percent of the goal.⁹⁵ Fears of complications were a factor in reducing volunteers, but as big a problem was that the federal Government never had an adequate answer to questions about who would pay for worker's compensation claims, medical care costs, and long-term injuries and death from the vaccine. This was further complicated by the comprehensive immunity that the Government, its agents, and manufacturers enjoy for all bioterrorism-related claims. Subsequent to the immunization campaign, a smallpox vaccine injury compensation act was passed, but it is limited and dependent on the discretion of the authority with no judicial review.⁹⁶ It is unlikely to provide reassurance to individuals and employers worried about who would pay for vaccine complications.

95. Ctrs. for Disease Control and Prevention, *Update: Adverse Events Following Civilian Smallpox Vaccination—United States, 2003*, 53 MORBIDITY & MORTALITY WKLY. REP. 97, 106 (2004). This number may include personnel who were vaccinated through the military reserves, further reducing the number of civilian volunteers.

96. The consent for smallpox vaccinations for persons at risk of potential complications states that the CDC will provide the vaccine immune globulin, but that “[t]he other costs of hospital and medical care will *not* be covered by CDC and will need to be paid by your insurer, Medicare, Medicaid or you.” CTRS. FOR DISEASE CONTROL AND PREVENTION, GUIDELINES FOR LARGE SCALE SMALLPOX VACCINATION CLINICS ANNEX 3, at 30 (2002) (emphasis in original).

XIII. THE CDC PLAN

The CDC plan⁹⁷ for controlling a smallpox outbreak is essentially unchanged since 2002. In some ways it is unchanged from 1968—the page describing the vaccine relies on data since 1968:

Although smallpox vaccine is considered a safe vaccine, postvaccination adverse events can occur. These adverse events and their rates as determined in a 1968 10-state survey include: 1) inadvertent inoculation (529.2/million primary vaccinations), 2) generalized vaccinia (241.5/million primary vaccinations), 3) eczema vaccinatum (38.5/million vaccinations), 4) progressive vaccinia (1.5/million primary vaccinations), and 5) postvaccinial encephalitis (12.3/million primary vaccinations). Death also occurred in about one per million primary vaccinations, usually as a result of progressive vaccinia, postvaccinial encephalitis, or severe eczema vaccinatum.⁹⁸

While the next paragraph of the plan does indicate that persons with HIV should only be vaccinated if they have been exposed to smallpox,⁹⁹ there is no indication that the risks of the

97. While this plan is put forward by the CDC, the CDC follows the direction of the Department of Homeland Security, and it is assumed that this is the Homeland Security as much as the CDC's plan. There is no official publication for the CDC smallpox response plan. It is currently available at: <http://www.bt.cdc.gov/agent/smallpox/response-plan/index.asp>. However, the federal Government in general, and the CDC in particular, do not assure that URLs for their documents are stable over time, and the CDC does not make previous versions of documents available. To assure access to these documents for readers of this article and scholars in general, the CDC smallpox response documents as of February 28, 2010, have been archived at: <http://biotech.law.lsu.edu/blaw/bt/smallpox/CDC-28feb2010/index.htm>. These documents appear to be the same, with some formatting changes, from the version of September 25, 2002, archived here: http://biotech.law.lsu.edu/blaw/bt/smallpox/CDC_25sept02/index.htm.

98. Executive Summary, Smallpox Response Plan (Mar. 20, 2003), at 2, available at <http://biotech.law.lsu.edu/blaw/bt/smallpox/CDC-28feb2010/exec-sections-i-vi.pdf>.

99. "Several groups have been identified as having a higher risk for developing postvaccination complications. These persons are advised not to receive smallpox vaccination **unless** they have been exposed or are at high risk of exposure to smallpox virus. These include 1) persons with atopic dermatitis or eczema (including a history of atopic dermatitis or eczema), 2) persons with acute, active, or exfoliative skin conditions, 3) persons with altered immune states (e.g., HIV, AIDS, leukemia, lymphoma, immunosuppressive drugs, etc.), 4) pregnant and breast-feeding women, 5) children younger than age 1 year, 6) persons who

vaccine in 1968 have little relevance to the risks in 2010. Even the characterization of the vaccine as “considered safe” is hardly justified. It would be more accurate to say that the smallpox vaccine is a dangerous vaccine, but one whose risks are justified in the face of a smallpox outbreak.

There are other parts of the plan that are out of touch with the best science, such as the one detailed by Dr. Henderson about the insistence on an outdated vaccination technique because no one had bothered to update the FDA approval from decades earlier.¹⁰⁰ This insistence on legalistic detail in situations where it will make it very difficult to rapidly vaccinate a large number of persons is most evident in the informed-consent requirements. These anticipate that in a mass vaccination situation each individual would get screened and watch a video, approximately twenty percent would get personal counseling, and all would fill out a packet of consent forms based on the smallpox vaccine being available as Investigational New Drug, i.e., as if smallpox vaccine was a new experimental drug.¹⁰¹

The plan itself is basically the same proven plan that was used during eradication: identify infected cases and their contacts, and use isolation,¹⁰² quarantine,¹⁰³ and vaccination¹⁰⁴ to limit the spread

have a serious allergy to any component of the vaccine.” *Id.* (emphasis in original).

100. See HENDERSON, *supra* note 30, at 294.

101. Annex 3, Guidelines for Large Scale Smallpox Vaccination Clinics, *Logistical Considerations and Guidance for State and Local Planning for Emergency, Large-Scale, Voluntary Administration of Smallpox Vaccine in Response to a Smallpox Outbreak*, at 3, available at <http://biotech.law.lsu.edu/blaw/bt/smallpox/CDC-28feb2010/annex-3.pdf>.

102. Isolation is the restriction of persons who are known to be infectious. For smallpox, isolation is severe, requiring respiratory precautions for all persons coming in contact with the patient, handling all linens and wastes as hazardous waste, and, ideally, holding the person in a negative pressure room, with the air drawn into a HEPA filter before exhausting it outdoors, away from any occupied areas. Since the consequences of violating isolation could be catastrophic, the patient would need to be locked in and guarded, unless very ill. Isolation for smallpox lasts until the last scabs have healed.

103. Quarantine is the restriction of persons thought to have been exposed to a communicable disease but who have not developed the symptoms of the disease. Quarantine lasts for a few days beyond the longest known incubation period of the disease, or until the person develops symptomatic disease and is transferred to isolation.

104. Vaccination for smallpox can abort or mitigate the disease even if done up to four days after exposure. Persons who are contacts must still be quarantined, even if they are vaccinated.

of the disease until it has been eradicated.¹⁰⁵ (There are additional sections for setting up mass immunization clinics if necessary.) This strategy is called ring immunization because it seeks to create a ring of immunized persons around every infected person. There is no question that this worked to eradicate smallpox, but have the assumptions it is based on changed sufficiently that it will not be effective in a contemporary outbreak? There are three key assumptions for ring immunization. First, each contagious person can be identified and isolated before exposing a large number of contacts. Second, the contacts can be identified, quarantined, and vaccinated. Third, there is a single, geographically limited outbreak.

XIV. HOW LONG TO GET STARTED?

Analyzing these assumptions in turn, the identification and isolation of the first cases in an outbreak depends on those persons getting to a health care provider who makes the diagnosis of possible smallpox and triggers the public health response. As described previously, during the incubation period, there is no evidence of disease, and the person is not contagious. Infectiousness starts during the prodrome, which looks like a generic flu-like illness with fever. Ideally, the infected person would stay home and in bed, until going to the hospital when the pustules appear, and the pustules would alert the ever vigilant emergency room or clinic staff to the presence of a potential case of smallpox.

In the real world, the H1N1 epidemic reminded us that many people go to work sick unless specifically told not to. Even then, those without benefits will still try to work because without working, they do not get paid. This is especially true for people in the black economy. Off the books illegal workers have little incentive to stay home if they can possibly work. Street criminals, such as drug dealers, do not figure in any bioterrorism or pandemic preparedness plans, but they may also be infected and are unlikely to stay at home, if they have a home.¹⁰⁶

105. *See supra* text accompanying note 18.

106. In one of the best public health movies, there is a plague case spread by a criminal who comes into New Orleans by sneaking off a ship. Tracing the cases is complicated because the persons he exposed are criminals, who are avoiding the public health officials and law enforcement. PANIC IN THE STREETS (Twentieth Century Fox Film Corp. 1950). For more information, see

Even if a person in the prodrome seeks medical care, there is little chance that a health care provider would think about smallpox unless the outbreak was already known. The likely scenario would be the infected person spending a long time in a crowded emergency room waiting room, exposing others nearby, then being seen by a physician who prescribes over the counter medication for fever and recommends that the person stay home and rest until the illness was over. In the process, the physician and ancillary staff would also be exposed.

Once pustules begin to develop, the person becomes much more infectious, but also much easier to diagnose. If the person returns for medical care or seeks first-time medical care once the pustules are obvious, the case will likely be flagged and public health authorities will be notified of a suspicious looking disease.¹⁰⁷ However, an atypical or milder case might go undiagnosed, further delaying the beginning of contact tracing. Meltzer estimated a minimum of twenty-five days from first exposure to full implementation of the plan.¹⁰⁸

XV. CHASING CONTACTS

Once a case is identified, the process of identifying and tracing contacts can begin. The difficulty of tracing contacts will be determined by how many people the infected person came in contact with, and whether the nature of the contact lends itself to investigation. If the case is in a small town, it will be much easier than in a big city. If the person goes to work on the subway in New York City, visited a busy emergency room, and worked until too sick to stand, it is going to be harder to identify contacts. In practical terms, the more potential contacts, the more personnel will be necessary to carry out the investigations. Health departments have lost a lot of expert disease control personnel over the past decade, and even with full staffing, would still have to bring in others such as police officers to do a widespread search for contacts.

<http://www.imdb.com/title/tt0042832/>.

107. It is likely, but not absolutely certain. In less urbanized areas, it is possible that the person would get a prescription for soothing lotion, a shot of steroids, and be told to stay away from poison ivy.

108. "Twenty-five days assumes 15 days for the first signs of overt symptoms (Figure 2), 2 days for initial clinical diagnosis, 1 day for specimen transport, 3 days for laboratory confirmation, and 4 days to mobilize and begin appropriate large-scale interventions." Meltzer et al., *supra* note 32, at 962.

In the Internet world, it will be impossible to keep a smallpox outbreak secret. More problematically, everyone will quickly know that any contacts of a case will be quarantined and will be very strongly encouraged to be vaccinated.¹⁰⁹ This will make contact tracing much more complicated. While the quarantine will worry them, most would be expected to want the vaccine and would not evade authorities. It would not be surprising, however, if some persons who were potential contacts would flee the area. More generally, it would be expected that large numbers of persons would attempt to flee the area to avoid contact with the disease.

If persons exposed to the disease leave the area, they will not be identified until they develop symptomatic disease. By the time their disease is diagnosed, they will have exposed others in new areas. This will defeat the ring immunization strategy. It was not an issue during eradication because few people had the resources to flee. Smallpox was well-known and was seen as less of a threat than it will be seen in the United States. Stopping this flight could require quarantining a major urban center, which is difficult to imagine being done successfully.

Closing roads and subways and stopping people from driving their SUVs across fields to avoid blockades would require massive personnel. The quarantine would have to continue for the duration of the outbreak, which could be for many weeks, since it is assumed that some contacts of the first cases will slip through. Supplying food would be difficult and economic activity would halt since most urban centers depend on a large number of commuters. Yet, given the public's suspicion of the Government and of vaccinations, not quarantining the area would assure that some infected persons would escape to other areas, something that would not be known until they were sick and had already exposed new contacts in those areas. Beyond outlining what quarantine would mean for a smallpox epidemic, the CDC documents are silent on how this could actually be done, just indicating that quarantine is a state matter¹¹⁰ and that the feds have the power to

109. The federal Government maintains that it will never force anyone to be vaccinated. It is impossible to tell if this is just a political ploy because of the firestorm of criticism the CDC would get over mandatory vaccinations. There is certainly constitutional authority to require vaccinations.

110. Guide C, Part 2: Quarantine Guidelines, at 2, *available at* <http://biotech.law.lsu.edu/blaw/bt/smallpox/CDC-28feb2010/guide-c-part-2.pdf>.

promulgate quarantine regulations.¹¹¹

XVI. WILL WE NEED MASS IMMUNIZATION?

While the CDC documents do not provide guidance on when the response would shift to mass immunizations, a multi-focal outbreak spread over several communities would make it impossible to rely on ring immunizations.¹¹² This would be immediately obvious if cases were detected in several communities at the same time, as would happen with a simultaneous release. But even if the outbreak were only detected in one community, would it be reasonable to assume that it would only stay in that community? That citizen cooperation with ring vaccination and quarantine would be sufficient to confine the spread? As Meltzer points out, it will take nearly two months to contain an outbreak of one hundred localized cases, as a best case scenario, and it will likely take longer.¹¹³ This is a long time for a population to see new cases and deaths on every news cast and website.

Even if one were willing to make the assumption that quarantine and ring vaccination could successfully contain the outbreak to one community, one is still left with the problem that the only source of a smallpox outbreak is a bioterrorist attack. As Richard Danzig, former Secretary of the Navy and noted bioterrorism consultant argues, bioterrorism preparedness must assume reload, that unlike conventional attacks such as 9/11, a bioterrorism attack will leave the terrorists undetected and with the capability to attack again.¹¹⁴ Once smallpox is out of the freezer and in the hands of terrorists, it would be very dangerous to assume that they would not do follow-up attacks while the United States was reeling from the primary attack.

111. *Id.* at 5.

112. E-mail from Dr. D.A. Henderson, Professor of Public Health and Medicine, University of Pittsburgh, to Edward P. Richards, Harvey A. Peltier Professor of Law and Director, Program in Law, Science, and Public Health at the Paul M. Herbert Law Center, Louisiana State University (Jan. 14, 2010) (on file with author).

113. Meltzer et al., *supra* note 32, at 966 tbl. 3.

114. See Richard Danzig, *Catastrophic Bioterrorism—What is to be done?*, CENTER FOR TECH. & NAT'L SECURITY POL'Y, Aug. 2003, available at <http://biotech.law.lsu.edu/blaw/general/danzig01.pdf>.

XVII. POTEMKIN PLANNING

In the spring of 2005, I had the privilege of presenting part of a smallpox bioterrorism exercise to a group of sophisticated federal government employees and military officers. I raised the question that is at the heart of this article: is the CDC plan workable, and how do we decide when to make the transition to mass immunizations? What is plan B, and when do we go to it? The response of the group was illuminating: the notion that plans do not work was not part of their analysis. Their world was premised on the plans working and everyone carrying out their designated functions. Perhaps military plans work like that, but my experience with state and local programs is very different.

The CDC plan is dependent on state and local public health and law enforcement for the detection of cases, maintaining quarantine, and, generally, setting up the infrastructure for the response. In itself, this is not unreasonable—public health is a very local enterprise, requiring local knowledge, and the feds do not have the personnel to mount a massive response on their own. This national response is driven by an elaborate top down federal planning effort, with the CDC plan being part of a general national response plan.

The problem is that the federal planning effort has no auditing function to assure that the states are really prepared to carry out the plan. All those assurances come from the same people who are doing the plans. From the perspective of state and local government employees, they have to do these plans or the feds will cut funding to programs they depend on, or otherwise harass them. Their state and local funding has been dramatically reduced over the past twenty years through a combination of budget cuts and expansion of the mission.¹¹⁵ State and local politicians who set these budgets do not want to hear that cuts have consequences for public health and safety, so that it is not an option to respond to the CDC or other federal agency that it is impossible to staff or carry out the requested plan with the existing levels of staff, expertise, and material.

The result is that most plans for large scale emergency

115. For just one example, as obesity has become a fashionable topic, health departments have been tasked with various programs to track obesity in children, set up education programs, and otherwise tackle the obesity epidemic. These new duties come with no money, at the same time that budgets are being cut, and they require different expertise than core communicable disease control activities.

response, including bioterrorism, are Potemkin plans, based on representations about expertise, personnel, and material that are not realistic. Such plans also indicate that the state and local officials will follow the federal lead and carry out actions as described in the plan. Yet everyone who has worked with state and local government knows that no elected official takes orders from other elected officials. When the time for emergency response comes, local issues will determine the shape of that response without regard to federal plans, mandates, or orders. Elected officials do what they think is best for their constituencies at the moment, with an eye on their constituencies that they will see the politician's actions at reelection time.

XVIII. THE HURRICANE KATRINA EFFECT

A few months after I was assured that response plans work and that all levels of Government carry out their roles, Hurricane Katrina threatened the Gulf Coast.¹¹⁶ While the roots of the Katrina disaster were 200 years of bad land use planning by the New Orleans and Louisiana governments, the most critical mistake was the failure to call for a timely evacuation of New Orleans and to provide the support for such an evacuation. Ironically, Louisiana state and local officials had completed a major federal planning exercise just the year before for a theoretical storm that would have done much more damage than Katrina. As with all good planning exercises, everyone went home assured they were ready.¹¹⁷

All cats are black in the dark and all plans work before the disaster. Disaster response plans have financial and political costs, which must be balanced against their benefits. Before the disaster, the benefits are only theoretical, but some of the costs are real. Balancing those real costs against the net present day cost of being prepared in the future is difficult and made much more difficult when the future event is difficult to predict, and thus can be seen as of low probability in the short run. The Hurricane Pam exercise and all the federal hurricane planning efforts for New Orleans ignored the most important political reality: state and local officials

116. This article is not meant to be an in-depth analysis of the governmental failures surrounding Hurricane Katrina. That has been the subject of endless post-hoc analyses, most of which are not well-informed about the actual events and their cause, but addressing these is beyond the scope of this article.

117. FEMA, *Hurricane Pam Exercise Concludes* (July 23, 2004), available at http://biotech.law.lsu.edu/blaw/FEMA/FEMA_Hurricane_Pam.pdf.

could not admit that New Orleans might flood.

The history of New Orleans is a history of attempting to expand the original core of the city which was built on the narrow stretch of high land along the river, into the swamps and eventually into the surrounding bays themselves.¹¹⁸ Combined with the subsidence of the crustal plate under South Louisiana, this leaves a significant part of New Orleans below sea level. New Orleans has flooded on a regular basis during its history, the most recent pre-Katrina flood being Hurricane Betsy in 1965, in which the levees broke and flooded most of the same areas flooded by Katrina.¹¹⁹ But that was forty years ago, and a mythology had grown up that the levees were now fine and would prevent any future flooding.¹²⁰ This was crucial to land values in New Orleans, as well as the retention of businesses in what was a declining city.

There had been several evacuations of New Orleans since Hurricane Betsy and all were pronounced great successes. As we learned with Hurricane Katrina, you do not really know how many people do not evacuate until you have the flood, so there was no reason to doubt the success of these evacuations. At no time did the politicians say that New Orleans could flood, because that would undermine property values, and the strategy had worked for forty years because all the hurricanes had missed New Orleans at the last minute. The assumption was that Katrina would be no different, so it was treated no differently. The evacuation was called at the last minute, because if evacuations were called two days before landfall, there would be a lot of false alarms because of the difficulty of predicting the course of hurricanes. There were shelters of last resort opened in the city, which further reinforced the message that New Orleans could not flood because no one would have shelters that would flood. The area hospitals were not evacuated, again reinforcing the message that the city could not flood. Had Katrina missed the city, as all the storms had since 1965, the Hurricane Katrina evacuation would have been logged as a success and an example of the effective state-federal disaster

118. See generally CRAIG E. COLTEN, *AN UNNATURAL METROPOLIS: WRESTING NEW ORLEANS FROM NATURE* (Louisiana State Univ. Press 2004).

119. THOMAS R. FORREST, *HURRICANE BETSY, 1965; A SELECTIVE ANALYSIS OF ORGANIZATIONAL RESPONSE IN THE NEW ORLEANS AREA* (U. Del., Disaster Res. Center 1979), available at <http://biotech.law.lsu.edu/katrina/betsy/HC-205.pdf>.

120. This may have been the longest interval between New Orleans major floods. The 1970s through the 1990s was a historical low period for hurricanes in the United States, which helped fuel a mass exodus to the Gulf and Atlantic coasts.

response.

Hurricanes are frequent events on the Gulf Coast, at least as compared to potential smallpox bioterrorism. The 2004 hurricane season was the worst on record, until the 2005 season. It was assumed that state and local officials would take the risks of a storm in 2005 very seriously after the 2004 season, yet they did not. A smallpox bioterrorism event is an event with an undeterminably low probability. It would be surprising if state and local governments, and, frankly, the federal Government (who did not do very well after Katrina itself), are as prepared as their plans indicate. It is also possible that the local response to a smallpox outbreak might not be very effective, and that the officials in charge might not realize that, or might have reasons to downplay their failure.

The first reason would be the economic consequences of a massive quarantine on the city and regional economies. The cost of the involved governmental resources would be huge, and the loss of a large fraction of the business income for weeks would be catastrophic, especially if the attack were to occur during an economic downturn that such state and local governments faced between 2008 and 2010. The second reason is that a mass immunization program would cause a large number of injuries, some deaths, huge health care costs, and potentially ruinous political consequences. A real political fear would be to go to mass immunizations very quickly and effectively stop the outbreak, but end up with more vaccine injuries than smallpox deaths. In political terms, it would be better to have a lot of bodies to justify the possible consequences of mass immunizations.

In the Hurricane Katrina disaster, the error in not supporting a timely and massive evacuation only became apparent when the water started filling the city and the emergency phone system was overwhelmed with calls for help. At that point, it was too late to save many of the people trapped in their flooding houses or in flooded hospitals and nursing homes, or in city shelters of last resort. In a smallpox outbreak, the failure of the primary ring immunization approach would only be evident as new generations of unanticipated infections appeared, especially if they appeared in new communities. This would either be evidence of reload—a second attack—or the escape of infected persons from the original target community. This would (hopefully) shift the response to mass immunizations as well as ring immunizations, but with a loss

of at least a couple of weeks. Under the conditions of the Dark Winter simulation, that would be enough for the smallpox to become a full-blown epidemic which would be very hard to contain, and which would gravely disrupt the U.S. economy.

XIX. FROM POTEMKIN PLAN TO WORKABLE PLAN

The CDC has trained epidemiologists who understand the science of communicable disease control in general and smallpox in particular. But the CDC is also a political organization and its political leadership has to be attentive to politically unpopular endeavors, regardless of their scientific merit. After the political fallout from the 1976 Swine Flu immunization campaign, the CDC has avoided controversial disease control measures.¹²¹ This is especially true of plans that are unlikely to be implemented—Why put controversial components in a plan that has little chance of being endorsed?

Mandatory vaccinations are controversial, so controversial that many states have even altered their routine childhood immunization law to allow parents to opt their children out of immunizations based solely on parental moral objections. There is no need to be a Christian Scientist anymore. Mass vaccination with smallpox vaccine, a live virus vaccine that can prove deadly to persons with immune system diseases, would require identifying everyone at higher risk of vaccine injury. This would, in turn, require knowing people's HIV status, which could include controversial mandatory HIV testing. More generally, plans that anticipate that state and local efforts may be inadequate, and that indicate that niceties such as an elaborate consent process for vaccinations may have to be abandoned, are also controversial.

This section will take a hard look at both contact tracing and the ring immunization strategies to indicate that it is an adequate plan for a smallpox bioterrorism event. It will conclude with an alternative plan that will better meet the specific needs of a smallpox outbreak and will improve public health preparedness in general.¹²²

121. For a detailed analysis of the swine flu vaccination program and its political dimensions, see RICHARD E. NEUSTADT & HARVEY V. FINEBERG, *THE SWINE FLU AFFAIR: DECISION-MAKING ON A SLIPPERY DISEASE* (1978).

122. The basic library for smallpox information has been collected at <http://www.nlm.nih.gov/nichsr/esmallpox/esmallpox.html>.

XX. A HARD LOOK AT RING IMMUNIZATION

The ring immunization approach to a smallpox outbreak makes good public health sense. It worked for eradication and is a good balance between the risks of smallpox vaccination and the risks of an unconstrained smallpox outbreak. Ring immunization starts with careful epidemiology. The index cases—the persons first infected with the introduction of the smallpox into the community—must be diagnosed and reported to public health authorities. As discussed earlier, this may take more time than plans anticipate because health care providers are likely to be unfamiliar with the disease and because of limited access to health care. Once the state or local health department is notified of a potential case, the department will decide whether to immediately call the CDC or to verify the case first. This decision will turn on how much the case looks like smallpox. A person covered with typical sores will trigger an immediate national response. However, a case with a less obvious presentation might be dismissed as measles or some other common disease, which could delay identification. During the early contagious period, before the sores are obvious, it is very unlikely that the disease would be identified, but would instead be dismissed as “flu.”¹²³

Everyone who comes into contact with the patient during the interval between when the patient becomes contagious and when the patient is diagnosed with smallpox and put into isolation must be assumed to be potentially infected with smallpox. Every contact must be identified, vaccinated, and quarantined for at least fourteen days to assure that if they develop smallpox, they do not pose a risk to more people. The process of contact tracing begins with an in-depth interview with the infected person to reconstruct the patient’s movements and all contacts from before the earliest point at which the patient could have been infectious. Depending on how long the diagnosis was delayed, this might be for the previous four to seven days. If the patient is too sick to provide information, to properly remember the information, or if the patient is unwilling to cooperate,¹²⁴ the history must be

123. See Meltzer et al., *supra* note 32, at 960–61; see also A.R. RAO, SMALLPOX 41–42 (The Kothari Book Depot 1972).

124. In the classic film noir, *Panic in the Streets* (Twentieth Century Fox Film Corp. 1950), a criminal smuggled off a ship was infected with plague. The heroic health officer and New Orleans officials had to track his contacts in the underworld, encountering resistance at all turns. For more information, see

reconstructed from family members, co-workers, or other persons who might know of the patient's behavior.

The clock is ticking during this investigation because every contact that becomes contagious before being identified and isolated will start another chain of investigation. Once a case of smallpox has been identified anywhere in the United States (or probably anywhere in the world), the index of suspicion will be very high, and anyone with a flu-like illness or a rash will seek medical care at once, and health care providers will treat every remotely suspicious case as smallpox.¹²⁵ This will create noise, i.e., the large number of cases that are assumed to be positive (false positives) will consume valuable epidemiologic resources to evaluate and quarantine cases until they are positively excluded as smallpox cases. The false positives and the difficulty of identifying all contacts of the initial cases guarantee that some contacts will not be identified until they develop smallpox, triggering the need for new chains of contact tracing.

Meltzer analyzes the effect of various levels of efficiency in quarantining and vaccinating contacts in the time necessary to end the outbreak and the total number of cases of smallpox that would occur.¹²⁶ Meltzer uses a conservative (low) estimate that each person with smallpox will infect three others if there is no intervention.¹²⁷ The model assumes an initial seed of one hundred cases.¹²⁸ The paper is silent on the nature of the geographical distribution of the cases, but since it does not mention overlap in the contact networks—which increases efficiency in contact identification—it appears that the model assumes that the contacts are spread over a fairly wide area. Meltzer did not model a mass vaccination program because of potential complications and

<http://www.imdb.com/title/tt0042832/>.

125. While this will shorten the time to diagnose the secondary cases, it will challenge the health care system and especially emergency rooms where most people will seek care. At the same time that there is a massive influx of people worried that they have smallpox, the emergency rooms and other clinic facilities will be implementing infection control procedures to prevent the spread of disease in the waiting and triage areas. This will require controlling access to hospitals, perhaps closing emergency rooms to walk-in patients, and other measures. The provision of care to infected persons and the protection of the health care system from shutdown due to contamination are critical issues, but they are beyond the scope of this article.

126. See Meltzer et al., *supra* note 32, at 961–67.

127. *Id.* at 961.

128. *Id.*

because it was assumed at the time of publication that there were only 40,000,000 doses of vaccine available. Meltzer shows that contact tracing and quarantine, combined with ring immunization, is more effective than either strategy alone. But Meltzer also shows that its assumptions on the effectiveness of contact identification and vaccination, which seem realistic, and even perhaps a bit conservative, result in an outbreak lasting several months or even up to a year long, with 3,200 to 12,400 cases, depending on whether the interventions were fully in place by the twenty-fifth day or the forty-fifth day.¹²⁹

XXI. IS RING IMMUNIZATION REALISTIC?

Meltzer's analysis raises three critical issues. First, the long delay needed to control an outbreak seems politically unsustainable. The public, the media, and politicians will fixate on each new case, and each death, likely paralyzing government in the affected areas and creating demands for complete travel restrictions to prevent the spread of smallpox to unaffected areas. The economic consequences of the disruptions and uncertainty will be very serious.

Second, Meltzer provides very powerful evidence that the start time of the interventions is the most critical variable. The start time for the outbreak is the initial exposure of the index cases, and Meltzer assumed that it would take twenty-five days to have full scale interventions working.¹³⁰ As the delay for starting interventions increases, the time to control the outbreak and the number of expected cases before control is achieved increases dramatically.

Third, the Meltzer model recognizes that delays in implementing the strategies or not being able to carry them out effectively can make control impossible.¹³¹ Ring immunization depends on a functioning public health system, a compliant public, and politicians willing to make unpopular decisions to support the quarantine and vaccination efforts. In these regards, the average U.S. city is likely less well-prepared to properly support ring

129. *Id.* at 963.

130. "Twenty-five days assumes 15 days for the first signs of overt symptoms (Figure 2), 2 days for initial clinical diagnosis, 1 day for specimen transport, 3 days for laboratory confirmation, and 4 days to mobilize and begin appropriate large-scale interventions." *Id.* at 962.

131. *Id.* at 965 fig.6.

immunization than an African village in 1970.

We have lost public health infrastructure, in particular the expert epidemiologists that are necessary for doing effective contact tracing. Studies have shown a consistent decline in the number of epidemiologists at both state and local health departments, except for a brief respite after 9/11 which augmented health department budgets—an increase that is now history.¹³² These studies underestimate the loss of infectious disease control expertise because they do not differentiate between chronic disease epidemiologists, who are primarily mathematicians, and infectious disease epidemiologists who deal with disease investigations and interventions.¹³³ Part of this loss is due to politicians who are unwilling to face the problems in the system, and a public that does not support, or is unwilling to cooperate with, public health activities such as immunization programs. Together, the loss of expert personnel and public and political support make it unlikely that a massive contact tracing and ring immunization program could be carried out effectively and quickly.

XXII. WHAT IS THE ALTERNATIVE?

Meltzer clearly identifies the key variable in a successful response to a smallpox outbreak: time. The number of cases increases dramatically with each new generation. Even using the conservative number of three infections per case, an initial seed of 100 cases yields 300 at 15 days, 900 at 30 days, and 2,700 at 45 days, with future growth dependant on the success of control measures.

132. The beginning of the problem was noted in the early 1990s. See Michael T. Osterholm, Guthrie S. Birkhead & Rebecca A. Meriwether, *Impediments to Public Health Surveillance in the 1990s: The Lack of Resources and the Need for Priorities*, J. OF PUB. HEALTH MGMT. & PRAC., Fall 1996, at 11–15; Lyn Finelli et al., *Epidemiologic Support to State and Local Sexually Transmitted Disease Control Programs: Perceived Need and Availability*, SEXUALLY TRANSMITTED DISEASES, Mar. 1998, at 132; Ctrs. for Disease Control and Prevention, *Assessment of the Epidemiologic Capacity in State and Territorial Health Departments—United States, 2001*, 52 MORBIDITY & MORTALITY WKLY. REP. 1049 (2003); Ctrs. for Disease Control and Prevention, *Assessment of the Epidemiologic Capacity in State and Territorial Health Departments—United States, 2004*, 54 MORBIDITY & MORTALITY WKLY. REP. 457 (2005); Ctrs. for Disease Control and Prevention, *Assessment of the Epidemiologic Capacity in State and Territorial Health Departments—United States, 2009*, 58 MORBIDITY & MORTALITY WKLY. REP. 1373 (2009).

133. See John J. Potterat, *Disease Intervention Specialists as a Corps, Not Corpse*, SEXUALLY TRANSMITTED DISEASES, July 2008, at 703, available at http://biotech.law.lsu.edu/cases/STDs/Disease_Intervention_Specialists_as_a_Corps.12.pdf.

If the initial seed is larger, or the number of new cases per index case is higher, the numbers grow faster. Under the assumptions in the Meltzer paper, effective control measures would not be in place until day twenty-five, which is after the second generation of cases has been infected, so there would already be a tripling before there could be any effect of the program. If the contact tracing was not as effective as expected, or there were more cases per index case than predicted, this would not be detected until the fourth and fifth generations, by which time the disease would likely have escaped control. The only alternative at that point would be mass immunizations, but with a high rate of smallpox in the community disrupting the immunization program and potentially leading to social disorder.

The CDC plan is based on a bet that the system will work, but this bet is undermined by the impossibility of including the substantial probability that state, local, and federal resources will fail: the Katrina problem. Yet if these resources fail, then the chance to control a smallpox outbreak without massive social and economic disruption and loss of life is lost. This is the risk that must be balanced against the risks of vaccine-related illness and death secondary to a mass immunization program, rather than the balance of the risks of mass immunizations against a successful ring immunization program. Plan B would be to start mass immunizations when the first case of smallpox is confirmed, with an emphasis on making vaccine available to health care workers and first responders, and their families, as fast as possible.¹³⁴ This would satisfy the public demand for vaccine and the accompanying disorder when that demand is not met. It would also start to fill the population with immune persons, making the ring immunization program more effective as the consequences of missing contacts diminish, because the chance that those contacts are already vaccinated increases. At two weeks past the first cases of smallpox, it would be clear whether ring immunization was working—if there were new cases among persons not previously identified by contacts, especially in new communities, this would either be evidence of additional attacks or break-down of the ring immunization program. If there are no unexpected new cases, then mass immunizations could be curtailed.

134. If you do not include families, people will likely not come to work because they are afraid of carrying infection home to their families.

XXIII. BUILDING INFRASTRUCTURE BEFORE THE OUTBREAK

Plan B requires more than just flipping the switch on the existing CDC mass immunization clinic guidelines.¹³⁵ As Hurricane Katrina demonstrates, plans on the shelf backed up by table-top exercises do not assure that the real system would work in an emergency—the time when it is most difficult to make anything work. The United States cannot effectively immunize the population against seasonal flu or H1N1, many states allow parents who do not like vaccinations to opt their children out of vaccinations for school attendance, and there are no provisions that address the problems that undermined the 2002 smallpox vaccination campaign, such as payment for vaccine-induced damage.

Building an effective response infrastructure for a smallpox bioterrorism event, or any other wide-spread public health emergency such as pandemic flu must be done in real time. It must be part of the routine public health infrastructure, supported and accepted by the public. The best way to accomplish this would be to put money and political will behind making our current public health system function properly. This would prepare us for future challenges and would provide immediate benefits. It would also allow effective quality control auditing because there would be real data on the effectiveness.¹³⁶ Problems would be detected quickly and the system refined to work better and gain more public support. This is impossible with academic exercises that have no real world implementation.

135. While the CDC does not provide much information on how the smallpox vaccine is stored, other information available about the Strategic National Stockpile indicates that it takes times to deploy all the way out of the final clinic settings. The CDC mass vaccination plan also assumes the use of a relatively small number of high volume clinics, so that each clinic can vaccinate about 10,000 persons per day. This creates logistic problems in people getting to the clinic, and crowd control at the clinic. As an alternative, vaccine could be widely distributed to health care workers and vaccinations could be done in the community, as was done during the 1947 outbreak. But this would require giving up the highly structured, legalistic control of the vaccination.

136. While it is beyond the scope of this article, all modern methods of statistical quality control and continuous quality improvement depend on analyzing a running program, detecting problems, and correcting those problems before they affect the quality of the end product or service. Programs that are only called into existence for a one-shot emergency can never be evaluated or refined, and are prone to unanticipated system failures. For quality control theory, see W. EDWARD DEMING, *OUT OF THE CRISIS* (2000).

As examples, there are two public health programs that would significantly improve public health and would also build professional and political infrastructure to improve bioterrorism-response capability. The first would be a program for seasonal flu immunizations that would quickly immunize ninety percent of the at-risk population. Since there is a flu pandemic each winter, with the occasional bonus of an additional epidemic such as H1N1, this would be an ongoing program that would pay for itself by saving thousands of lives each year, improving productivity by reducing workplace illness, and by saving flu-related medical costs. Making this program work would require educating the public about the value of vaccinations, eliminating legal barriers to vaccination programs, and developing an effective system of vaccine distribution and administration. All of these would improve the ability to respond to a bioterrorism event as well as improve vaccination rates for both childhood and adult diseases.

The best way to improve infectious disease epidemiology staffing would be to develop a proper HIV control program that could identify every person infected with the disease, help them get better treatment, and more effectively limit the spread of HIV.¹³⁷ This would also put persons with HIV on notice of their status, which would help them avoid smallpox vaccine complications. There are presently about one million persons living with HIV in the United States, augmented by 40,000 newly infected persons annually, with 15,000 dying annually. The economic and human cost is tremendous, making it easy for an effective HIV control program to pay for itself, while developing invaluable contact tracing and identification infrastructure for a future smallpox outbreak.

Such public health epidemiology and disease management programs would improve the health of the public, reduce health care costs, and support the necessary expertise and infrastructure for a proper response to smallpox and other pandemic and bioterrorism threats.¹³⁸ If such programs could be made to work and were used to build acceptance for disease control by the

137. John J. Potterat, *Partner Notification for HIV: Running Out of Excuses*, SEXUALLY TRANSMITTED DISEASES, Jan. 2003, at 89–90, available at http://biotech.law.lsu.edu/cases/STDs/Partner_Notification_for_HIV.pdf.

138. For an example of such an all-hazards plan, see Edward P. Richards et al., U.S. Dep't of Justice, *The Role of Law Enforcement in Public Health Emergencies: Special Considerations for an All-Hazards Approach* (2006), available at <http://www.dr-kate.com/docs/214333.pdf>.

public, we might not need a Plan B for smallpox because we could have more confidence that Plan A could be successfully implemented.

XXIV. CONCLUSION

The CDC smallpox bioterrorism response plan is founded on good science, empirically proven during the smallpox eradication program of the 1960s and 1970s. Its weakness is that it is based on assumptions about the public health infrastructure, political leadership, and public cooperation that are at odds with observed realities. More fundamentally, it is a victim of the larger federally-driven emergency response system. This is based on cram-down planning exercises that blindly assume that state and local government agencies have the resources they claim and that they can and will do what they promise in the plan when there is an emergency.

The result is a theoretical plan-based system that cannot be audited or refined and whose failure modes will only be detected when it is too late to prevent the consequences of those failures. In contrast, rebuilding public health infrastructure to address real public health threats would provide both real benefits in the short-term and a verifiable response system for bioterrorism events, pandemics, and emerging infectious diseases.