



# **A Biodefense Failure: The National Smallpox Vaccination Program One Year Later**

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## Executive Summary

The release of smallpox virus by bioterrorists remains a serious threat. The United States government believes some nations may still possess undeclared stocks of the virus and the legacy of the massive Soviet bioweapons program poses the particular risk that smallpox may have already fallen into the hands of terrorists or may in the future.

A smallpox attack could be devastating. A well coordinated, multi-site attack could cause widespread disease and immense terror, potentially killing hundreds of thousands. Vaccinating health care workers and first responders across the nation against smallpox is an important preparedness step. Personnel already immune to the virus will be essential in rapidly responding to an outbreak, saving lives through further vaccination and treatment, and maintaining essential services. Limiting vaccination to healthy, carefully screened, personnel would reduce the smallpox threat while avoiding the public health risk of a mass vaccination.

Under the Administration's smallpox vaccination plan, 500,000 workers were to be vaccinated within 30 days. One year later, the effort is stalled, with less than 40,000 vaccinated volunteers across the country. A state-by-state analysis of the vaccination program's current progress suggests that preparedness and capability to respond to a smallpox attack vary widely across the nation. For example, only four states have reached even 50% of their original vaccination goals. Of the 1400 people targeted for vaccination in Nevada, only 17 have actually been vaccinated, while only 71 of the 4000 targeted for vaccination in the city of Chicago are immunized. Twenty states have reported that they cannot vaccinate their population within 10 days of an outbreak. This situation leaves much of the nation vulnerable to a smallpox attack.

Three key failures are responsible for the continuation of this serious gap in biodefense:

- Sufficient resources were not allocated nor requested in time for public health agencies to properly implement the program, leaving state and local agencies without the funding to manage vaccinations without cutting other health services.
- An adequate compensation plan to compensate volunteers who may suffer side effects from the vaccine was not in place when vaccinations began
- Healthcare workers, first responders, and the public at large are not persuaded that smallpox is a serious threat that warrants participation in a limited vaccination program.

As a result of poor management and leadership of the vaccination program, the confidence and credibility in the government from vaccinated and unvaccinated healthcare workers, first responders, and the public is being undermined. The Administration's missteps threaten the success of this and other preparedness efforts, leaving the U.S. vulnerable to bioterrorism.

As long as smallpox bioterrorism poses a threat, complacency and lack of preparedness is dangerous. The Administration must take immediate steps to reassess the threat of smallpox, improve our preparedness, and regain the confidence of those citizens crucial to our biodefense efforts.

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## **A Biodefense Failure**

### **The National Smallpox Vaccination Program One Year Later**

On January 24, 2003, the first civilians were inoculated as part of the Administration's plan to vaccinate millions of healthcare workers and emergency first responders against smallpox, a deadly, disfiguring and contagious disease that could be devastating if used as a weapon by terrorists. One year later we have little reason to feel much safer against this threat. While our military has prepared for a smallpox attack, with over 500,000 key personnel vaccinated, the civilian population has not. Instead, the civilian vaccination program is stalled and in disarray, threatening the security of millions of Americans.

Information contained in this report provides a picture of where our homeland's security against smallpox stands today. It reveals only a patchwork of preparedness. States with thousands of vaccinated volunteers and completed programs border others with a few hundred or less and stuck in indefinite "programmatic pauses." Most are nowhere near the goals originally set in December of 2002. Still waiting for direction from federal officials, most states lack the means to measure their own readiness for smallpox. The viability of state and local smallpox preparedness and response plans remains in doubt, as the nation's health system drifts in the absence of a national biodefense plan or strategy.

An assessment of the program's short history shows a series of misjudgments, poor planning, ignorance of outside advice, and simple neglect. The vaccination of millions of Americans in the face of an uncertain but real bioterror threat is an endeavor heavily dependant on effective government leadership and management. A failure of provide these crucial elements is leaving tens of millions of citizens vulnerable to bioterrorism from smallpox.

#### **Smallpox: A Potent Bioterror Weapon**

Smallpox has been called one of the great scourges of humanity. The disease is highly contagious, killing up to 30 percent of its victims and leaving many survivors disfigured and blind. For those displaying symptoms, there is no approved treatment. Smallpox became the target of a successful worldwide eradication campaign in the late 1970's. More than 20 years later and with vaccinations discontinued, America and much of the world has become immunologically "naive" and dangerously susceptible to infection.<sup>1</sup> The U.S. population today is vulnerable in the same way as colonial-era Native Americans, a highly susceptible population devastated by smallpox contracted from European explorers and colonists who arrived with the disease.<sup>2</sup>

Although officially declared eradicated in 1979, stocks of the virus were maintained in some laboratories, and the world's nations were asked to either declare or destroy their stocks. Only two declared repositories of this deadly virus remain, both in high security facilities in Atlanta, Georgia and Novosibirsk, Russia. However, there is reason to

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<sup>1</sup> D.A. Henderson, "Bioterrorism as a Public Health Threat," *Emerging Infectious Disease*, 4, no.3 (1998): 488-92.

<sup>2</sup> P.J. Bianchine, T.A. Russo, "The Role of Epidemic Infectious Disease in the Discovery of America," *Allergy Proceedings*, 13, no. 5 (1992): 225-32.

believe the virus is not confined solely to these two laboratories, and it may be accessible to terrorists. In violation of international law, the Soviet Union conducted a secret bioweapons program which reportedly included building the capacity to produce tons of weaponized smallpox for possible delivery with bombs and missiles.<sup>3</sup> Although the Soviet Union collapsed, the Russian government has failed to fully account for or secure the activities, locations, and products of their program.<sup>4</sup> These factors, combined with the poor state of the Russian economy, mean Soviet stockpiles may be vulnerable or already compromised by terrorists. Moreover, other nations may have disregarded the international call to destroy their stockpiles, and maintained samples of the virus for their own bioweapons programs.<sup>5</sup> The former deputy director of the Soviet biological weapons program, Dr. Ken Alibek, considers it certain that the virus has escaped from the Soviet program.<sup>6</sup> Dr. D.A. Henderson, the former director of the world smallpox eradication effort, points out that the technology and expertise developed in the Soviet Union is now spread throughout the world, heightening the threat of a smallpox attack.<sup>7</sup>

If released, a smallpox attack would likely be devastating. Estimates range from thousands to millions of deaths, depending on the type of attack scenario, transmission rates, and types of interventions implemented.<sup>8</sup> Without any prior vaccination, estimates of a smallpox release at an airport, resulting in rapid and widespread geographic diffusion of infected people, could cause over 50,000 deaths.<sup>9</sup> Airborne dispersion could infect hundreds of thousands, many more if smallpox is released at multiple sites.<sup>10</sup> While some residual immunity in the population exists from those vaccinated prior to 1972, the degree of immunity present is unknown. According to D.A. Henderson, “one can only speculate on the probable rapidity of spread of the smallpox virus in a population where no one younger than 25 years of age has ever been vaccinated and older persons have little remaining immunity.”<sup>11</sup> As a result, the country could be thrown into disarray,

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<sup>3</sup> (a) Ken Alibek, *Biohazard: The Chilling True Story of the Largest Covert Biological Weapons Program in the World*, (New York: Random House Inc. 1999); (b) *The 1971 Smallpox Epidemic in Aralsk, Kazakhstan, and the Soviet Biological Warfare Program*, Jonathan Tucker and Raymond Zilinskas, Eds., Chemical and Biological Weapons Nonproliferation Project, Monterey Institute of International Studies, Occasional Paper No. 9, July 2002.

<sup>4</sup> (a) U.S. General Accounting Office, *Weapons of Mass Destruction: Additional Russian Cooperation Needed to Facilitate U.S. Efforts to Improve Security at Russian Sites*, GAO-03-482, (Washington, D.C.: GPO, March 2003); (b) Scott Shane, “Smallpox Fears Renewed,” *Baltimore Sun*, June 15, 2002, <http://www.ph.ucla.edu/epi/bioter/smallpoxfearsrenewed.html>.

<sup>5</sup> “Smallpox: United States Fingers Four Countries with Covert Stockpiles” *Global Security Newswire*, November 5, 2002.

<sup>6</sup> Ken Alibek. Testimony before the Committee on Government Reform, Subcommittee on National Security, Veterans Affairs, and International Relations, October 12, 2001.

<sup>7</sup> David McGlinchey, “Smallpox Immunization Program Stalls,” *National Journal*, November 7, 2003.

<sup>8</sup> Martin I. Meltzer, Inger Damon, James W. LeDuc, and J. Donald Millar. “Modeling Potential Responses to Smallpox as a Bioterrorist Weapon,” *Emerging Infectious Disease*, 7, no. 6 (2001): 959-969.

<sup>9</sup> Samuel A. Bozette, et al. “A Model for Smallpox-Vaccination Policy,” *The New England Journal of Medicine*, 348, no. 5 (2003): 416-425.

<sup>10</sup> Richard Danzig, *Catastrophic Bioterrorism: What Is To Be Done?* August 2003.

<sup>11</sup> Donald A. Henderson. “Smallpox: Clinical and Epidemiological Features,” *Emerging Infectious Disease*, 5, no. 4 (1999): 537-539.

threatening the stability of national systems and the well-being and livelihood of the national and global population.<sup>12</sup>

### **The Logic of Limited Pre-Attack Vaccinations**

If a smallpox attack does occur, a quick, deliberate response is essential to saving lives, preventing panic, and maintaining essential services. Health care workers and emergency responders already immune to the virus could be crucial in responding to an outbreak, assessing potential victims, administering treatment, caring for isolated and quarantined individuals, and vaccinating the public for protection. If smallpox is released, hospital workers and laboratory employees will be more essential than ever. Their own safety must be assured in order to keep hospitals open, diagnostic laboratories operating, and the health care system running.<sup>13</sup> Located strategically in every state, teams of trained, vaccinated personnel will be able to respond to an incident anywhere in the U.S. and treat victims and the public at local hospitals. In this way, several studies indicate that prior, limited vaccination of health care workers and first responders would save lives and protect the public.<sup>14</sup> One such study suggests that about roughly 2 million people, including ambulance drivers, police officers and vaccinators would be needed for a mass vaccination effort.<sup>15</sup>

From a public health standpoint, limited vaccination of key personnel is preferable to a program of mass vaccination. While it is true that the threat of smallpox could be eliminated if we revaccinated the entire population, and maintained this protection until we could be sure all stockpiles of the virus in the world were secured, the only vaccine currently available presents its own risks.

The vaccine can have serious side effects for a small percentage of those vaccinated, and and, because it involves a live virus, for those with whom vaccinated individuals come in contact.<sup>16</sup> Those most at risk include pregnant women, immuno-suppressed individuals (such as those with AIDS, lupus, or undergoing certain cancer treatments), or those who have hypertension. Based on evidence from the 1960s, up to 1,250 serious reactions per 1 million vaccinations, including 2 deaths, have been predicted, a rate of 0.1 percent.<sup>17</sup>

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<sup>12</sup> Tara O'Toole, Michael Mair, and Thomas V. Inglesby. "Shining Light on 'Dark Winter,'" *Clinical Infectious Diseases*, 34, no. 7 (2002): 972-983.

<sup>13</sup> Melinda Wharton and others, "Recommendations for Using Smallpox Vaccine in a Pre-Event Vaccination Program," *Morbidity and Mortality Weekly*, 52, RR07 (April 4, 2003): 1-16.

<sup>14</sup> (a) Samuel A. Bozette and others "A Model for Smallpox-Vaccination Policy," *The New England Journal of Medicine*, 348, no. 5 (2003): 416-425; (b) Elizabeth Halloran and others, "Possible Containment of Bioterrorist Smallpox," *Science*, 298, (2002): 1428 – 1432; (c) Edward H. Kaplan and others, "Emergency Response to a Smallpox Attack: The Case for Mass Vaccination," *Proceedings of the National Academy of Sciences*, 99, no. 16 (2002): 10935-10940.

<sup>15</sup> Kendall Powell, "Smallpox Strategies Simulated," *Nature: Science Update*, November 15, 2002, [<http://www.nature.com/nsu/021111/021111-13.html>].

<sup>16</sup> John Bartlett and others, "Smallpox Vaccination in 2003: Key Information for Clinicians," *Clinical Infectious Disease*, 36, no. 7 (2003): 883-902.

<sup>17</sup> (a) J. Lane, F. Ruben, J. Neff, J. Millar, "Complications of Smallpox Vaccination," *New England Journal of Medicine*, 281, (1969): 1201-8; (b) J. Lane, F. Ruben, J. Neff, J. Millar, "Complications of Smallpox Vaccination, 1968: Results of Ten Nationwide Surveys," *Journal of Infectious Disease*, 122, (1970): 303-9;

When smallpox still occurred naturally, the risks of vaccination were far outweighed by the much greater harm of actually contracting the disease. Today, because smallpox is no longer in the environment, we must weigh the risks of vaccination against the much less certain potential of a bioterrorist attack. Because of potential side effects, without specific information relating to an attack, mass vaccination of the public before an attack is not wise.

Moreover, if those soldiers, health care workers, and first responders most at risk are screened and excluded from the program, a limited vaccination program can substantially reduce the smallpox threat while avoiding the public health risk of a mass vaccination. Thus, while the risk is not zero, the benefits to our preparedness and public health system argue in favor of limited vaccination.

### **The Challenge of Smallpox Preparedness: The Need for Strong Federal Leadership**

The threat of smallpox bioterrorism poses a challenge for homeland security. In addition to inoculating military personnel, pre-event vaccination means we must ask many civilian health care workers and first responders to volunteer to take on the small but real risk of side effects today in order to protect the public from a possible release of smallpox in the future. In calling for such an action, federal officials must be careful in their planning, sincere in their belief of the threat of smallpox, and responsive to the needs of the state and local health departments and hospitals that must carry out vaccinations, as well as of the volunteers themselves. The federal government, however, has not taken strong, effective leadership. As a result, the National Smallpox Vaccination program has failed and the nation remains vulnerable.

### **The National Smallpox Vaccination Program**

When announced on December 13, 2002, the Administration called for a three phase civilian vaccination plan to enhance homeland security, as well as the vaccination of a half-million military personnel.<sup>18</sup> Since 1999, Congress has appropriated \$560 million to purchase enough vaccine for every man, woman, and child in the United States. Phase 1 involved the use of this stockpile to vaccinate volunteers who would constitute trained public health and health care response teams within every state. These teams would be responsible for responding to a possible outbreak, treating victims, and vaccinating others to keep the virus from spreading.<sup>19</sup> CDC indicated the benchmark for measuring the state of preparedness would include the ability to vaccinate the entire state population within 10 days.<sup>20</sup> Plans submitted to CDC by state and local jurisdictions indicated about

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(c) J. Lane, F. Ruben, E. Abrutyn, J. Millar, "Deaths Attributable to Smallpox Vaccination, 1959 to 1966, and 1968," *Journal of the American Medical Association*, 212, (1970): 441-444.

<sup>17</sup> *Protecting America: Smallpox Vaccination Program*, December 13, 2002, [<http://www.whitehouse.gov/news/releases/2002/12/20021213-1.html>].

<sup>19</sup> Congressional Research Service, *Smallpox Vaccine Stockpile and Vaccination Policy*, RL31694, January 9, 2003, by Judith A. Johnson.

<sup>20</sup> Ceci Connolly, "Bush Smallpox Inoculation Plan Near Standstill," *Washington Post*, February 23, 2003, A6.



500,000 people would be vaccinated in this phase.<sup>21</sup> CDC intended for these teams to be ready within 30 days after the program’s start. After this effort, Phase 2 of the plan envisioned the vaccination of up to 10 million additional health workers and traditional first responders (fire, police, emergency medical personnel) over a one year period. These groups would provide essential services during a large scale outbreak. Finally, the Administration announced its intention to offer the smallpox vaccine to the general public on a restricted basis.<sup>22</sup>

**One Year Later: A Program in Disarray, a Nation Left Vulnerable**

While the military vaccination program was completed successfully in October, with well over 500,000 personnel vaccinated,<sup>23</sup> data collected by the CDC, the Association of State and Territorial Health Officials (ASTHO), and the Democratic Staff of the Select Committee on Homeland Security show the civilian program has fared much more poorly.

**Table 1. The Original Goals and Progress To-Date of the National Smallpox Immunization Program**

	Date Initiated	Date Completed	Expected Number of Vaccinations	Number Vaccinated To-Date
Military	December 12, 2002	October 19, 2003	500,000	517,958
Civilian Phase 1	January 24, 2003	ongoing	500,000	39,213
Phase 2	?	ongoing	10 million	?
Phase 3	not started	-	?	0

The most obvious evidence of serious problems with the vaccination program is the large disparity between the planned number of vaccinees in Phase 1 of the program and the actual number vaccinated to date. The Administration announced that its target of 500,000 would be achieved in only 30 days. One year later, just over 39,000 have actually been vaccinated.<sup>24</sup>

A state-by-state analysis further highlights this deficit and shows just how far from their original goals each jurisdiction remains (Table 2). Only four states, New Hampshire, Alaska, Arkansas, and Georgia, have achieved even 50% of their projected vaccination numbers. In New York City, with a population of 8 million, only 342 people have been vaccinated, about 2% of the targeted amount. Chicago is even worse off, with only 71 healthcare workers and first responders vaccinated and integrated into the city’s smallpox response plan. Clearly, the plans developed by most states and localities to respond to a

<sup>21</sup> U.S. General Accounting Office, *Smallpox Vaccination: Implementation of National Program Faces Challenges*, GAO-03-578, (Washington, D.C: GPO, April 2003).

<sup>22</sup> Jay Cohen and Martin Enserink, “Rough-and-Tumble Behind Bush’s Smallpox Policy,” *Science*, 298, (December 20, 2002): 2312.

<sup>23</sup> U.S. General Accounting Office, *Military Smallpox Vaccination Program*, GAO-04-215R, December 1, 2003.

<sup>24</sup> Centers for Disease Control and Prevention, *Smallpox Vaccination Program Status by State*, December 31, 2003, [<http://www.cdc.gov/od/oc/media/spvaccin.htm>].

**Table 2. Smallpox Vaccinations Planned and Completed by State or City**

State	Population (2000 Census)	Planned Number of Vaccinees, December 2002 <sup>1</sup>	Actual Number Vaccinated, December 2003 <sup>2</sup>
Alabama	4,447,100	12000	503
Alaska	626,932	175	96
Arizona	5,130,632	7700	39
Arkansas	2,673,400	1700	1138
California (excluding Los Angeles)	30,176,906	40000	1611
Colorado	4,301,261	1126	224
Connecticut	3,405,565	6300	697
Delaware	783,600	750	109
D.C.	572,059	3000-5000	105
Florida	15,982,378	33000	3981
Georgia	8,186,453	300-500	175
Hawaii	1,211,537	3500	181
Idaho	1,293,953	3000	200
Illinois (excluding Chicago)	9,523,277	8000-16000	305
Indiana	6,080,485	2900	765
Iowa	2,926,324	1000	492
Kansas	2,688,418	4400	448
Kentucky	4,041,769	5000-10000	840
Louisiana	4,468,976	15000-20000	1107
Maine	1,274,923	3000	63
Maryland	5,296,486	5500	752
Massachusetts	6,349,097	10000	156
Michigan	9,938,444	5000-7000	925
Minnesota	4,919,479	5000-10000	1476
Mississippi	2,844,658	5600	403
Missouri	5,595,211	6000-8000	1253
Montana	902,195	3300	144
Nebraska	1,711,263	4000	1470
Nevada	1,998,257	1400	17
New Hampshire	1,235,786	200	331
New Jersey	8,414,350	15000	671
New Mexico	1,819,046	12000	233
New York (excluding NYC)	10,968,179	16000	788
North Carolina	8,049,313	7500	1305
North Dakota	642,200	2000	415
Ohio	11,353,140	5000-13000	1921
Oklahoma	3,450,654	13000	376
Oregon	3,421,399	700	115
Pennsylvania	12,281,054	22500	288
Rhode Island	1,048,319	1200	36
South Carolina	4,012,012	7800	890
South Dakota	754,844	4300	737
Tennessee	5,689,283	5900	2429

State	Population (2000 Census)	Planned Number of Vaccinees, December 2002 <sup>1</sup>	Actual Number Vaccinated, December 2003 <sup>2</sup>
Texas	20,851,820	40000	4563
Utah	2,233,169	3000-5000	288
Vermont	608,827	2000	130
Virginia	7,078,515	12765	876
Washington	5,894,121	7000	554
West Virginia	1,808,344	2500	734
Wisconsin	5,363,675	4700	759
Wyoming	493,782	1000	414

#### Metropolitan Areas

Chicago	2,896,016	4000	71
Los Angeles	3,694,742	9200	243
New York City	8,008,278	15000	342

#### Notes:

1. State plans submitted to and approved by CDC, see Appendix for sources.
2. CDC, *Smallpox Vaccination Program Status by State*, December 31, 2003 (<http://www.cdc.gov/od/oc/media/spvaccin.htm>).

smallpox attack are not viable today. Nevada, known to contain high-value terrorist targets such as Las Vegas and Hoover Dam, has only 17 personnel vaccinated.<sup>25</sup> Overall, those that have been vaccinated are spread unevenly throughout the country, raising doubts about the ability of local, state, or federal health officials to mount an effective response to an outbreak in many areas.

An analysis of vaccinated individuals per capita (Figure 1) further suggests that the smallpox preparedness and the capability to respond to an attack varies widely across the nation. For example, Florida and Pennsylvania have similar sizes and populations, but Florida has ten times more healthcare workers and first responders vaccinated. Assuming that, in the event of an outbreak, the speed of vaccination of the general public will depend on the number of pre-vaccinated healthcare workers, several states appear poorly prepared.<sup>26</sup> Other states with few vaccinees, such as California, New York, Nevada, and Massachusetts, contain likely terrorist targets including major tourist destinations, national and cultural assets, and prominent critical infrastructure.

State officials themselves report a widespread lack of preparedness. Survey results from ASTHO indicate that 28 states have not completed Phase 1 of the vaccination program, and need further volunteers to achieve the first stage of preparedness under the Administration's plan (Figure 2). Moreover, in an "anonymous" survey question, where states would not be identified, state health officials reported that 40 percent of states cannot effectively vaccinate their population within 10 days of a smallpox outbreak, a key benchmark set by the CDC.

<sup>25</sup> (a) Tony Laci, "Source Gave U.S. Details of New Plot," *USA Today*, January 12, 2004, A1; (b) J. M. Kalil, "Terror Investigations Not New to Las Vegas," *Las Vegas Review-Journal*, January 1, 2004, 6A.

<sup>26</sup> Edward H. Kaplan and others, "Emergency Response to a Smallpox Attack: The Case for Mass Vaccination," *Proceedings of the National Academy of Sciences*, 99, no. 16 (2002): 10935-10940.

Figure 1. Number of Vaccinated Workers Per Capita

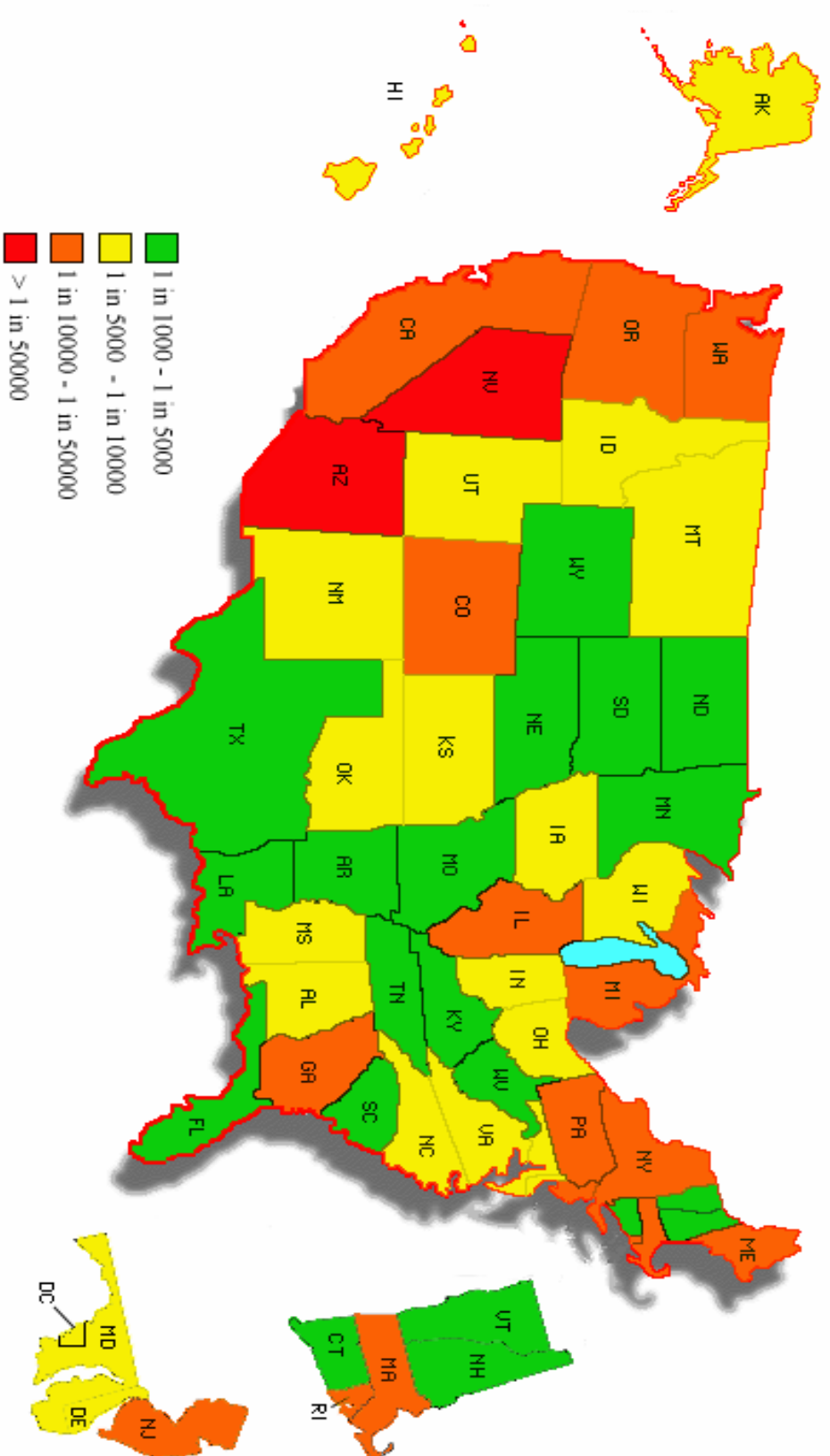
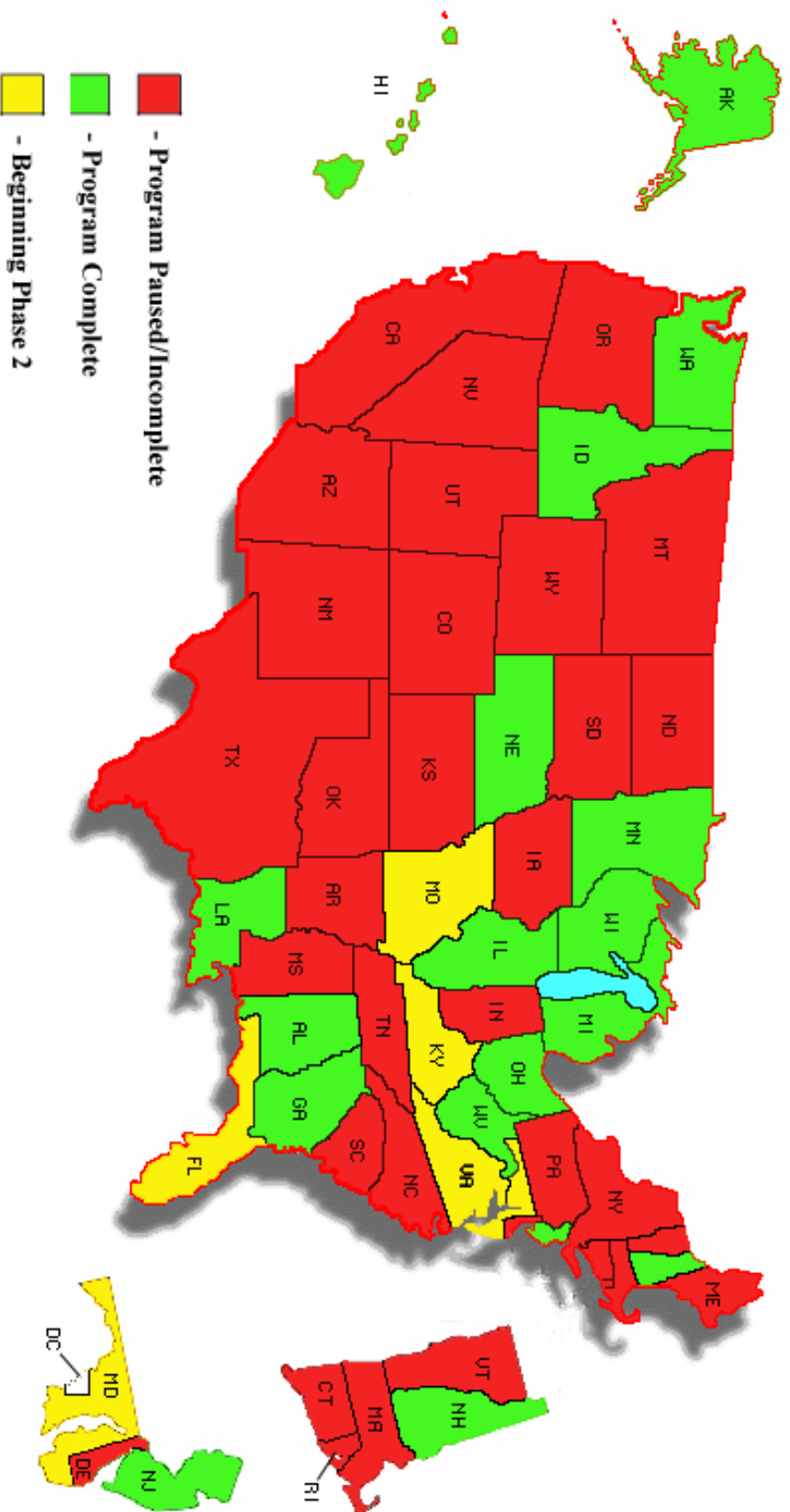
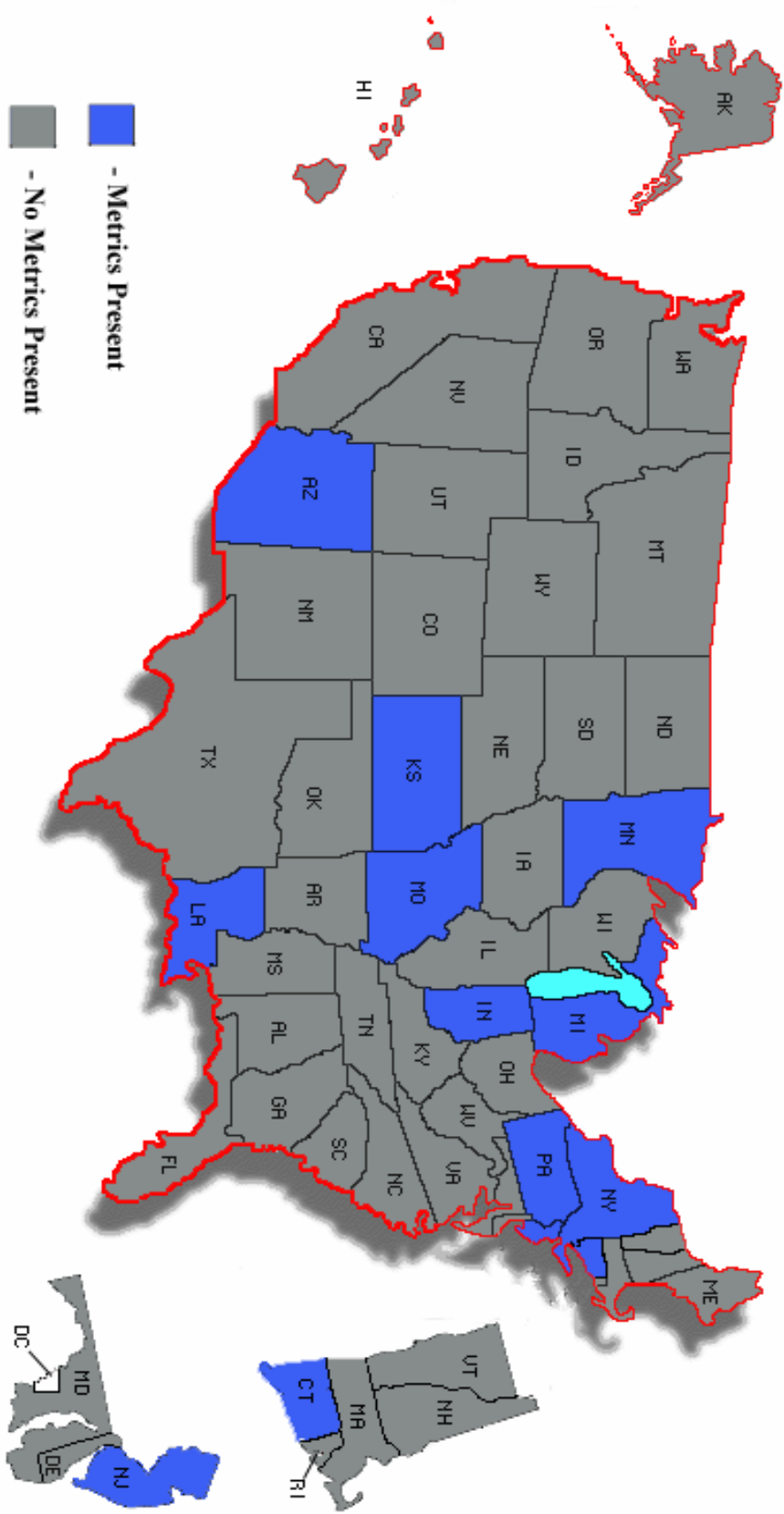


Figure 2. Status of National Smallpox Vaccination Program By State



Source: Association of State and Territorial Health Officials, October 2003 Survey

Figure 3. Ability to Measure Smallpox Preparedness



Source: Association of State and Territorial Health Officials, October 2003 Survey

The preparedness of those states with “completed” programs should also be questioned, as 12 of these states are among the 39 that report being unable to measure their preparedness for smallpox (Figure 3).<sup>27</sup> In fact, the Institute of Medicine has pointed out that states lack even a minimum standard for smallpox preparedness.<sup>28</sup> Reports indicate that the state and local level capabilities required for a smallpox response are weak. A recent assessment by the nonpartisan group *Trust for America’s Health* found that only two states have enough workers to distribute vaccines and other medicines from the Strategic National Stockpile, a key step in response to a smallpox attack.<sup>29</sup> The 2003 TOPOFF 2 exercise, which included a simulated bioterrorist attack in Illinois, demonstrated the “enormous logistical challenge of distributing medication to a large metropolitan area” and highlighted the continuing lack of surge capacity in hospitals, including staff shortages.<sup>30</sup> These problems would be aggravated in the event of a smallpox outbreak, where the disease is contagious, post-exposure pharmaceutical prophylaxis and treatments are unproven, and post-exposure vaccination may not prevent further spread.<sup>31</sup>

These state-by-state analyses demonstrate that the status of the program, the ability to measure preparedness, and actual preparedness and ability to respond to smallpox is inadequate in most of the nation. The evidence suggests that the 39,000 who are vaccinated are not appropriately distributed across states to be effectively deployed for a response, and that they are, in most cases, not integrated into a clear local, state, or federal smallpox preparedness plan.

According to some experts, this situation leaves the nation vulnerable to a smallpox attack. Michael T. Osterholm, director of the University of Minnesota’s Center for Infectious Disease Research and Policy and a leading bioterrorism expert, believes “we are still unprepared to respond to even two cases of smallpox anywhere in the world.”<sup>32</sup> Tara O’ Toole, director of the University of Pittsburgh’s Center for Biosecurity, has pointed out that too few healthcare workers are vaccinated and that preparedness has advanced “some small increment,” but “essentially our readiness has not improved since 2001.”<sup>33</sup> With the current state of readiness, vaccinating the public in the event of a smallpox attack could take months, instead of days, and endanger thousands of lives.

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<sup>27</sup> Association of State and Territorial Health Officials, *Results of the October 2003 Smallpox Status Survey* [<http://www.astho.org/pubs/StateSmallpoxVaccinationProgramStatusOctober152003.pdf>].

<sup>28</sup> Committee on Smallpox Vaccination Program Implementation, Institute of Medicine, *Review of the Centers for Disease Control and Prevention’s Smallpox Vaccination Program Implementation, Letter Report #4*, August 12, 2003.

<sup>29</sup> Trust for America’s Health, *Ready or Not: Protecting the Public’s Health in the Age of Bioterrorism*, December 2003, [<http://healthyamericans.org/state/bioterror/>].

<sup>30</sup> Department of Homeland Security, *Top Officials Exercise Series: TOPOFF 2-After Action Summary Report for Public Release*, December 19, 2003, [[http://www.dhs.gov/interweb/assetlibrary/T2\\_Report\\_Final\\_Public.doc](http://www.dhs.gov/interweb/assetlibrary/T2_Report_Final_Public.doc)].

<sup>31</sup> Michael S. Bronze and Ronald A. Greenfield, “Preventive and Therapeutic Approaches to Viral Agents of Bioterrorism,” *Drug Discovery Today*, 8, no. 16 (August 2003): 740.

<sup>32</sup> Ceci Connolly, “Bioterror Preparedness Still Lacking, Health Group Concludes,” *The Washington Post*, December 12, 2003, A2.

<sup>33</sup> Jonathan Rauch, “Smallpox is Bush’s Worst Failure,” *National Journal*, November 17, 2003.

## **Reasons for the Failure of the National Smallpox Vaccination Program**

The Administration has been unable to restart a program that has been stalled since May of 2003, leaving a conspicuous gap in our biodefenses. There has been no attempt by the Administration to change this situation, and no indication of a strategy or intention of sufficient magnitude to do so. Instead, the program appears to be an embarrassing failure of government, with serious implications for homeland security. One year after the program's initiation, it is now an appropriate time to reflect on the three central reasons why the program has not achieved its goals.

### *Reason 1: An Unfunded Federal Mandate*

The Administration failed to recognize that smallpox vaccinations would be a serious strain on state and local healthcare resources, and sent an unfunded federal mandate to state and local public health agencies and hospitals. Federal officials originally estimated that the cost of vaccine Administration would be \$13 per vaccine.<sup>34</sup> However, this appears to be a substantial underestimation, given certain basic factors. The smallpox vaccine is unfamiliar to most healthcare workers and carries a risk of serious adverse effects. This requires an extensive pre-vaccination planning, training, education, and consultation to eliminate those at highest risk from the vaccine. In some cases, confirmation of these conditions can require costly testing. Post-vaccination follow-up is also necessary to assure successful immunization and to prevent secondary transmission. According to one study, the average cost of the program at the local level would be about \$204 per vaccinee,<sup>35</sup> with some states estimating costs as high of \$400.<sup>36</sup> Thus, the costs for 500,000 vaccinations under Phase 1 of the program could be \$100-\$800 million, with Phase 2 potentially reaching well into the billions of dollars.

After initiating the program, no funding was provided to accommodate these costs. Instead the Administration expected states to pay with federal bioterrorism preparedness funding. However, this funding, totaling about \$1 billion in FY 2002, was never intended by Congress for smallpox vaccinations. Congress approved these funds to improve the surveillance, laboratory and surge capacity, communication capabilities, and other infrastructure necessary for public health and hospital emergency preparedness across the United States. By the time vaccinations were to begin, many health agencies had already obligated this funding for other preparedness or public health purposes.<sup>37</sup>

Without sufficient funds, states, localities, and hospitals were forced to put other important programs for bioterrorism preparedness, as well as their routine public health operations on hold in order to implement the smallpox vaccination program.<sup>38</sup> During 2003, many health departments were stretched to the limit with nationwide surveillance

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<sup>34</sup> Julie Gerberding, Director of the Centers for Disease Control and Prevention, Testimony before the Senate Committee on Health, Education, Labor and Pensions, January 30, 2003.

<sup>35</sup> National Association of County and City Health Officials, "Costs of Smallpox Vaccination Program: Summary of Preliminary Data," *Research Brief*, March 2003, Number 10.

<sup>36</sup> Jane Colacecchi for the Iowa Department of Public Health, Testimony before the Senate Appropriations Committee, Subcommittee on Labor, HHS and Education, January 28, 2003.

<sup>37</sup> Patrick Libbey for the National Association of County and City Health Officials, Testimony before the Senate Appropriations Committee, Subcommittee on Labor, HHS and Education, January 28, 2003.

<sup>38</sup> Donald McNeil. "Many Balking at Vaccination for Smallpox," *New York Times*, February 7, 2003.



efforts for SARS and other emergencies, such as syphilis outbreaks in Boston, Miami, and San Francisco, and the worst tuberculosis rates in Seattle in 30 years. The outcome of this severe miscalculation was predictable: bioterrorism and normal public health programs were disrupted,<sup>39</sup> while the lack of funding contributed to inconsistent levels of smallpox vaccination around the country. Because the Administration failed to adequately budget for the vaccination program, Congress provided a supplemental \$100 million appropriation in April to fill the gap.<sup>40</sup> However, by the time HHS released the extra funds made available by Congress, the program had already lost its momentum.

*Reason 2: An Adequate Compensation Plan Was Not Provided*

The provision of adequate compensation to those volunteers suffering side effects from vaccination is a critical element to a successful smallpox preparedness program. A strong compensation program sends a message to volunteers that their participation and willingness to accept a small risk of serious injury for the public good is appreciated and necessary for homeland security. It also affects the personal calculation of risk that each health care worker makes when deciding whether to volunteer. Even with adequate screening, serious adverse reactions to the vaccine can and do occur. Although fears that some fatal heart attacks were caused by the vaccine now appear unfounded,<sup>41</sup> 49 serious reactions have been reported to CDC, the predicted rate of about 0.1 percent.<sup>42</sup> In addition to the rare side effects, more common reactions, including temporary fatigue, nausea, and other mild illnesses can cost a worker lost wages, injury time, or other benefits. Moreover, because of the nature of the vaccine, the vaccinated worker risks sickening others with whom he or she comes in contact (such as family members). All of these possible occurrences may be considered by a potential volunteer and lead to a refusal to be vaccinated. The availability of compensation is more likely to make volunteers willing to take these risks.

Unfortunately, the Administration did not properly manage the critical issue of compensation. While the 2002 Homeland Security Act provided liability protection to those manufacturing and administering the vaccine, no clear remedy existed at the time of the initiation of the campaign for those who were injured by the vaccine without negligence.<sup>43</sup> Instead, Administration officials expected individual workers' compensation plans to provide compensation.<sup>44</sup> But this assumption was not consistent with advice from public health officials, lawyers, and unions, all of whom pointed out that, with the highly variable coverage and quality of insurance plans, the

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<sup>39</sup> Patrick Libbey for the National Association of County and City Health Officials, Testimony before the Senate Appropriations Committee, Subcommittee on Labor, HHS and Education, January 28, 2003

<sup>40</sup> Public Law 108-11.

<sup>41</sup> Steve Mitchell, "Study: Smallpox Shots Not Linked to Deaths" *United Press International*, October 2, 2003.

<sup>42</sup> Centers for Disease Control and Prevention, *Smallpox Vaccination Adverse Events Report*, [<http://www.cdc.gov/od/oc/media/spadverse.htm>].

<sup>43</sup> Congressional Research Service, *Homeland Security Act of 2002: Tort Liability Provisions*, RL31649, July 22, 2003.

<sup>44</sup> Tommy Thompson, *HHS Teleconference on Smallpox Policy*, December 14, 2002 [<http://www.cdc.gov/od/oc/media/transcripts/t021214.htm>].

Administration's approach would be a recipe for confusion and rejection by potential volunteers and their employers.<sup>45</sup>

Again, Congress had to act to develop and pass a compensation plan, the Smallpox Emergency Personnel Protection Act of 2003.<sup>46</sup> By then, warnings of adverse reactions and reports of three deaths linked to the vaccine had already contributed to a growing reluctance among health workers to participate. By the time the Administration established a system to provide compensation eight months later,<sup>47</sup> the vaccination program was stalled.

### *Reason 3: A Failure to Communicate the Threat of Smallpox*

The Administration has failed to adequately inform the public of the dangers of smallpox and convince essential healthcare workers to participate in the vaccinations. The smallpox vaccination program is unlike any other civilian immunization plan ever attempted. Usually, vaccination campaigns require the weighing of the risk of adverse effects of vaccination against the risk of developing the targeted disease. But smallpox does not pose a naturally occurring danger. Instead, volunteers must weigh the risk of adverse effects against the potential of a smallpox bioterrorist attack.<sup>48</sup> Thus, clearly making the case for the need for smallpox preparedness and maintaining the trust of healthcare workers and first responders is essential to a successful smallpox vaccination campaign and, ultimately, all biodefense preparedness programs.

In announcing its plan, the Administration initially did a good job of making a strong case about the threat and the need for vaccination. The program was announced by President Bush with a national press conference and was soon followed by Bush's own inoculation with the vaccine. However, as the vaccination program slowed, the Administration began to ignore the campaign. CDC's last briefing updating progress in the program was held in March of 2003, and the last relevant press release was issued in June. Meanwhile, Administration officials have distanced themselves from the original vaccination figure of 500,000, indicating that the nation might need only 50,000 immunized health workers to be prepared<sup>49</sup> or that "it is not about should we have 40,000 people or 400,000 people, or 4 million people."<sup>50</sup> Federal agencies responsible for bioterrorism preparedness appear confused and lost. According to one CDC official

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<sup>45</sup> (a) National Association of City and County Health Officials, "National Public Health Associations Urge Legislative Action to Protect Smallpox Vaccine Volunteers," Press Release, March 7, 2003 [[www.naccho.org/press66.cfm](http://www.naccho.org/press66.cfm)], visited November 20, 2003; (b) Congressional Research Service, *Smallpox Vaccine Injury Compensation*, RL31960, June 13, 2003, by Susan Thaul; (c) AFL-CIO, *State and Federal Smallpox Compensation*, [<http://www.aflcio.org/yourjobeconomy/safety/smallpoxcomp.cfm>]; (d) Meg Fletcher, "Vaccine Raises Claim Issues," *Business Insurance*, Jan. 13, 2003, 1.

<sup>46</sup> Public Law 108-20.

<sup>47</sup> "Interim Final Rule: Smallpox Vaccine Injury Compensation Program: Smallpox Administrative Implementation," *Federal Register*, December 16, 2003, 68(241):70080-70106.

<sup>48</sup> W. Katherine Yih and others "Attitudes of Healthcare Workers in U.S. Hospitals Regarding Smallpox Vaccination," *BMC Public Health*, 3, (2003): 20-28.

<sup>49</sup> David McGlinchey, "CDC Says It Never Aimed for 500,000 Smallpox Vaccinations," *Global Security Newswire*, February 26, 2003.

<sup>50</sup> Julie Gerberding, "Update on Monkeypox and Severe Acute Respiratory Syndrome Investigation," *CDC Telebriefing Transcript*, June 19, 2003, [<http://www.cdc.gov/od/oc/media/transcripts/t030619.htm>].

quoted in the national press, “the fact is [the vaccination program] has ceased, not that anyone’s issued an edict to say stop.”<sup>51</sup> This report prompted the director of the CDC, Julie Gerberding, to demand that the program remains underway,<sup>52</sup> although she continues to deny that the Administration ever had specific vaccination targets.<sup>53</sup> At the same time, despite ample evidence to the contrary, Department of Homeland Security officials maintain that the vaccination program in its current state is sufficient to protect America against a disastrous smallpox outbreak.<sup>54</sup>

As a result of the Administration’s failures, healthcare workers and the public at large have become complacent about the smallpox threat and resistant to vaccination. CDC officials report that healthcare workers today are “skeptical about the smallpox threat,” contributing to their reluctance to participate, while the public at-large perceives smallpox preparation to be “near zero” and “not worth the risk.”<sup>55</sup> These attitudes stand in stark contrast to attitudes prevalent less than two years ago. A fall 2002 survey by Harvard researchers found the public strongly supporting limited vaccination (81%) and willing to volunteer for inoculations (69%),<sup>56</sup> while healthcare workers themselves also originally expressed a strong propensity to be vaccinated.<sup>57</sup>

According to the Departments of Defense, Homeland Security, and the CIA, al-Qaeda and other international terrorist groups remain active and interested in obtaining biological weapons,<sup>58</sup> and the Department of Health and Human Services recently declared that the threat conditions present last year continue to exist.<sup>59</sup> Yet the Administration’s efforts to protect us from the threat of terrorist use of smallpox have failed through poor management and absent leadership. Ultimately, this behavior undermines confidence in the U.S. government that is essential to achieve the cooperation

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<sup>51</sup> Anita Manning, “Smallpox Vaccination Plan Ceased,” *USA Today*, October 16, 2003, A1.

<sup>52</sup> Julie Gerberding, “Smallpox Vaccination Program Continues,” *USA Today*, October 23, 2003, A14.

<sup>53</sup> David McGlinchey, “CDC Director Denies Existence of Smallpox Immunization Program,” *Global Security Newswire*, November 19, 2003.

<sup>54</sup> Anita Manning, “Smallpox Vaccination Plan Ceased,” *USA Today*, October 16, 2003, A1.

<sup>55</sup> Joseph A. Henderson, *Update on Smallpox Readiness*, Presentation before the Secretary’s Council on Public Health Preparedness, Department of Health and Human Services, Washington, D.C., January 22, 2004.

<sup>56</sup> Robert J. Blendon and others, “The Public and the Smallpox Threat,” *New England Journal of Medicine*, 348, no. 5 (2003): 426-432.

<sup>57</sup> (a) W. Katherine Yih and others “Attitudes of Healthcare Workers in U.S. Hospitals Regarding Smallpox Vaccination,” *BMC Public Health*, 3, (2003): 20-28; (b) Worth W. Everett and others, “Smallpox Vaccination: A National Survey of Emergency Health Care Providers,” *Academic Emergency Medicine*, 10, no. 6, (2003): 606-611; (c) National Network for Immunization Information, “Nurses Perceptions and Intentions Regarding Smallpox Vaccine: A National Survey,” January 23, 2003, [<http://www.immunizationinfo.org/features/index.cfm?ID=51>].

<sup>58</sup> (a) Central Intelligence Agency, *Terrorist CBRN: Materials and Effects*, [[http://www.cia.gov/cia/reports/terrorist\\_cbrn/terrorist\\_CBRN.htm](http://www.cia.gov/cia/reports/terrorist_cbrn/terrorist_CBRN.htm)], visited January 22, 2004; (b) Department of Homeland Security, “Maintaining Awareness Regarding Al-Qaeda’s Potential Threats to Homeland,” *Press Release*, September 4, 2003, [<http://www.dhs.gov/dhspublic/display?content=1442>]; (c) Matt Kelley, “Pentagon: Al Qaeda Pursuing Bioweapons,” *Associated Press*, May 23, 2003.

<sup>59</sup> Tommy Thompson, *Amendment to Extend 2003 Declaration on Administration of Smallpox Countermeasures*, January 21, 2004, [<http://www.bt.cdc.gov/agent/smallpox/vaccination/pdf/012403-declaration-extension.pdf>].

of those we need to protect us. It breeds cynicism, skepticism, and complacency among volunteers, all healthcare workers, and the public, leaving some to conclude that the government is not serious about smallpox preparedness. It is a path that threatens the entire biodefense effort.

### **Achieving Smallpox Preparedness: An Imperative for Homeland Security**

As long as smallpox bioterrorism poses a threat, complacency and lack of preparedness is dangerous. As a result of a poorly conceived, inadequately supported, and neglected National Smallpox Vaccination Program, we may remain highly vulnerable to smallpox attack. But we have also damaged the success of this and other preparedness programs that involve broad civilian participation. Unfortunately, a serious loss of public confidence is not easily overcome. Nevertheless, it is essential that steps be taken to improve our preparedness and restore credibility as soon as possible. The Administration must immediately:

1. Reaffirm or, if intelligence has changed since December 2002, modify the threat assessment of smallpox.
2. If it is determined that a bioterror attack with smallpox remains a serious threat, the following steps should be taken:
  - a. Integrate the national smallpox vaccination program into a larger smallpox preparedness program. Develop indicators of smallpox preparedness and provide guidance to states and localities to help them assess their current readiness and further needs. These steps, recommended by the Institute of Medicine's Committee on Smallpox Vaccination Program Implementation, should have been in place before the vaccination program was implemented.<sup>60</sup> It cannot continue without them.
  - b. Based on an assessment of each state's current smallpox readiness, reassess the need for further pre-event vaccinations of public health, healthcare workers, and first responders.
  - c. If warranted by the assessments, renew public communication efforts from the highest levels of government to promote the participation of public health, healthcare workers, and first responders in smallpox vaccination. Specifically, the President, the Secretary of Homeland Security, and the Secretary of Health and Human Services should:
    1. Communicate the seriousness of the smallpox threat;
    2. Communicate the existence and benefits of the Smallpox Vaccine Injury Compensation Program;

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<sup>60</sup> Committee on Smallpox Vaccination Program Implementation, Institute of Medicine, *Review of the Centers for Disease Control and Prevention's Smallpox Vaccination Program Implementation*, Letter Report #5, December 19, 2003.

3. Make a clear, direct appeal to healthcare workers and first responders to participate in their state or city-based smallpox preparedness program.
  - d. Provide adequate funds to cover state and local costs for the implementation of the vaccination program without harming other critical public health functions. A congressional budget request should be submitted that reflects the actual cost of vaccine administration to achieve a reasonable level of smallpox preparedness that is based on meaningful and viable indicators, assessments, and plans.
  - e. Integrate the smallpox preparedness program into a broader national preparedness strategy for response to bioterrorism and other public health emergencies.

**The Democratic Plan: Making America Safer, Maintaining the Confidence of Americans**

Effective homeland security will require a strong cooperative effort between the federal government, local and state government, private industry, and the public. But it also requires leadership, including a vision of national preparedness and a strategy for achieving it. In this endeavor, leadership supports the crucial bonds of trust among those essential to our fight against bioterrorism, including all levels of government, the private sector, tens of thousands of individual first responders and healthcare workers, and the public.

The lessons learned from the failure of the National Smallpox Vaccination Program must not be ignored. Strong, consistent leadership and the public's credibility and confidence in government is essential to protect the health of the American people from the devastating effects of a bioterrorism attack. In moving forward in homeland security, well planned and executed programs, based on goals and strong accountability, will be the key to both America's safety and respect.

## Appendix

### Sources for Planned Number of Vaccinees by State or City, Table 2

Alabama	Alabama Department of Public Health, "Voluntary Smallpox Immunizations to Be Provided," Press Release-December 13, 2002, <a href="http://www.adph.org/NEWSRELEASES/default.asp?TemplateNbr=0&amp;DeptID=107&amp;TemplateId=1868">http://www.adph.org/NEWSRELEASES/default.asp?TemplateNbr=0&amp;DeptID=107&amp;TemplateId=1868</a> .
Alaska	"Civilians to Receive Smallpox Vaccinations," <i>Associated Press State and Local Wire</i> , January 25, 2003.
Arizona	Arizona Department of Health Services, "Arizona Submits Smallpox Vaccination Plan," Press Release-December 10, 2002, <a href="http://www.hs.state.az.us/news/2002-phs/smallpox_vac_plan.htm">http://www.hs.state.az.us/news/2002-phs/smallpox_vac_plan.htm</a> .
Arkansas	Arkansas Department of Health, "Arkansas Begins Vaccination of Public Health Smallpox Response Team Members," Press Release-February 19, 2003, <a href="http://www.healtharkansas.com/news/pr_smallpox_021902.html">http://www.healtharkansas.com/news/pr_smallpox_021902.html</a> .
California	Office of the Governor, "Governor Submits Plan to Guard Against Terrorist Smallpox Outbreak," Press Release-December 10, 2002.
Colorado	Colorado Department of Public Health and the Environment, "Shipment of 1800 Doses of Smallpox Vaccine Arrives in Colorado," Press Release-January 28, 2003, <a href="http://www.cdph.state.co.us/release/2003/012803.html">http://www.cdph.state.co.us/release/2003/012803.html</a> .
Connecticut	Connecticut Department of Public Health, <i>Smallpox Stage 1 Vaccination for Core Hospital Medical Care Teams</i> , December 4, 2002, <a href="http://www.dph.state.ct.us/BT/STAGE1VACCINATIONFORHOSPITALS.PPT">http://www.dph.state.ct.us/BT/STAGE1VACCINATIONFORHOSPITALS.PPT</a> .
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D.C.	District of Columbia Department of Health, "DOH Releases Plan to Vaccinate against Smallpox," Press Release-December 18, 2002, <a href="http://dchealth.dc.gov/news_room/release.asp?id=128&amp;mon=200212">http://dchealth.dc.gov/news_room/release.asp?id=128&amp;mon=200212</a> .
Florida	Florida Department of Health, "Florida Receives Smallpox Vaccine," Press Release-February 4, 2003, <a href="http://www.doh.state.fl.us/Communications/office/pressreleases/2003/02.04.03SmallpoxVaccineReceipt.pdf">http://www.doh.state.fl.us/Communications/office/pressreleases/2003/02.04.03SmallpoxVaccineReceipt.pdf</a> .
Georgia	M.A.J. McKenna, "Georgia to Limit Vaccine_Smallpox Shots Would Go to a Small Pool of Emergency Health Workers," <i>Atlanta Journal-Constitution</i> , December 4, 2002, A1.
Hawaii	Hawaii Department of Health, "Department of Health Plan for Immunizing Hawaii Smallpox Response Teams," Press Release-December 11, 2003, <a href="http://www.state.hi.us/health/about/press/2002/02-76imm.html">http://www.state.hi.us/health/about/press/2002/02-76imm.html</a> .
Idaho	Idaho Department of Health and Welfare, "Vaccine On Its Way for Idaho's Smallpox Response Teams," Press Release-February 11, 2003, <a href="http://www2.state.id.us/dhw/news/2003/02_11_smallpox.htm">http://www2.state.id.us/dhw/news/2003/02_11_smallpox.htm</a> .
Illinois	Illinois Department of Public Health, "Smallpox Vaccination Plan Formulated," Press Release-December 9, 2002, <a href="http://www.idph.state.il.us/public/press02/smallpox.htm">http://www.idph.state.il.us/public/press02/smallpox.htm</a> .
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Iowa	David Pitt, "State Health Officials Develop Smallpox Vaccination Plan," <i>Associated Press State and Local Wire</i> , January 8, 2003.
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Louisiana	Louisiana Department of Health and Hospitals, "Louisiana to Vaccinate for Smallpox," Press Release-December 18, 2002, <a href="http://www.dhh.state.la.us/NEWS/Spoxvaccine.htm">http://www.dhh.state.la.us/NEWS/Spoxvaccine.htm</a> .
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Mississippi	Matt Volz, "Health Department Plans to Vaccinate 5,600 Against Smallpox," <i>Associated Press State and Local Wire</i> , December 16, 2002.

Missouri	Missouri Department of Health and Senior Services, "Missouri Submits Plan to Provide Smallpox Vaccinations to Medical and Public Health Response Teams," Press Release-December 11, 2002, <a href="http://www.health.state.mo.us/NewsReleases/smallpox1216.htm">http://www.health.state.mo.us/NewsReleases/smallpox1216.htm</a> .
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