# The Pitfalls of Bioterrorism Preparedness: the Anthrax and Smallpox Experiences

Bioterrorism preparedness programs have contributed to death, illness, and waste of public health resources without evidence of benefit. Several deaths and many serious illnesses have resulted from the smallpox vaccination program; yet there is no clear evidence that a threat of smallpox exposure ever existed. The anthrax spores released in 2001 have been linked to secret US military laboratories—the resultant illnesses and deaths might not have occurred if those laboratories were not in operation.

The present expansion of bioterrorism preparedness programs will continue to squander health resources, increase the dangers of accidental or purposeful release of dangerous pathogens, and further undermine efforts to enforce international treaties to ban biological and chemical weapons. The public health community should acknowledge the substantial harm that bioterrorism preparedness has already caused and develop mechanisms to increase our public health resources and to allocate them to address the world's real health needs. (Am J Public Health. 2004;94:1667-1671)

Hillel W. Cohen, DrPH, MPH, Robert M. Gould, MD, and Victor W. Sidel, MD

#### RECENT BIOTERRORISM

preparedness programs that illustrate irrational and dysfunctional responses to inadequately characterized risks should be of urgent concern to all members of the public health community. Since anthrax spores were released in the US mail system in 2001 and caused 5 fatalities and widespread panic, the spores have been linked to a US military research program, suggesting that the release might not have occurred had the anthrax program never existed. The smallpox vaccination program has also been linked to fatalities and other serious adverse events, although evidence of risk of exposure to smallpox has been minimal. Indeed, the smallpox vaccination campaign may have been motivated by a political rather than health agenda. Continuing bioterrorism preparedness programs are similarly characterized by failure to apply reasonable priorities in the context of public health and failure to fully weigh the risks against the purported benefits of these programs. Such programs may cause substantial harm to the public health if allowed to

Efforts by the United States to prepare for the use of biological agents in war based on flawed evaluations of risks have had serious health consequences for military personnel and have led to significant weakening of international agreements against the use of biological agents. Massive campaigns focusing on "bioterrorism preparedness" have had adverse health consequences and have resulted in the diversion of essential public health personnel, facilities, and other resources from urgent, real public health needs. Preparedness proponents argued that allocating major resources to what were admittedly low-probability events would not represent wastefulness and would instead heighten public awareness and promote "dual use" funding that would serve other public health needs.<sup>2</sup> Public health resources are woefully inadequate, and the notion that bioterrorism funding would bolster public health capability seemed plausible to many, even though we and others have argued that the "dual use" rationale is illusory.3,4 An evaluation of recent experience concerning anthrax and smallpox can help illuminate these issues.

# **ANTHRAX**

Despite extensive work on the possible weaponization of anthrax, there has been no example of effective use of anthrax as a weapon of indiscriminant mass destruction. In 2001, shortly after the events of September 11, weapons-grade anthrax spores were mailed to several addressees, but none of the intended targets were injured. Of 11 people who developed inhalation anthrax, 5 died. Of the 12 who had cutaneous infections, all recovered after administration of

antibiotics.<sup>5</sup> Thousands of people in potentially exposed areas such as postal sorting centers were advised to use antibiotics prophylactically. Millions of people were terrified, and many thousands in areas where there was no possible risk of exposure also took antibiotics. Congress was closed for days, mail service was disrupted for months, and state and county public health laboratories were inundated with white powder samples that ranged from explicit anthrax hoaxes to spilled powdered sweeteners.

Despite early speculation linking the anthrax release to "foreign terrorists," evidence led investigators to suspect an individual who had been working in a US military facility that may have been in violation of the Biologic and Toxin Weapons Convention.<sup>6,7</sup> Whether or not that specific individual was involved, it appears likely that the perpetrator or perpetrators were associated in some way with a US military program, that the motive for the extremely limited release was political, and that, without the existence of a US military laboratory, the material for the release would not have been available.

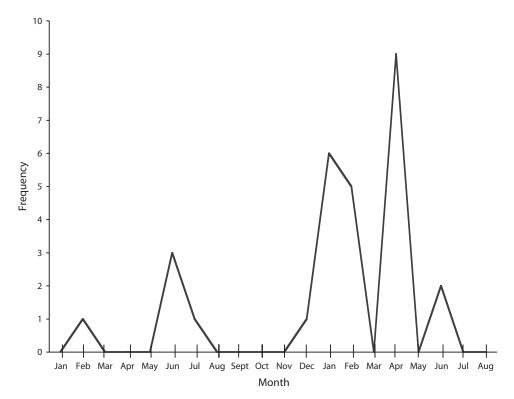
This experience supports the view that, as a consequence of the inherent difficulties in obtaining and handling such material, mass purposeful infection is highly improbable and the likely impact on morbidity and mortality limited. <sup>1.8</sup> However, the nature of US "biodefense" programs

may modify this prognosis; such programs may result in dangerous materials being more readily available, thus undermining the Biologic and Toxin Weapons Convention.9-11 Despite an absence of evidence of anthrax weapon stocks posing a threat to US military personnel, and despite problematic experiences of the military anthrax vaccination program, the US government announced plans to spend as much as \$1.4 billion for millions of doses of an experimental anthrax vaccine that has not been proven safe or effective and the need for which has not been opened to public debate. 12

## **SMALLPOX**

The 2002-2003 campaign to promote smallpox as an imminent danger coincided with the Bush administration's preparations for war on Iraq and the now discredited claims that Iraq had amassed weapons of mass destruction and could launch a biological or chemical attack in "as little as 45 minutes." 13,14 A media campaign describing the dangers of smallpox coincided with the buildup for the war (Figure 1). An unprecedented campaign advocating "preevent" mass smallpox vaccinations, to be carried out in 2 phases-involving half a million members of the armed forces and half a million health workers in phase 1 and as many as 10 million emergency responders in phase 2-was announced in December 2002.15

Before then, the debate on smallpox had been whether the stocks of stored stand-by vaccine were adequate or whether they should be increased. The World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC), and virtually



Note. Monthly tallies were derived from a search of the White House Web site (at: http://www.whitehouse.gov). All documents labeled "News Releases" that included the word "smallpox" were counted.

FIGURE 1—Numbers of White House news releases per month mentioning smallpox from January 1, 2002, through August 31, 2003.

every public health official took the position that the vaccine involved too many adverse events-was too dangerous-to warrant mass vaccination when no case of smallpox existed or had existed for more than 20 years.16 When the Bush administration announced support for mass vaccinations, WHO did not change its position, but the CDC and other US public health officials and organizations, including the American Public Health Association (APHA), decided to acquiesce.17

The coincidence of the Bush war calendar and the smallpox vaccination calendar, while not conclusive, is nonetheless consistent with an inference that the war agenda was the driving force behind the smallpox vaccination campaign. Since the invasion, evidence has emerged that allegations regarding Iraqi weapons of mass destruction were deliberate exaggerations or lies. <sup>18</sup> The evidence is highly suggestive that the smallpox vaccination program was launched primarily for public relations rather than public health reasons.

The vaccination campaign did not proceed as planned. Opposition arose on both safety and political grounds, <sup>19,20</sup> and most front-line health professionals simply did not volunteer to participate. Of the 500 000 health professionals who were targeted for inoculations in phase 1, fewer than 8% participated. <sup>21</sup> Despite efforts to avoid vaccination of

those who might be at elevated risk, the CDC reported that there were 145 serious adverse events (resulting in hospitalization, permanent disability, life-threatening illness, or death) associated with smallpox vaccinations among civilians.<sup>21</sup> Of these cases, at least 3 were deaths.

Three deaths resulting from thousands of inoculations would have been justifiable in preparation for a real threat of smallpox or in the midst of a smallpox outbreak, when vaccination could have saved many more lives. However, in the absence of any smallpox cases worldwide or any scientific basis for expecting an outbreak, these deaths and other serious adverse events are inexcusable. In August 2003, an Insti-

tute of Medicine committee that had been charged with reviewing the vaccination program came back to the position that had been generally accepted before 2002: that mass, preevent inoculations were unwarranted. According to the committee report:

In the absence of any current benefit to individual vaccinees and the remote prospect of benefit in the future (as such benefit would be realized only in the event of a smallpox outbreak, and the outbreak occurred in the vaccinee's region), the balance of benefit to the individual and risk to others (through contact with the vaccinee or through disruption of other public health initiatives) becomes unfavorable. . . . In the absence of other forms of benefit, therefore, offering vaccination to members of the general public is contrary to the basic precepts of public health ethics.22(p18-1

The report further cited "lingering confusion about the vaccination program's aims."22(p5-6) We find it difficult to comprehend how a program with confused aims and known serious risks can be viewed as having a positive risk-benefit ratio or how public health organizations could accept such a program without subjecting it to extensive critical examination and debate.

The smallpox vaccinations harmed others beyond those who suffered side effects. Considerable public health resources were used in the campaign. In a climate of state and local budget crises coinciding with the war and occupation, a downturn in employment, and a tax cut for the wealthy, public health services have been cut or are at serious risk. Funding for bioterrorism programs is not correcting the deficit, because such funds have been for the most part specifically earmarked for preparedness efforts and cannot be trans-

ferred to other public health programs. In general, federal increases in public health funding are much less extensive than state or local cuts.<sup>23</sup> During the height of the smallpox vaccination effort, a number of state health officials complained that important work, including tuberculosis screening and standard children's inoculations, had to be scaled back.<sup>24</sup> The siren song of dual use-that bioterrorism funding would strengthen public health infrastructure—has shown itself to be an empty promise, as preparedness priorities have weakened rather than strengthened public health.

### **BROADER PROBLEMS**

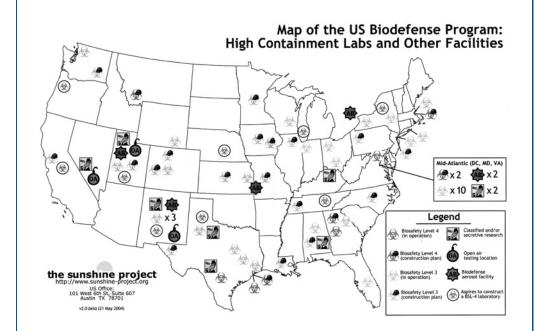
Even worse, bioterrorism "preparedness" programs now under way include the development of

a number of new secret research facilities that will store and handle dangerous materials<sup>25,26</sup> (Figure 2), thus increasing the risk of accidental release or purposeful diversion.<sup>27</sup> Reports of accidental leaks and improper disposal of hazardous wastes at the US Army facility at Fort Detrick serve as further warnings, 28,29 as do revelations of mishandling of biological agents at the Plum Island, New York, facility that studies potential bioweapons that affect animals.30

Most important, the proposed development of "biodefense" programs at sites, such as national nuclear weapons laboratories, that are traditionally secretive in their operations also provides an impetus for a potential global "biodefense race" that would likely spur proliferation of offensive biowarfare capabili-

ties.31,32 Accidents or purposeful diversions from these facilities seem at least as likely as terrorist events, and perhaps more so, since the deadly materials are already present. The Patriot Act has greatly expanded the cloak of secrecy that shields these facilities from public awareness and oversight.33

In short, bioterrorism preparedness programs have been a disaster for public health. Instead of leading to more resources for dealing with natural disease as had been promised, there are now fewer such resources. Worse, in response to bioterrorism preparedness, public health institutions and procedures are being reorganized along a military or police model that subverts the relationships between public health providers and the communities they serve.



Note. Facilities at biosafety levels 3 and 4 are authorized to handle dangerous biological materials. Level 4 facilities may handle the most deadly and contagious pathogens like smallpox and Ebola viruses.

Source. Reprinted with permission from the Sunshine Project (available at: http://www.sunshine-project.org).<sup>26</sup>

FIGURE 2-Map of proposed new and upgraded US biodefense laboratories (biosafety levels 3 and 4).

What can we do? Advocacy groups and local coalitions have emerged to oppose the widespread siting of potentially dangerous bioterrorism laboratories and have demanded that such facilities be open to the public. Labor unions that helped resist the smallpox vaccinations can be vigilant against further efforts to enlist health workers in poorly conceived and misguided campaigns that pose unnecessary risks to patients, workers, and communities.

Above all, it is imperative that public health organizations such as APHA take a fresh and critical look at the government's biopreparedness agenda and advocate for a comprehensive program that promotes global health security. Such a program would initiate appropriate and focused preparedness efforts *only* in the context of concerted and cooperative international steps designed to reduce the likelihood of infection from all sources. The modalities employed would range from strengthened treaties to provision of adequate clean water, food, shelter, education, and health care for all.34 Those of us working in public health can insist on a reevaluation of the entire bioterrorism preparedness agenda and demand a close examination of its goals and consequences before additional resources are invested in programs that so far seem to have done more harm than good.

In light of the *daily toll* of thousands of deaths from illnesses and accidents that could be prevented with even modest increases in public health resources here and around the world, we believe that the huge spending on bioterrorism preparedness programs constitutes a reversal of any reasonable sense

of priorities. While some still believe that bioterrorism preparedness programs will protect us from catastrophe, we agree with David M. Ozonoff, chairman emeritus of the Department of Environmental Health at the Boston University School of Public Health, that these programs represent "a catastrophe for American public health," <sup>24(pB1)</sup> and we hope it is not too late to change this dangerous direction.

War, poverty, environmental degradation, and misallocation of resources are the greatest root causes of worldwide mortality and morbidity, as well as ultimately being the underlying causes of terrorism itself. Bringing an awareness of this reality to the public is no easy task. However, one important step will be for the public health community to acknowledge the substantial harm that bioterrorism preparedness has already done and develop mechanisms both to increase our public health resources and to allocate them in a manner that will do the most good for all inhabitants of our increasingly fragile planet.

#### **About the Authors**

Hillel W. Cohen is with the Department of Epidemiology and Population Health, Albert Einstein College of Medicine, Bronx, NY. Robert M. Gould is with the Department of Pathology, Kaiser Hospital, San Jose, Calif. Victor W. Sidel is with the Montefiore Medical Center and Albert Einstein College of Medicine, Bronx, NY.

Requests for reprints should be sent to Hillel W. Cohen, MPH, DrPH, Department of Epidemiology and Population Health, Albert Einstein College of Medicine, 1300 Morris Park Ave, Bronx, NY 10461 (e-mail: hicohen@aecom.yu.edu).

This article was accepted May 25, 2004.

# **Contributors**

All authors contributed to the ideas for this article. H.W. Cohen led the writing.

# **Acknowledgments**

We wish to thank Susan M. Hailpern for assistance in assembling the data and graph for Figure 1. Thanks to the Sunshine Project (at: http://www.sunshine-project. org) for the map of US biodefense facilities shown in Figure 2.

# References

- 1. Cohen HW, Gould RM, Sidel VW. Bioterrorism initiatives: public health in reverse? *Am J Public Health*. 1999;89: 1629–1631.
- 2. Fraser MR, Brown DL. Bioterrorism preparedness and local public health agencies: building response capacity. *Public Health Rep.* 2000;115: 326–330.
- 3. Cohen HW, Gould RM, Sidel VW. Bioterrorism preparedness: dual use or poor excuse? *Public Health Rep.* 2000; 115:403–405.
- 4. Levy BS, Sidel VW, eds. *Terrorism and Public Health*. New York, NY: Oxford University Press Inc; 2003.
- Update: investigation of bioterrorismrelated inhalational anthrax—Connecticut, 2001. MMWR Morb Mortal Wkly Rep. 2001;50:1049–1051.
- Regaldo A, Fields G, Schoofs M. FBI makes military labs key focus on anthrax. Wall Street Journal. February 12, 2002:A4.
- 7. Broad WJ, Johnston D, Miller J. Subject of anthrax inquiry tied to antigerm training. *New York Times*. July 2, 2003:Al.
- 8. Combating Terrorism: Need for Comprehensive Threat and Risk Assessments of Chemical and Biological Attacks: Report to Congressional Requesters. Washington, DC: US General Accounting Office; 1999:1–35. GAO publication NSIAD-99-163.
- 9. Sidel VW, Cohen HW, Gould RM. Good intentions and the road to bioterrorism preparedness. *Am J Public Health*. 2001;91:716–718.
- 10. Tucker JB. Bioterrorism is the least of our worries. *New York Times*. October 16, 1999:A19.
- 11. Miller J, Engelberg S, Broad WJ. US germ warfare research pushes treaty limits. *New York Times*. September 4, 2001:A1.
- 12. Gorner P. US war on anthrax has its risks: rush to stock new vaccine has scientists wary. *Chicago Tribune*. March 28, 2004:14.
- 13. Bush GW. President Bush discusses Iraq with congressional leaders. Available at: http://www.whitehouse.gov/news/releases/2002/09/20020926-7.html. Accessed September 9, 2003.
- 14. Associated Press. US weapons hunters find no evidence Iraq had

- smallpox. USA Today [online]. September 18, 2003. Available at: http://www.usatoday.com/news/world/iraq/2003-09-18-iraq-smallpox\_x.htm. Accessed October 29, 2003.
- 15. Bush's comments on his plan for smallpox vaccinations across the US *New York Times*. December 14, 2002:A12.
- Brundtland GH. World Health Organization announces updated guidance on smallpox vaccination. Available at: http://www.who.int/inf-pr-2001/en/state2001-16.html. Accessed September 9, 2003.
- 17. American Public Health Association Executive Board. APHA policy on smallpox vaccinations. Available at: http://www.apha.org/legislative/policy/smallpox.pdf. Accessed September 9, 2003.
- 18. Linzer D. No trace found of reputed smallpox in Iraq. *Miami Herald*. September 19, 2003:A1.
- California Nurses Association. CNA adds voice to opposition to smallpox vaccination plan. Available at: http://www. calnurse.org/cna/calnursejanfeb03/ smallpox.html. Accessed July 15, 2004.
- 20. Cohen HW, Eolis S. Smallpox vaccine: don't do it. *Am J Nurs.* 2003; 103:13.
- 21. Centers for Disease Control and Prevention. Update: adverse events following civilian smallpox vaccination— United States, 2003. MMWR Morb Mortal Wkly Rep. 2003;53:106–107.
- 22. Institute of Medicine, Committee on Smallpox Vaccination Program Implementation, Board on Health Promotion and Disease Prevention. Review of the Centers for Disease Control and Prevention's smallpox vaccination program implementation. Washington, DC: National Academy Press; 2003.
- 23. Elliott VS. Public health funding: Feds giveth but the states taketh away. Available at: http://www.ama-assn.org/sci-pubs/amnews/2002/10/28/hll21028.htm. Accessed August 31, 2003.
- 24. Smith S. Anthrax vs. the flu. *Boston Globe*. July 29, 2003:C4.
- 25. Eserink M. New biodefense splurge creates hotbeds, shatters dreams. *Science*. 2003;302:206–207.
- 26. Sunshine Project. Map of high containment and other facilities of the US biodefense program. Available at: http://www.sunshine-project.org/biodefense/. Accessed May 24, 2004.
- 27. Miller J. New biolabs stir debate over secrecy and safety. *New York Times*. February 10, 2004:F1.
- 28. Weiss R, Snyder D. 2nd leak of anthrax found at army lab. *Washington Post.* April 24, 2002:B1.
- 29. Williamson E. Ft. Detrick unearths

# **COMMENTARIES**

hazardous surprises. *Washington Post.* May 27, 2003:B1.

- 30. US General Accounting Office. Combating bioterrorism: actions needed to improve security at Plum Island Animal Disease Center. Available at: http://
- www.gao.gov/atext/d03847.txt. Accessed October 29, 2003.
- 31. Sidel VW, Gould RM, Cohen HW. Bioterrorism preparedness: cooptation of public health? *Med Global Survival*. 2002;7:82–89.
- 32. Kelley M, Coghlan J. Mixing bugs and bombs. *Bull Atomic Scientists*. 2003;59(5):24–31.
- 33. Divis DA, Horrock NM. Living terror: lab secrets in dispute. Available at: http://www.upi.com/view.cfm?StoryID=
- 20030806-061348-4757r. Accessed September 9, 2003.
- 34. Sidel VW, Levy B. Security and public health. In: Gould RM, Sutton P, eds. *Global Threats to Security: Social Justice*. 2002;29(3):108–119.