

# Chapter 74

## Legal Aspects of Bioterrorism

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The Anthrax Attacks  
The "Model" State Emergency Health Powers Act

Federal Public Health (and Smallpox)

A chapter on bioterrorism was made necessary by 9/11/2001 and its aftermath. Although terrorism has been a worldwide scourge for decades (and in international law can be traced back to the pirates), large-scale terrorism on American soil is more recent, and 9/11 signaled what seems to have been a change in kind rather than degree. This chapter concerns the legal aspects of a specific kind of terrorism, the use of a biological agent to cause terror in the civilian population, or simply "bioterrorism." It is a preliminary overview of the most immediately relevant legal issues rather than a final or definitive catalog of them.

Medicolegal experts are not usually called on for their views on terrorism in general, but are needed to explain and explore the variety of legal and ethical issues raised by the use of pathogens to spread disease and terror. In this regard we can view legal responses from the perspective of legal jurisdictions. Ultimately, the most important response is to strengthen prevention efforts at the international level, most centrally by strengthening the Biological and Toxin Weapons Convention. This is a long-term strategy that merits wide support. The threat of a bird flu (H5N1) pandemic in the fall of 2005 helped illustrate the necessity of worldwide cooperation in a "naturally occurring" virus, and has helped mobilize greater attention to global health issues and new mechanisms to address them. In this chapter, however, I will concentrate on the United States exclusively, and examine legal responses at the federal and state levels. Although public health has historically been primarily a matter of state law, it now seems inevitable that responses to the threat of bioterrorism, because they are primarily concerned with national security and the federal defense powers, will be overseen and controlled by the federal government and its new Department of Homeland Security. Also, because we are concerned with the "bio" in bioterrorism, federal efforts will be directed primarily at the development and deployment of vaccines and drugs that can be used to prevent widespread harm from various pathogens, and this is exemplified in new legislation, often referred to as "Bioshield I" and "Bioshield II," to provide incentives to private drug manufacturers to develop these agents.

Public fear of a possible bioterrorist attack on the United States was high after 9/11, and although it has lessened over the years, fear has fueled many legal initiatives at both the state and federal levels. In exploring the legal issues raised by the possibility of a bioterrorist attack on the

United States, it is useful to examine the response to the post-September 11 anthrax attacks, proposals for new state laws, and attempts to vaccinate U.S. citizens against smallpox.<sup>1</sup> A central question to consider is whether in our new reality, modern medical law, complete with informed consent and human rights, will be more effective in responding to threats of bioterrorism than reverting to nineteenth-century public health laws that are based on virtually unchecked state coercion.<sup>2</sup> Put another way, must we give up some civil liberties to increase our security?

### THE ANTHRAX ATTACKS

In the anthrax attacks via the mails after 9/11, 22 people developed anthrax (about half inhalation and half cutaneous) and 5 died.<sup>3</sup> More than 10,000 people were advised to take antibiotics on the presumption that they were at risk for inhalation anthrax.<sup>4</sup> In late December 2001, the Food and Drug Administration (FDA), the Department of Defense (DOD), and the Centers for Disease Control and Prevention (CDC) together released the anthrax vaccine, previously only available to the military, and approved by the FDA only to prevent cutaneous anthrax, for use by those exposed to anthrax in the attacks.<sup>5</sup> Of the 10,000 people eligible to take the vaccine, only 152, or a remarkably low 2%, did.<sup>6</sup>

The anthrax bioterrorist (still unidentified as of early 2006) was extremely effective in meeting his goal: not mass killing (the goal in biowarfare), but terrorizing the civilian population. It is important to understand the belated response of the federal government in making the anthrax vaccine available, and why the public rejected its use, in order to be better prepared for the next bioterrorist attack or similar public health emergency. The basic rules regarding the use of investigational drugs in biowarfare, the closest analogy to bioterrorism, go back to the first Gulf War.

### Investigational Drugs in War and Biowarfare

Just prior to the first Gulf War, the Pentagon sought an FDA waiver of informed consent requirements for the use of specific investigational drugs and vaccines on U.S. troops in the Gulf.<sup>7</sup> Informed consent is, of course, required for all human experiments, including the use of investigational drugs and vaccines. Specifically, the DOD

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sought waivers of informed consent under FDA rules so they could use an investigational drug (pyridostigmine bromide, to be used as a pretreatment against an attack by the nerve gas soman) and an investigational vaccine (botulinum toxoid, a protective against *Clostridium botulinum*) without obtaining informed consent from the soldiers.<sup>8</sup>

The basis of the DOD waiver request was that informed consent was not feasible because the military mission could be compromised if individual soldiers could opt out of taking these agents.<sup>9</sup> The FDA adopted a new regulation permitting waiver of consent for military operations, and approved the requested waivers under the provisions of the new regulation.<sup>10</sup> The FDA did, however, require the military to make information sheets on the agents available to the troops, and to collect, review, and report on adverse experiences.<sup>11</sup>

Because it was an approved drug, the military use of pyridostigmine bromide as a “pretreatment” for a gas attack could have alternatively been legally justified as use of an approved drug for an unapproved indication, based on the argument that it was a safe drug, even if not proven effective for this particular use.<sup>12</sup> Moreover, the military command ultimately decided to make botulinum toxoid vaccination voluntary.<sup>13</sup> Nonetheless, the FDA’s 1990 waiver-of-consent rule itself cannot be legally justified on the facts. Obtaining consent was feasible in the Gulf, and failure to obtain it in the case of investigational drugs and vaccines is a direct violation of the consent requirements of the Nuremberg Code that the military had adopted as their own in 1953.<sup>14</sup> The FDA policy also turned out to be counterproductive and dangerous. It led to a situation in which the troops were put in much more jeopardy by taking pyridostigmine bromide than they would have been by not taking it. This is because while the drug may protect against soman (the agent that US intelligence thought Iraq had), the nerve gas the Iraqis were actually ready to use was sarin—and pyridostigmine can make sarin more deadly to humans.<sup>15</sup>

The FDA and DOD defended their waiver of consent rule after the Gulf War, but almost no one else did. Ultimately, Congress passed a law that repealed the FDA’s military combat exception to informed consent, and put sole authority to grant any future wartime exception to informed consent in the hands of the President.<sup>16</sup> Currently, only the President can authorize the military to use an unapproved or investigational drug or vaccine in wartime without consent, and to do so the President must find, in writing, that obtaining consent is not feasible, is contrary to the best interests of the military, or is not in the interests of national security.<sup>17</sup> The FDA has also adopted regulations to help the President and his advisers make this decision.<sup>18</sup> As of 2006, no president has used this authority.

A more basic medicolegal question regarding drugs and vaccines designed for emergency use in events like biowarfare and bioterrorism remains, however: Assuming that it is impossible to ethically test the efficacy of a drug or vaccine designed for a bioterrorist or biowarfare agent (because it would be unethical to expose human volunteers to a potentially lethal agent), should there be an alternative

way for the FDA to approve such agents for use in a war or other national emergency?

In 1999 the FDA proposed a set of new rules to permit the approval of such agents upon demonstration of safety in human subjects, and efficacy in appropriate multiple animal studies, and these rules were finalized in mid-2002.<sup>19</sup> Using multiple animal models for efficacy testing seems reasonable in this context, since the FDA is right to conclude that it would be unethical to expose human subjects to toxins that could be lethal to them (this would, for example, violate another provision of the Nuremberg Code). But the ethical rule requiring the informed consent of competent adults before they are subjected to drugs or vaccines that have not been demonstrated effective in human populations is equally applicable. No soldier or civilian should be required to take any such drug or vaccine (which would be offered on the basis that it could be effective) where the only scientific support for efficacy is the result of animal studies. This same rule should, of course, apply in a natural pandemic. For example, should the world experience a flu pandemic, bird or otherwise, individuals should retain the right to refuse any vaccine that has not been proven safe and effective—and it is likely that only vaccines with some safety results will be available in time to be of any use during a pandemic. On the other hand, it is likely that since any such experimental vaccine will be the only effective agent available that could prevent pandemic flu, the real problem will not be forcing people to use it, but supplying enough vaccine to those members of the public who are demanding it.

### Informed Consent to the Anthrax Vaccine

Anthrax vaccine has been approved for use to prevent cutaneous anthrax and was mandatorily given to the troops in the Gulf War on the basis that it was an approved agent that could be given for an unapproved but closely related use (inhalation anthrax).<sup>20</sup> This vaccine was developed in 1970. After the Gulf War, the DOD signed a sole source contract with a new company, Bioport, to produce anthrax vaccine.<sup>21</sup> In 1998, Secretary of Defense William Cohen ordered that all active-duty troops be given the anthrax vaccine, which was to be delivered in a series of six injections over an 18-month period.<sup>22</sup> Some soldiers refused, and challenged the orders, arguing that the vaccine was experimental and thus could not be given without informed consent. Many of them were court-martialed, and this defense has so far not succeeded, although litigation has continued into 2006, and is unlikely to be resolved soon.<sup>23</sup>

The bioterrorist anthrax attacks in the United States were on civilians, none of whom had been vaccinated. The recommended course of treatment for exposure to anthrax is 60 days of antibiotics, and antibiotics were made available to the 10,000 people potentially exposed.<sup>24</sup> The anthrax vaccine was not available to civilians in the immediate aftermath of the October 2001 anthrax attacks. In late December 2001, however, the DOD agreed to supply

sufficient vaccine to vaccinate the 10,000 exposed civilians. Since the anthrax vaccine was an investigational drug when used for postexposure inhalation anthrax, it could only be used in the context of a clinical trial, and then only with the informed consent of the subjects.<sup>25</sup>

The FDA and CDC designed a consent form, together with a counseling process, for use in obtaining the consent of the exposed civilians to participate in the research project. Unlike the case of the military in the Gulf War, or even the peacetime military with the anthrax vaccine, in which the government required soldiers to be vaccinated, the choice was left entirely to the individual civilians. Government officials did not even make a recommendation as to what they thought any individual should do. No survey of the exposed civilians has been conducted. Nonetheless, it seems likely that the potential subjects mostly decided for themselves that their 60 days (or less) of antibiotics was sufficient protection.

It is also unlikely that anyone who actually read and understood the information in the consent forms provided (for adults, adolescents, and children) would have chosen to take the vaccine. Specifically, the consent forms (which are essentially identical), are five-page, single-spaced documents. Designed for a clinical trial, the forms are nonetheless captioned “Anthrax Vaccine and Drugs Availability Program for Persons Possibly Exposed to Inhaled Spores.” Most of the form is in regular typeface, but the following information is in bold:

- *Anthrax vaccine has not been shown to prevent infection when given to people after exposure to anthrax spores . . . .*
- *The vaccine that you will receive in this program has not been approved by the Food and Drug Administration (FDA) for this use and is considered investigational . . . .*
- *FDA has not approved this lot of vaccine (Lot FAV-063) because the company's license to produce the vaccine is under review . . . .*
- *You should not consider the vaccine as a treatment for anthrax . . . .*
- *You may have undesirable side effects from taking the vaccine.  
 . . . DHHS is not making any recommendation whether you should or should not take this vaccine . . . .*<sup>26</sup>

The form also tells potential subjects that the vaccine is to be given in three injections, once every 2 weeks, and is to be supplemented by 40 days of additional antibiotics, although taking antibiotics is not required to obtain the vaccine. A 2-year follow-up is planned.

The fact that it is unethical to expose human subjects to potentially lethal toxic agents does not, of course, mean that studies cannot be undertaken with individuals who have been exposed by a terrorist and who may need an investigational drug or vaccine that has not been approved. The FDA's new regulations make provisions for such research, and appropriately so.<sup>27</sup> The FDA reasonably recognized that this investigational anthrax vaccine should be made available to exposed civilians only with their informed consent.<sup>28</sup> In this respect, the FDA learned

from its experience in the Gulf War that there is no justification for waiving informed consent for competent adults, even in the face of a bioterrorist attack and uncertainty about the usefulness of the anthrax vaccine. Informed consent for research on competent adults is always feasible and is always ethically required. Informed consent is also required for medical treatment of competent adult civilians—only military personnel agree to accept reasonable and necessary approved medical procedures without specific consent.<sup>29</sup> Civilians have not joined the military or volunteered to waive any of their constitutional rights, including the right to refuse treatment. That is only one reason why it is dangerous to civilians to argue that after 9/11 “we are all soldiers now.”

The anthrax attacks convinced Congress and the public that the United States does not have sufficient safe and effective drugs and vaccines available to respond to a bioterrorist or biowarfare attack on civilians. The primary reason for the drastic increases in NIH funding, for example, are to increase research in areas that might lead to better bioterrorist-related drugs and vaccines.<sup>30</sup> Congress agrees with the FDA that these new agents should be approvable on the basis of animal studies of efficacy.<sup>31</sup>

A related drug and vaccine question is whether there should be a new, narrower category of FDA approval for products that cannot be tested for efficacy, and whose use would be limited to certain populations in specific circumstances. Although there is no precedent for this, teratogenic drugs like accutane and thalidomide have labeling that attempts to limit their prescription to people taking effective birth control measures.<sup>32</sup> This is reasonable. Similarly, when drugs and vaccines are developed for the use of soldiers in war it seems reasonable to restrict their use to competent adults, and to exclude children. It also seems reasonable to limit the use of the agent to military personnel—at least if combat and the military mission are the rationales used to approve the use—and to require that the product be labeled “For Military Use Only.”<sup>33</sup> If such a restriction is not made, there is at least the potential for the drug to be used for other reasons (since once the drug or vaccine is approved for one purpose, physicians can lawfully prescribe it for others if it is available to civilians), although the primary reason shortcuts were taken in its testing was military necessity. The labeling of bioterrorist drugs and vaccines is more complicated because the consumers are primarily civilians. A label like “For Use Only in the Event of a National Emergency or Bioterrorist Attack” might not be sufficient, although that will be the primary reason the drug or vaccine has been approved without the usually required human efficacy studies. To permit it to be used by physicians for other purposes is thus not ethically or legally justified.

There is no sufficient reason to require civilians (or soldiers) to trade liberty for safety in an emergency in which unapproved or partially tested drugs or vaccines are made available. The choice to use these agents should continue to be theirs, as it properly was for civilians in the case of the anthrax vaccine. It seems reasonable to insist, nonetheless, that public health or military authorities that

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make these drugs and vaccines available be prepared to recommend their use. Otherwise the decision to make them available becomes purely a political one, made to cover the behinds of government officials, not a medical or public health one.<sup>34</sup>

### THE “MODEL” STATE EMERGENCY HEALTH POWERS ACT

In the immediate aftermath of 9/11 and the subsequent anthrax attacks, hospitals, cities, states, and federal officials began developing or revisiting plans for future biological attacks. The federal response almost immediately emphasized stockpiling drugs and vaccines that could be used to respond to a future attack, especially one involving smallpox.<sup>35</sup> Other initiatives have proposed enhancing the public health infrastructure of the country (especially its ability to monitor emergency department diagnoses and pharmacy sales of relevant drugs), and the training of first responders to recognize and treat the diseases most likely to be caused by a bioterrorist attack (such as anthrax, smallpox, and plague). Major efforts are also underway to improve coordination and communication among local, state, and federal officials responsible for emergencies, and to more clearly delineate lines of authority involving “homeland security.” All of these are reasonable and responsible steps our government should take, although we learned from the response to Hurricane Katrina from all levels of government that there is very little current capacity for cooperation, and that the Department of Homeland Security is not ready to respond to a major emergency—even a predictable one with days of warning, like the New Orleans hurricane.

Although planning for better communication with each other and the public is reasonable and appropriate, planning for mass quarantine and forced vaccination—likely with investigational vaccines—is unreasonable because it is likely to be ineffective and even counterproductive since it is more likely to foster public panic and distrust. Mass quarantine was a staple of public health from the fourteenth century to the end of the nineteenth century, and its implementation has been historically justified by labeling those groups quarantined as not only dangerous but almost diabolical.<sup>36</sup>

Properly worried that many state public health laws are outdated and perhaps inadequate to permit state officials from effectively containing an epidemic caused by a bioterrorist attack, in the wake of 9/11 the CDC advised all states to review the adequacies of their laws with special attention to quarantining people in the event of a smallpox attack.<sup>37</sup> In addition, the CDC released a proposed model law for the states, entitled the “Model State Emergency Health Powers Act” (model act) on October 23, 2001.<sup>38</sup> The proposal was written under extreme time pressure and in the state of high emotion.

The draft act permits the Governor to declare a public health emergency, after which the state’s public health

officials are given extraordinary power to essentially take over all of the health care facilities in the state, order physicians to act in certain ways, and order citizens to submit to examinations and treatment on the threat of being quarantined or criminally punished for refusing. Under the act, public health officials, and those working under their authority, are immune from liability for their actions (except for gross negligence and willful misconduct), including those that cause permanent injury or death. Specifically, the act defines a public health emergency (the condition that permits the Governor to declare a state of public health emergency) as “an occurrence or imminent threat of an illness or health condition, caused by bioterrorism, epidemic or pandemic disease, or novel and highly fatal infectious agent or biological toxin, that poses a substantial risk of a significant number of human fatalities or incidents of permanent or long-term disability.”<sup>39</sup>

An emergency declaration permits the Governor to suspend state regulations, transfer personnel, and mobilize the militia. All public health personnel will be issued special identification badges, which they shall wear “in plain view” and that “shall indicate the authority of the bearer to exercise public health functions and emergency powers....” In regard to health care facilities, public health personnel may “compel a health care facility to provide services or the use of its facility if such services or use are reasonable and necessary for emergency response... includ[ing] transferring the management and supervision of the health care facility to the public health authority...”<sup>40</sup>

Public health personnel are given exceptionally broad powers for the examination and testing of citizens, and failure of physicians and citizens to follow their orders is a crime that can be punished by having the order immediately enforceable by a police officer. For example:

*Sec. 504(b) Vaccination and treatment. Individuals refusing to be vaccinated or treated shall be liable for a misdemeanor. If, by reason of refusal of vaccination or treatment, the person poses a danger to the public health, he or she may be subject to isolation or quarantine . . . (c) An order of the public health authority . . . shall be immediately enforceable by any peace officer.*<sup>41</sup>

Of course, state public health, police, fire, and emergency planners should be clear about their authority, and to the extent the model act encouraged states to review their emergency laws, this was constructive. On the other hand, many of the provisions of this draft act, especially those giving authority to public health officials over physicians and hospitals, and authority to quarantine without meaningful standards, seem to be based on the assumption that neither physicians nor the public are likely to cooperate with public health officials in the aftermath of a bioterrorist attack. This assumption itself seems to be based on the results of tabletop exercises involving simulated bioterrorist attacks, including TopOff and Dark Winter. TopOff involved a simulated bioterrorist attack on Denver by using aerosolized *Yersinia pestis*, the bacteria that causes plague.<sup>42</sup> Dark Winter was a tabletop exercise that simulated a smallpox attack on Oklahoma City.<sup>43</sup> Using these simulated cases as a basis

for legislation, however, is unreasonable, given the overwhelming voluntary cooperation of the public, physicians, and hospitals to both 9/11 and the anthrax attacks.

Excessive reliance on coercion was perhaps inevitable in the immediate aftermath of 9/11, but this reliance suggests three major objections to the initial draft of the model act. First, it is far too broad, applying as it does not just to a smallpox attack, but to nonemergency conditions as diverse as our annual flu epidemic and the HIV epidemic.<sup>44</sup> Second, although it may make sense to put public health officials in charge of responding to a smallpox attack, it may not make sense to put them in charge of responding to every type of a bioterrorism event. This is because although the state public health department has a major role to play in limiting the public’s exposure to a bioterrorist agent, contact tracing, and information gathering and dissemination, most of the actual treatment of affected individuals, and preventive actions at the level of identifiable patients, will be done by physicians, nurses, emergency medical personnel, and hospitals.<sup>45</sup> The primary role of public health authorities will usually be, as it was after the anthrax attacks, to provide guidance to the public and other government officials about how to identify and deal with the disease, and to provide laboratory facilities to assess exposure and definitively establish diagnoses. Hurricane Katrina again provides a real-world example. Almost all of the care of people was provided by physicians and nurses; public health officials mostly help the medical teams by providing them with medical supplies and staying out of their way.

The third objection is that there is no evidence from either 9/11, the anthrax attacks, or Katrina that physicians, nurses, or members of the public are reluctant to cooperate in responding to a bioterrorist attack, or are reluctant to take drugs or vaccines recommended by public health or medical officials. Quite the opposite, physicians and hospitals in the areas affected universally volunteered their time, space, and expertise to respond to 9/11, and the public lined up to be tested for anthrax and stockpiled ciprofloxacin. Instead of resisting treatment or testing, the public actually wanted treatment and testing so much that the CDC had to publicly recommend against both.<sup>46</sup> Another important lesson learned from 9/11 and Katrina was that Americans are primarily concerned about the safety of their families—and it will not be possible to separate people from their families, even by threats of force, if they do not believe separation is in their family’s best interests.

Of course anthrax is not spread from person to person like smallpox. The response could have been different in a Dark Winter-type smallpox attack, or if thousands or tens of thousands of people had become infected with anthrax. Nonetheless, there is no empirical evidence to suggest that a draconian state criminal quarantine law of the type authorized in the act is necessary or desirable. Individuals with smallpox, for example, are most infectious only after they develop fever and a rash; and then they are usually so sick and immobile that they will likely accept whatever care is available.<sup>47</sup> Moreover, the “long incubation period (10–17 days before a rash develops) almost ensures that

some persons who are infected in the [smallpox] attack will have traveled great distances from the site of exposure before the disease is recognized or quarantine could be implemented.”<sup>48</sup> The key to an effective public health response is making voluntary treatment available. Without a sufficient supply of smallpox vaccine, for example, even police-supported quarantine would not likely be effective. People who do come to centers will come for diagnosis and treatment; they will avoid centers if they do not want diagnosis or treatment, especially if all that is offered is confinement and separation from their families.

It is, nonetheless, reasonable to conclude that a limited quarantine law could be useful to respond to a bioterrorist-induced emergency (e.g., by permitting the few exposed Americans, if there are any, who are unwilling to be treated or vaccinated, to be quarantined). Such a law, however, should be a federal law, not a state law. This is because bioterrorism is a matter of national security, not just state police powers. Existing federal quarantine law based on the commerce clause (and which has special provisions for diseases like plague, smallpox, typhus, and most recently SARS and bird flu) could usefully be examined and updated to deal with bioterrorism.<sup>49</sup> Unfortunately, the CDC has so far moved in the opposite direction, proposing in late 2005, in response to the bird flu threat, new federal powers that rely on force instead of science, including an Orwellian concept of “provisional quarantine.” The indifference to science can be seen by retaining two diseases on the quarantine list that we have known for almost a hundred years are extraordinarily difficult, if not impossible, to transmit person to person: yellow fever and cholera. In proposing its new quarantine regulations the CDC seems to be suffering from Post-Katrina Distress Syndrome.

### Civil Liberties and Public Health Emergencies

The first draft of the model state act is based on the almost universal assumption that in public health emergencies there must be a tradeoff between protecting civil rights and effective public health interventions.<sup>50</sup> There is, of course, precedent for this belief, and the preamble to the act cites the 1905 case of *Jacobson v. Massachusetts* for the proposition that “the whole people covenants with each citizen, and each citizen with the whole people, that all shall be governed by certain laws for the ‘common good.’”<sup>51</sup> *Jacobson* involved a Massachusetts statute that permitted local boards of health to require vaccinations when they deemed it “necessary for the public health or safety.” There were no quarantine provisions in that law, and refusal was punishable by a \$5 fine. Vaccination refusals at the beginning of the last century—before the Flexner report—were anticipated because vaccination itself remained controversial, there were no antibiotics, physicians were not universally trusted, science and medicine were in their infancy, and hospitals were seen primarily as “pest houses.”<sup>52</sup> Tradeoffs between civil liberties (the right to refuse treatment) and public health (mandatory vaccinations) seemed necessary in such circumstances.

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There was no FDA, no such thing as an investigational drug or vaccine, and the doctrine of informed consent would not be articulated for more than half a century.

The U.S. Supreme Court cited the military draft as precedent for upholding the Massachusetts law.<sup>53</sup> The point is not that the constitution does not give both state and federal government wide latitude to respond in times of war and public health emergencies—it does; the point is that civil rights tradeoffs are not always required for effective public health response, and draconian responses are likely to be counterproductive today. Just as we have been able to abolish the draft and go to all-volunteer armed forces, so it seems reasonable to think that we can predictably rely on well-informed Americans—who are not the enemy in a bioterrorist attack—to follow the reasonable instructions of government officials they trust for their own protection.

Almost one hundred years after Jacobson, neither medicine nor constitutional law is what it was. We now take constitutional rights much more seriously, including the constitutional right of a competent adult to refuse any medical treatment, even life-saving treatment.<sup>54</sup> Of course, we still would permit public health officials to quarantine individuals who have a serious communicable disease who either cannot or will not accept treatment for it or agree to stay in their home, and who threaten to infect others with it, such as active tuberculosis. Even then, however, we require public officials to use the “least restrictive alternative” and resort to quarantine only after other interventions, such as directly observed therapy, have failed.<sup>55</sup> Confinement is also accompanied by other procedural due process protections, including the right to legal representation and to a hearing.<sup>56</sup> At the very least, the individual with a contagious disease should have the option of identifying a qualified examining physician of their own, and if isolation is necessary, isolating him or herself in their own home. Requiring physicians to treat patients against their will and against their medical judgment under penalty of criminal law has no precedent at all, and makes no sense. Governors already have broad emergency powers; there is no compelling reason to expand them.<sup>57</sup>

Public trust is critical to effective response to a bioterrorist attack, and insofar as the act undermines public trust, it will be counterproductive and induce panic. Unlike 1900, for example, we now have 24-hour-a-day news television, the Internet, cell phones, and automobiles. These make effective large-scale quarantine impossible unless the public is convinced that it is absolutely necessary to prevent the spread of fatal disease and is fairly and safely administered. Former Senator Sam Nunn, who played the president in the Dark Winter exercise, accurately observed after it was over: “There is no force on earth strong enough to get Americans to do something they do not believe is in their own best interests or that of their families.”<sup>58</sup> Treating our fellow citizens as the enemy, and using police tactics or martial law to force treatment and isolate them, is much more likely to cost lives than to save them. This is one reason why there has not been a large-scale quarantine in the

United States for more than 80 years, and why bioterrorism experts doubt that such a quarantine could be effective.<sup>59</sup>

### The Revised Model Act

On December 21, 2001, a revised version was released. The new draft is labeled simply a “draft for discussion,” and does “not represent the official policy, endorsement, or views” of anyone, including the authors themselves and the CDC.<sup>60</sup> Although the revised draft, still the one being pushed on state legislatures as of early 2003, is a modest improvement, all the fundamental problems remain. Failure to comply with the orders of public health officials for examination or treatment is no longer a crime but results in isolation or quarantine. Criminal penalties continue to apply for failure to follow isolation or quarantine “rules” that will be written at a future time. Physicians and other health care providers can still be required “to assist” public health officials, but cooperation is now coerced as “a condition of licensure” instead of a legal requirement with criminal penalties for noncompliance. The quarantine provisions have been improved, with a new requirement that quarantine or isolation be imposed by “the least restrictive means necessary” and stronger due process protection, including hearings and legal representation for those actually quarantined. Nonetheless, on the basis of a written directive by a public health official, a person can still be quarantined for 15 days before a hearing must be held, and the hearing itself can be for groups of quarantined persons rather than individuals.<sup>61</sup> Perhaps most critically in the real medicolegal world, nothing in the revised act distinguishes between approved drugs and vaccines and investigational agents, even though the latter are the most likely to be used, and even though state law cannot override federal drug laws that govern their use and informed consent requirements.<sup>62</sup>

Some of the revised quarantine provisions were improved, but others were made even more arbitrary. For example, quarantine can be ordered when the person’s refusal to be examined or tested “results in uncertainty regarding whether he or she has been exposed to or is infected with a contagious or possibly contagious disease or otherwise poses a danger to public health.”<sup>63</sup> This is no standard at all, and simply permits public health authorities to quarantine anyone who refuses to be examined or treated, for whatever reason, since all refusals will result in uncertainty—if you were already certain, you wouldn’t order the test. Vague standards are especially troublesome because the act’s incredible immunity provision remains unchanged. All state public health officials and all private companies and persons operating under their authority are granted immunity from liability for their actions (except for gross negligence or willful misconduct), even in the case of death or permanent injury. The immunity provision serves only to promote arbitrary state action and thus to undermine the public’s trust in public health authorities. Citizens are not soldiers, and should never be treated against their will by their government. But if they ever are,

they should be fully compensated for injuries suffered as a result.<sup>64</sup>

### **Uniform Bioterrorism Law Necessary?**

In December 2005, at the height of worry about a bird flu pandemic, the International Association of Chiefs of Police labeled the CDC's attempt to use the model act to get uniformity for state quarantine laws a failure, saying that the result has been "a patchwork-quilt of legislation" that offers little specific assistance to local police.<sup>65</sup> There never was any chance that every state, or even many states, would adopt the suggested act as written, so that if uniformity is seen as necessary or desirable, it is clear now (and should have been in 2001) that only a federal statute can provide it. Obviously, it is also much more important what states like New York and California (large states that are likely bioterrorist targets) do than what states like Montana, Wyoming, or Arkansas do. As of late 2005, only a few states, including Delaware, Oklahoma, and South Carolina, had adopted the suggested act wholesale. More typically states have ignored it or, like California and New York, have considered it and rejected it outright, or have modified only one or two provisions of their existing legislation. For example, Minnesota, modified its quarantine law, but updated it to be consistent with contemporary medical ethics and constitutional rights, rather than making it more arbitrary.

Under the new Minnesota law, for example, even in a public health emergency, "individuals have a fundamental right to refuse medical treatment, testing, physical or mental examination, vaccination, participation in experimental procedures and protocols, collection of specimens and preventive treatment programs." The law further requires a health care provider to "notify the individual of the right to refuse."<sup>66</sup> When isolation or quarantine are necessary, family members are specifically given the right to choose to enter the isolation or quarantine area to visit. Most of the other provisions of the suggested act, including the immunity provisions, were referred to the Minnesota commissioner of health for further study.<sup>67</sup>

Sensible public health and bioterrorism legislation must be drafted in a calm atmosphere, in a transparent, public process. Perhaps most importantly, as public health law expert Ken Wing has noted, "statute drafting is a technical and instrumental job—one that should follow, not precede the more fundamental task of deciding what the statute ought to say."<sup>68</sup> Public health must ultimately rely not on force but on persuasion, and never on blind trust. Trust itself must be based on transparency, accountability, democracy and human rights.

The challenge remains to draft and debate a twenty-first-century federal public health law that takes constitutional rights seriously, unites the public with its medical caretakers, treats medicine and public health as true partners, and moves us in the direction of global cooperation. The revised act can still be useful as a checklist or template for action, but only if it is continuously subject to scrutiny and

improvement, and is redrafted to be consistent with federal statutory, regulatory, and constitutional law.

## **FEDERAL PUBLIC HEALTH (AND SMALLPOX)**

At the outset of the twenty-first century, bioterrorism, although only one threat to public health, can be the catalyst to effectively federalize and integrate much of what is now uncoordinated and piecemeal state and local public health programs. This should include a renewed effort for national health insurance, national licensure for physicians, nurses, and allied health professionals, and national patient safety standards.<sup>69</sup> Federal public health leadership will also encourage us to look outward, and to recognize that prevention of future bioterrorist attacks and even ordinary epidemics, like a possible bird flu pandemic, will require international cooperation.<sup>70</sup> In this regard the threat of bioterrorism not only demonstrates the need to federalize public health, but to globalize it as well. Unfortunately, the Bush administration has been slow to realize this, and as of early 2006 continues to believe that the lead agency for planning for both bioterrorism and naturally occurring epidemics should be the Department of Homeland Security and not either HHS or its CDC.

No one can quantify the risk of a smallpox bioterrorism event; it is very low, but its potential for harm is so great should it happen that it cannot be ignored.<sup>71</sup> Post-9/11 planning to attempt to mitigate the effects of a smallpox attack illustrates how dramatically the locus of public health planning has actually shifted from the states to the federal government, and federal law is likely to be central to a new public health law paradigm for the twenty-first century. Unfortunately, it also illustrates how fear can overcome common sense and lead to counterproductive overreactions to imagined risks.<sup>72</sup> The Bush administration specifically used the threat of a smallpox attack from Iraq as one reason for us to fear Iraq, and as the almost sole justification for its massive three-phase smallpox vaccination program. That now-abandoned and disgraced program was a public policy and a public relations disaster, resulting in providing smallpox vaccinations to only about 40,000 of the initially proposed 500,000 health care workers the government planned to vaccinate during phase one (phase two would have encompassed up to 10 million first responders, and phase three would have included all willing civilians).<sup>73</sup> Why?

The major reason for the failure of its smallpox vaccination program is that the administration failed to persuade physicians and nurses that the known risks of serious side effects with the vaccine were justified, given the fact that there is (and was) no evidence that Iraq (or anyone else) has both smallpox virus and the wish to use it in an attack on the United States. The information provided to physicians and nurses was in the same spirit as the Iraq nuclear threat information, except that it contained no facts at all, not even misleading or false ones. The Director of the Centers for

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Disease Control and Prevention, Julie Gerberding, and the person in charge of the program, for example, told a U.S. Senate Appropriations Subcommittee on January 29, 2003, about a month after the smallpox vaccination campaign began, and just before the beginning of the Iraq war,

*I can't discuss all of the details because some of the information is, of course, classified. However, I think our reading of the intelligence that we share with the intelligence community is that there is a real possibility of a smallpox attack either from nations that are likely to be harboring the virus or from individual entities, such as terrorist cells that could have access to the virus. Therefore, we know it is not zero. And, I think that's really what we can say with absolute certainty that there is not a zero risk of a smallpox attack.*<sup>74</sup>

This is wonderful double-talk that proves nothing except that the CDC's director does not seem to know much about the risk, if any, of a smallpox attack. Most importantly, however, if the U.S. government knows that an individual, group, or nation has smallpox and is working to make it into a weapon, this information should be made public. It is the terrorists who want to keep their methods and intentions secret; the best defense from a potential target is to make this information public. Since most Americans probably know this, the failure of the administration to offer any evidence at all of anyone possessing weaponized smallpox meant it was highly probable that the administration had no such evidence. Thus, as U.S. physicians and nurses seemed to realize, the real risks of the vaccine could not be offset by any measurable benefits. Few were surprised then when after the Iraq war, during which no smallpox—or any other biological weapon—was found, an Institute of Medicine panel recommended that smallpox vaccination for civilians be abandoned; and by the summer of 2004 the entire effort was abandoned.<sup>75</sup> The bottom line is that the potential for bioterrorism is real, but very low, and in almost any foreseeable attack the number of deaths is likely to be low. Planning is reasonable, but overreaction creates more problems than it solves.

It cannot be emphasized enough that the primary goal and purpose of public health is prevention of disease in the first place. In the case of bioterrorism, this means that prevention of the attack is much more important to public health than responding to it after the fact. In addition, contemporary public health prevention of epidemics and bioterrorism is not primarily a local or state issue, but is fundamentally a global security issue that must be dealt with by the community of nations working together. National laws and treaties, with realistic inspection and sanctions devoted to preventing the development and production of biological weapons, are the most important tool in the prevention of bioterrorism. We are also right to want to modernize the WHO International Health Regulations and, as WHO recognizes, in order for them to be effective, revised regulations must be founded on respecting and protecting human rights, not trampling on them. Our war against bioterrorism should be built on protecting liberty,

not restricting it. To date, arbitrary and unlawful responses to 9/11 have not helped make Americans safer or more secure; instead they have often threatened the very liberties that make our country worth protecting. New public health laws should be judged on transparency, trust, science, and most importantly, respect for human rights.

## Endnotes

1. For a more detailed discussion, see G.J. Annas, *Blinded by Bioterrorism: Public Health and Liberty in the 21st Century*, 13 Health Matrix 33 (2003), and G.J. Annas, *Puppy Love: Bioterrorism, Civil Rights, and Public Health*, 55 Fla. L. Rev. 1171 (2003).
2. G.J. Annas, *Bioterrorism, Public Health, and Human Rights*, 21 Health Affairs 94–97 (2002), and G.J. Annas, *Bioterrorism, Public Health, and Civil Liberties*, 346 New Engl. J. Med. 1337–42 (2002).
3. J.L. Gerberding, J.M. Hughes & J.P. Koplan, *Bioterrorism Preparedness and Response*, 287 J.A.M.A. 898 (2002).
4. *Id.*
5. T.V. Inglesby et al., *Anthrax as a Biological Weapon*, 287 J.A.M.A. 2236, 2243–44 (2002).
6. S. Twomey, *Vaccine Offer Draws Few Postal Workers*, Washington Post (Dec. 28, 2001) at A6.
7. For a more detailed discussion of the Gulf War waiver, see G.J. Annas, *Protecting Soldiers from Friendly Fire: The Consent Requirement for Using Investigational Drugs and Vaccines in Combat*, 24 Am. J. Law & Med. 245 (1998).
8. *Id.*
9. Informed Consent for Human Drugs and Biologics; Determination that Informed Consent is not Feasible, 55 Fed. Reg. 52,814 (1990) (codified at 21 C.F.R. Part 50).
10. *Id.*
11. Human Drugs and Biologics; Determination that Informed Consent is NOT Feasible or is Contrary to the Best Interests of Recipients; Revocation of 1990 Interim Final Rule; Establishment of New Interim Final Rule, 64 Fed. Reg. 54, 180, 54, 184 et seq.
12. Annas, *supra* note 7. The use of other drugs during the Gulf War was apparently justified on this basis.
13. *Supra* note 11.
14. Memorandum of Secretary of Defense C.E. Wilson dated February 26, 1953, and reprinted in *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation*, 343–45 (George J. Annas & Michael A. Grodin, eds., Oxford University Press, 1992).
15. R.W. Haley & T.L. Kurt, *Self-Reported Exposure to Neurotoxic Chemical Combinations in the Gulf War*, 277 J.A.M.A. 231, 232 (1997); I. Koplovitz et al., *Reduction by Pyridostigmine Pretreatment of the Efficacy of Atropine and 2-PAM Treatment of Sarin and VX Poisoning in Rodents*, 18 Fundamental & Applied Toxicology 102, 103–5 (1992).
16. 10 U.S.C. 1107(f) (2000).
17. *Id.*
18. *Supra* note 11.
19. New Drug and Biological Drug Products; Evidence Needed to Demonstrate Efficacy of New Drugs for Use Against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot be Conducted, Proposed Rule, 64 Fed. Reg. 53,960 (1999); and New Drug and Biological Drug Products; Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible; Final Rule, 67 Fed. Reg. 37,988 (2002).

20. The vaccine has been shown to protect rhesus monkeys from inhalation anthrax. See T.C. Dixon, M. Meselson, J. Guillemin & P. Hanna, *Anthrax*, 341 New Engl. J. Med. 815, 822 (1999)
21. See Thomas V. Inglesby et al., *Anthrax as a Biological Weapon: Medical and Public Health Management*, 281 J.A.M.A. 1735, 1740 (1999).
22. S. L. Myers, *U.S. Army Forces to Be Vaccinated Against Anthrax*, New York Times (Dec. 16, 1997) at A1.
23. K. Morris, *U.S. Military Face Punishment for Refusing Anthrax Vaccine*, 353 Lancet 130 (1999), and L. Johannes & M. Maremont, *Worries about Safety of its Anthrax Vaccine Put the Army in a Bind*, Wall St. J. (Oct. 12, 2002) at A1.
24. L. Altman, *Many Workers Ignored Anthrax Pill Regimen*, New York Times (Oct. 30, 2002) at A14.
25. L. Altman, *In Offering Anthrax Vaccines, Officials Admit to Unknowns*, New York Times (Dec. 25, 2001) at B5. Bioport's contract with the Pentagon may also permit it to sell up to 20% of its annual production to others. J. Miller, *Anthrax Vaccine Maker Calls Finances Shaky*, New York Times (Aug. 5, 2002) at A10.
26. Consent forms available on the CDC website at <http://www.cdc.gov/od/oc/media/adult.pdf> (adult); <http://www.cdc.gov/od/oc/media/adolescent.pdf> (adolescent); and <http://www.cdc.gov/od/oc/media/parental.pdf> (pediatric).
27. *Supra* note 19.
28. S. Vedantam & M. Flaherty, *CDC Pushed Paperwork for Anthrax Vaccinations*, Washington Post (Dec. 22, 2001) at A10.
29. And it is probably time to reexamine this policy, at least in peacetime, as well. Moreover, the anthrax vaccine seems to be used currently in the military as a protection against cutaneous anthrax (which it is licensed for, but which is no real risk to soldiers) rather than as a protection against inhalation anthrax (which it is not licensed for, but which is a combat risk).
30. *NIH Breaks Down How it Will Spend Bioterrorism Funds*, Wall Street Journal (Feb. 19, 2002) at A4.
31. Congress required the FDA to adopt the regulation cited in note 19 by legislation; see H.R. 3448 (2002), Public Health Security and Bioterrorism Response Act of 2001, and S. 1765 (2001), Bioterrorism Preparedness Act of 2001, both of which contained this language and which became law in 2002.
32. See G.J. Annas & S. Elias, *Thalidomide and the Titanic: Reconstructing the Technology Tragedies of the Twentieth Century*, 89 Am. J. Public Health 98 (1999).
33. During the Gulf War, pyridostigmine bromide (as a pretreatment for a poison gas attack) was labeled "For military use and evaluation" instead of the usual IND label, "Caution: New Drug—Limited by Federal Law to Investigational Use." See *supra* note 19.
34. In this regard there are many lessons to be learned from the 1976 attempt to vaccinate all Americans against swine flu. See, e.g., Richard E. Neustadt & Harvey V. Fineberg, *The Swine Flu Affair: Decision-Making on a Slippery Disease* (U.S. Dept. HEW, Washington, D.C., 1978). See also Gina Kolata, *Flu: The Story of the Great Influenza Pandemic and the Search for the Virus that Caused It*, 129-95 (Farrer Straus & Giroux, 1999).
35. W. Broad, *U.S. Acts to Make Vaccines and Drugs Against Smallpox*, New York Times (Oct. 9, 2001) at D1.
36. Howard Markel, *Quarantine! East European Jewish Immigrants and the New York City Epidemics of 1892* (Johns Hopkins University Press, 1997)
37. CDC, Smallpox Response Plan and Guidelines, available at [www.bt.cdc.gov/agent/smallpox/response-plan/index.asp](http://www.bt.cdc.gov/agent/smallpox/response-plan/index.asp). And see J. Gillis & C. Connolly, *U.S. Details Response to Smallpox: Cities Could Be Quarantined and Public Events Banned*, Washington Post (Nov. 27, 2001) at A1.
38. This model was released on October 23, 2001, to great fanfare, but has since been removed from the sponsor's website. A copy is on file with the author.
39. Model Act, sec. 104(f).
40. *Id.*, sec. 402(b).
41. *Id.*
42. TopOff (Top Officials) was a Congressionally mandated exercise, to simulate three simultaneous attacks: chemical in New Hampshire, nuclear in Washington, D.C., and biological in Denver. The most dramatic was the scenario involving the aerosol release of pneumonic plague at the Denver Performing Arts Center and the 4-day sequel played out in May 2000, which included the closing of Colorado's borders on day 3. Among the questions raised by Denver TopOff were: who is in charge, how to handle drug supply, how to avoid a hospital crisis, whether and how to quarantine those infected, whether to close city and state borders to contain the disease. See [www.biohazardnews.net/scen\\_plague.htm](http://www.biohazardnews.net/scen_plague.htm).
43. Dark Winter, played out June 22 and 23, 2001, was a simulated smallpox attack on Oklahoma City. The exercise resulted in five major "learning points," including that biological weapons could threaten vital national security interests, current organizational structures are not well suited to managing a biological attack, there is no surge capacity in our health system, dealing with the media is critical, and finally, "Should a contagious bioweapon pathogen be used, containing the spread of disease will present significant ethical, political, cultural, operational and legal challenges." See [www.homelandsecurity.org/darkwinter/index.cfm](http://www.homelandsecurity.org/darkwinter/index.cfm).
44. See W. Parmet & W. Mariner, *A Health Act That Jeopardizes Public Health*, Boston Globe (Dec. 1, 2001) at A15.
45. D.A. Henderson, "Public Health Preparedness," Committee on Science, Engineering and Public Policy, *Science and Technology in a Vulnerable World*, 33-40 (AAAS, 2002); M. Hamberg, *Addressing Bioterrorist Threats: Where Do We Go from Here?*, 5 Emerging Infectious Diseases 564 (1999).
46. J. Bor, *Americans Are Taking Antibiotics into Own Hands in Case of Anthrax*, Baltimore Sun (Oct. 13, 2002) at 5A; and see Tara O'Toole, *Terrorism Through the Mails: Testimony Before U.S. Senate Comm. on Government Affairs* (Oct. 31, 2001), Fed. News Service.
47. See, e.g., D. A. Henderson et al., *Smallpox as a Biological Weapon: Medical and Public Health Management*, 281 J.A.M.A. 2127 (1999).
48. J. Barbera, A. Macintyre, L. Gostin, et al., *Large-Scale Quarantine Following Biological Terrorism in the United States: Scientific Examination, Logistic and Legal Limits, and Possible Consequences*, 286 J.A.M.A. 2711 (2001).
49. Public Health Service Act, 42 U.S.C. 264 (1983), and Quarantine, Inspection, Licensing: Interstate Quarantine, 42 C.F.R. 70.1-8 (2000). Of course, bioterrorism is fundamentally a global issue as well. See W. Mariner, *Bioterrorism Act—The Wrong Response*, National Law Journal (Dec. 17, 2001) at A21, and D. F. Fidler, *Bioterrorism, Public Health and International Law*, 3 Chi. J. Int'l L. 7 (2002).
50. J. Hodge, *Bioterrorism Law and Policy: Critical Choices for Public Health*, 30 J. Law, Med. & Ethics 254 (2002).
51. *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).
52. Charles Rosenberg, *The Care of Strangers: The Rise of America's Hospital System* (Basic Books, 1987).
53. *Jacobson*, *supra* note 51.
54. See G. J. Annas, *The Bell Tolls for a Constitutional Right to Physician-Assisted Suicide*, 337 New Engl. J. Med. 1098 (1997) (discussing *Washington v. Glucksberg*, 521 U.S. 702 (1997) and *Vacco v. Quill*, 521 U.S. 793 (1997)). See also *Sell v. U.S.*, 2003 U.S. LEXIS 4594 (June 16, 2003).
55. See, e.g., *Greene v. Edwards*, 164 W.Va. 326, 263 S.E. 2d 661 (W.Va. 1980); *City of Newark v. J.S.*, 279 N.J. Super. 178 (1993); and G. J. Annas, *Control of Tuberculosis: The Law and the Public's Health*, 328 New Engl. J. Med. 585 (1993). The analogy modern

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courts have adopted is to the due process protection now constitutionally required to confine a person to an institution because they are mentally ill and dangerous.

56. *Id.*

57. See *supra* note 44.

58. Quoted by Tara O'Toole, oral presentation, Boston University School of Public Health (Oct. 18, 2002).

59. See *supra* note 48. Those quarantines that were undertaken in the past century primarily involved recent immigrants and ethnic minorities.

60. The text of the December 21, 2001, version is available at [www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf](http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf).

A comparison of the cover pages of the two versions of "The Model State Emergency Health Powers Act" is both instructive and deeply disturbing. The **October 23, 2001, version** contains the following language immediately under the act's title and the date: "Prepared by The Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities For the Centers for Disease Control and Prevention In collaboration with the: National Governors Association, National Conference of State Legislatures, Association of State and Territorial Health Officials, National Association of City and County Health Officers, and National Association of Attorneys General."

The cover page of the **December 21, 2001, version** (apparently the final one) reads as follows after the title of the Act: "Draft as of December 21, 2001. A Draft for Discussion Prepared by: *The Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities* For the Centers for Disease Control and Prevention [CDC] To Assist: National Governors Association [NGA], National Conference of State Legislatures [NCSL], Association of State and Territorial Health Officials [ASTHO], and National Association of County and City Health Officials [NACCHO]."

The cover page also contains a footnote to the title of the Act which reads: "Members of the National Association of Attorneys General (NAAG) also provided input and suggestions to the drafters of the Model Act. The language and content of this draft Model State Emergency Health Powers Act do not represent the official policy, endorsement, or view of the *Center for Law and the Public's Health*, the CDC, NGA, NCSL, ASTHO, NACCHO, or NAAG, or other governmental or private agencies, departments, institutions, or organizations which have provided funding or guidance to the Center for Law and the Public's Health. This draft is prepared to facilitate and encourage communication among the various interested parties and stakeholders about the complex issues pertaining to the use of state emergency health powers."

61. *Id.*, sections 605(a) and (b).

62. *Supra* notes 16 to 34 and accompanying text.

63. Section 602(c).

64. See, e.g., G.J. Annas, *The Nuremberg Code in U.S. Courts: Ethics vs. Expediency*, in *The Nazi Doctors and Nuremberg Code*, *supra* note 14, at 201, 212–19. A good example of how arbitrary power tends to be used in emergencies is the use of potentially lethal gas by Russian commandos to "rescue" hostages held by Chechen nationals in October 2002. See S. Myers, S. Travernise & M. Wines, *From Anxiety, Fear and Hope, the Deadly Rescue in Moscow*, *New York Times* (Nov. 1, 2002) at A1.

65. Kevin Johnson, *Police Want Quarantine Rules*, *USA Today* (Dec. 14, 2005) at 3A.

66. Minn. Stat. §12.39 (2002).

67. *Id.*

68. K.Wing, *The Model Act: Is It the Best Way to Prepare for the Next Public Health Emergency?*, 19 *Northwest Public Health* 10 (2002). Epidemiological models for responding to a smallpox attack did not begin to appear in the literature until almost a year after the model act was drafted. Controversy continues about which model is most likely to mirror reality, and all are based on assumptions about the number of people each person with smallpox is likely to affect. As one commentator put it, "Without appropriate data, models cannot indicate us whether we should target contacts for quarantine or vaccination when those contacts have been made in households, schools, workplaces, at public events, or under other circumstances." J. Koopman, *Controlling Smallpox*, 298 *Science* 1342, 1343 (2002). *And see* M.E. Halloran et al., *Containing Bioterrorist Smallpox*, 298 *Science* 1428 (2002) and S.A. Bozzette, R. Boer, V. Bhatnagar, et al., *A Model for a Smallpox-Vaccination Policy*, 348 *New Engl. J. Med.* 416 (2003). Of course, developing an effective legal strategy is dependent upon reasonable epidemiology, and without it legal plans are likely to be unresponsive or irrelevant to real-world epidemics—whether naturally occurring or terrorist-created.

69. See Annas, *supra* note 2.

70. Although I have argued in this chapter that modern public health will from now on be considered primarily a federal rather than a state responsibility, it would be even better if it were treated as a global issue, since epidemic diseases know no geographic boundaries and effective public health measures demand international action. See generally Laurie Garrett, *Betrayal of Trust: The Collapse of Global Public Health* (Hyperion, 2000), Institute of Medicine, *Microbial Threats to Health in the United States* (National Academy Press, 1992), and L. Asher, *Confronting Disease in a Global Arena*, 9 *Cardozo J. Int'l & Comp. L.* 135 (2001).

71. See, e.g., G. Kolata, *With Vaccine Available, Smallpox Debate Shifts*, *New York Times* (Mar. 30, 2002) at A8; L. Altman, W. Broad & D. Grady, *White House Debate on Smallpox Slows Plan for Wide Vaccination*, *New York Times* (Oct. 13, 2002) at 10.

72. See, e.g., G.J. Annas, *The Statue of Security: Human Rights and Post-9/11 Epidemics*, 38 *J. Health Law* 319 (2005).

73. R. Stevenson & S. Stolberg, *Threats and Responses: Vaccinations, Bush Lays Out Plan on Smallpox Shots*, *N.Y. Times* (Dec. 14, 2002) at A1. See also CDC Smallpox Response and Guidelines, Draft 3.0 (Sept. 21, 2002), available at [www.bt.cdc.gov/agent/smallpox/response-plan](http://www.bt.cdc.gov/agent/smallpox/response-plan).

74. *Smallpox Vaccination Plan: Hearing Before the Senate Appropriations Comm., Subcomm.on Labor, Health & Human Services*, 108th Cong., 2d Sess. (Jan. 29, 2003) (Statement of Dr. Julie Gerberding). See also M. Enserink & J. Kaiser, *Has Biodefense Gone Overboard?*, 307 *Science* 1396 (2005).

75. See M. Calabresi & M. August, *Was Smallpox Overhyped*, *Time* (July 26, 2004) at 16. See also M. Chase & G. Hitt, *Ugly Side Effects of Smallpox Vaccine Color Terror Plans*, *Wall Street Journal* (Oct. 21, 2002) at A1.