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ARTICLE

PREPAREDNESS AND RESPONSE PARALYSIS: RAMIFICATIONS FOR PANDEMIC PLANNING

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INTRODUCTION

The anthrax mailings of 2001, recent terrorist attacks, disasters like tsunamis and hurricanes, and the potential for emerging infections such at H5N1 and H1N1 to become pandemic have led to significant developments in the field of disaster preparedness and response as scientists, public health officials, health care personnel, and governments realize that adequate preparation is the only way to meet these challenges. The U.S. government and others have therefore placed a high priority on preparedness and response, as have many public and private companies and organizations, designating specialists to develop effective plans for them.[1]

In this paper, we discuss preparedness and response paralysis in the context of the U.S. public health system, including factors and specific issues that contribute to paralysis, and its overall effect on preparedness. Our intention is to develop a planning mechanism for quick and effective pandemic and bioterrorism response that will bypass obstacles encountered by planners and responders, and that can be implemented well before an event occurs.

The words "public health" describe, in the context of this paper, the organized efforts of society to protect, promote, and restore people's health. It is the combination of science and skills directed toward the maintenance and improvement of health through collective actions. Public health activities shift to accommodate variations in technology and social values, but the

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1. Press Release, Bus. Wire, CDC Expands Existing Vaccine Distribution Partnership with McKesson to Include H1N1 Flu Vaccine (Aug. 10, 2009), http://www.businesswire.com/portal/site/home/permalink/?ndmViewId=news_view&newsId=20090810005445&newsLang=en.

goal remains the same: to reduce the amount of disease, premature death, and disease-produced discomfort and disability. To this end, public health in the United States is made up of loosely affiliated local, state, and federal agencies. While the state and federal health agencies will play a role in responding to a bioterrorist attack, the initial response must come from the local public health agency because it is crucial that the response be as rapid as possible in order to minimize loss of life.[2]

The authors of this paper coined the term "preparedness and response paralysis" to describe the point many planners reach where they find themselves lacking the resources, support, information, and leadership necessary to continue developing a concrete and actionable plan that can be implemented in the face of a particular type of disaster. It is at this point that many cease planning altogether, arguing that they must wait for further instructions from authorities like the Centers for Disease Control and Prevention (CDC) or their own state governments. Others may continue, but only at a very general level, producing plans that are difficult to understand, are often unrealistic in their expectations of what resources and support are available, and fail to give the kind of specific information needed for effective responses. Moreover, these plans rarely include the input of interested stakeholders, without whose assistance no plan or response can be complete. Interested stakeholders include business people, emergency medical technicians (EMTs), first responders, public health workers, and others who would help create an actionable plan. Those who must try to respond to a disaster based on an incomplete plan often deal with what the authors call "response paralysis." Because the plans are so poor, the responders are unable to react in a way that addresses the problems at hand, so they either fall back on inappropriate but familiar strategies, or else give up entirely.

Two preparedness areas of particular concern to public health are bioterrorism and pandemic influenza. In the following section, we will provide an overview of bioterrorism, the agents most likely to be employed by terrorists, and their characteristics and commonalities. We will also provide an example of a simulated biological attack and the lessons to be learned from it, as well as from past attacks. The following sections will include a discussion of the obstacles to effective planning and response, as well as briefly describe the structure of the U.S. public health system and some of its weaknesses. This will provide background for a discussion of the ramifications these issues have for preparedness and response, and how they feed into planning and response paralysis. We will conclude with recommendations for improving the current process of preparing for and responding to a bioterrorist or naturally occurring pandemic.

2. R. Gregory Evans & Bruce W. Clements, *Public Health Preparedness*, *in* BIODEFENSE: PRINCIPLES AND PATHOGENS 49 (Michael S. Bronze & Ronald A. Greenfield eds., 2005).

BIOTERRORISM[3]

A review of the bioterrorist agents for which plans must be prepared will provide good background for the discussion of preparedness and response paralysis. Furthermore, it will explain not only what we are faced with, but how the characteristics of the agents may lead to a sense that planning for them is beyond our capabilities, and that we gain little by pursuing sophisticated preparedness and response.

Terrorists can choose from among hundreds of lethal biological agents to weaponize and unleash against any population they choose. That they plan to make use of such weapons has long been established by global and U.S. intelligence services, and supported with direct threats from terrorists themselves, including a recent threat on an Al Qaeda video in which operatives spoke of their intention to smuggle bioweapons into the United States through tunnels that run between Mexico and Texas.[4] Such weapons may have similarities that can assist us in planning, but they also can come in many forms, including liquid or powder, and can be dispersed as aerosols in a particle size specially tailored to enter the lungs and cause maximal damage.[5] Particles can be aerosolized from a line or point source,[6] either outdoors or indoors. Indoor delivery is more likely because it would give terrorists more control, less agent would be needed, and environmental factors like wind, sun, and humidity, which can all reduce the effectiveness of any biological agent, would not be factors.

Another common characteristic of many biological agents is that they can be delivered in contaminated food or water. Food contamination is somewhat easier to achieve than water contamination and, as we have recently seen, even small amounts of food like lettuce or peanuts that have been naturally contaminated can cause injury and death, while frightening consumers and producing serious economic consequences.[7] Introducing a biological agent into a large body of water such as a reservoir is a terrifying scenario, but this kind of approach leads to significant dilution of the agent, and the chlorination of U.S. water supplies kills most bacteriological

3. R. Gregory Evans et al., *Terrorism from a Public Health Perspective*, 323 AM. J. MED. SCI. 291, 291–98 (2002).

4. Sara Carter, *Al Qaeda Eyes Bio Attack from Mexico*, WASH. TIMES, June 3, 2009, *available at* http://www.washingtontimes.com/news/2009/jun/03/al-qaeda-eyes-bio-attack-via-mexico-border/.

5. Michael S. Bronze et al., *Viral Agents as Biological Weapons and Agents of Bioterrorism*, 323 AM. J. MED. SCI. 316, 316–25 (2002).

6. A line source could be a plane, truck, or other vehicle moving through a city spraying a biological agent. A point source is a stationary mechanism for the release of a biological agent, such as an aerosolizing device placed in a building or a plastic bag that is punctured to release the agent.

7. MARION NESTLE, SAFE FOOD: BACTERIA, BIOTECHNOLOGY AND BIOTERRORISM 113–38 (Darra Goldstein, ed., 2003).

agents.[8] Nevertheless, those who manage the nation's water supply are being alerted to possible attempts at intentional contamination.

In order to better understand the consequences of a bioterrorist attack and to help determine complications that could occur with current preparedness plans, we worked with the National Geospatial Intelligence Agency to model the release of five pounds of anthrax spores from the top of a building (point source) in downtown St. Louis, Missouri. Five pounds is a moderate amount of anthrax, particularly when compared to the two to three ounces contained in the letter sent to Senator Daschle in 2001.[9] Anthrax is a naturally occurring disease that usually appears cutaneously (as a skin infection), though it can also be gastrointestinal; and it is often found among people who work on farms or with animal skins.[10] This kind of anthrax is highly treatable and rarely lethal. The most lethal form of anthrax (mortality 45%–87%) is inhaled directly into the lungs, and is thus called inhalational.[11] Inhalational anthrax almost never occurs naturally because the spores needed to infect a victim must be aerosolized in a way which does not occur naturally.[12] Thus, even a single case of inhalation anthrax could indicate a terrorist attack.

Once anthrax spores are inhaled and deposited in the alveolar spaces of the lungs, they migrate to the mediastinum and begin to germinate and set off a deadly infection.[13] Although the incubation period is one to ten days, treatment with antibiotics must begin as soon as possible or mortality will increase.[14] Indeed, the panic around the 2001 anthrax letters led to many people being treated for the disease when they were not infected because of fears that it would be missed and caught too late.[15] At that point, poor communications among public health agencies, public spokespeople, the government, and media ultimately led to more confusion and terror than would have occurred if an effective response plan had been in place—something which, arguably, has not yet occurred, despite the passage of eight years

8. American Chemistry Council, *Chlorine Chemistry: Essential$_2$ Safer Water for 100 Years, and Running. . .*, http://www.americanchemistry.com/schlorine/sciencesec.asp?CID=1327&DID=8248&CTYPEID=113 (last visited Sept. 16, 2009).

9. *See* Stephen Engelberg & Judith Miller, *Daschle Letter Called First Use of Anthrax as Weapon*, N.Y. TIMES, Oct. 17, 2001, *available at* http://www.nytimes.com/2001/10/17/national/17WEAP.html?scp=Dascj;e%20Letter%20Called%20First%20Use%20of%20Anthrax%20as%20Weapon&st=cse.

10. Sirisanthana Thira & Arthur E. Brown, *Anthrax of the Gastrointestinal Tract*, 8 EMERGING INFECTIOUS DISEASES 649, 649–51 (2002).

11. Medline Plus, *Inhalation Anthrax*, May 30, 2009, http://www.nlm.nih.gov/medlineplus/ency/imagepages/19058.htm.

12. John A. Jernigan et al., *Bioterrorism-Related Inhalational Anthrax: The First 10 Cases Reported in the United States*, 7 EMERGING INFECTIOUS DISEASES 933, 941 (2001).

13. ALAN L. MELNICK, BIOLOGICAL, CHEMICAL, AND RADIOLOGICAL TERRORISM EMERGENCY 14 (2008).

14. Thi-Sau Migone et al., *Raxibacumab for the Treatment of Inhalational Anthrax*, 361 NEW ENG. J. MED. 135, 135-44 (2009).

15. MELNICK, *supra* note 13, at 14.

and multiple reports and studies. At one point, there was even a shortage of the appropriate antibiotic for treatment, as the public did not receive accurate information about who should be treated; response was a patchwork of recommendations, warnings, and uncertainty.[16] Such a response in reaction to another agent could easily leave medical stores depleted and lead to paralysis in planning and response.

The five-pound bag of "anthrax" with which we created a theoretical release could have been produced quite easily by one well-trained person or group in a relatively small lab, as only a small proportion of the spores need to be in the range of one to five microns in order to enter the lungs.[17] On the basis of this model, we calculated that approximately sixty-two thousand individuals would be killed,[18] and that number might be understated, since it is assumed that two-thousand five hundred to fifty-five thousand anthrax spores are required to cause disease.[19] In fact, evidence from the mailed anthrax attack suggests that fewer spores suffice for infectivity.

Mortality from such dispersal would be highly dependent on the rapid distribution of antibiotics. Maximum antibiotic effectiveness in this case would require the entire metropolitan population to be treated within as little time as possible, since it would be impossible to know precisely who had been exposed without a time-consuming and detailed analysis of exactly how wind and weather influenced dispersal patterns.[20] A swift and effective response could reduce mortality by 40–60 percent depending on how quickly antibiotic stockpiles could be delivered to the area, how rapidly distribution sites could be set up, and how effectively a mechanism could be implemented to provide transportation to those unable to get to the distribution sites on their own.[21] Most current bioterrorism plans lack the detail, resources, and personnel to implement a response that could deliver antibiotics to over 2.8 million people (the population of St. Louis county added to the population of St. Louis proper) within one to three days.[22] Moreover, even with successful rapid distribution of antibiotics, the mortal-

16. Elin Gursky et al., *Anthrax 2001: Observations on the Medical and Public Health Response*, 1 BIOSECURITY AND BIOTERRORISM 97, 97–110 (2003).

17. Phillip S. Brachman et al., *An Epidemic of Inhalation Anthrax: The First in the Twentieth Century* (pt. 2), 72 AM. J. HYGIENE 6, 16–19 (1960).

18. Authors' calculation.

19. MELNICK, *supra* note 13, at 14.

20. *See* Medical News Today, Special Issue of Medical Decision Making Explores Bioterrorism and Disaster Preparedness, July 28, 2009, http://www.medicalnewstoday.com/articles/159050.php.

21. *See* RedOrbit.com, *Most Effective Anthrax Treatment: Rapid Diagnosis, Antibiotics and Lung Drainage, VA-Stanford Study Finds*, http://www.redorbit.com/news/health/398810/most_effective_anthrax_treatment_rapid_diagnosis_antibiotics_and_lung_drainage/index.html.

22. U.S. CENSUS BUREAU, STATE AND COUNTY QUICKFACTS: ST. LOUIS COUNTY, MISSOURI (2008), http://quickfacts.census.gov/qfd/states/29/29189.html; U.S. CENSUS BUREAU, STATE AND COUNTY QUICKFACTS: ST. LOUIS CITY, MISSOURI (2008), http://quickfacts.census.gov/qfd/states/29/29510.html.

ity could be as high as 40–60 percent of the exposed population.[23] This would mean that any response plan would have to include provisions for handling a large number of sick people in need of hospitalization, dead bodies, and provisions for dealing with the psychological trauma experienced by family members and first responders. Any degree of preparedness paralysis in such a situation would result in an increase in preventable deaths.

BIOTERRORISM AGENTS

The North Atlantic Treaty Organization (NATO) has identified thirty-one potential agents that could be used in a biological attack.[24] The United States Army Medical Research Institute of Infectious Diseases has reduced this list to six primary agents, in part so as to make preparation and response easier, on the assumption that plans for all will be similar, if not the same.[25] This choice was based upon five criteria: availability of the agent, ease of production, lethality, infectivity, and stability.[26] Agents that have high infectivity and lethality would be the most desirable to a terrorist because of their quick spread and high mortality. Stability would allow for easier transport and dispersal of the weaponized materials by terrorists.

The six agents are subdivided into three categories. Category 1 agents include anthrax and smallpox, Category 2 agents are plague and tularemia, and Category 3 includes botulinum toxin and agents of viral hemorrhagic fever.[27] Category 1 agents rank the highest on a scale based on the criteria provided by the United States Army Medical Research Institute of Infectious Diseases. Interestingly, this list predates the anthrax attacks of 2001, and can be said to have correctly placed, if not predicted, anthrax as the single most dangerous potential bioterror agent.

Smallpox is a Category 1 agent because it can be easily transmitted person-to-person and has the potential for aerosolization; however, the availability of the agent is quite low because the disease has been eradicated and the only known samples of smallpox are stored in secured locations in the United States and Russia. If a terrorist could procure a sample of smallpox and grow it in a laboratory, they could aerosolize a suspension of the virus that could infect at very low doses. Infected individuals could then infect others within seven to twelve days, and a full-scale epidemic might

23. Personal observation of authors.

24. CDC, *Bioterrorism Agents / Diseases*, http://www.bt.cdc.gov/agent/agentlist-category.asp (last visited Oct. 2, 2009).

25. U.S. MED. RESEARCH INST. OF INFECTIOUS DISEASES, USMRIID'S MEDICAL MANAGEMENT OF BIOLOGICAL CASUALTIES HANDBOOK (5th ed. 2004), *available at* http://www.usamriid.army.mil/education/bluebookpdf/USAMRIID%20Blue%20Book%205th%20Edition.pdf [hereinafter USMRIID].

26. *Id.*

27. *Id.*

ensue before public health authorities could respond.[28] It is estimated that the attack rate for unvaccinated contacts would be 25–40 percent with a mortality rate of 30 percent or more among the infected.[29]

Recent research into the effectiveness of vaccinations given to people in the 1970s (when smallpox was eradicated and vaccinations ceased) or earlier indicates some possible element of residual protection from first vaccines.[30] However, according to Steve Laurence M.D., the calculations based on the most recent research suggest that first-time vaccination with "take" (production of antibodies) provides five to ten years of solid protection, with partial protection probably lasting twenty years or more.[31] Second-time vaccination provides an additional ten or more years of solid protection, with partial lifelong protection, while three or more vaccinations provide lifelong immunity for most people.

For the non-vaccinated who are exposed, the only known treatment is vaccination within four to seven days of exposure, which may only be partially effective.[32] As with the anthrax scenario, the need for this kind of immediate response and the limited supply of vaccines would put great pressure on public health systems. Assuming that adequate supplies of the vaccine were available, a response mechanism would have to already be in place to quickly requisition the vaccine from the Strategic National Stockpile (SNS) and transport it to distribution centers. There, assuming a city with the metropolitan area of St. Louis, Missouri (an area which contains 1.5 million people), skilled and trained vaccinators would have to be available to staff the centers in sufficient numbers to vaccinate 375,000 people a day.[33]

In addition, responders would need detailed information to respond to legal concerns, such as who is licensed to vaccinate during an emergency, what to do given an estimated 40% absentee rate among those licensed, and who decides if it is permissible to use a vaccine. For example, one of the authors (RGE) participated in a smallpox exercise where school nurses were faced with a smallpox pandemic and a school full of quarantined children. The nurses were required to decide whether to vaccinate the children and protect them from the disease, or to wait until they could somehow reach parents to obtain official parental permission. Having no plan or guidance, the nurses were unable to make a clear decision and kept waiting until some higher authority, which never materialized, made the decision

28. Ira M. Longini, Jr. et al., *Containing a Large Bioterrorist Smallpox Attack: A Computer Simulation Approach*, 11 INT'L J. INFECTIOUS DISEASES 98, 99 (2007).

29. *Id.*

30. Stephani Gallwitz et al., *Smallpox: Residual Antibody after Vaccination*, 41 J. CLINICAL MICROBIOLOGY 4009, 4068–70 (2003).

31. Personal communication on June 3, 2009.

32. CDC, *Smallpox Vaccination Overview*, http://www.bt.cdc.gov/agent/smallpox/vaccination/facts.asp (last visited Sept. 17, 2009).

33. Authors' calculation.

for them. The result was that their paralysis prevented the vaccination of a school full of vulnerable children. If they had been facing an actual outbreak, all the children would likely have been exposed and possibly infected, and many might have died. The public health simply cannot afford such paralysis and abortive responses.

Another bioterror agent of concern is *Yersinia pestis* (plague).[34] Plague is a naturally occurring disease.[35] In fact, two cases of bubonic plague and one death were reported on June 4, 2009, in the United States, and are believed to have been the result of flea bites.[36] On average, ten to fifteen people contract the disease from natural causes in the United States each year.[37] Treatment with antibiotics must begin as soon as possible and, if timely, usually leads to complete recovery.[38]

Historically, there have been three recorded plague pandemics killing more than 200 million people—most notably the Black Death epidemics in fourteenth-century Europe.[39] Prior to the 1950s, the plague organism had been studied by Japan and the United States as a potential bioweapon.[40] Its least common, but most severe form, is primary pneumonic plague, which carries an overall mortality of nearly 60 percent.[41] Aerosolization, the most likely form a terrorist attack would take, would probably cause the pneumonic form of the disease.[42] But while mortality rates are high with plague, they can be reduced substantially if antibiotic therapy is initiated within eighteen to twenty-four hours of symptom onset.[43] In a metropolitan area the size of St. Louis, antibiotics would have to be distributed to all 1.5 million people within the first day. Therefore, yet again, response is only effective if it is swift, organized, and accomplished with trained first responders.

34. USAMRIID, *supra* note 25.

35. The Official Website of Santa Fe, New Mexico, *Plague Warning*, http://www.santafenm.gov/index.aspx?NID=1794 (last visited Sept. 18, 2009).

36. CDC Plague Homepage, http://www.cdc.gov/ncidod/dvbid/plague/ (last visited Sept. 18, 2009).

37. CDC, DIVISION OF VECTOR-BORNE INFECTIOUS DISEASES, PLAGUE FACT SHEET 1–2 (2005), *available at* http://www.cdc.gov/ncidod/dvbid/plague/resources/plagueFactSheet.pdf.

38. CDC, *Plague Prevention and Control*, http://www.cdc.gov/ncidod/dvbid/plague/prevent.htm (last visited Sept. 18, 2009).

39. R. S. BRAY, ARMIES OF PESTILENCE: THE IMPACT OF DISEASE ON HISTORY 11–88 (Barnes and Noble Books 2000) (1996).

40. CDC, *History of Bioterrorism Podcast: Plague*, http://www2a.cdc.gov/podcasts/player.asp?f=5 (last visited Sept. 19, 2009).

41. R. Gregory Evans et al., *Terrorism from a Public Health Perspective*, 323 AM. J. MED. SCI. 291, 295 (2002).

42. Raymond Gani & Steve Leach, *Epidemiologic Determinants for Modeling Pneumonic Plague Outbreaks*, 10 EMERGING INFECTIOUS DISEASES 608 (2000).

43. USAMRIID, *supra* note 25; *see also* CDC, MORBIDTY AND MORTALITY REPORT WEEKLY, BIOLOGICAL AND CHEMICAL TERRORISM: STRATEGIC PLAN FOR PREPAREDNESS AND RESPONSE (2000), *available at* http://www.cdc.gov/mmwr/PDF/rr/rr4904.pdf (proposing a strategic plan to prepare the United States for a chemical or biological terrorist attack).

Francisella tularensis (tularemia) is another agent likely to be used by bioterrorists, as it is, like anthrax and plague, naturally occurring and relatively easy to obtain.[44] Six forms of tularemia are classified by clinical presentation and determined by route of exposure.[45] The pneumonic form is the most likely to be lethal, since it results from aerosolization of the bacteria and has a 30–60 percent untreated mortality.[46] While all forms of tularemia are naturally occurring and can be contracted by contact with infected rodents or ticks or contaminated food, the organism was weaponized by the United States, and possibly by other countries, prior to the termination of bioweapon programs.[47] Although there is a live attenuated vaccine available, it is not recommended for generalized post-exposure prophylaxis.[48] Instead, as in the case of plague, antibiotic treatment must begin as soon as possible after exposure.[49] In the event of a massive attack, treating a large population with ten to fourteen days of antibiotics would require vast supplies, and likely require that non-physicians be allowed to prescribe according to preset directions and training. The legal issues this could raise might seriously slow response time and cost lives; thus, potential legal issues should be resolved in advance.

Another bacterial agent of concern is *Clostridium botulinum.* Like anthrax, botulinum toxin was a major element of the Iraqi bioweapons program.[50] As with the other biological agents, inhalation would be the most likely route of exposure, but botulinum toxin could be used to contaminate the food supply. The inhalational form is not seen naturally, and its presence is therefore a likely indication of bioterrorism.[51] Since the inhalational form of botulism has not been studied in humans, the case mortality rate is not known, making it more difficult to prepare for and more likely to cause terror and uncertainty that can lead to preparedness and response paralysis.[52] In the event of a large scale attack using botulinum toxin, antitoxins have to be obtained from the strategic national stockpile quickly because every hour that passes without treatment—and with botulinum the treat-

44. CDC, *Tularemia: Key Facts about Tularemia*, http://emergency.cdc.gov/agent/tularemia/facts.asp (last visited Sept. 18, 2009).

45. *Id.*

46. David T. Dennis et al., *Tularemia as a Biological Weapon: Medical and Public Health Management*, 285 JAMA 2763, 2767 (2001).

47. CDC, *supra* note 44.

48. *Id.*

49. *Id.*

50. *Id.*

51. CDC, *Botulism Facts for Health Care Providers*, http://emergency.cdc.gov/agent/botulism/hcpfacts.asp (last visited Sept. 18, 2009).

52. CDC, *The History of Bioterrorism Video: Botulism*, http://emergency.cdc.gov/training/historyofbt/05botulism.asp (last visited Sept. 18, 2009).

ment window is measured in hours, not days—increases the potential severity of the disease.[53]

If, for example, the toxins were introduced through contaminated food at several restaurants, the antitoxin would need to be disbursed to potentially thousands of people. Moreover, the antitoxin will not prevent the disease; it will only reduce its severity.[54] Thus, even after they have received the antitoxin, many patients will require artificial ventilation, intensive care, and other interventions.[55] Planning must provide for access to hundreds, or even thousands, of ventilators.[56] If the attack occurred in multiple locations throughout the United States, there would not be an adequate supply of ventilators anywhere in this country, even including the ventilators stored in the SNS.[57] Many planners already assume that such an attack would leave them with no choice but to accept what might otherwise be unacceptable losses and prepare for difficult triage decisions.[58] Other planners refuse to accept that things will reach such a point and have not planned for it.[59] Unless they change this approach and make realistic preparedness plans, their failure to face reality will ultimately result in additional deaths.

The last agents on the list are the hemorrhagic fever viruses, of which Ebola and Marburg are probably the most familiar examples.[60] Naturally occurring viral hemorrhagic fever is transmitted by contact with infected blood or secretions.[61] However, the airborne virus has been suspected of causing disease in primates, and possibly in humans.[62] Terrorists would need to develop an aerosolized form of the virus to have an effective bioweapon.[63] Treatment for hemorrhagic fever will be similar to treatment for botulinum toxin, resulting in similar planning problems and the addition of paralysis to the list of issues that must be overcome.[64]

53. CDC, *Conference Call with William Bower: Overview of Bioterrorism Agents* (Aug. 19, 2008) (transcript available at http://www.bt.cdc.gov/coca/summaries/BT-Agents081908.asp).

54. CDC, *supra* note 51.

55. *Id.*

56. Charles Kemp, *Botulism Information Page*, http://bearspace.baylor.edu/Charles_Kemp/www/botulism.htm (last visited Sept. 18, 2009).

57. *Id.*

58. Personal observation of authors.

59. Personal observation of authors.

60. WHO, *Haemorrhagic Fevers, Viral*, http://www.who.int/topics/haemorrhagic_fevers_viral/en/ (last visited Oct. 4, 2009).

61. CDC & WHO, INFECTION CONTROL FOR VIRAL HAEMORRHAGIC FEVERS IN THE AFRICAN HEALTH CARE SETTING 3–4 (Dec. 1998), *available at* http://www.cdc.gov/ncidod/dvrd/spb/mnpages/vhfmanual/entire.pdf.

62. John King, M.D., *Ebola Virus: Follow-up*, E-MEDICINE, http://emedicine.medscape.com/article/216288-followup (last updated Apr. 2, 2008).

63. Cagatay Ustun & Ozge Ozgurler, *Ebola: A Significant Threat as an Infectious Disease, and as a Potential Bioterrorism Agent*, 35 TURKISH J. OF MED. SCI. 1, 3 (2005).

64. *See* USAMRIID, *supra* note 26.

BIOTERRORISM: HOW LACK OF PLANNING CAN CAUSE AND PERPETUATE PARALYSIS

It is not necessary for terrorists to actually release a biological agent to cause major disruption. In 1997, the mailroom at the B'nai B'rith offices in Washington, D.C., received a leaking package that contained a Petri dish.[65] It was early in our understanding of bioterrorist agents, and the first responders did not know that bacteria in a Petri dish is not a likely source of exposure and does not require decontamination. In fact, security initially called the bomb squad, thinking it was an explosive. As it turned out, this was only a hoax, but in the process of discovering this fact, an entire city block around the building was closed down, and terrified personnel suffered the embarrassment of undergoing decontamination in public and waiting in quarantine, fearing for their lives for nine hours until test results confirmed the hoax.[66] A Federal Emergency Management Agency (FEMA) report on the response pointed out a number of failures, but the Chief of Security for the B'nai B'rith building, Carmen Fontana, simply said, "No one really knew what to do."[67]

Since the first actual anthrax-tainted letters were received in the Senate on September 18, 2001, thousands of hoax mailings all across the country have closed down schools, businesses, and government offices, resulting in millions of dollars of expenses and lost revenue, and anxious citizens.[68] If effective plans had been in place to deal with such events, trained personnel could have evaluated each situation and prevented unnecessary terror and disruptive and misguided responses. However, such planning requires the participation of all stakeholders and responders so that, rather than hoping for the best, they can count on having experienced professionals directing appropriate responses.

Another problem in response to bioterrorism is the lack of diligence and training on the part of first responders. On a Saturday in March of 1997, seven hundred passengers arrived at Sun Harbor Airport in Phoenix, Arizona, from Acapulco, Mexico.[69] More than fifty of the passengers had diarrhea.[70] Emergency Medical Services offloaded twenty-five passengers to ambulances, and six of them were admitted to a local hospital.[71] County health officers, who should have been informed immediately, only learned of the event by listening to the radio Monday morning—a full two days

65. U.S. FIRE ADMIN., FED. EMERGENCY MGMT. AGENCY, FIRE DEPARTMENT RESPONSE TO BIOLOGICAL THREAT AT B'NAI B'RITH HEADQUARTERS WASHINGTON, DC 4 (Apr. 1997), *available at* http://www.interfire.org/res_file/pdf/Tr-114.pdf.

66. *Id.* at 2–7.

67. LEONARD COLE, THE ANTHRAX LETTERS: A MEDICAL DETECTIVE STORY 164 (2003).

68. Bob Drogin, *Anthrax Hoaxes Pile Up, as Does Their Cost*, L.A. TIMES, Mar. 8, 2009, National Section.

69. Evans et al., *supra* note 3, at 295.

70. *Id.*

71. *Id.*

after the flight had landed.[72] By that time, all the victims had been released from the hospital. There were no stool samples to determine what might have caused the disease, and the airplane itself had been thoroughly cleaned. No one had even recorded the names of the sick passengers.[73] Had the outbreak been the result of a bioterrorist attack or an emerging infectious disease instead of simple food poisoning, the public health service would have been notified too late to mount an effective intervention. Indeed, any infectious disease would have been widely spread as passengers caught connecting flights and made their way home to families and friends. If, for example, the passengers had been infected with H1N1, which is believed to have originated in Mexico, the disease could have spread more quickly than it has, and possibly claimed more lives.

It is entirely possible that the county health officers, if informed immediately, would have been in a position to respond quickly and effectively, possibly using temporary quarantine, isolation, and tracking. However, the first responders in this case were neither prepared nor trained, and they did not contact the appropriate authorities. This kind of paralysis frequently occurs when all responders and stakeholders (including, in this case, airport authorities) fail to work together to create and exercise a joint plan. When an emergency occurs, lacking an effective and appropriate plan, they respond by default, doing what seems to them to be the most obvious. In this case, the default response could have led to the spread of a bioterrorist agent that caused a nationwide pandemic. This lapse of judgment would be less likely to have occurred if an effective plan for such an emergency had already been in place, all parties had been familiar with the plan, and the plan had been exercised.

The bombings of the World Trade Center and the mailing of anthrax spores have provided us with many lessons. We know that terrorists can be well organized, execute an attack employing dozens of individuals over an extended period, and not be detected by current counter terrorism efforts. Seeing themselves as martyrs, they are in a position to do extensive damage and cause mass casualties in ways that the United States had not been accustomed to before 9/11. We cannot depend on past experiences with terrorism to predict what terrorists will do in the future, as they develop new strategies and targets. Our best chance to minimize their effect is to create a security and public health infrastructure that responds quickly and cooperatively, and communicates clearly and appropriately to everyone involved in the actual response, as well as the public. This avoids confusion, unnecessary fear, and panic, and allows responders to do their jobs quickly and according to exercised plans that will make the most of available resources and personnel, rather than strengthen the hands of the terrorists by spread-

72. *Id.*
73. *Id.*

ing a sense of helplessness. As we have learned, sometimes the hard way, if good information and transparency in communicating to the public fail, the authorities will lose the public's trust, and that can lead to unwillingness to follow instructions meant to save lives and property.

In 2007, the Center for Strategic and Budgetary Assessments concluded that, "[I]t is prudent to assume that, in the foreseeable future, one or more terrorist groups will acquire the means to use biological weapons to cause mass casualties, and be inclined to launch such an attack."[74] As we have seen, such attacks are already in the planning stages among certain terrorist groups, and our record of preparing for them effectively is poor at best, leaving the entire nation vulnerable to bioterror attacks. Recognizing this lack of cooperation in planning and response, and the failure to develop and disseminate actionable information and direction, many have given up on creating the kind of detailed and realistic plans that are needed in the event of bioterrorism attacks. Such paralysis has already caused problems in preparedness and response to other disasters and potential disasters. We cannot afford to allow it to continue. Only when senior state and local officials, experts, businesspeople, first responders, and others work together will effective plans be written—plans that will lead to better responses and will lessen paralysis among responders.

PANDEMIC INFLUENZA

A pandemic is a global outbreak of a new disease or a new subtype of an existing disease. Seasonal epidemics of influenza are caused by subtypes of influenza viruses that already circulate among people, whereas a pandemic outbreak is caused by a new subtype of the virus that has never circulated among people or has not done so for many years, leaving the majority of the population vulnerable. A severe pandemic in which there are not adequate controls could result in over 30 percent of the population infected, ten million hospitalizations, and two million deaths.[75] In addition, over 40 percent of the population might be unable or unwilling to work, and the economic impact could be well over $260 billion.[76] These estimates could differ by tenfold depending on the virulence of the disease. In addition to these challenges, a pandemic would strike health care workers and first responders as hard as or harder than the general population, reducing their ability to work by 50 percent or more, leaving hospitals dangerously under-

74. ROBERT SHERMAN, CTR. FOR STRATEGIC & BUDGETARY ASSESSMENTS, AVOIDING THE PLAGUE: AN ASSESSMENT OF US PLANS AND FUNDING FOR COUNTERING BIOTERRORISM i (2007).

75. U.S. DEP'T OF HEALTH & HUMAN SERVICES, FLU.GOV PANDEMIC PLANNING ASSUMPTIONS, http://www.flu.gov/professional/pandplan.html (last visited Oct. 4, 2009).

76. INT'L MONETARY FUND, THE GLOBAL ECONOMIC AND FINANCIAL IMPACT OF AN AVIAN FLU PANDEMIC AND THE ROLE OF THE IMF (Feb. 28, 2006), *available at* http://www.imf.org/external/pubs/ft/afp/2006/eng/022806.pdf.

staffed and lacking resources, beds, equipment, and supplies needed to treat the sick.[77]

Three twentieth century influenza pandemics have spread around the world within a year of being detected.[78] The most virulent was the 1918–19 Spanish Flu (A H1N1) that resulted in five-hundred thousand deaths in the United States and forty million deaths worldwide over three successive waves.[79] Many of the deaths occurred within a few days after infection and others were the result of secondary complications.[80] Nearly half of those who died were young, healthy adults, or pregnant women, as opposed to the usual victims of a seasonal flu: the old and very young.[81] Of the 116,000 troop casualties in WWI, forty-three thousand resulted from the Spanish Flu, with a percentage dying of pneumonia.[82] Hospitals were overcrowded and unable to handle the majority of the ill people.[83] Communities fell apart as social, economic, and health problems devastated them. Many people died of hunger because there was no one willing to bring them food, and the dead went unburied or were interred in mass graves.[84]

Lessons from the Spanish Flu pandemic are still being applied today. Cities that imposed social containment measures shortly after the first case of flu was recorded reduced mortality by half compared to cities that waited weeks to impose these controls or did nothing at all.[85] Some of the more successful measures instituted included closing theatres, churches, and dance halls, despite pressure from businesses and the population to keep them open. Some cities mandated staggering factory shifts to reduce rush hour traffic, especially in trains and buses. Seattle's mayor ordered residents to wear face masks.[86]

77. Balicer et al., *Local Public Health Workers' Perception Toward Responding to an Influenza Pandemic*, 6 BMC PUBLIC HEALTH 99 (2006).

78. Monica Schoch-Spana, *Hospital's Full-Up: The 1918 Influenza Pandemic*, 116 PUB. HEALTH REP. 32, 32 (2001).

79. *Id.*

80. *See generally* Arthur Schoenstadt, MD, Flu Complications, http://flu.emedtv.com/flu/flu-complications.html (last updated Aug. 28, 2006).

81. Jeffrey Taubenberger & David Morens, *1918 Influenza: The Mother of All Pandemics*, 12 EMERGING INFECTIOUS DISEASES 12, 19 (2006).

82. NYGreene.com, War Years, http://www.nygreene.com/index.htm (last accessed Nov. 10, 2009).

83. Jim Duffy, *The Blue Death – Flu Epidemic of 1918*, MAG. JOHNS HOPKINS BLOOMBERG SCH. PUB. HEALTH (Fall 2004), *available at* http://www.jhsph.edu/publichealthnews/magazine/archive/Mag_Fall04/prologues/index.html.

84. *See* Jennifer Rosenberg, About.com Guide, 1918 Spanish Flu Pandemic, http://history1900s.about.com/od/1910s/p/spanishflu.htm (last visited Nov. 21, 2009); Steve Inskeep, Host of *Morning Edition*, NPR, Lesson Learned from the Great Influenza (May 5, 2009), http://www.npr.org/templates/transcript/transcript.php?storyId=103805839.

85. Martin C. J. Bootsma & Neil M. Ferguson, *The Effect of Public Health Measures on the 1918 Influenza Pandemic in U.S. Cities*, 104 PNAS 7588, 7588–89 (2007).

86. TRUST FOR AMERICAN'S HEALTH & THE AMERICAN ACADEMY OF PEDIATRICS, PANDEMIC INFLUENZA: WARNING, CHILDREN AT-RISK 10 (2007).

In general, it appears that the more social distancing interventions imposed, the lower the mortality rates. Planners today must take this information into account in creating plans and explaining them to the general public, so that if the plans must be implemented, people will understand why and will comply, rather than resisting and making response less effective. As it stands, planners are by no means certain that recommendations of social distancing would be followed by a majority of the population, especially without prior instruction and explanation, and enforcing such requirements would be difficult, if not impossible.

Two other pandemics struck the United States in the twentieth century. The Hong Kong Flu (A H3N2) in 1968–69 resulted in thirty-four thousand deaths (approximately the same as would be expected during a seasonal flu).[87] The Asian Flu of 1957–58 resulted in over seventy thousand deaths in the United States.[88] Three epidemics were also classified as pseudo-pandemics: one in 1947 with low death rates, one in 1977 that was pandemic in children, and a swine flu outbreak in 1976 that never developed, but had pandemic potential.[89] Thus, a pandemic could strike at any time.

Scientific evidence suggests that pandemics develop from changes in a virus's hemagglutinin (H) subtypes that arise from genetic reassortment with animal influenza A viruses in a process called antigenic shift.[90] Currently, there are two influenza viruses of special concern: H5N1 (Avian Flu) and H1N1.[91]

The H5N1 has resulted in 423 cases worldwide with 262 deaths as of June 2, 2009, and an average of 60 percent mortality.[92] The first recorded case was in 2003, and while there have been no recorded cases in the United States, the disease continues to spread and has been especially virulent recently in Egypt and Indonesia.[93]

The H1N1 virus has reached a higher level on the World Health Organization's pandemic alert stage (currently stage five), in large part because it has spread so quickly.[94] This phase is characterized by human-to-

87. GlobalSecurity.org, *1968* Hong Kong Flu, http://www.globalsecurity.org/security/ops/hsc-scen-3_pandemic-1968.htm# (last visited Sept. 16, 2009).

88. Charlene Porter, *Destruction of Asian Flu Virus Nearly Done, United Nations Says*, AMERICA.GOV, Apr. 15, 2005, http://www.america.gov/st/washfile-english/2005/April/20050415154315cmretrop0.3807642.html.

89. David J. Sencer & J. Donald Millar, *Reflections on the 1976 Swine Flu Vaccination Program*, 12 EMERGING INFECTIOUS DISEASES 29, 29–33 (Jan. 2006).

90. National Institute of Allergy and Infectious Diseases, Flu (Influenza): Antigenic Drift vs. Antigenic Shift, http://www3.niaid.nih.gov/topics/Flu/Research/basic/AntigenicDriftShift.htm (last visited Sept. 16, 2009).

91. Pandemic Flu Watch, http://panfluwatch.blogspot.com/2009/05/h1n1-h5n1.html (last visited Oct. 4, 2009).

92. WHO, *Avian Influenza*, http://www.who.int/csr/disease/avian_influenza/en/ (last visited Sept. 16, 2009).

93. *Id.*

94. Martin Enserink, *Swine Flu Outbreak: Worries About Africa as Pandemic Marches On*, 325 SCI. 662, 662 (2009).

human spread of the virus into at least two countries.[95] Classification in this stage is a strong signal that a pandemic is imminent and that the time to finalize the organization, communication, and implementation of the planned mitigation measures is short.[96] As of June 5, 2009, sixty-nine countries had reported 21,940 laboratory-confirmed cases with 125 deaths. Mexico has reported 5,563 laboratory-confirmed cases including 103 deaths. In the United States, there were 11,054 confirmed cases of H1N1 with seventeen deaths. However the CDC indicates that the actual number of cases is much greater.[97] Although the virus is spreading, the mortality is quite low, making it seem, in the words of interim CDC director Richard Besser, "very similar to seasonal flu."[98] There is, however, concern that a second wave of the virus might occur with the beginning of the fall flu season, and that this H1N1 might be more severe, having mutated over the summer months, much as occurred with the 1918–19 Spanish Flu. Indeed, the flu might even combine with the less contagious, but more lethal, H5N1 and create a more dangerous disease.[99]

Like a terrorist-caused pandemic, a naturally occurring pandemic could result in school and theater closings, disruption of communications services, and hospital and healthcare facilities becoming overwhelmed. So far, H1N1, though widespread, has resulted in only fifteen schools closures in New York City, as well as closures in California and several other states, and some relatively non-intrusive additional steps by public health and medical agencies to increase preparedness.[100] However, there has been significant uncertainty about how to deal with even this relatively mild pandemic, and many responders and planners argue that if this had been a severe illness, plans and resources would have been inadequate.[101]

PLANNING FOR DISASTERS: ON WHOSE AUTHORITY?

In the cases of bioterrorism and the H5N1 and H1N1 viruses, public health planners[102] have been working to improve preparedness so they will

95. *Id.*

96. WHO, Current WHO Phase of Pandemic Alert, http://www.who.int/csr/disease/avian_influenza/phase/en/ (last visited May 11, 2009).

97. CDC, *Seasonal Influenza* (Flu), http://www.cdc.gov/flu/ (last visited Sept. 16, 2009).

98. The Medical News, *Swine Flu Could Come Round Again*, May 11, 2009, http://www.news-medical.net/news/2009/05/11/49306.aspx.

99. Pandemic Flu Watch, *supra* note 91.

100. THE U.S. DEPARTMENT OF EDUCATION, ARCHIVED INFORMATION: H1N1 FLU & U.S. SCHOOLS: ANSWERS TO FREQUENTLY ASKED QUESTIONS, http://docs.google.com/gview?a=v&q=cache:riZVPJZ6hZkJ:www.ed.gov/admins/lead/safety/emergencyplan/pandemic/guidance/flu-faqs.pdf=+1n1+school+closures&hl=en&gl=us (last updated May 5, 2009).

101. Robert Roos, *Analysis of H1N1 Flu Response Shows Progress, Problems*, CENTER FOR INFECTIOUS DISEASE RESEARCH & POLICY (CIDRAP), June 4, 2009, *available at* http://www.cidrap.umn.edu/cidrap/content/influenza/panflu/news/jun0409tfah-jw.html.

102. The authors use the term "planners" to describe a broad range of people involved in the planning process at government and private organizations.

be ready to respond in the event that a bioterrorist agent or either of these viruses becomes easily transmissible from human to human, turns pandemic, or spawns a large-scale epidemic. These planners and the bodies they represent naturally turn to their governments for guidance and information on how to proceed. They often find, however, that many of their important questions go unanswered, or that the answers are changing and sometimes inconsistent or contradictory, even among officials and experts in the field. Indeed, anyone who reads the U.S. government's own Pandemic Response Plan or Bioterrorism Response Plan will find it open to interpretation at best, and a source of confusion at worst.[103] The Pandemic Response Plan lacks the specifics that local communities will require to respond to a pandemic and does not adequately address the role of the medical community.[104] Also, this planning guide was first released over three years after it was recognized that the H5N1 virus could develop into a pandemic. Richard Serino, Chief of the Emergency Medical Services Department in Boston, indicated to the Senate Subcommittee on Bioterrorism and Public Health Preparedness that the medical community was not adequately incorporated into planning and training, saying that preparedness is so far behind that stakeholders who should have already developed plans based on mutual needs only "[trade] business cards at the scene of a disaster."[105] To prevent this kind of situation, Serino argues that preparing for bioterrorism and pandemics must be part of standard health care planning.

Faced, on the one hand, with uncertainty about subjects like the use of personal protective equipment (type, efficacy, instructions, and so on); recommendations on stockpiling anti-virals; legal, social, and economic ramifications of work and school closures; home health care recommendations; and vaccination priority lists, and, on the other hand, a reluctance of government and public health officials to make concrete recommendations and assume a leadership role, many organizations have slowed or even stopped their planning and are simply waiting for definitive instruction from the Federal Government, CDC, and scientists.[106] Even those who soldier ahead produce plans that lack specificity and truly actionable information.[107]

103. Christopher Lee, *Federal Pandemic Plan Called Inadequate; Local Officials Point to Stress on Hospitals*, THE WASH. POST, Feb. 3, 2008, at A1.

104. Troy Anderson, *U.S. Plans Inadequate For 1918-Type Pandemic: Doctors Say All Health Systems Would Stumble*, L.A. DAILY NEWS, Oct. 6, 2005, *available at* http://www.thefreelibrary.com/U.S.+PLANS+INADEQUATE+FOR+1918-TYPE+PANDEMIC+DOCTORS+SAY+ALL+HEALTH. . .-a0137250317.

105. *All-Hazards Medical Preparedness and Response: Hearing of the Subcomm. on Bioterrorism and Public Health Preparedness of the S. Comm. on Health, Education, Labor, and Pensions*, 109th Cong. 27–29 (2005) (statement of Richard Serino, Chief of Department, Boston Emergency Medical Services).

106. Personal observation of authors.

107. Personal observation of authors.

The authors call the situation described above a state of "preparedness paralysis." As more planners reach the limit of authoritative recommendations and feel unable to move forward, the planning process stagnates. Those involved, however well-trained they are, cannot be expected to make decisions on crucial medical, political, and legal issues that officials are unwilling to make. This leads to failure to think creatively to address challenges. Networking and cooperation between planning bodies slows down, and significant energy and funds are wasted as planning and preparedness bodies scramble to justify their existence. Preparedness paralysis then leads to response paralysis. If no effective and well-rehearsed plan is in place, response is bound to be limited at best and counterproductive at worst.

In its January 2009 report, the House of Representatives Committee on Homeland Security recognized that serious efforts were being made to prepare for pandemic outbreaks.[108] However, the committee was forced to conclude that, despite these efforts, the United States is "not prepared as a Nation to fully withstand the impact of . . . a devastating widespread biological event."[109] In fact, Peter Ginaitt, Director for Emergency Preparedness at the Lifespan Hospital Network in Rhode Island, testified that regional preparedness meetings were resulting in little more than checking the box for the Department of Homeland Security as a way of acknowledging it was an important resource, while he had to scrounge for extra supplies for the hospital and fight for the small amounts of funding available for preparation.[110] "[W]e need to get beyond getting ready," Ginaitt insisted, highlighting the problems in a process that seems to progress very little, despite the best efforts of many.[111]

Indeed, we have seen the same battle for preparedness and planning resources going on all over the nation. Local, state, and federal organizations, and private agencies are finding themselves stuck in the "getting ready" phase, unable to move beyond it for lack of support, instruction, and definitive guidelines. This situation has led many to a state of preparedness paralysis, as no forward progress can be made, and there is no reliable source of leadership and information on which to depend. And while the January 2009 report of the House of Representatives Committee on Homeland Security referred to pandemic preparedness without direct reference to bioterrorism, the authors of this paper argue that there is little difference between a pandemic caused naturally and one that results from intentional

108. MAJORITY STAFF OF H.R. COMM. ON HOMELAND SECURITY, 110TH CONG., GETTING BEYOND GETTING READY FOR PANDEMIC INFLUENZA (2009), http://homeland.house.gov/SiteDocuments/20090114124322-85263.pdf.

109. *Id.* at 2.

110. *Id.* at 5.

111. *Id.*

release of an infectious disease.[112] In fact, those preparing for both types of pandemic are facing similar preparedness problems.

The following are some of the major problems recognized by the House of Representatives Committee on Homeland Security in its final report, adapted for the purposes of this article to include bioterrorism and to address the scope of the planning paralysis problem.

Early Warning and Detection Is Inadequate

In order for an effective response to be mounted against a pandemic, it is crucial that accurate and timely information about disease status be transmitted to authorities, responders, and others. Unfortunately, the kind of surveillance necessary for this is not currently available in most of the country, and what is in use is often incompatible across various systems. Moreover, with different reporting requirements for health status in different states, overlap and gaps remain serious problems.[113]

In addition, public health and hospital-based health systems report diseases at differing levels, so what might be considered an outbreak in one state might not even be considered reportable in another. Varied levels of training, most of them inadequate, compound confusion in attempts to coordinate responses, leading to a sense that nobody is actually in charge and clear information is lacking. Furthermore, failures of biosurveillance at the Department of Health and Human Services (HHS), the Department of Homeland Security (DHS), the CDC, and elsewhere, have led to a lack of integration of disease data, without which, in the event of an outbreak, timely tracking and adequate warning of a developing pandemic would be nearly impossible.[114]

Execution of Key Planning Activities Is Incomplete

Largely due to the failure to include key stakeholders in planning, many plans do not take into account vital response elements. For example, what will happen in corrections facilities? How will bodies be dealt with? What will happen to public transportation? What will happen to schools and universities? When those who know the most about these fields are left out of planning, specificity and actionability are weakened, and yet greater gaps are left in response capabilities. This approach leads to overly general and sometimes confusing guidelines for states, public and private agencies, and individuals who rely upon uniform and definitive recommendations and instructions, increasing the likelihood of preparedness paralysis on all response levels. Only strong leadership can overcome this kind of

112. *See id.* at 2, n.14.
113. *Id.* at 6.
114. MAJORITY STAFF OF H.R. COMM. ON HOMELAND SECURITY, *supra* note 108, at 6.

uncertainty, and it has not emerged so far in most jurisdictions or on the federal level.

Challenges Posed by Key Medical Response Requirements Are Only Partially Addressed

Because many difficult and specific issues have been left unaddressed at the executive level, defining treatment priorities and determining access to hospital resources have been hindered. Thus, it remains unclear who would receive prophylaxis first, who would receive vaccines, and in what order. Issues including an altered standard of care have been discussed but not settled. The certainty that pharmaceuticals will be in short supply for months, if not years, has not been adequately addressed. Nor have the options for non-pharmaceutical interventions like social distancing, standard personal protective equipment (PPE) procedures, and closures of schools and businesses been settled, and these will be the first line of defense against a pandemic. Such decisions must be made using the best available information in order to facilitate training and preparedness, and to avoid confusion and response failure. If an event occurs which calls for a different approach, that can be determined based on the available facts at the time. However, waiting for an event to occur in order to make basic decisions regarding major management issues undermines the entire preparedness and response process.

Level of Preparedness for Pandemic Influenza Is Unclear

Whether naturally occurring or engineered through intentional human actions, we can be certain that pandemics will occur. Recent outbreaks of SARS, H5N1, and even H1N1 have shown us that we are not prepared, and have left many fearing that we can never be prepared. Too many questions remain unanswered despite our having had the opportunity to test our response capabilities during these outbreaks. It is perhaps important to note that there is no one point at which one reaches "total preparedness." Certainly each event has its own context and agent, but our failure to learn from the lessons of the most recent outbreaks must be met by U.S. leaders with efforts to encourage preparedness through funding, example, research, and communication. At this point, pandemic preparedness has been relegated to a lower priority, with cuts in funding and personnel, while opportunities for cooperation between federal agencies and executive branch departments have not been taken seriously. The resultant lack of readiness speaks to a state of paralysis at the highest levels of government and does not bode well for overall response.

Recommendations by the Committee on Homeland Security arising from these reported problems include:

Establish Effective Management and Coordination

Executive leadership must visibly deal with preparedness issues and be aware that its credibility and the nation's preparedness levels are strongly connected. A consistent system to receive, process, and disseminate reports on disease status must be created across the nation. Accuracy and timeliness of reports, and strong leadership will go a long way toward easing preparedness paralysis.

Address and Meet Key Medical Requirements

Overwhelming issues, which have often been ignored or set aside for later, must now be dealt with directly. These include issues of triage, altered standards of care, and vaccine and prophylaxis priority. They must also be integrated into realistic and actionable plans that take into account actual availability of resources and personnel.

Moreover, the issue of inadequate national capacity to produce vaccines and medical supplies in the face of a pandemic disaster must be addressed immediately to allow responders reliable access to whatever resources are available. This is especially true at a time (as in pandemics) when there are limited medical supplies on hand. One of the most problematic elements of preparedness paralysis is the certainty that not only is there no treatment available for pandemics, but that even if it is developed, supplies will be so limited and so late to arrive that very few will have access to them. Increased production capacity will help quell those fears and can also be leveraged to play an important part in preventing deaths from seasonal influenza, which average around thirty-six thousand per year.

Evaluate and Update Plans

If the government is to require updated plans for states and local public health agencies, among other institutions, the government itself must have in place an updated national strategy for pandemic influenza that limits duplication among agencies and takes all the necessary stakeholders into account. Good communication between agencies on all levels must be established now and exercised. A better understanding of how terrorists might use a pandemic agent is needed, and plans must be arranged to cope with such an event. In any type of pandemic outbreak, continuity of operations plans should be given high priority.

Improve Early Warning and Detection

Working in concert with the World Health Organization and other agencies, the United States must develop and implement a uniform, global, biological surveillance program to provide warning of suspicious incidents or outbreaks. On the local level, the public must be educated using all means necessary to ensure their effective response, increase their resilience,

and prevent the planning paralysis that could leave them entirely vulnerable to a pandemic event.

STRUCTURE OF THE U.S. PUBLIC HEALTH SYSTEM: RAMIFICATIONS FOR PREPAREDNESS AND RESPONSE

The fundamental structure of the U.S. public health system is one of the primary causes for difficulties faced by pandemic preparedness planners. The United States Constitution and the political and historical record of tension between federal and local authorities work against any strict enforcement of health laws from the federal level upon the state and local authorities.[115] Thus, unlike in China, where government response to the Severe Acute Respiratory Syndrome (SARS) outbreak could be focused and directed at the national level, the U.S. public health system is not centralized.[116] No single organization sets mandatory health policy. Each state and local health department sets its own policies. Even the CDC, the federal government's public health arm, has little actual power to enforce or require actions, but can, instead, only recommend and present guidelines to state and local authorities, who will use this information as they see fit.[117]

An article in the Bulletin of the Atomic Scientists states, "Of the many ways in which the United States is unprepared to deal with an infectious disease outbreak or bioterrorist attack, here's one of the most problematic: The responsibility for public health is a state concern."[118] The article's authors go on to argue that this problem will likely result in an inefficient piecemeal response during a multi-state event. The solution proposed by the Center for Strategic and Budgetary Assessments is to federalize the system for a multi-state response.[119] In this approach, the CDC would be required to function along the lines of the Federal Bureau of Investigation (FBI) which has fifty-six field offices in large cities and over four hundred resident agencies in smaller cities and towns. The CDC would station highly trained epidemiologists in field offices throughout the country who would be able to provide broad coverage and a reliable feedback loop.[120]

Such a system might translate into public health as follows: in the State of Missouri, 114 local public health agencies each produce their own version of a preparedness plan based on the information made available to them through the State Department of Health and Senior Services (DHSS) and the CDC. Yet, because this information is often so vague and non-

115. INST. OF MED., COMM. FOR THE STUDY OF THE FUTURE OF PUB. HEALTH, THE FUTURE OF PUBLIC HEALTH 125–26 (National Academy Press 1988).

116. *Id.* at 123–25.

117. *Id.* at 125.

118. Laura H. Kahn, *Unifying the U.S. Government Response to Bioterrorism*, BULL. OF THE ATOMIC SCIENTISTS (WEB–EDITION), Dec. 8, 2008, http://www.thebulletin.org/node/5137.

119. SHERMAN, *supra* note 74, at vii.

120. Kahn, *supra* note 118.

directive, and so rarely addresses their specific needs—and because the State is unable and unwilling to give answers to local agencies' questions if they have not been laid out by the CDC or another government body with authority—the local agencies' plans, if completed, do not address the needs of the population or of responders.[121] The presence of a local field office would guarantee that guidelines, questions, and updated information could be transmitted in both directions, clarifying needs and providing timely updates.

This approach, if applied to a current disease, could make a significant difference in preparedness response. In the case of Avian Flu, the CDC distributed government dollars earmarked for preparedness at the local level. But beyond making receipt of the funds contingent upon a few basic requirements, like having some sort of local and state response plan and arranging training exercises, the CDC has very limited influence over the specific allocation and use of the funds.[122] Moreover, because of federal reluctance to be seen as dictating to state and local authorities, the CDC avoids presenting concrete Avian Flu preparedness recommendations on everything from stockpiling anti-virals to appropriate choice and use of personal protective equipment (PPE).[123] Instead, it leaves important policy and preparedness decisions up to the state and local entities, which as we have seen feel unable to make such decisions without guidance.[124]

A field center could oversee the spending of federal dollars and make recommendations about how such money could best be used. It could report back to the federal government regarding actual needs and the funds required to meet them. The establishment of field centers might also make it possible for the government to purchase supplies en masse for certain jurisdictions and thus provide specifically needed material like PPE, Tamiflu, and hospital supplies, rather than simply giving large grants which might be misspent by local agencies.

The current system, while leaving local agencies unencumbered by government mandate, also leaves them without the information they need to make important planning decisions, and increases the paralysis problem. The problem is further compounded as federal, state, and local authorities scramble to avoid being put into the position of making a decision that might prove wrong, or leave them open to legal actions, loss of authority or position, or other unpleasant consequences. During the 1918–19 Spanish Flu pandemic, this situation meant that, when decisive action was needed to

121. Scott D. Holmberg et al., *Policy Review: State Plans for Containment of Pandemic Influenza*, 12 EMERGING INFECTIOUS DISEASES 1414, 1416 (2006).

122. ASS'N OF STATE AND TERRITORIAL HEALTH OFFICIALS, PANDEMIC INFLUENZA FY10 APPROPRIATIONS (2009), *available at* http://www.astho.org/Advocacy/2009-Advocacy-Materials/Pan-Flu-FY10-Appropriations-and-Stories/.

123. Personal observation of authors.

124. Personal observation of authors.

prevent, contain, and treat disease, it fell to city mayors and local health department directors to take decision-making responsibility upon themselves, closing schools, limiting public gatherings, and so on, solely on their own authority.[125] Those who moved quickly to institute social distancing measures despite extensive resistance were more successful in limiting the disease than those who did not.[126]

If any doubt remained about who would have the final authority to make crucial decisions during an Avian Flu pandemic, recent statements by the U.S. government have made it clear that most, if not all, preparedness and response will be local.[127] This provides all the more reason for CDC representatives to be available at the local level.

PLANNING PARALYSIS: WAITING FOR GUIDANCE

In a Policy Review article published in the September 2006 Emerging Infectious Diseases Journal, researchers examined forty-nine state pandemic preparedness plans, assessing similarities and differences in a number of areas including surveillance, vaccination priorities, and non-pharmaceutical community interventions.[128] In their findings, the researchers cite a lack of explicit direction and clear guidance for states, lack of centralized coordination, and insufficient epidemiological information about flu itself as significant problems in the field of preparedness.[129] The result, they note, is "confusion and lack of specificity" in plans, fully two-thirds of which do not explicitly address the basic strategies of self-quarantine or isolation of affected adults.[130] Others do not even provide basic recommendations for social distancing, infection control, and containment.[131]

In addition to these difficulties, the authors would add that, in absence of a successful track record in declaring a state of emergency in such situations, planners and responders are unable to take advantage of a potentially helpful structure in the event of a pandemic: the state of emergency rules. Recent disasters like Hurricanes Rita and Katrina serve as unfortunate reminders of how poorly the state of emergency rules are understood and how ineffectively they are applied, leading to negative public reactions from victims who felt doubly victimized by the failures of local, state, and federal agencies to assist them. The result is not better leadership, but increased fear among legislators and planners of taking decisive steps that could en-

125. Harry Levins, *What He Knew in 1918 Could Save Millions of Lives*, ST. LOUIS POST DISPATCH, July 9, 2006, at B1.

126. *Id.*

127. *Id.*

128. Holmberg et al., *supra* note 121, at 1414.

129. *Id.* at 1415–16.

130. *Id.* at 1416.

131. *Id.*

courage responsible decision-making and structured preparedness and response.

Points of Preparedness Paralysis

The following two examples of how lack of adequate guidance and direction have led to significant preparedness paralysis are by no means the only points of paralysis in the planning process, but the authors have found them to be major stumbling blocks to completion of successful pandemic plans on a state and local level, and they are virtually universal.

As noted in the Policy Review article discussed above, one issue that has been the cause of great confusion and failure is the use of "social distancing," and in some cases, quarantine and isolation.[132] In the absence of a vaccine, and with limited supplies of anti-virals whose effectiveness is uncertain, social distancing is seen by most experts as a vital piece of the arsenal available to contain or mitigate a pandemic.[133] Social distancing, however, cannot be recommended or imposed at the last minute. This strategy depends upon significant planning, coordination, training, and community education if it is to be used with any kind of success when a pandemic strikes.

The social distancing decisions that need to be made well ahead of any outbreak include: when and if schools should be closed, and for how long; when and if public gathering should be banned in theaters, malls, and work places; when and if rules regarding how many people can be in a store, elevator, or subway car should be enforced; and how, if at all, quarantine and isolation will be used or enforced. Plans that address these issues must, of course, be flexible and should be regularly reviewed and updated, ideally on the national level, as well as state and local levels, allowing for a more coordinated approach among all responders.

Although the CDC's Interim Pre-pandemic Planning Guidance attempts to address these issues, it lacks the specificity that states require for implementing these recommendations.[134] The very terms "interim" and "guidelines" (among others used) suggest an unwillingness to take responsibility for planning decisions. As a result, most state and local planners, if they address these issues at all, do so indirectly. Using rubrics like "points to consider," they sidestep the actual decision, leaving it to whoever will be willing to make it in the midst of the outbreak.[135] Others suggest that the decision will eventually be made by some authoritative body, and final decisions must be put off until that body, sometime in the future (again, pre-

132. *Id.*

133. *Id.*

134. U.S. DEP'T OF HEALTH & HUMAN SERVICES, FLU.GOV COMMUNITY STRATEGY FOR PANDEMIC INFLUENZA MITIGATION (Feb. 2007), http://www.pandemicflu.gov/professional/community/commitigation.html.

135. Authors' comment.

sumably during an outbreak), will take the responsibility of decision-making upon itself.[136]

Another issue that causes significant problems for planners is the lack of guidance on use and distribution of the preferred anti-viral medications: neuromidinase inhibitors Zanmavir and Oseltamivir. So far, faced by high costs, uncertain supply, and lack of evidence as to the effectiveness of these drugs, some jurisdictions have even decided not to purchase them.[137] As of 2006 (the last date such information was available), only 25 percent of states planned to use or would "consider using" either chemoprophylaxis (such as Oseltamivir) or vaccines (when they become available) to slow the spread of the disease.[138] Despite government-provided matching funds intended to encourage the purchase of anti-viral supplies, no actual recommendations have been made on how much, if any, to purchase, making it less likely that states will do so.[139]

Among the most realistic approaches to dealing with pandemic and emergency situations (and indeed, most likely to occur by sheer default) is home health care by family members. Planners agree that, in the event of a pandemic, hospitals and other health care facilities will be so overwhelmed by the flood of sick people seeking care that they will be unable to function except using altered (read "lowered") standards of care.[140] They will certainly not be able to admit most of the people who are ill, and thus much of the care will fall to relatives and friends working and living in their homes. Most of these cases will have no access to drugs, ventilators, or other basic medical supplies. Yet, despite general agreement about this scenario, the issue is not being addressed by government planners, and there are no algorithms or guidelines to assist families with making home health care decisions. In fact, families today have even less experience in dealing with sick people at home than they did only a generation ago.[141]

The authors are well aware that epidemiological research is lacking on questions like: How effective are N95 and other masks in preventing influenza transmission, and if they are effective, how and when should they be used or stockpiled? How effective are anti-virals in treating/preventing disease? If employed, who should receive anti-virals and under what circum-

136. Authors' observations and experience in the field.

137. GUY DANSIE & ROBERT ROLFS, GOVERNOR'S TASKFORCE FOR PANDEMIC INFLUENZA PREPAREDNESS ISSUE BRIEF: STOCKPILING AND MANAGEMENT AND USE OF ANTIVIRAL MEDICATIONS DURING AN INFLUENZA PANDEMIC 5–6 (2006), *available at* http://www.pandemicflu.utah.gov/docs/IssuePaper-Antiviralstockpile12-4-06.doc.

138. *Id.*

139. *Id.* at 5.

140. Laura A. Stokowski, *Ethical Dilemmas for Healthcare Professionals: Can We Avoid Influenza?*, MEDSCAPE INFECTIOUS DISEASES, May 6, 2009, http://www.medscape.com/viewarticle/702371_6.

141. SANDRA L. SCHWANBERG & MAURINE RENVILLE, PANDEMIC FLU HOME CARE 37 (2008), *available at* http://www.pandemichomecare.com/files/2261183/uploaded/PFHCeBook09.15.08.zip.

stances? In order for any acceptable level of pandemic preparedness to exist, even the most basic decisions must be made about these issues using the information currently available. Algorithms must be available for distribution to families, including explanations of how to deal with fever and how to manage someone with trouble breathing, as well as specific guidelines for drug usage and priorities in hospitals. If these and other issues are ignored, mass mortality is almost a certainty. Therefore, despite a paucity of information, concern about liability, and general unwillingness to take a risk of being wrong, it is crucial that a mechanism for making such decisions be devised.

Accountability for Reasonableness: A New Approach to Decision-Making

Planning and response paralysis can only be addressed if public health develops a process for decision-making that is based on evidence and that all stakeholders find fair. This will require both a dedicated planning staff and the involvement of committees made up of cross-sections of public health and community stakeholders, augmented by external consultation as needed. Planning staff, in consultation with experts, can organize the evidence, but the more difficult task is to use the evidence to arrive at decisions.

Norman Daniels and James Sabin have developed a framework for decision-making that can be adapted to improve the pandemic planning process. The framework, called "accountability for reasonableness," has been used in both public and private hospital settings to establish priorities for determining insurance coverage and for rationing scarce pharmaceuticals.[142] According to accountability for reasonableness, decisions can be considered fair if they satisfy four conditions. The authors have adapted these conditions to pandemic planning:

1. Rationales for making decisions must be publicly accessible;
2. Rationales must be considered relevant and evidence based;
3. There must be a mechanism for appealing decisions and their rationales;
4. There must be a means of ensuring that the first three conditions are met.[143]

This decision-making process will require health departments to establish committees that take responsibility for making specific recommendations to decision-makers concerning steps that should be taken to prepare

142. Norman Daniels & James Sabin, *Limits to Health Care: Fair Procedure, Democratic Deliberation and the Legitimacy Problem for Insurers*, 26 Phil. & Pub. Aff. 303, 310–13 (1997); Norman Daniels & James Sabin, *Ethics of Accountability in Managed Care Reform*, 17 Health Aff. 50, 55–61 (1998).

143. Douglas Martin et al., *Fairness, Accountability for Reasonableness, and the Views of Priority Setting Decision-Makers*, 61 Health Pol. 279, 280 (2002).

for and minimize the consequences of a pandemic. According to research evaluating the decision-making process, the inclusion of "representatives from multiple perspectives was the single most important element of fair priority setting."[144] Thus, these committees must be made up of a cross-section of stakeholders with multiple perspectives and backgrounds, and led by a committee chair who is skilled at working through the decision-making process to arrive at a consensus, or if this is not possible, at least for the committee members to accept the process as being fair and valid.

Trained leaders will have to make sure that all members have an opportunity to express views and have input into agenda setting. The process should also be transparent, both internally and externally. Not only must the committee be well-informed about the issues, but the deliberations, decisions, and reasoning of the committee must be made available to stakeholders external to the membership. Committee members must be honest with each other, presenting all the facts with no hidden agendas and identifying potential conflicts of interest. If a committee member strongly disagrees with a recommendation, there should be an appeals process that allows a recommendation to be reconsidered.

Application of a process that uses these four conditions may not necessarily lead to ideal outcomes; we cannot know challenges or outcomes ahead of time, and success will require a great deal of advance work, as well as education of the participants and the public regarding the way the process works and why it is being used. The process will, however, allow for decisions to be made and accepted through a system acknowledged as equitable and reasonable, and which can provide confidence that the decision-makers themselves are operating according to best practices and available knowledge. Most importantly, the process allows its users to avoid the planning paralysis that has, in so many cases, made it impossible to prepare for disaster at all.

144. *Id.* at 283.