

LEGAL PREPAREDNESS FOR PANDEMIC INFLUENZA: IS VIRGINIA READY?

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I. INTRODUCTION

On Wednesday, April 29, 2009, a Mexican child, being treated at a hospital in Texas, became the first casualty of the swine flu in the United States.¹ By that time, hundreds of cases had already been reported worldwide.² Healthcare officials have been worried about and planning for an influenza pandemic since the first bird flu scare in the early 2000s.³ Now those plans are being put to the test. Countries as far away as China have put people under quarantine in an effort to stop the spread of the H1N1 influenza strain.⁴ In the United States, some schools have even cancelled their graduation ceremonies.⁵

Virginia has been taking its own precautions. On April 27, 2009, Dr. Karen Remley, Virginia's Health Commissioner, declared the Commonwealth to be in a state of public-health emergency.⁶ Virginia Governor Timothy Kaine also requested an extra 280,000 courses of antiviral medications to add to Virginia's stockpile, bringing the state's total

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1. *Toddler Dies as Swine Flu Cases Mount*, CNN.COM, Apr. 30, 2009, <http://www.cnn.com/2009/HEALTH/04/29/swine.flu.cases/index.html?iref=newssearch> (last visited Mar. 15, 2010).

2. *Id.*

3. Ctr. for Disease Control, *Past Avian Influenza Outbreaks*, <http://www.cdc.gov/flu/avian/outbreaks/past.htm> (last visited Mar. 15, 2010).

4. *Farmer May Have Given Swine Flu to Pigs, Canada Says*, CNN.COM, May 2, 2009, <http://www.cnn.com/2009/HEALTH/05/02/swine.flu/index.html> (last visited Mar. 15, 2010).

5. Mallery Simon, *Students Can't Be Part of Main Graduation Because of Mexico Trip*, CNN.COM, May 2, 2009, <http://www.cnn.com/2009/HEALTH/05/01/swine.flu.schools/index.html> (last visited Mar. 15, 2010).

6. Tammie Smith & Jim Nolan, *State Prepares for Flu Outbreak*, RICH. TIMES-DISPATCH, Apr. 28, 2009, at A1, available at http://www.timesdispatch.com/rtd/news/local/article/VFLU28_20090427-222106/264318/.

stockpile to over one million.⁷ While the state's efforts show that it is being vigilant in preparing for a mass outbreak, there is only so much that can be done before the virus hits on a widespread scale.

Though it is too early to tell if this H1N1 strain will become a pandemic, it will at least serve to keep decision-makers alert and thinking about how to improve plans for pandemic response. One often forgotten aspect of planning is the consideration of legal issues, which permeate every aspect of a pandemic—from the planning to the clean-up stages. A public health emergency, especially one for a contagious disease like influenza, is quite different than a natural or manmade disaster, like a hurricane or a terrorist attack. There is no ground zero. Because the virus is spread through human contact, it will spread to every corner of the globe. A pandemic has the potential to affect every sector of the nation, from schools to banking, from food distribution to, most obviously, the healthcare system. The question is not whether hospitals will be overwhelmed; it is whether hospitals will be open since healthcare workers are just as susceptible to the virus as anyone.

So how can Virginia officials make sure that the Commonwealth is legally prepared for a pandemic? One overarching problem of pandemic planning throughout the country is that there has not been enough communication between the legal community and the health community.⁸ Healthcare workers have a set of norms they use every day, and they can instinctively react to emergencies. In a pandemic, all of those norms get thrown out the window, and what they instinctively want to do may not be legal.⁹ The first step to preparing for a pandemic must be to bring both sides of the problem together. Another difficulty has been that even when the legal and healthcare communities come together, they look at a few issues, independent from each other.¹⁰ For example, they will decide what they can do about social distancing, distributing antivirals, and dealing with the surge in hospitals, but they might forget to ask who has the authority and when they have that authority to make these decisions. And what if their plans rely on a neighboring state's aid, but that state cannot afford to provide any additional resources? We cannot look at the legal issues of pandemic influenza in a vacuum. This paper attempts to identify the legal issues at stake during a pandemic and how those issues need to be discussed as a

7. *Id.*

8. U.S. Dep't of Health & Human Servs., HHS Pandemic Influenza Plan, <http://www.hhs.gov/pandemicflu/plan/sup8.html> (last visited Mar. 15, 2010).

9. *See id.*

10. *See id.*

whole when preparing for a pandemic. Part II of this paper will give a brief description of pandemic influenza and look at the Spanish Flu pandemic of 1918.¹¹ Part III will examine the origins of legal authority during a pandemic at the federal, state, and local levels of government. Part IV will look at some of the specific legal issues that may arise during a pandemic and discuss what decision-makers need to be thinking about in order to plan comprehensively. Part V will conclude by determining whether or not Virginia is legally prepared for pandemic influenza.

II. HISTORY OF PANDEMIC INFLUENZA

A. What is Pandemic Influenza?

The problem with pandemic influenza is the unknown. Pandemic influenza (“pan flu”) is different from the seasonal flu we experience on an annual basis.¹² “Pandemic influenza is a global outbreak of disease that occurs when a new influenza A virus appears in humans, causes serious illness and then spreads easily from person to person worldwide.”¹³ Because it is so rare and because it is a mutated form of the seasonal virus, humans normally have not built up immunities to it, making its effects more severe, even for healthy adults.¹⁴ Normally, when a person in their twenties gets the flu, he might take two or three days off of work (or not, if he is a law student) and feel better by the end of the week, especially if he received a flu shot at the beginning of the season. This is not the case for pandemic influenza. There is no flu shot for pandemic influenza, at least in its beginning stages, because labs can only make vaccines for a known virus.¹⁵

The high level of contagiousness and severe symptoms of pan flu can potentially lead to a catastrophic situation affecting every part of our

11. There were also pandemics in 1957 and 1968, but it is outside the scope of this paper to discuss each outbreak in the United States. Ctr. for Disease Control, *Influenza Pandemics of the 20th Century*, <http://www.cdc.gov/ncidod/EID/vol12no01/05-1254.htm> (last visited Mar. 15, 2010). Instead, I will discuss the 1918 pandemic because it was the most severe in the country’s history and note its implications for legally preparedness now.

12. Va. Dep’t of Health, *Pandemic Influenza*, <http://www.vdh.virginia.gov/PandemicFlu/> (last visited Mar. 15, 2010) [hereinafter *VDH Pandemic Influenza*].

13. *Id.*

14. See U.S. Dep’t of Health & Human Servs., *How Does Seasonal Flu Differ from Pandemic Flu*, http://pandemicflu.gov/season_or_pandemic.html (last visited Mar. 15, 2010).

15. Va. Dep’t of Health, *Pandemic Influenza: Vaccines and Antivirals*, http://www.vdh.virginia.gov/PandemicFlu/Vaccines_Antivirals.htm (last visited Mar. 15, 2010).

daily lives. No country will be safe, and every age group will be vulnerable. In a time when global travel is the norm, the virus will spread faster than ever across the world.¹⁶ A pandemic could affect global markets and create an economic crisis.¹⁷ Access to utilities like power and water could be disturbed if enough people become sick.¹⁸ If our military is exposed, which it no doubt would be in a widespread pandemic, our war-fighting effort could be hampered.¹⁹ While there is a possibility that it could be mild, effecting thousands instead of millions, there is also the possibility that the death toll could be astronomical, like it was in 1918.²⁰

B. The Spanish Flu of 1918

Perhaps one of the reasons the United States is so fearful of an influenza pandemic is the history of the disease. In 1918, it is estimated that an influenza pandemic (the “Spanish Flu”) killed 675,000 Americans in a period of only ten months.²¹ As World War I ended, thousands of soldiers came home from Europe, bringing the virus with them.²² This strain of the virus brought 105 degree temperatures, severe body and joint aches, and sometimes led to pneumonia.²³ The Spanish Flu also demonstrated a common characteristic of pan flu—it occurred in waves.²⁴ The Spanish Flu occurred in three different waves, one beginning in the Spring of 1918, the second in the Fall of 1918, and the

16. World Health Org., Pandemic Preparedness, <http://www.who.int/csr/disease/influenza/pandemic/en> (last visited Mar. 15, 2010) [hereinafter WHO Pandemic Preparedness].

17. See U.S. DEP’T OF HOMELAND SEC., PANDEMIC INFLUENZA: PREPAREDNESS, RESPONSE, AND RECOVERY 20–25 (Sept. 19, 2006) available at <http://www.flu.gov/professional/pdf/cikrpandemicinfluenzaguide.pdf>.

18. See VDH Pandemic Influenza, *supra* note 12.

19. See WHO Pandemic Preparedness, *supra* note 16.

20. See VDH Pandemic Influenza, *supra* note 12.

21. ALFRED W. CROSBY, AMERICA’S FORGOTTEN PANDEMIC: THE INFLUENZA OF 1918, at 206 (Cambridge University Press 2003) (1976). While we cannot be sure how many died worldwide due to inaccurate reporting, experts estimate that the Spanish flu killed an estimated twenty million people throughout the world. U.S. Dep’t of Health & Human Servs., The Great Pandemic: Influenza Strikes, http://1918.pandemicflu.gov/the_pandemic/01.htm (last visited Mar. 15, 2010) [hereinafter Influenza Strikes]. In Virginia alone, over 15,500 people died. U.S. Dep’t of Health & Human Servs., The Great Pandemic: Virginia, http://1918.pandemicflu.gov/your_state/virginia.htm (last visited Mar. 15, 2010).

22. Influenza Strikes, *supra* note 21.

23. *Id.*

24. THE THREAT OF PANDEMIC INFLUENZA 8 (Stacey L. Knobler et al. eds., 2005).

third in the Spring of 1919.²⁵ The second wave was actually the deadliest, claiming ninety percent of the total casualties.²⁶

There are numerous lessons to learn from the Spanish Flu. In 2006, the Centers for Disease Control and Prevention and the U.S. Department of Health and Human Services hosted a workshop to discuss lessons learned from the 1918 pandemic.²⁷ The panel identified the necessity of truthful communication between public officials and private citizens as an important issue.²⁸ During the Spanish Flu, because of the political climate created by World War I, public officials, in an attempt to subdue the fears of the public, routinely lied about the seriousness of the virus.²⁹ There was great disconnect in the information the public was getting from their elected officials and public health officials.³⁰ This led to an atmosphere of distrust, and it is this distrust that decision-makers need to be aware of when planning, because, as one panelist said, “It is when people feel totally alienated and isolated that society breaks down.”³¹ When people feel helpless, there is more potential for rioting or other outbreaks, requiring the use of law enforcement during public health emergencies. Truthful communication about the disease to the public may be the first step in legal preparedness, because it has the ability to repress social unrest. While this atmosphere of distrust can stem from poor communication, it can also result from ill preparedness—what is the point of communicating with the public if the government has no plans to ensure its safety? For this reason, fully planning for pandemic response is vital to making sure that the government does not have to respond to social unrest on top of a public health emergency. This planning must incorporate legally preparing for issues that will arise during a pandemic.

25. Influenza Strikes, *supra* note 21.

26. GlobalSecurity.org, Homeland Security: Flu Pandemic Timeline/Event Dynamics, http://www.globalsecurity.org/security/ops/hsc-scen-3_flu-pandemic-timeline.htm (last visited Mar. 15, 2010).

27. CTRS. FOR DISEASE CONTROL & PREVENTION & U.S. DEP’T OF HEALTH & HUMAN SERVS., PANDEMIC INFLUENZA, PAST, PRESENT, FUTURE: COMMUNICATING TODAY BASED ON THE LESSONS FROM THE 1918–1919 INFLUENZA PANDEMIC (Oct. 17, 2006), available at <http://www.pandemicflu.gov/general/workshop.pdf>.

28. *Id.* at 8.

29. *See id.* at 7 (“There was a lot of cognitive dissonance. People heard from authorities and newspapers that everything was fine, but at the same time, bodies were piling up.”).

30. *See id.* at 10 (“In Baltimore, there were fights between elected officials and public health officials In Pittsburg, the Mayor actually told the public to ignore public health officials.”).

31. *Id.*

III. LEGAL AUTHORITY

An essential aspect of legal preparedness is a firm understanding by all those involved in pandemic response of who has what power and when they have that power. Many times, the answers will be different depending on the state, and even the locality.

A. Federal Powers

Federal authority for regulating matters that affect public health initially comes from the Commerce Clause and Congress's "power of the purse."³² These Constitutional authorities, read broadly, have become the foundation for numerous laws enacted by Congress to regulate public health emergencies. The majority of federal powers to act during a public health emergency are created in three laws: the Robert T. Stafford Disaster Relief and Emergency Assistance Act ("Stafford Act"), the Public Health Services Act, and the Pandemic and All-Hazards Preparedness Act ("PAHPA").³³ Under the Stafford Act, the President may declare a state of emergency at the request of a Governor when there is a disaster "of such severity and magnitude that effective response is beyond the capabilities of the State and the affected local governments and that Federal assistance is necessary."³⁴ Once the President has declared a state of emergency, federal resources, including "personnel, equipment, supplies, facilities, and managerial, technical and advisory services" can be deployed to the state in support of state and local recovery efforts.³⁵ Governors and their senior emergency management staff need to be cognizant when asking the President to declare a state of emergency that these federal resources will likely be coordinated by federal authorities.³⁶ This may come as a surprise to some state officials and could present command and control problems in the response and recovery of a pandemic. For example, if federal resources in the form of antivirals are being distributed by federal employees, those employees may not be aware of (or not be required to abide by) a state plan for distribution. This could cause public confusion about who will get the antivirals and where they are supposed to go.

32. Brian Kamoie et. al., *Assessing Laws and Legal Authorities for Public Health Emergency Legal Preparedness*, 36 J.L. MED. & ETHICS 23, 24 (2008) (citing U.S. CONST. art. I, § 8).

33. James G. Hodge, Jr. & Evan D. Anderson, *Principles and Practice of Legal Triage During Public Health Emergencies*, 64 N.Y.U. ANN. SURV. AM. L. 249, 257 (2008).

34. 42 U.S.C. § 5170 (2006).

35. *Id.* § 5170a(1).

36. *Id.* § 5170a(2).

Part of the legal preparation for a possible declaration of a state of emergency must be a plan for the integration of federal resources into the state's preexisting response plans.

Under the Public Health Services Act, the Secretary of the Department of Health and Human Services may determine that there is a public health emergency, allowing him to "take such action as may be appropriate to respond to the public health emergency, including making grants, providing awards for expenses, and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of [the] disease."³⁷ This declaration will last ninety days or upon termination by the Secretary, whichever is sooner, but it may be renewed if needed.³⁸ Specifically, this Act allows the Secretary to track and distribute federally purchased vaccines during a pandemic.³⁹ Finally, the Act has an incentive built into it, allowing the Secretary to make awards to states that have completed and implemented, among other things, a pandemic influenza plan as part of their All-Hazards Public Health Emergency Preparedness and Response Plan.⁴⁰

In 2006, Congress enacted the PAHPA when the aftermath of Hurricane Katrina revealed the confusion caused by multi-layers of declarations, each carrying its own authorizations for federal assistance.⁴¹ PAHPA answers the "who" question by identifying the Secretary of Health and Human Services as the leader of "all Federal public health and medical response to public health emergencies and incidents."⁴² While centralizing federal power in one official should ease communication issues between states and the federal government, decision-makers need to be aware of this power to account for it in pandemic planning.

37. *Id.* § 247d(a).

38. *Id.*

39. *Id.* § 247d-1(a), (b).

40. *Id.* § 247d-3a(b)(2)(A). This is an example of how the federal government uses its purse to influence state governments. Though it is not able to mandate that states adopt certain plans, it is able to provide incentives for them to do so. See Ernest B. Abbott, *Law, Federalism, the Constitution, and Control of Pandemic Flu*, 9 *ASIAN-PAC. L. & POL'Y J.* 185, 192–93 (2008). See also *Printz v. United States*, 521 U.S. 898, 935 (1997) ("Congress cannot compel the States to enact or enforce a federal regulatory program The Federal government may neither issue directives requiring the States to address particular problems, nor command the States' officers, or those of their political subdivision, to administer or enforce a federal regulatory program.").

41. See Hodge & Anderson, *supra* note 33, at 261–62.

42. 42 U.S.C. § 300hh(a) (2006).

B. State Powers

The Governor of Virginia is the Director of Emergency Management and has power to declare a state of emergency whenever “the safety and welfare of the people of the Commonwealth require the exercise of emergency measures due to a threatened or actual disaster.”⁴³ He also has the power to request that the President declare a disaster so the Commonwealth may be able to obtain federal assistance.⁴⁴

The position of State Health Commissioner of Virginia (“Commissioner”) is established in the Code of Virginia at section 32.1-17.⁴⁵ The State Health Commission is the head of the Virginia Department of Health (“VDH”)⁴⁶ and is responsible for coordinating VDH’s response to public health emergencies.⁴⁷ Virginia also has the Virginia Board of Health,⁴⁸ which has the responsibility to “promulgate regulations and orders to meet any emergency or to prevent a potential emergency caused by a disease dangerous to public health.”⁴⁹

A declaration of a state of emergency in Virginia triggers special powers for the Commissioner. For example, during a state of emergency, the Commissioner may authorize certain persons to dispense drugs when they would not normally be authorized to do so.⁵⁰ The Commissioner may also make use of any private or public building to enforce an order of quarantine or isolation.⁵¹ Even when a state of emergency has not been declared, the Commissioner may “require quarantine, isolation, immunization, decontamination, or treatment of any individual or group of individuals when he determines any such measure to be necessary to control the spread of any disease of public health importance.”⁵² This power is important, especially at the beginning of a pandemic when only a few localities are affected and the Governor has not yet declared a state of emergency. The Commissioner

43. VA. CODE ANN. § 44-146.17(7) (2009).

44. *Id.* § 44-146.17(8).

45. VA. CODE ANN. § 32.1-17 (2009).

46. *Id.* § 32.1-16.

47. *Id.* § 32.1-19(D).

48. *Id.* § 32.1-5.

49. *Id.* § 32.1-42.

50. *Id.* § 32.1-42.1.

51. *Id.* § 32.1-48.017.

52. *Id.* § 32.1-43.

may also require citizens to be immunized during a pandemic if a vaccine exists.⁵³

C. Local Powers

In Virginia, each locality (both cities and counties) must have its own local health department.⁵⁴ Typically pan flu spreads so quickly that the Governor would react immediately and the state response system would go into effect. However, before that happens, local health departments may promulgate and follow their own rules and regulations, as long as they are not “less stringent in the protection of public health than any applicable state law or applicable regulations of the Board [of Health].”⁵⁵ Localities will want to have plans in place for dealing with a sudden outbreak in a hospital. In addition, the state needs to make sure that when writing its pan flu plan, it accounts for the differences in localities, especially in Virginia, where Fairfax County will have much more robust healthcare facilities than Washington County.

D. First Responders

In addition to knowing who is in charge, it is important to understand who will respond to a pandemic and how they fit into the command structure of that response. The magnitude of a pan flu response will require the assistance of numerous agencies, organizations, and individuals. While very few of these individuals are actually “in charge,” many times they are operating within a complex and confusing response network. One of the first steps to legal preparedness must be to help every responder understand his role in the system and how to get what he needs to adequately fulfill this role. As the Principal of the Federal Emergency Management Agency Law Associates noted, “[g]iven the number and the diversity of organizations that respond to a disaster and the lack of a single ‘commander’ of those resources, it is critical that these institutions ‘speak the same language.’”⁵⁶

The federal government and many states, including Virginia, have enacted laws and procedures to ensure that everyone “speaks the same language” during an emergency response. After 9/11, President Bush issued Homeland Security Directives 5 and 8, requiring the Department

53. *Id.* § 32.1-48(A).

54. *Id.* § 32.1-30.

55. *Id.* § 32.1-34.

56. Abbott, *supra* note 40, at 193.

of Homeland Security to create a National Incident Management System (“NIMS”) to ensure that responses are quick and seamless between agencies.⁵⁷ NIMS was approved on March 1, 2004 and “establishe[ed] standard incident management processes, protocols and procedures so that all local, state, federal and private-sector emergency responders can coordinate their responses, share a common focus and place full emphasis on resolving the event.”⁵⁸ Because NIMS provides a template for managing emergencies, each locality and state should have the same information during a large scale disaster.⁵⁹ During a pandemic, if all localities and states are NIMS compliant, volunteers will be able to travel from one locality to another without having to learn a new system for providing help and requesting resources. This coordination will be vital to a successful response, especially in the chaotic atmosphere of a pandemic.⁶⁰ The federal government once again uses funding to incentivize the states to adopt NIMS—compliance is required by both local governments and state agencies to receive federal preparedness assistance.⁶¹

IV. LEGAL ISSUES

On top of these complex systems of authority numerous legal issues for pandemic response arise. This section will identify a number of these issues and also show why it is important that decision-makers not look at them independently, but comprehensively and within the existing law for public health emergencies.

A. Social Distancing

Though many automatically think of quarantine as the first response

57. Press Release, Office of the Press Sec’y, Homeland Security Presidential Directive/HSPD-5 (Feb. 28, 2003), *available at* <http://www.fas.org/irp/offdocs/nspd/hspd-5.html>; Press Release, Office of the Press Sec’y, Homeland Security Presidential Directive/HSPD-8 (Dec. 17, 2003), *available at* http://www.dhs.gov/xabout/laws/gc_1215444247124.shtm. Part of these directives codified NIMS in the Homeland Security Act. *See* 6 U.S.C. §§ 319, 320 (2002 & Supp. 2009). Note how this was a legal response to an operating issue. *See also* Abbott, *supra* note 40, at 194.

58. Va. Dep’t of Emergency Mgmt., Programs & Services: NIMS, <http://www.vaemergency.com/programs/nims/index.cfm> (last visited Mar. 15, 2010).

59. *See generally* Fed. Emergency Mgmt. Agency, About the National Incident Management System (NIMS), <http://www.fema.gov/emergency/nims/AboutNIMS.shtm> (last visited Mar. 15, 2010).

60. *See* Demetrios L. Kouzoukas, *Public Health Emergency Legal Preparedness: Legal Practitioner Perspectives*, 36 J.L. MED. & ETHICS 18, 20–21 (2008).

61. *See* Va. Dep’t of Emergency Mgmt., Programs & Services: NIMS, <http://www.vaemergency.com/programs/nims/index.cfm> (last visited Mar. 15, 2010).

to a widespread public health emergency involving a contagious disease, there are other less drastic steps that can be taken first. There are several ways to create social distance between populations to try to stop the spread of pan flu, including closing schools or offices, isolating infected individuals, and quarantining others.

1. Closing Schools and Offices

The first step in social distancing is voluntary. Parents can choose to keep a sick child home from school and take time off work during the incubation period, which is five days after the onset of symptoms.⁶² After that, communities need to consider closing schools for a period of time in order to reduce the level of exposure to the larger community.⁶³ As one report noted, “modeling and analyses suggest that widespread school closures may reduce the incidence of infection (i.e. the attack rate) in a community over a period of time.”⁶⁴ The same would be true of closing offices or allowing people to work from home.

While closing schools may help to mitigate the spread of pan flu, depending on the length of the closure, it could also have an adverse effect on families and communities. Besides children missing school, potentially for months, parents will also have to make plans to care for them.⁶⁵ If parents have to leave their jobs to stay home with their children, the economic stability of the community could be at risk.⁶⁶ For this reason, states should work with the private sector to establish guidelines for alternative work schedules during a pandemic, such as telecommuting. Fortunately, because of advances in technology, this will be much more feasible than during past pandemics.

Virginia has identified school closures as an option for controlling the spread of pan flu in its Pandemic Influenza Plan.⁶⁷ This plan identifies who has the authority to close schools: (1) “the ability of local school boards and superintendents to close school is inherent in the power given

62. U.S. DEP’T OF HEALTH & HUMAN SERVS., HHS PANDEMIC INFLUENZA PLAN: SUPPLEMENT 4, INFECTION CONTROL, at S4-17 (Nov. 2005), *available at* <http://www.hhs.gov/pandemicflu/plan/pdf/S04.pdf>.

63. CTR. FOR LAW & THE PUB. HEALTH, LEGAL PREPAREDNESS FOR SCHOOL CLOSURES IN RESPONSE TO PANDEMIC INFLUENZA AND OTHER EMERGENCIES 8 (Apr. 2008), *available at* <http://www.pandemicflu.gov/professional/school/schoolclosures.pdf>

64. *Id.* at 10.

65. *Id.*

66. *Id.*

67. *See* VA. DEP’T OF EDUC., PANDEMIC INFLUENZA PLAN: GUIDELINES FOR VIRGINIA PUBLIC SCHOOLS 5 (May 2008), *available at* <http://www.doe.virginia.gov/VDOE/studentsrvcs/panflu.pdf>.

to them in Article VIII, Section 7 of the Constitution of Virginia,” and (2) “the Board of Health has the authority to close schools in order to prevent a potential emergency caused by a disease dangerous to public health (Code of Virginia at § 32.1-42).”⁶⁸ The problem with these authorizations is that they are not clear as to when and who may close a school. According to this plan, section 32.1-42 of the Code of Virginia authorizes the Board of Health to close schools. This section reads:

The Board of Health may promulgate regulations and orders to meet any emergency or to prevent a potential emergency caused by a disease dangerous to public health, including, but not limited to, procedures specifically responding to any disease listed pursuant to § 32.1-35 that is determined to be caused by an agent or substance used as a weapon or any communicable disease of public health threat that is involved in an order of quarantine or an order of isolation pursuant to Article 3.02 (§ 32.1-48.05 et seq.) of this chapter.⁶⁹

This section never clearly states that the Board of Health may close schools and does not say whether or not there must be a declaration of a state of emergency by the Governor beforehand. Similarly vague, article VIII, section 7 of the Virginia Constitution, which the plan claims gives authority to local school board to close schools states, “[t]he supervision of schools in each school division shall be vested in a school board, to be composed of members selected in the manner, for the term, possessing the qualifications, and to the number provided by law.”⁷⁰ Neither of these sources expressly gives authority to either entity to close schools. While that authority would probably be deemed by a court to be inherent, it leaves the officials confused as to when they can close a school. This confusion could lead to slow reactions, whereas, if the law expressly created the authority, response would be faster and more effective.

2. Isolation and Quarantine

Isolation and quarantine are more drastic steps aimed at restricting people’s movements to limit the spread of pan flu by creating a “social distance” between the exposed and the general population. Isolation

68. *Id.*

69. VA. CODE ANN. § 32.1-42 (2009).

70. VA. CONST. art. VIII, § 7.

occurs when a patient who has been diagnosed with a communicable disease is removed from the public.⁷¹ A quarantine occurs when people who have not been diagnosed with a communicable disease, but have been or may have been exposed to one, are isolated from the public.⁷² This difference is important because where people who have been diagnosed will probably be willing to be isolated because they know they pose a health risk to the public, people who have not been diagnosed may see no reason for their quarantine and so may challenge it on constitutional due process grounds.⁷³ For this reason, it is vital that lawmakers carefully and clearly lay out the circumstances in which people can be mandatorily isolated or quarantined. It is equally important that these steps are followed during a public health emergency.

For example, in *Best v. St. Vincents Hospital*, Best was diagnosed with tuberculosis and detained by the hospital as a health risk to the community because he was contagious and refused to complete his treatment.⁷⁴ He sued the hospital and the State, claiming that his Fifth and Fourteenth Amendment due process rights had been violated.⁷⁵ Best first argued that his substantive due process rights had been violated because New York's tuberculosis control statutes violated his fundamental right to liberty.⁷⁶ The court noted that "substantive due

71. See Abbott, *supra* note 40, at 195. See also VA. CODE ANN. § 32.1-48.06 (2009) ("Isolation" means the physical separation, including confinement or restriction of movement, of an individual or individuals who are infected with or are reasonably suspected to be infected with a communicable disease of public health threat in order to prevent or limit the transmission of the communicable disease of public health threat to other uninfected and unexposed individuals.").

72. See Abbott, *supra* note 40 at 196. See also VA. CODE ANN. § 32.1-48.06 (2009) ("Quarantine" means the physical separation, including confinement or restriction of movement, of an individual or individuals who are present within an affected area, as defined herein, or who are known to have been exposed or may reasonably be suspected to have been exposed to a communicable disease of public health threat and who do not yet show signs or symptoms of infection with the communicable disease of public health threat in order to prevent or limit the transmission of the communicable disease of public health threat to other unexposed and uninfected individuals.").

73. See Abbott, *supra* note 40, at 196-99.

74. *Best v. St. Vincents Hosp.*, No. 03CV.0365, 2003 WL 21518829, at *1 (S.D.N.Y. 2003). The statute that authorized Best's detention allowed quarantine for a person with tuberculosis when:

there is a substantial likelihood, based on the person's past or present behavior, that the individual cannot be relied upon to participate in or complete an appropriate prescribed course of medication or, if necessary, follow required contagion precautions for tuberculosis. Such behavior may include the refusal or failure to take medication or to complete treatment for tuberculosis, to keep appointments for the treatment of tuberculosis, or a disregard for contagion precautions.

Id. at *9.

75. *Id.* at *1.

76. *Id.* at *5-6.

process comes into play where, regardless of the procedures followed, a governmental decision or action is so contrary to a fundamental right that it cannot be countenanced.”⁷⁷ Here, the court found that Best’s liberty was a fundamental right, which had been substantially infringed when he was held in the hospital against his will.⁷⁸ The only way the hospital could overcome violating Best’s due process rights would be to show that the State had a “substantial governmental interest” in detaining him against his will.⁷⁹ The court noted that previously the Supreme Court of the United States had upheld the constitutionality of quarantine laws as public health measures.⁸⁰ Finally, it found that there must be an assessment of each individual to determine whether he would comply with the hospital’s recommendations for social isolation during the contagious period of tuberculosis and that according to Best’s past behavior, like refusing to continue his treatment, he would not be willing to comply with the hospital’s recommendations.⁸¹ Therefore, while Best’s substantive due process rights were violated, the hospital had a substantial governmental interest in continuing his detention to protect the community.⁸²

Best also claimed that his procedural due process rights were violated.⁸³ The statute allowing Best’s quarantine set out specific procedural guidelines to be followed, such as obtaining a court order for the detention after a certain number of days, and the court found that the hospital followed them when detaining Best.⁸⁴ Additionally, the court found that the processes laid out in the statute were sufficient to protect his procedural due process under the Constitution.⁸⁵

Best highlights potential legal issues with quarantine laws for pan flu and conveys the message that to confront constitutional challenges, states must be legally prepared to handle possible quarantine. If a state is not legally prepared for a quarantine, then, in the midst of an influenza pandemic, the

77. *Id.* at *6.

78. *Id.*

79. *Id.*

80. *Id.* See *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905) (“Although this court has refrained from any attempt to define the limits of [the state’s police] power, . . . it has distinctly recognized the authority of a State to enact quarantine laws and health laws of every description.”) (internal quotations omitted).

81. *Best*, 2003 WL 21518829 at *7.

82. *Id.*

83. *Id.* at *9.

84. *Id.* at *10.

85. *Id.* at *13.

courts could become backlogged with complaints and sick people could be allowed back into the community on a legal technicality.

Fortunately in Virginia, the Attorney General's Office and VDH have worked hard to ensure that the Commonwealth is legally prepared for quarantine during pan flu.⁸⁶ Under section 32.1-43 of the Code of Virginia, the Commissioner has the authority to require quarantine or isolation of an individual or group when he determines that it is "necessary to control the spread of any disease of public health importance."⁸⁷ Under normal circumstances, before a person can be isolated or quarantined, there are detailed procedures that must be followed.⁸⁸ During a pandemic, these procedures, which include an investigation to find that the individual has a communicable disease and is engaging in "at-risk" behavior, will likely be too cumbersome and lengthy to make the isolation or quarantine effective.⁸⁹ In this situation, the Commissioner may find that there are "exceptional circumstances"⁹⁰ and,

initiate a more rapid response by: issuing orders to immediately isolate an infected or potentially infected person; issuing orders to immediately quarantine exposed or potentially exposed persons; [or] issuing orders to isolate and/or quarantine individuals as a group through defining an "affected area" (when a state of emergency has been declared by the Governor for the affected area).⁹¹

Even during exceptional circumstance, there are specific procedures that must be followed to insure that an individual's due process is not violated.⁹²

Virginia's legal and health communities have created a comprehensive legal scheme for isolation and quarantine. This preparation will enable health care officials (as long as they abide by the procedures set forth in the Code of Virginia) to efficiently and effectively distance exposed and infected individuals from the general population without major legal

86. See VA. DEP'T OF HEALTH & VA. ATTORNEY GEN'S. OFFICE, AN OVERVIEW OF THE COMMONWEALTH OF VIRGINIA'S STATUTORY AUTHORITIES RELEVANT TO SOCIAL DISTANCING (July 31, 2007), available at http://www.vdh.virginia.gov/EPR/pdf/Social%20Distancing%20Law%20Project%20Phase%20I%207_31_07.pdf [hereinafter OVERVIEW OF VIRGINIA SOCIAL DISTANCING].

87. VA. CODE ANN. § 32.1-43 (2009).

88. See *id.* §§ 32.1-48.02, 32.1-48.03, 32.1-48.04.

89. *Id.* § 32.1-48.02.

90. VA. CODE ANN. § 32.1-48.05 (2009).

91. OVERVIEW OF VIRGINIA SOCIAL DISTANCING, *supra* note 86, at 14.

92. See VA. CODE ANN. §§ 32.1-48.05, 32.1-48.07 (2009).

problems encumbering the process. This fast response is key to ensuring the spread of pan flu is curtailed as quickly as possible.

B. Mutual Aid and Liability Concerns

During any public health emergency, a community's resources can be quickly overwhelmed, making it necessary to rely on outside assistance. This assistance can come from other states, volunteer organizations, or the private sector. However, the additional assistance comes with liability concerns. According to one study,

Almost sixty percent of clinicians indicated that having medical malpractice insurance coverage would be important (24.3%) or essential (35.4%) to their decision to travel out of state to provide assistance during an emergency. Almost seventy percent of respondents answered that immunity from civil lawsuits would be an important (35.6%) or essential (33.8%) factor when considering whether to volunteer in an emergency.⁹³

Especially amidst the chaos of a pan flu epidemic, health care professionals and volunteers will have to work quickly and perhaps at a lower standard of care than what they would normally provide. This opens the door to negligence suits, from which they will want immunity if they are going to provide assistance.

1. Emergency Management Assistance Compact ("EMAC")

Developed as a mutual aid agreement among the states, EMPAC addresses issues of liability and resource sharing so a state does not have to be concerned with these issues during an emergency.⁹⁴ Virginia codified EMAC in 1995.⁹⁵ One of the main purposes of EMAC is to promote "[t]he prompt, full, and effective utilization of resources of the participating states, including any resources on hand or available from the federal government or any other source, that are essential to the safety, care, and welfare of the people in the event of any

93. Sharona Hoffman, *Responders' Responsibility: Liability and Immunity in Public Health Emergencies*, 96 GEO. L.J. 1913, 1917 (2008).

94. See generally Nat'l Emergency Mgmt. Ass'n, Emergency Management Assistance Compact, <http://www.emacweb.org/> (last visited Mar. 15, 2010) (explaining that EMAC is an organization that provides "form and structure to interstate mutual aid" and allows impacted states to request and receive assistance quickly and efficiently).

95. VA. CODE ANN. § 44-146.28:1 (2009).

emergency.”⁹⁶ As long as the assisting state does not need the resources for its own emergency, it must provide assistance (including use of National Guard Forces) to the requesting state.⁹⁷

Two important provisions of EMAC discuss licensing and liability. Under Article V, a person who is licensed in one state to provide services will be deemed to be licensed in the requesting state to provide those same services during a declared emergency.⁹⁸ This is important because normally a nurse, for example, would only be able to practice in the state in which she is licensed.⁹⁹ EMAC recognizes that during a pandemic, nurses do not have time to register in another state and carves out an exception from the existing law for assistance during declarations of emergencies.

Under Article VI, EMAC limits liability for officers or employees of the assisting state.¹⁰⁰ It provides:

No party state or its officers or employees rendering aid in another state pursuant to this compact shall be liable on account of any act or omission in good faith on the part of such forces while so engaged or on account of the maintenance or use of any equipment or supplies in connection therewith.¹⁰¹

While EMAC limits liability for acts or omissions “in good faith,” it does not limit liability for willful misconduct, gross negligence, or recklessness.¹⁰² This is an important distinction, because resources will be coming in from many different places—individuals must have a legal recourse for injuries they sustain due to a complete lack of care by officials or employees of the assisting state. Some experts have noted that legal gaps remain in this section of EMAC. The limited liability protection only applies to officers and employees of the assisting state, but not to other individuals, and it does not apply before the governor of the requesting state has declared a state of emergency.¹⁰³ These important issues will have to be addressed in other sections of the law.

96. *Id.* § 44-146.28:1, art. II.

97. *See id.* § 44-146.28:1, art. IV.

98. *See id.* § 44-146.28:1, art. V.

99. *See id.* §§ 54.1-3005, 54.1-3008.

100. *See id.* § 44-146.28:1, art. VI.

101. *Id.*

102. *Id.*

103. Rick Hogan et al., *Assessing Cross-Sectoral and Cross-Jurisdictional Coordination for Public Health Emergency Legal Preparedness*, 36 J.L. MED. & ETHICS 36, 39 (2008).

2. Volunteers and the Private Sector

During a pandemic, Virginia's state and local resources will quickly be exhausted. Federal aid may or may not be available, depending on the severity and spread of the virus. Volunteers, both individuals and organizations, will be critical to Virginia's response. As was previously noted, volunteers may be hesitant to come forward if there are no limitation of liability laws to protect them. Virginia has recently expanded immunity statutes, which traditionally only protected government employees, to cover volunteers during emergencies.

Like many states, Virginia also has a Good Samaritan statute that limits liability for individuals who render aid at the scene of an accident.¹⁰⁴ The Code of Virginia protects individuals and doctors who render aid without receiving compensation during an emergency.¹⁰⁵ This statute, however, leaves a gap for pan flu, which is an ongoing condition and not an "emergency" as we would generally think of the word. There is another statute specifically granting immunity to healthcare providers who provide aid during disasters or emergencies, and an emergency in this statute will include pan flu.¹⁰⁶ This statute may assist healthcare providers who will be the primary responders during pan flu, but they will still need the assistance of other groups to provide additional aid and resources.

In 2004, Virginia codified immunity for two volunteer groups: the Virginia Medical Reserve Corps and Community Emergency Response Teams.¹⁰⁷ The Virginia Medical Reserve Corps are "teams of local volunteer medical, public health professionals, and community members who volunteer to contribute their skills, expertise, and time to support ongoing public health initiatives and public health emergencies in localities across Virginia."¹⁰⁸ Community Emergency Response Teams ("CERTs") are locally based groups of volunteers (training is open to any citizen) that come in during a disaster to provide assistance to first responders.¹⁰⁹ Virginia provides these groups civil immunity as long as

104. *See* VA. CODE ANN. § 8.01-225(A)(1) (2009).

105. *Id.* § 8.01-225(B).

106. *Id.* §§ 8.01-225.01, 8.01-225.02.

107. *Id.* § 31.2-48.016.

108. Va. Dep't of Health, Virginia Medical Reserve Corps, <http://www.vdh.state.va.us/mrc/> (last visited Mar. 15, 2010).

109. *See, e.g.*, Charlottesville-UVA Albemarle County CERT, What is CERT?, <http://www.charlottesvillecert.org/> (last visited Mar. 15, 2010).

they perform their duties in good faith and in accordance with Virginia law and regulations.¹¹⁰

But what about the volunteers who are not part of these groups (like church groups or Red Cross volunteers)? In 2009, the Virginia General Assembly passed limited liability legislation for individuals and groups who volunteer:

1) pursuant to a Governor-declared emergency or during a formal exercise or training of the State Department of Emergency Management or a responsible county or city emergency management entity; and 2) at the request and direction of the State Department of Emergency Management or a county or city employee whose responsibilities include emergency management.¹¹¹

Though there is no case law to test this new statute as of now, it seems that it would cover volunteers rendering aid during a pandemic and provide them with immunity from civil liability for injury or death.¹¹²

3. Standards of Care

The primary cause of action brought by individuals who are harmed during a pandemic will be for negligence. Whether or not they are successful with a negligence claim will be depend on what the court determines the standard of care during a pandemic to be. Some healthcare professionals have tried to alter the normal medical standards of care for public health emergencies because they know their resources—and their services—will be overwhelmed and they will not be able to perform as they normally would.¹¹³

The Virginia Hospital and Healthcare Association put together a working group to address altered standards of care in Virginia.¹¹⁴ The legal standard of care requires that a practitioner “use the degree of skill and diligence in the care and treatment of his patient that a reasonably

110. VA. CODE ANN. § 31.2-48.016 (2009).

111. *Id.* § 44-146.23(F).

112. *See id.*

113. *See generally* Agency for Healthcare Research & Quality, Altered Standards of Care in Mass Casualty Events: Bioterrorism and Other Public Health Emergencies, <http://www.ahrq.gov/research/altstand/> (last visited Mar. 15, 2010).

114. *See* STEVEN D. GRAVELY, ALTERED STANDARDS OF CARE: AN OVERVIEW 5, available at www.vdh.state.va.us/EPR/pdf/Health_and_Medical_Subpanel.pdf.

prudent doctor in the same field of practice or specialty in this State would have used *under the circumstance of this case*.¹¹⁵ According to this definition, during a pandemic, a court would take into consideration the circumstances under which the treatment was given, including the scarcity of resources.¹¹⁶ Virginia should adopt clear guidelines for distribution of scarce resources during an emergency so that healthcare providers may be sure that they will be deemed to have followed the standard of care if they adhere to those guidelines.¹¹⁷

C. Allocation of Scarce Resources

Resources will be quickly expended in the event of a public health emergency in which a large percentage of the population is infected. It is important to remember that resources are not just things, like hospital beds and medication, but also people.

1. Things: Distribution of Vaccines and Antivirals

When allocating scarce resources, liability is only a minor concern for healthcare providers compared to the ethical considerations of using resources to save some lives while letting others die. During a pandemic, “healthcare providers will be in the conspicuous and unfortunate position of turning away many deathly ill people.”¹¹⁸

Virginia has a stockpile of about one million courses of antiviral medication for influenza,¹¹⁹ but Virginia also has a population of almost eight million.¹²⁰ Even if Virginia decides to use its entire stockpile during a pandemic, seven million people will not receive the medication. When people find out they will not be able to obtain the antiviral, there is a potential for civil unrest, delaying response efforts even further. For this reason,

[I]t is imperative that we begin drafting and publically justifying our selection criteria now, well before a pandemic is upon us. The stakes are so high, and the

115. *Id.* at 6.

116. *Id.* at 7.

117. *See id.* at 10.

118. Meir Katz, *Bioterrorism and Public Law: The Ethics of Scarce Medical Resource Allocation in Mass Casualty Situations*, 21 GEO. J. LEGAL ETHICS 795, 795–96 (2008).

119. *See supra* note 7 and accompanying text.

120. U.S. Census Bureau, *State and City Quick Facts*, <http://quickfacts.census.gov/qfd/states/51000.html> (last visited Mar. 15, 2010).

issue so volatile, that the public must come to understand and accept, if only somewhat passively, the rationale for distribution well before an epidemic strikes that will inevitably stir up chaos in its wake.¹²¹

The Center for Disease Control (“CDC”) recognizes that pandemic influenza is inherently different than normal seasonal flu vaccine allocation, in which the criteria for providing vaccines is based on who is at the highest risk for death.¹²² During a pandemic, the CDC suggests that the criteria should be based on “preserving the functioning of society” and that “[t]hose individuals who are essential to the provision of health care, public safety and the functioning of key aspects of society should receive priority in the distribution of vaccine, antivirals and other scarce resources.”¹²³

Virginia, of course, does not have to accept this guidance when developing its own allocation plan. The U.S. Department of Health and Human Services has actually created a priority list in its Pandemic Influenza Plan which includes the population to be vaccinated or given antivirals and the rationale for putting them in certain tiers.¹²⁴ For example, the top tier includes vaccine and antiviral manufacturers and healthcare workers who are in direct patient contact.¹²⁵ The rationale for putting vaccine and antiviral manufacturers in the top tier is “to assure maximum production of vaccine and antiviral drugs.” The rationale for putting healthcare workers who are in direct patient contact in the top tier rests on the premise that “healthcare workers are required for quality medical care” and “there is little surge capacity among healthcare sector personnel to meet increased demand.”¹²⁶

Whatever course Virginia takes, it is essential that the justifications for prioritization are legally sound and that the process for distribution is fair. The CDC noted that there needs to be “consistency in applying

121. John D. Arras, *Rationing Vaccine During an Avian Influenza Pandemic: Why it Won't Be Easy*, 78 YALE J. BIOLOGY & MED. 283, 284 (2005).

122. ETHICS SUBCOMM. OF THE ADVISORY COMM. TO THE DIR., CTRS. FOR DISEASE CONTROL & PREVENTION, ETHICAL GUIDELINES IN PANDEMIC INFLUENZA 2-3 (Feb. 15, 2007), available at http://www.cdc.gov/od/science/phethics/panFlu_Ethic_Guidelines.pdf [hereinafter ETHICAL GUIDELINES].

123. *Id.* at 3.

124. U.S. DEP'T OF HEALTH & HUMAN SERVS., HHS PANDEMIC INFLUENZA PLAN: APPENDIX D: NVAC/ACIP RECOMMENDATIONS FOR PRIORITIZATION OF PANDEMIC INFLUENZA VACCINE AND NVAC RECOMMENDATIONS ON PANDEMIC ANTIVIRAL DRUG USE (Nov. 2005), available at <http://www.hhs.gov/pandemicflu/plan/pdf/AppD.pdf>.

125. *Id.* at D-13.

126. *Id.*

standards across people and time.”¹²⁷ If Virginia does not distribute vaccines and antivirals based on a fair classification of individuals or groups, it opens itself up to claims of equal protection violations.¹²⁸

2. People: Compelling Healthcare Professionals to Work

Vaccines and antivirals are not the only resources that will be scarce during a pan flu epidemic; convincing healthcare providers to work while their families are sick and there is a high risk of infection will not be easy. The American Medical Association “declared that ‘individual physicians have an obligation to provide urgent medical care during disasters’ and expressly stated that ‘[t]his ethical obligation holds even in the face of greater than usual risks to their own safety, health or life.’”¹²⁹ Yet other experts have stated, “physicians should not be expected to place themselves at greater risk than the benefit they can provide.”¹³⁰ It is unknown what the response of healthcare providers will be in the event of a 1918-scale pan flu epidemic. On one hand, during the HIV crisis in the 1980s, some physicians refused to treat patients who had the virus.¹³¹ On the other hand, most physicians continued to work during the SARS epidemic.¹³²

Some states require healthcare providers to work after a declaration of a public health emergency.¹³³ While Virginia has no such statute, the Commonwealth does have one provision that directs officers and personnel to cooperate with the Governor or the Virginia Department of Emergency Management in any requests for “services, equipment, supplies and facilities.”¹³⁴ This language is much softer than the South Carolina statute and will not compel individuals, even those employed by a state agency, to work during a declared emergency. Whether healthcare professionals work will likely be left to their individual judgment, which will be heavily influenced by their ability to obtain vaccines and antivirals and immunity from civil liability. This is an

127. ETHICAL GUIDELINES, *supra* note 122, at 5.

128. *See generally* Katz, *supra* note 118, at 805–06.

129. Carl H. Coleman, *Beyond the Call of Duty: Compelling Health Care Professionals to Work during an Influenza Pandemic* 94 IOWA L. REV. 1, 12 (2008) (quoting Council on Ethical & Judicial Affairs, Am. Med. Ass’n, Code of Medical Ethics: Current Opinions with Annotations § 9.067 (2008)).

130. Karine Morin et al., *Physician Obligation in Disaster Preparedness and Response*, 15 CAMBRIDGE Q. HEALTHCARE ETHICS 417, 420 (2006).

131. Coleman, *supra* note 129, at 11.

132. *Id.* at 13–14.

133. *See, e.g.*, S.C. CODE ANN. § 44-4-570 (2002).

134. VA. CODE ANN. § 44-146.24 (2009).

example of how preparedness for the allocation of scarce resources directly relates to other aspects of pandemic planning.

V. CONCLUSION

Planning for pandemic influenza presents special challenges. It is not a typical emergency type situation, like a hurricane or even a terrorist attack, where the emergency is centrally located in one area of the country. Pan flu has the potential to reach every community in the United States and spread throughout the world. Resources will be scarce, and healthcare professionals will not be able to rely on normal standards of operation. Pan flu requires early and extensive planning, and that planning must include the legal community. Each issue that will come up during a pandemic affects the others, and a firm legal basis for the plans the government does adopt is essential to efficient response.

To answer the question presented in the title, “Is Virginia Ready?,” is impossible. We will not know if we are ready until a pandemic has come and gone. Virginia has a strong start for pandemic planning, though there are still some areas that need to be clarified.¹³⁵ While the Code of Virginia may be clear as to some issues like quarantine and isolation, decision-makers need to make sure the law is properly translated into the plans and that those plans are properly understood by those who will be in charge of responding to pan flu. The creation of laws and procedures is only one step; the best response will be characterized by open communication between all levels of government, responders, and citizens as well as comprehensive planning, which must be anchored by a foundation of legal preparedness.

135. *See supra* Part IV.A.1.

