ASSESSING THE IMPACT OF FEDERAL LAW ON PUBLIC HEALTH PREPAREDNESS

BENJAMIN E. BERKMAN,* SUSAN C. KIM** & LINDSAY F. WILEY***

I. INTRODUCTION

Over the past decade, the United States has faced an array of large-scale public health threats. The events of September 11, 2001, quickly followed by the anthrax mailings, exposed the country's vulnerability to physical and biological terrorist attacks.[1] Global outbreaks of various life-threatening infectious diseases, such as severe acute respiratory syndrome (SARS), the West Nile Virus, and pandemic influenza have not only taken lives, but have also significantly affected political and economic systems on a national and international scale.[2] Furthermore, the inadequate response to—and the aftermath of—Hurricane Katrina highlighted the direct link

* Benjamin E. Berkman, JD, MPH, is a faculty member in the Department of Clinical Bioethics, National Institutes of Health. He also serves as the Deputy Director of the Bioethics Core at the National Human Genome Research Institute and is an adjunct professor at Georgetown University Law Center. The opinions expressed here are the author's and do not reflect the policies and positions of the National Institutes of Health, the U.S. Public Health Service, or the U.S. Department of Health and Human Services. This research was sponsored by a grant from the Centers for Disease Control and Prevention. The research was also supported in part by the Intramural Research Program of the National Human Genome Research Institute, National Institutes of Health. The authors would like to thank Peter Jacobson and Jeffrey Wassermann for their excellent comments and guidance. The authors would also like to thank Peter Currie, Astrid Dorelien, Brittany Griffin, Lindsay Holden, Meredith Larson, and Lee Melvin Peralta for their research assistance.

** Susan C. Kim, JD, MPH, is a Project Manager and Manager of Grants and Communications at the O'Neill Institute for National and Global Health Law at Georgetown University.

*** Lindsay F. Wiley, JD, MPH, is an Assistant Professor of Law at the American University Washington College of Law.

1. *See* Susan West Marmagas, Laura Rasar King & Michelle G. Chuk, *Public Health's Response to a Changed World: September 11, Biological Terrorism, and the Development of an Environmental Health Tracking Network*, 93 AM. J. PUB. HEALTH 1226, 1227 (2003) (discussing the need for increased protection of the public health infrastructure after the September 11 attacks).

2. Lawrence O. Gostin, *Why Rich Countries Should Care About the World's Least Healthy People*, 298 JAMA 89, 90 (2007).

between the destruction of infrastructure caused by natural disasters and public health crises.[3]

The emergence of these public health threats has prompted robust efforts to improve United States emergency preparedness[4] at all levels of government. While states and localities have traditionally had primary responsibility for conducting these kinds of public health activities,[5] it has become clear that there is also a salient need for federal involvement in preparing for and responding to public health emergencies. An effective response to a large-scale public health threat will require coordinated action across all levels of government. Events of significant size and scope will almost certainly not be limited to one state or locality and will demand an extensive commitment of federal resources and guidance.

As the public health community has engaged in efforts to improve the nation's emergency preparedness infrastructure,[6] many of the most dramatic changes have occurred at the federal level, including the creation of the Department of Homeland Security (DHS) as a new Cabinet department—the largest restructuring of federal administrative agency responsibility since the New Deal.[7] For many years, the federal government has provided funding and guidance for disaster preparedness and recovery through its power to spend for the general welfare and its power to regulate interstate commerce.[8] However, following the terrorist attacks of 2001 and 2002 and outbreaks of emerging and reemerging infectious diseases, the federal government began to take a more proactive role in prevention of,

3. *See generally* SELECT BIPARTISAN COMM. TO INVESTIGATE THE PREPARATION FOR & RESPONSE TO HURRICANE KATRINA, A FAILURE OF INITIATIVE: FINAL REPORT OF THE SELECT BIPARTISAN COMMITTEE TO INVESTIGATE THE PREPARATION FOR AND RESPONSE TO HURRICANE KATRINA, H.R. REP. NO. 109-377, at 1, 267 (2006) [hereinafter COMM. TO INVESTIGATE KATRINA], *available at* http://www.gpoaccess.gov/serialset/creports/katrina.html#zip (explaining the ineffectiveness of the public health infrastructure in the wake of the destruction caused by Hurricane Katrina).

4. For purposes of this paper, we will use the term "public health emergency preparedness" (or just "emergency preparedness") to encompass the policies and laws undertaken to protect the public from biological harms, including the prevention and mitigation of dangers to the public's health posed by diseases, natural disasters, and bioterrorism.

5. COMM. TO INVESTIGATE KATRINA, *supra* note 3, at 201. *See also* David L. Feinberg, *Hurricane Katrina and the Public Health-Based Argument for Greater Federal Involvement in Disaster Preparedness and Response*, 13 VA. J. SOC. POL'Y & L. 596, 597 (2006).

6. U.S. DEP'T OF HOMELAND SEC., NATIONAL RESPONSE PLAN 1-2 (2004) [hereinafter NRP], *available at* http://www.iir.com/global/FusionCenter/NRPbaseplan.pdf.

7. *Id*. at 9, 78-79. *See also* U.S. DEP'T OF HOMELAND SEC., FACT SHEET: LEADERSHIP AND MANAGEMENT STRATEGIES FOR HOMELAND SECURITY MERGER (2004), *available at* http://www.dhs.gov/xnews/releases/press_release_0345.shtm.

8. EILEEN SALINSKY, NAT'L HEALTH POL'Y FORUM, NHPF BACKGROUND PAPER: PUBLIC HEALTH EMERGENCY PREPAREDNESS: FUNDAMENTALS OF THE "SYSTEM" 13 (2002), *available at* http://www.nhpf.org/library/background-papers/BP_Public_Health_4-02.pdf.

preparedness for, and response to biological weapons attacks and infectious disease outbreaks under the auspices of providing for national security.[9]

This shift represents a departure from the traditional federal-state relationship in the area of emergency preparedness. A longstanding principle of federal involvement in disaster response, which is clearly embodied in the National Response Plan (NRP), is the premise that "[i]ncidents are typically managed at the lowest possible geographic, organizational, and jurisdictional level."[10] The view of federal action as supplementary to state and local actions with respect to emergency preparedness is rooted in our federalist system, which grants limited powers to the federal government.[11] As federal involvement in emergency preparedness grows, consideration of the constitutional bases for federal action in this arena and the potential constitutional limits on federal encroachment into traditional state functions becomes increasingly important.

Increased federal involvement in emergency preparedness has also raised important questions about the way that federal laws, policies, and programs affect state and local preparedness and response efforts. Emergency preparedness combines one of the most fundamental functions of the federal government – national security[12] – with one of the most fundamental functions of the state governments – public health.[13] Among national security concerns, emergency preparedness is unique in that jurisdiction for preparedness and response is not exclusively federal.[14] Among public health concerns, biological weapons attacks and infectious disease outbreaks are distinguished by increasing federalization of preparedness and response.[15] The result is "a myriad of laws [at the local, state, and federal level] that must be considered, most of which were developed to address more mundane public health matters, or designed to respond to more traditional emergency situations."[16]

9. GEORGE W. BUSH, THE DEPARTMENT OF HOMELAND SECURITY 1 (2002), *available at* http://www.dhs.gov/xlibrary/assets/book.pdf.

10. *Id.* at 6.

11. SALINSKY, *supra* note 8, at 12.

12. *Homeland Security*, WHITEHOUSE.GOV, http://www.whitehouse.gov/issues/homeland-security (last visited Sept. 3, 2010).

13. *See* Wendy E. Parmet, *Health Care and the Constitution: Public Health and the Role of the State in the Framing Era*, 20 HASTINGS CONST. L.Q. 267, 272 (1993).

14. *See* Wendy E. Parmet, *After September 11: Rethinking Public Health Federalism*, 30 J. L. MED. & ETHICS 201, 201 (2002).

15. *See id.*

16. John D. Blum, *Too Strange to be Just Fiction: Legal Lessons from a Bioterrorist Simulation, the Case of TOPOFF 2*, 64 LA. L. REV. 905, 915 (2004).

This article will present qualitative interview data that were collected as part of a larger project to explore the impact of federal law on public health preparedness.[17] As a foundation, Section II will briefly outline some of the most salient ways in which the federal role in public health preparedness has expanded in the past decade. Section III will provide some background about the structure and purpose of the larger Centers for Disease Control and Prevention (CDC)-funded project. Section IV will present our findings from the final phase of this project—a series of qualitative interviews with federal policymakers. These data will be presented in four parts: methods, results, discussion, and conclusion.

II. AN INCREASING FEDERAL ROLE IN PUBLIC HEALTH PREPAREDNESS

The last decade has been marked by increasing federalization of public health preparedness and response—an area that was traditionally handled almost exclusively at the state and local level.[18] The terrorist attacks of 2001 and 2002, the SARS outbreak, and concerns about pandemic influenza prompted a series of federal legislative efforts to enhance emergency preparedness. These include the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act),[19] the Project Bioshield Act of 2004 (Project Bioshield),[20] the Public Readiness and Emergency Preparedness Act of 2005 (PREPA),[21] and the Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA).[22] These legislative reforms were followed by federal efforts to develop comprehensive emergency response plans intended to implement and coordinate federal preparedness and response law, including the National Response Framework (NRF)[23] and the National Strategy for Pandemic Influenza Implementation Plan (NSPIIP).[24]

17. Peter D. Jacobson et al., The Role of Law in Public Health Preparedness: Opportunities and Challenges, Final Project Report 1 (April 23, 2010) (unpublished manuscript) (on file with author).

18. COMM. TO INVESTIGATE KATRINA, *supra* note 3, at 201.

19. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (codified as amended in scattered sections of 42 U.S.C.).

20. Project BioShield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835 (codified as amended in scattered sections of 42 U.S.C.).

21. Public Readiness and Emergency Preparedness Act of 2005, 42 U.S.C. §§ 247d-6d, 247d-6e (2006).

22. Pandemic and All-Hazards Preparedness Act, Pub. L. No. 109-417, 120 Stat. 2831 (2006) (codified as amended in scattered sections of 42 U.S.C.).

23. NATIONAL RESPONSE FRAMEWORK, U.S. DEP'T OF HOMELAND SEC. 1 (2008) [hereinafter NRF], *available at* http://www.fema.gov/pdf/emergency/nrf/nrf-core.pdf.

24. *See* HOMELAND SEC. COUNCIL, EXEC. OFFICE OF THE PRESIDENT, NATIONAL STRATEGY FOR PANDEMIC INFLUENZA IMPLEMENTATION PLAN 1-2 (2006) [hereinafter NSPIIP], *available at* http://hosted.ap.org/specials/interactives/wdc/documents/pandemicinfluenza.pdf.

Although nearly any federal statute might come into play in preparing for and responding to a public health emergency, there are two key statutes in which the majority of relevant federal law (including the reforms described above) is codified: The Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act)[25] and the Public Health Service Act (PHSA).[26] The Stafford Act provides the framework for federal involvement in disaster relief and emergency assistance and sets forth various provisions for disaster and emergency preparedness.[27] Relevant portions of the PHSA specifically address public health emergencies, which include biological security events as well as the public health consequences of other types of events.[28] The NRF draws from both Acts, as well as from other sources of authority, to establish what is intended to be an "all-hazards" plan[29] for responding to a variety of disasters and emergencies. Similarly, the NSPIIP sets forth a coordinated plan for pandemic preparedness.[30]

Both the Stafford Act and PHSA have been expanded to provide for an increased federal role. While much of the Stafford Act deals with emergency and disaster response, the Act also now addresses the federal government's role in preparedness efforts.[31] Originally, the Act contained only a few provisions on preparation and mitigation,[32] and some of these were limited to post-disaster mitigation – they applied only to areas that had already experienced a major catastrophe.[33] Several amendments[34] to the

25. Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§ 5121-207 (2006). *See also* NRP, *supra* note 6, at 5, 79 (presenting an overview of the Stafford Act).

26. Public Health Service Act, 42 U.S.C. § 201 (2006).

27. *See* Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§ 5121-207 (2006).

28. Public Health Service Act, 42 U.S.C. §§ 201, 247d, 300hh-13, 300hh-14 (2006).

29. *See, e.g.*, Ernest B. Abbot, *Homeland Security in the 21st Century: New Inroads on the State Police Power*, 36 URB. LAW. 837, 840-41 (2004) (describing the evolution of the "all-hazards" approach to emergency management).

30. NSPIIP, *supra* note 24.

31. Although the original version of the Stafford Act contained some provisions on disaster mitigation, such provisions were significantly multiplied when the Act was amended by the Disaster Mitigation Act of 2000. *See* Disaster Mitigation Act of 2000, Pub. L. No. 106-390, 114 Stat. 1552 (codified as amended in scattered sections of 42 U.S.C.).

32. *See, e.g.*, Disaster Relief Act of 1974 §§ 101, 401, 42 U.S.C. §§ 5121, 5171 (1982).

33. *See, e.g.*, §§ 301-03, 306.

34. *See, e.g.*, §§ 102, 302; Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA Patriot Act) Act of 2001, Pub. L. No. 107-56, § 1013(b)(1), 115 Stat. 399; Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 2002, Pub. L. No. 107-73, 115 Stat. 688 (2001); Department of Homeland Security Appropriations Act, 2007, Pub. L. No. 109-295, 120 Stat. 1355 (2006).

Act have since circumvented this limitation and have expanded the federal government's authority to encourage disaster preparedness in all parts of the country.

The PHSA,[35] which "supplements, but does not supplant" the Stafford Act,[36] similarly provides for a prominent federal role in planning for and responding to public health emergencies.[37] In addition to outlining the role of the Secretary of Health and Human Services in declaring a public health emergency to trigger federal assistance,[38] a series of amendments to the PHSA have sought to enhance national preparedness for public health emergencies. For example, in 2002, the Bioterorrism Act amended the PHSA to set aside funds specifically for assessing national public health preparedness needs and for grants to assist state and local government and private health-care sector preparedness efforts.[39]

In 2006, PAHPA attempted to increase accountability for state and local spending of federal preparedness funds by requiring the Department of Health and Human Services (DHHS) Secretary to "develop and apply measurable evidence-based benchmarks and objective standards to measure the preparedness of state and local grantees, including annual test and exercise requirements."[40] PAHPA also specifically mandated the development of criteria for evaluating state pandemic influenza plans[41] and DHHS and DHS have worked together to release an initial template for review criteria.[42] However, the law allows use of "existing objective standards,"[43] which means that for general all-hazards preparedness, DHHS and DHS may revert to the status quo of requiring states to collect data and

35. *See* Vickie J. Williams, *Fluconomics: Preserving Our Hospital Infrastructure During and After a Pandemic,* 7 YALE J. HEALTH POL'Y L. & ETHICS 99, 134-35 (2007) (stating that the PHSA specifically addresses the responsibilities of the federal government during public health emergencies). *See also* Public Health Service Act, 42 U.S.C. §§ 201-300 (2006).

36. *Id.* at 135.

37. *Id.*

38. 42 U.S.C. § 247d(a) (2006).

39. 42 U.S.C. §§ 247d-1 to -3, 247d-3a to-3b (2006).

40. TRUST FOR AMERICA'S HEALTH, READY OR NOT? PROTECTING THE PUBLIC'S HEALTH FROM DISEASES, DISASTERS, AND BIOTERRORISM 49-50 (2007).

41. Pandemic and All-Hazards Preparedness Act Pub. L. No. 109-417, § 201, 120 Stat. 2831, 2837, 2839-40 (2006) (codified as amended at 42 U.S.C. § 247d-3a (2006)).

42. ASSISTANT SEC'Y FOR PREPAREDNESS & RESPONSE, U.S. DEP'T OF HEALTH & HUMAN SERVS., PANDEMIC AND ALL-HAZARDS PREPAREDNESS ACT PROGRESS REPORT 17 (2007), *available at* http://healthyamericans.org/reports/bioterror07/PAHPAProgressReport.pdf.

43. Pandemic and All-Hazards Preparedness Act § 201 (codified as amended at 42 U.S.C. § 247d-3a (2006)).

report on six of the twenty-three performance measures set forth in the existing CDC preparedness goal.[44]

In addition to increased federal funding of state and local preparedness, legislative reforms have also significantly expanded the federal government's relatively recent forays into direct federal involvement in preparedness through the development and enhancement of the National Disaster Medical System (NDMS),[45] the Emergency System for Advance Registration of Volunteer Health Professions (ESAR-VHP),[46] the Strategic National Stockpile ("SNS")[47] of essential pharmaceutical resources, and the CDC's National Electronic Disease Surveillance System ("NEDSS").[48] The establishment and expansion of these programs signal that the federal government is moving beyond the confines of its traditional role as adviser and financer of state and local preparedness and response efforts.[49]

In 2008, updates to the NRF similarly reflected an evolution in the relationship between federal, state, and local players in emergency and disaster response.[50] Language that had once emphasized the primacy of

44. *See, e.g.*, Announcement from Sylvia Dawson, Grants Team Lead, Centers for Disease Control and Prevention to Colleagues at Centers for Disease Control and Prevention app. 1, at 7-8 (Sept. 21, 2007), *available at* http://www.bt.cdc.gov/planning/coopagreement/pdf/fy07announcement.pdf; CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T OF HEALTH & HUMAN SERVS., PANDEMIC INFLUENZA GUIDANCE SUPPLEMENT TO THE 2006 PUBLIC HEALTH EMERGENCY PREPAREDNESS COOPERATIVE AGREEMENT PHASE II 5, 20-25 (2006), *available at* http://www.bt.cdc.gov/planning/coopagreement/pdf/phase2-panflu-guidance.pdf.

45. The NDMS operates pursuant to section 2812 of the Public Health Service Act. *See* 38 U.S.C. § 8117(e) (2006).

46. HEALTH RES. & SERVS. ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., EMERGENCY SYSTEM FOR ADVANCE REGISTRATION OF VOLUNTEER HEALTH PROFESSIONALS (ESAR-VHP) – LEGAL AND REGULATORY ISSUES 9-14 (2006), *available at* http://www.publichealthlaw.net/Research/PDF/ESAR%20VHP%20Report.pdf. The name has changed from ESAR-HPV to ESAR-VHP. *See About ASPR*, U.S. DEP'T OF HEALTH & HUMAN SERVS., http://www.phe.gov/about/Pages/default.aspx (last visited Oct. 23, 2010).

47. 42 U.S.C. § 247d-6b (2006).

48. *National Electronic Disease Surveillance System*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/nedss/index.htm (last visited July 30, 2010).

49. *See, e.g.*, Bill Frist, *Public Health and National Security: The Critical Role of Increased Federal Support*, HEALTH AFF., Nov.-Dec. 2002, at 117, 120-21 ("Congress appropriated a record $3 billion in December 2002 for antibioterrorism activities, including more than $1 billion dedicated to upgrading state and local public health capabilities and hospital preparedness.").

50. The National Response Plan of 2004 emphasized that "incidents are typically managed at the lowest possible geographic, organizational, and jurisdictional level." *See* NRP, *supra* note 6, at 6. The National Response Framework of 2008 softened this statement and added new language pointing to the importance of federal involvement: "Incidents must be managed at the lowest possible jurisdictional level and supported by additional capabilities when needed. It is not necessary that each level be overwhelmed prior to requesting resources from another level." *See* NRF, *supra* note 23, at 10.

local control was softened to highlight the importance of the federal role, while stopping short of promising federal responsibility for response efforts.[51] Furthermore, the Catastrophic Incident Annex of the NRF now provides for expedited and increased federal involvement in response efforts under certain extreme conditions.[52] When triggered by a catastrophic event, the revisions bypass traditional requirements that a state governor request federal assistance and that an incident first must overwhelm state and local resources before federal authorities may become involved.[53]

Estimates of overall federal funding for emergency preparedness vary, depending how broadly one defines the term. One report from the Government Accountability Office calculates that from 2002 through 2007, approximately $19 billion was distributed by DHS for emergency preparedness, equipment, and training.[54] It should be noted that this estimate includes grants intended to help prepare for and respond to major disasters of all types, including terrorist attacks.[55] Alternatively, a Congressional Research Service report focusing specifically on public health preparedness states that "Congress has provided more than $9 billion in grants to states to strengthen public health and hospital preparedness" (approximately $1 billion per year) since 2002.[56] In a recent analysis of U.S. emergency preparedness efforts, Trust for America's Health determined that total federal funding for state and local all-hazard public health and pandemic preparedness efforts amounts to more than $11 billion over the past seven years.[57]

51. NRF, *supra* note 23, at 10.

52. FED. EMERGENCY MGMT. AGENCY, DEP'T OF HOMELAND SEC., CATASTROPHIC INCIDENT ANNEX 1, 6 (2008), *available at* http://www.fema.gov/pdf/emergency/nrf/nrf_CatastrophicIncidentAnnex.pdf.

53. *See id.*

54. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-08-488T, HOMELAND SECURITY: DHS IMPROVED ITS RISK-BASED GRANT PROGRAMS' ALLOCATION AND MANAGEMENT METHODS, BUT MEASURING PROGRAMS' IMPACT ON NATIONAL CAPABILITIES REMAINS A CHALLENGE 1 (2008).

55. *Id.*

56. SARAH A. LISTER, CONG. RESEARCH SERV., R40159, PUBLIC HEALTH AND MEDICAL PREPAREDNESS AND RESPONSE: ISSUES IN THE 111TH CONGRESS 5 (2009).

57. TRUST FOR AMERICA'S HEALTH, *supra* note 40, at 57. While these estimates vary, they all indicate that significant federal funding is being allocated for state and local preparedness activities. Given that our analysis is designed to focus on the effect of federal laws on state and local preparedness activities, we do not attempt to resolve this debate. The exact amount is less important than the shape of these federal funding mechanisms and the impact that these grant programs are having on state and local preparedness efforts.

III. A PROJECT TO ASSESS THE IMPACT OF FEDERAL LAW ON PUBLIC HEALTH EMERGENCY PREPAREDNESS

To date, there has been little systematic examination of the effects (positive or negative) that this expanding federal role has on public health emergency preparedness. Except for the on-going studies funded by the CDC's Public Health Law Program (PHLP),[58] existing public health research efforts that examine how public health operates have not often considered law to be an important variable.[59] The PHLP studies are a promising beginning, though most of their projects deal with the effects of law on specific programs (such as AIDS and immunization laws)[60] as opposed to studying the law's influence on the broader public health system as this paper will begin to describe.

To be sure, reforming public health law has been a topic of considerable discussion, especially for bioterrorism preparedness.[61] The development of the CDC's Model State Emergency Health Powers Act[62] by the Georgetown/Hopkins CDC Collaborating Centers for Law and the Public's Health (CLPH) is a prime example of the role law plays in organizing public health practice.[63] With the help of government officials, public health experts, and other major stakeholders, CLPH faculty and staff drafted and disseminated the Model State Emergency Health Powers Act (MSEHPA), which gave local and state officials increased authority to protect

58. *See Public Health Law Program*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www2a.cdc.gov/phlp/research.asp (last visited Sept. 2, 2010). *See also* Edward L. Baker, Jr. & Jeffrey P. Koplan, *Strengthening The Nation's Public Health Infrastructure: Historic Challenge, Unprecedented Opportunity*, HEALTH AFF., Nov.-Dec. 2002, at 22. ("To improve the legal foundation for public health practice and particularly to examine the need for updating of public health statutes, the Public Health Law Program was created in 2000").

59. Scott Burris et al., *Making the Case for Laws That Improve Health: A Framework for Public Health Law Research*, 88 MILBANK Q. 169, 170 (2010).

60. *See, e.g.*, *Public Health Law Program*, *supra* note 58.

61. *See generally, e.g.*, INST. OF MED. OF THE NAT'L ACADS., THE FUTURE OF THE PUBLIC'S HEALTH IN THE 21ST CENTURY (2002) (stating that pioneering work has gone into assisting states in reforming their public health laws to address health preparedness needs, but a more comprehensive effort is needed); Laura H. Kahn, *State Report: A Prescription for Change: The Need for Qualified Physician Leadership in Public Health*, HEALTH AFF., July-Aug. 2003, at 241, 241-48 (stating that since the threat of future bioterrorism attacks will remain in the future, state public health laws must be reformed).

62. *See generally* CTR. FOR LAW & PUBLIC'S HEALTH AT GEORGETOWN & JOHNS HOPKINS U., THE MODEL STATE EMERGENCY HEALTH POWERS ACT 1 (2001) [hereinafter MSEHPA], available at http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf. ("The Act requires the development of a comprehensive plan to provide a coordinated, appropriate response in the event of a public health emergency.").

63. Lawrence O. Gostin, *Public Health Law in an Age of Terrorism: Rethinking Individual Rights and Common Goods*, HEALTH AFF., Nov.-Dec. 2002, at 83, 83.

individuals and property during states of emergency.[64] Forty-four states and the District of Columbia have passed laws incorporating some portion of MSEHPA.[65] The Turning Point initiative has similarly stimulated reforms of state-level public health codes.[66] Neither project, however, was designed to investigate empirically the role of law in public health practice.

This article presents data seeking to address this empirical void. Given increased federal involvement in public health preparedness activities, we undertook a project to provide policymakers with the first systematic empirical analysis to understand how federal law shapes the public health system's disease preparedness activities and how public health officials are adjusting to the changing federal legal environment. In particular, we aimed to study the mechanisms through which federal laws provide funds for specific activities and how these mechanisms shape, or constrain, the ways in which states and localities can spend the funds.

As a framework for this project, we adopted the model set forth by Mendez et al., which depicts a mechanism whereby physicians are influenced by both an objective legal environment and a perceived legal environment (see Figure 1).[67] The study framework anticipated that public health officials will not necessarily have an accurate understanding of the key legal requirements in public health preparedness laws, but are more likely to be influenced by what they perceive the legal environment to be.

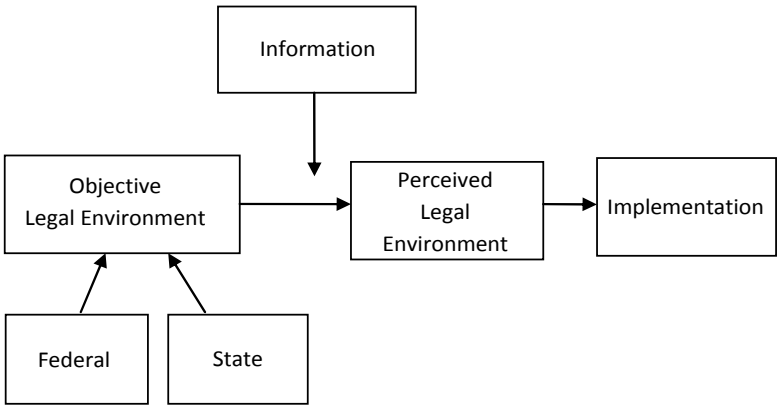

Figure 1

64. *Id*. at 84.

65. CTR. FOR LAW & THE PUBLIC'S HEALTH, MODEL STATE EMERGENCY HEALTH POWERS ACT (MSEHPA): STATE LEGISLATIVE ACTIVITY 1 (2006), *available at* http://www.publichealthlaw.net/MSEHPA/MSEHPA%20Leg%20Activity.pdf.

66. Bobbie Berkowitz & Jack Thompson, *The Turning Point Initiative: Responding to Challenges in Public Health*, 17 WASH. PUB. HEALTH 44, 44-45 (2000).

67. David Mendez et al., *The Effect of Legal and Hospital Policies on Physician Response to Prenatal Substance Exposure*, 7 MATERNAL & CHILD HEALTH J. 187, 188 (2003).

Phase 1 of the project involved constructing a detailed account of the objective legal environment. To examine how law affects the structure of the public health system and its ability to respond more effectively to the threat of emerging infectious disease threats and other public health preparedness needs, we first described, categorized, and analyzed current federal mandates and funding arrangements affecting state and local public health systems. This work was based on the premise that federal law provides a general structure and framework for public health activities,[68] while state and local law provides parameters for the implementation and delivery of specific programs and services.[69]

Although bioterrorism and emergency response efforts largely take place at the local level, with public health as the core of first responders,[70] federal law substantially influences how state and local health departments allocate their resources.[71] Thus, our research in federal law focused on identifying specific topical mandates, as well as analyzing funding mechanisms provided to achieve those mandates.

Phase 2 involved a series of comparative case studies to determine how state and local public health departments respond to emerging infectious disease threats, bioterrorism, and other public health preparedness challenges and how state laws shape those responses. These case studies enabled us to capture the perceived legal environment: local policymakers' understanding of what they are expected, or required, to accomplish and the programmatic choices they make under federal law. We anticipated that public health officials would be influenced by what they believe they are expected to do, but that their perceptions may not match the objective legal requirements.

Phase 3 involved a study of the federal government's evolving role in shaping policy and law affecting public health. Through a series of interviews with a variety of federal policymakers, we aimed to determine their understanding of the relationship between federal laws and state and local preparedness activities. We attempted to explore how federal officials view current public health preparedness functions; what public health role they see for the federal government in the future; how their views will affect state and local public health functions; how bioterrorism and emergency response funds have been monitored, with particular attention to the relation to other public health funding streams; and how funding streams for

68. *See* Anne Morse, *Bioterrorism Preparedness for Local Health Departments*, 19 J. COMMUNITY HEALTH NURSING 203, 205 (2002).

69. *Id.*

70. *Id.*

71. *Id.*

pandemic flu and other emergent infectious diseases have been determined and coordinated.

The remainder of this article presents our qualitative interview data about how federal policy-makers view the federal government's current role in preparedness activities and how that role will evolve in the future. The analysis will focus on the extent to which there is discordance between the objective legal framework and the subjective views of federal policy-makers about how the federal legal framework impacts state preparedness activities.

IV. IMPACT OF FEDERAL LAW ON STATE PREPAREDNESS: FEDERAL POLICY-MAKER PERSPECTIVE

The original data reported here were collected to specifically explore federal policy-makers' subjective perceptions of the relationship between federal law and state/local public health preparedness activities. Our goal was to examine how federal policymakers view the federal government's current role in preparedness activities and how that role will evolve in the future. Given our previous work on the objective federal legal framework for preparedness activities, we also wanted to compare these findings to the respondents' subjective understanding of the ways in which federal law affects state and local public health functions. In particular, our study was interested in the implementation and monitoring of federal public health funding mechanisms and the implications that these programs have for state and local public health preparedness activities.

A. Methods

1. Selection of Respondents

In selecting interview candidates, attention was paid to ensuring a diverse range of respondents in terms of experience, training, and institutional affiliation. Even though the majority of questions were legal in nature, both lawyers and non-lawyers were interviewed. In order to capture high-level policy perspectives, as well as detailed on-the-ground experience, both junior and senior agency officials were selected. Given the range of federal agencies involved in public health preparedness activities, respondents were recruited from all key governmental entities, with a focus on DHS [including the Federal Emergency Management Agency (FEMA)] and the Department of Health and Human Services (DHHS) [including the Office of the Assistant Secretary for Preparedness and Response (ASPR), CDC, and the National Institutes of Health (NIH)].

Recruitment of potential respondents was an iterative process. After the relevant federal organizations had been identified, target individuals within these organizations were selected to interview. Once that process was completed, formal invitation letters were sent out via email. Subsequent

follow-up was conducted through additional emails and telephone calls. After a sufficient number of affirmative responses had been received, the interview process was started. As interviews were conducted, recruitment efforts were augmented by asking each respondent to identify potential respondents at the close of each interview. In total, fourteen individuals were interviewed. Respondents from all agencies included senior-level administrators responsible for general oversight of their agencies' preparedness activities, as well as key staff tasked with day-to-day operational duties. As such, a range of experiences and expertise was captured at both DHS and DHHS (and their affiliated sub-agencies). We do not expect that additional interviews would have altered our results.

All participants were assured confidentiality and were promised that neither they, nor their institution, would be identifiable. Therefore, this paper does not report any information that could uniquely identify any institution or respondent.

2. Interview Format and Design

A semi-structured interview protocol was developed for use in both in-person and telephone interviews. This protocol was designed in parallel with the state and local interview protocol, but was adjusted for federal respondents. Additionally, the protocol was structured so that questions could be asked in either an individual or group setting. Overall, the protocol was designed to provide consistency across interviews and institutions, as well as to help organize note-taking. To account for the type of position and level of responsibility of each respondent, there were slight variations made to the protocol for each interview.

The protocol generally consisted of open-ended questions that gave the interviewers flexibility to explore unanticipated, but fruitful, avenues of inquiry. The questions fell into three broad categories: 1) evaluation and oversight of preparedness activities; 2) collaboration and communication; and 3) suggested improvements. Within these categories, additional topics were explored in greater depth, such as the allocation and tracking of federal funds to support state preparedness efforts, federal oversight over state initiatives, barriers to effective implementation of state preparedness activities, and communications among federal, state, and local entities.

3. Data Collection and Analysis

The interviews were conducted both in-person and on the telephone. Generally lasting about sixty minutes, the interviews were primarily conducted by a project investigator. Student research assistants provided additional note-taking support for a number of interviews. If the respondent consented, the interviews were digitally recorded for transcription purposes. As such, transcripts were generated either from the audio recording or

hand-written notes. To the extent possible, transcripts captured participants' verbatim responses.

Once transcribed, N6 qualitative data analysis software, the latest version in the NUD*IST series, was utilized. Qualitative analysis software offers a number of tools to organize and compare complex data in one file. After reviewing the transcripts, a list of key words was chosen for preliminary analysis using a text search, which placed the selected word or phrase in context. The results of these text searches led to the development of nodes, which organized the data into broader concepts.

This was followed by a comprehensive review of the transcripts by the research team. The interviews were read independently by four people, two of whom were not involved in administering the interviews. To minimize bias, initial content theme analysis was conducted by the fourth reader who was not present at any of the interviews. Each reader was instructed to review all interviews, placing salient statements into one or more nodes, not limited to the categories identified by the qualitative data software. Readers were then instructed to examine the statements in each individual node to determine if they could be organized into coherent subtopics. After extensive discussion between the readers, this analysis was revised and expanded.

4. Study Limitations

This study has methodological limitations that should be considered when interpreting the results. First, basic resource constraints limited the number of interviews that we were able to conduct. Though our respondents' respective agencies are generally reflective of the institutional diversity in the federal government, the small number of participants cannot completely capture the range of opinions within and between these agencies. While we believe that we interviewed a sample of very knowledgeable and influential people, we recognize that we have no way of assessing whether their views on the issues discussed mirror those of the larger population of people who are responsible for formulating and executing public health policy.

Second, our sampling may be limited by self-selection bias. We only spoke to participants who agreed to be interviewed, so it is possible that individuals who were particularly occupied disproportionately declined interview. Although our respondents provided us with a diversity of information, we may not have fully captured all existing perspectives. The participants may not be fully representative of all views at each organization. Some of the individuals whom we would have liked to interview were either unwilling or unable to meet with us. For the most part, we believe we did not encounter this problem to any significant degree.

Third, our findings are limited to our participants' self-reports. We did not engage in an analysis of whether our participants' statements reflect actual preparedness outcomes.

B. Results

The respondents' comments can be divided into four distinct categories, each with a number of subtopics. First, we begin with the respondents' descriptions of the respective roles of federal and state governments. Second, we examine the respondents' discussion of coordination between agencies and between different levels of government. Third, we explore the perceived impact of federal funding mechanisms and procedures on states' preparedness activities. Finally, we investigate the techniques used to improve compliance and to ensure accountability.

1. Delineating State and Federal Responsibilities

a. The Role for Federal Government

While a minority of respondents mentioned the need for further clarification and definition of federal and state roles, overall there seemed to be a broadly shared understanding of the federal role vis-à-vis states and localities. Most respondents noted that the primary role of the federal government should be to provide resources and to empower, inform, and educate states and localities to effectively plan for emergencies. This dominant position implies an understanding that there are limits on the appropriate role of the federal government with regard to preparedness activities. While recognizing its limits, a minority of these respondents expressed that the federal government must also be cognizant of the limited capacity of the state and local governments in some situations and must be ready to respond accordingly. A few of the respondents stressed that some activities should be exclusively under the purview of the federal government, such as the development of countermeasures.

Furthermore, a majority of the respondents expressed that there is a unique role for the federal government as a coherent "enterprise" capable of supporting research that leads to the development of capacity to deliver products that will protect the public's health in the event of an emergency (e.g., vaccines, antitoxins). The development of such products should be a "national" priority as opposed to one that could be reserved to a particular state or locality. As one respondent noted, the federal government is best positioned to stimulate and translate research into the actual development of the products that will protect the public's health. Federal officials have the requisite bargaining power to coordinate the mass production of drugs and diagnostic technology. Consistent with this position, the majority of

participants also seemed to agree that states and localities cannot (and should not) support their own drug and diagnostic research.

b. State Autonomy

A vocal minority emphasized the importance of state autonomy. So long as they abide by broad federal parameters, states should be given the discretion to establish their own prioritization decisions. States should be allowed to establish priorities based on their respective capacities. For example, with respect to centralized countermeasure distribution, some states may not be able to effectively engage in that type of activity due to geographic distribution, population characteristics, and general infrastructure. As such, in defining parameters, these respondents articulated that it is import for the federal government to acknowledge that states will have different capacities for preparedness planning. Moreover, federal guidance and parameters should be flexible enough to allow for the inevitable variance across states.

c. The Role of Non-governmental Actors

In addition to the roles of federal and state governments, a few respondents raised the issue of the role for private entities and individuals. These participants discussed an emerging paradigm shift within preparedness activities: effective planning for all-hazards is a model built upon "shared responsibility." Experts no longer have the ability to solve problems on their own. This means that the government at both the state and federal levels should recognize and take advantage of entities outside of the government. Furthermore, governments should acknowledge that some individuals and businesses may have a more efficient ability to disseminate information and products in the event of an emergency. For example, large private retailers, such as Wal-Mart may be more centrally and conveniently placed in remote areas to serve as distribution centers for countermeasures.

d. Removing Barriers

A minority of respondents further noted that where there is room for participation by multiple actors in public health preparedness initiatives (ranging from research to delivery), the federal government should encourage all relevant actors to participate by removing barriers. For example, private stakeholders may be reluctant to engage in preparedness activities because they are concerned with liability issues. These respondents pointed out that legislation, such as the PREP Act, in specific situations provides limited liability protection for actors who participate in emergency

response, as well as a compensation fund for individuals injured by those private actors.[72]

Along these lines, a few respondents noted particular concern regarding barriers posed by procurement law. Currently, both the federal government and many state governments engage with the private sector as a vendor in response to an event.[73] This, in turn, makes it difficult to identify the assets and capabilities that the private sector can provide during a public health emergency without some sort of pre-event contracting.[74] These respondents found that the continued contractual relationship between public and private entities in the course of preparedness activities does not sufficiently address current public health preparedness concerns. The primary identified problem with this relationship is that state and federal governments are unable to work with the private sector in advance of an event. The public-private relationship begins during or after a threat has manifested, which means that the response is reactionary as opposed to being planned and coordinated in advance. For example, if the federal government was able to develop a national contract with large transportation companies beforehand, states would know then which companies to turn to during an event. Along these lines, having to contract with private vendors in the midst of an event may lead to working with entities that are not objectively the most appropriately positioned to respond to a given situation.

2. Encouraging Coordination and Shared Focus Between Various Emergency Preparedness Actors

a. Silos of Perceived Authority

A majority of respondents expressed that there is a disconnect between entities because of inter-institutional authority disputes, or "silos of perceived authority" as one respondent described it. At the federal level, most participants seemed to agree that bureaucratic turf battles between federal agencies will impede any attempts to create a truly unified and coordinated system. This situation is exacerbated by the tension between the divergent priorities of Congress and the various federal agencies. Furthermore, there was a concern that relevant bodies at the state and federal level do not sufficiently collaborate with each other. While a minority of respondents

72. Public Readiness and Emergency Preparedness Act § 3, 42 U.S.C. § 247d-6e (2006).

73. BARBARA ANDERSEN ET AL., INST. FOR NAT'L SEC. & COUNTERTERRORISM, ARE WE READY?: A PRACTICAL EXAMINATION OF THE STRATEGIC NATIONAL STOCKPILE IN RESPONSE TO PUBLIC HEALTH CRISES 14-15 (2006).

74. Brooke Courtney et al., *Healthcare Coalitions: The New Foundation for National Healthcare Preparedness and Response for Catastrophic Health Emergencies*, 7 BIOSEC. & BIOTERRORISM 153, 156 (2009).

expressed a belief that this is largely due to the much documented lack of clarity about jurisdiction and role, a separate minority articulated a concern that states are not given sufficient voice in the development of federal preparedness policies. By this latter account, the regularly changing and inconsistent guidance and parameters associated with federal grants merely confuse and frustrate states, leading to a perception that federal and state authorities are not aligned. One respondent also identified resource constraints as a contributing factor. This respondent expressed that most preparedness entities, post-September 11, are dramatically under-resourced and therefore lack the capacity to create connections with other parts of the government that they need to get their jobs done.

b. Unity of Effort

A majority of respondents, representing all of the selected agencies, concurred that federal agencies must jointly create a shared vision. Harmonization is especially important today, where a great deal of funding is directed towards preparedness efforts.[75] A minority of participants noted the multitude of stakeholders with disparate agendas fighting over the spoils. Even though many respondents described coordination barriers, there was an increasing sense of optimism. The dominant position was one of hope about the direction of federal funding, finding that there seems to be an emerging "unity of effort" related to a deliberate federal attempt to harmonize emergency preparedness grant-making programs. A few respondents noted the overarching administrative attempts to harmonize grant programs. For example, Homeland Security Presidential Directive 21 (HSPD-21), the Executive Directive establishing the National Strategy for Public Health and Medical Preparedness, notes the necessity of a rational, inclusive, public health response and delivery system.[76] Additionally, a few respondents mentioned the regular meetings of inter-agency workgroups to discuss common issues, including an enterprise governance board comprised of influential members of DHHS, DHS, and the Department of Defense (DoD).

75. Eileen Salinsky & Elin A. Gursky, *The Case for Transforming Governmental Public Health*, 25 HEALTH AFF. 1017, 1021 (2006). *See also* Frist, *supra* note 49, at 120 (stating that federal funding has increased six hundred percent for antibioterrorism activites).

76. EXEC. OFFICE OF THE PRESIDENT, HOMELAND SECURITY PRESIDENTIAL DIRECTIVE 21: PUBLIC HEALTH AND MEDICAL PREPAREDNESS *passim* (2007) [hereinafter PRESIDENTIAL DIRECTIVE 21], *available at* http://www.dhs.gov/xabout/laws/gc_1219263961449.shtm (indicating that this directive will transform the national approach to protecting public health against all disasters).

3. Issues Relating to Federal Funding

a. Matching and Maintenance Requirements

A strong minority of respondents raised issues surrounding the problem of matching funds. Federal grants are often contingent on states allocating a predetermined matching amount each year in order to maintain eligibility to receive continued funding for a specific project. Such legal provisions are designed to encourage states to allocate their own resources to preparedness programs. For example, the Emergency Management Performance Grants require states to match at a fifty percent level of federal funds.[77] States that cannot commit to matching funds for preparedness activities will be forced to reject corresponding federal funding. A similar problem was identified relating to maintenance funding requirements.

b. Mismatched Budgetary and Appropriations Cycles

A majority of respondents discussed the reality that local, state, and federal appropriations and budgetary cycles are frequently not aligned. At the federal level, funds are often available for only a short time. For example, the CDC awards money in early August, but must close its books by mid-September.[78] These mismatched cycles often do not allow enough time for states to apply for grants or plan for the implementation of federally funded programs.

c. Inconsistent, Single-year Funding

A strong minority also identified multiple barriers presented by inconsistent and unpredictable grant levels, much of which has been implemented through emergency supplemental funding in one-year increments. Funding peaks and troughs (often associated with the rise and fall of a specific threat, such as pandemic influenza)[79] make it difficult to create and then provide continuous support for programs.

77. U.S. DEP'T OF HOMELAND SEC., EMERGENCY MANAGEMENT PERFORMANCE GRANTS: GUIDANCE AND APPLICATION KIT 5 (2008).

78. Announcement from Sharon H. Robertson, Grants Management Officer, Centers for Disease Control and Prevention to Colleagues at Centers for Disease Control and Prevention (May 13, 2010), *available at* http://www.bt.cdc.gov/cdcpreparedness/coopagreement/10/PHEP%20BP10%20Extension%20Guidance_Instructions_Appendices_05-13-2010_FINAL.pdf.

79. Jennifer B. Nuzzo, Michael Mair & Crystal Franco, *Preserving Gains from Public Health Emergency Preparedness Cooperative Agreements*, 7 BIOSEC. & BIOTERRORISM 35, 36 (2009).

4. Accountability, Performance Evaluation, and Enforcement

a. Overlapping, Inconsistent, and Unclear Grant Guidance

A few respondents discussed the implications of allowing federal funding to come from multiple sources. With so many streams of funding, there are a correspondingly diverse set of statutes, regulations, and agency guidelines, all of which states are expected to follow.[80] For example, one respondent gave a detailed account of a potential confusion arising from a discrepancy between the specific record-keeping requirements imposed by various Office of Management and Budget (OMB) circulars and the flexible language contained in many specific grant guidance documents. These respondents also specifically mentioned that the volume of reporting requirements can be overwhelming to states.

b. Role, Scope, and Effect of Grant Guidance

There was much discussion about the impact that federal grant guidance has on state preparedness activities. The majority of respondents, representing all selected agencies, described a generally permissive environment with significant state flexibility to achieve broad goals articulated by federal policy-makers. One respondent characterized grant guidance as the laying out of objectives and expectations to help shape state actions, with examples of allowable-type costs to provide more detail if necessary. Another respondent acknowledged that grant guidance contains provisions requiring certain state activities, but preferred to see grant guidance less as an imposition of requirements and more as a way of influencing programmatic priorities at the state and local levels. A third respondent echoed the notion of guidance as a tool to influence state and local priorities, but characterized his agency as a conduit between Congress and the states, with grant guidance serving as the mechanism that helps states determine how best to organize their preparedness activities. In slight contrast, one respondent from DHS believed that state autonomy was important, but also discussed how some recent grant guidance has gotten more proscriptive by narrowing the menu of allowable activities, describing this as a strategy to focus efforts in areas perceived to need the most urgent work.

80. 44 C.F.R. § 13.40 (2009); NAT'L ASS'N OF COUNTY & CITY HEALTH OFFICIALS, FEDERAL FUNDING FOR PUBLIC HEALTH EMERGENCY PREPAREDNESS: IMPLICATIONS AND ONGOING ISSUES FOR LOCAL HEALTH DEPARTMENTS 2, 7, 9 (2007); SALINSKY, *supra* note 8, at 15.

c. Progress Reporting and Monitoring

A strong minority of respondents acknowledged that objective, quantifiable measurement of preparedness benchmarks or standards is difficult, especially since it is hard to define preparedness and response, and it is extremely challenging to measure these capacities outside of an actual emergency event. Nevertheless, efforts to design appropriate metrics are ongoing. Early progress reporting was somewhat unsuccessful: data returned from the states had significant information missing, variation was extremely wide, and much of the data were limited by caveats. Recently, federal policy-makers have had success using metrics based on capacity to act, focusing on time as the quantifiable variable.

d. Penalties for Non-compliance

Most respondents generally did not perceive punitive measures for non-compliance as a productive strategy. Consistent with other findings, the federal officials that discussed penalties articulated the notion that they were not looking to fund specific processes, but rather were concerned about state-level preparedness outcomes. They saw the federal role as one of encouraging learning and improvement in state planning and preparedness systems; federal grants were designed to leave each jurisdiction the flexibility to achieve the stated goal through whatever techniques or strategies they wanted. As such, the majority of respondents repeatedly stressed that it was never their intention or desire to articulate specific tasks, and then punish states for failing to meet those specific goals. In fact, there was concern expressed about mandatory punitive measures, specifically statutory withhold requirements. Under the recent Pandemic and All-Hazards Preparedness Act (PAHPA), federal agencies are required to develop performance measures and evidence-based benchmarks.[81] If states do not meet these standards, the statute theoretically requires the withholding of funds.[82] A few respondents remained uncertain about how this provision will be implemented and the effects it might have.

81. Pandemic and All-Hazards Preparedness Act, Pub. L. No. 109-417, § 201, 120 Stat. 2831 (2006).

82. *Id*. *See also* SARAH A. LISTER, CONG. RESEARCH SERV., RS 22602, PUBLIC HEALTH AND MEDICAL PREPAREDNESS AND RESPONSE: ISSUES IN THE 110TH CONGRESS 2 (2008) [hereinafter LISTER, ISSUES IN THE 110TH CONGRESS] (noting that the PAHPA gives added authority to withhold funds for failure to meet requirements).

C. *Discussion*

1. An Emerging "Shared Responsibility" Paradigm

Emergency preparedness and response has traditionally been a predominantly local concern.[83] The role of federal agencies has been expanding in recent years, however, particularly as federal funding mechanisms for emergency preparedness have proliferated.[84] These competing claims have resulted in predictable confusion about the proper role for federal, state, and local governments in preparing for a public health emergency. This was most striking after Hurricane Katrina, when local, state, and federal preparedness and response efforts were heavily criticized as government entities battled uncertainties about jurisdictional authority and took turns blaming one another for shortcomings.[85]

As such, it was not surprising that respondents repeatedly discussed the need for a better understanding of the various roles of state and federal governments with respect to preparedness activities. Even though federal policy-makers acknowledged that more clarity was needed, there was a widely-held view that further delineation of roles should be strongly guided by the principle of federalism. Notably, the majority of respondents did not believe that the federal government should take an overly assertive role in state preparedness activities. Rather, the dominant articulated view was consistently one of complementary partnership, collaboration, and shared responsibility; whenever possible, state autonomy should be respected, and federal involvement should be limited to activities that it is uniquely situated to perform.

This vision of shared responsibility is clearly still evolving. When probed for details about the specific delineation of responsibilities, the line between state and federal responsibilities proved to be somewhat less defined. Certainly, broad consensus existed surrounding some types of non-contentious activities. For example, the federal government, with concentrated funds and access to broad scientific resources, should be responsible for providing collective goods (e.g., medical countermeasures) that individual states would be unable to produce on their own.

More controversially, a minority of respondents held that the federal government should also be responsible for identifying and addressing common barriers that might hinder preparedness activities, such as fear of liability, or unwieldy procurement mechanisms. While all states have their

83. *See* SALINSKY, *supra* note 8.

84. *See* Betty Bekemeier & Jan Dahl, *Turning Point Sets the Stage for Emergency Preparedness Planning*, 9 J. PUB. HEALTH MGMT. & PRAC. 377, 377 (2003).

85. *See* Neil Malhotra & Alexander G. Kuo, *Attributing Blame: The Public's Response to Hurricane Katrina*, 70 J. POL. 120, 120 (2008).

own liability laws and procurement relationships,[86] a couple of respondents felt that federal actors may be in a position to more efficiently or effectively mitigate these sorts of barriers through the passage of a national law or policy, or through the promulgation of model laws or policies that states can voluntarily adopt.

Finally, even though there was much discussion of partnership and "shared responsibility" between federal and state governments, a minority of respondents implied concern about balancing roles in a crisis. These respondents indicated that the federal government must remain alert to the limited abilities of state and local governments. As such, they felt that federal policymakers must be prepared to step in with preparedness efforts when states are not successfully preparing themselves.

It should not be surprising that the majority of federal policymakers articulated a vision of shared preparedness responsibility. Federal policymakers understand that for historical, constitutional, and practical reasons, centralized government could never replace state and local responsibility for their populations' health.[87] But a framework of "shared responsibility" does not answer the vital question of how to allocate and divide roles between different levels of government. While there seems to be an emerging consensus about the appropriateness of primary federal involvement in some areas, and the need to defer to states whenever possible, clearly further discussion is needed to clarify and define less obvious roles.

2. Encouraging a Shared Focus and Coordination of Activities

A majority of respondents articulated general concern about a perceived lack of coordination between federal agencies, and between state and federal levels of government. A range of explanations was presented, some unsurprising ("bureaucratic turf battles" and lack of jurisdictional clarity) and some more intriguing. It was interesting to hear federal policymakers articulate the notion that inter-governmental coordination could be improved by providing more funding to states, and by articulating less confusing federal grant guidance (discussed in more detail below).[88]

Even though there was significant concern about improved coordination, optimism was an extremely common theme based on an emerging "unity of effort." Multiple examples of harmonization efforts were discussed and can be divided into three categories: federal intra-agency, federal inter-agency, and federal/state relationships. While coordination efforts continue to

86. Khi V. Thai, *Public Procurement Re-Examined*, 1 J. PUB. PROCUREMENT 9, 11-12 (2001).

87. *See* discussion *supra* Part IV.B.1.

88. *See* discussion *supra* Part IV.B.2.

evolve and expand, by all accounts they have already begun to demonstrate some progress. Notably, officials were most enthusiastic in their description of simple communication strategies (i.e., regularly scheduled conference calls, working group meetings, etc.) that have helped to coordinate activities within and among different agencies and levels of government. Additionally, there was strong support for the idea that federal agencies can increase shared focus and coordination through technical support and circulation of best practices or model laws. For example, CDC provides technical guidance to states to help them think through legal issues, without imposing a one-size-fits-all solution.[89] Instead, CDC encourages states to address an important issue themselves, while clarifying the respective roles of the various players at the federal and state levels.[90]

Unfortunately, one area where serious coordination problems remain seems to be in the relationship between Congress and executive agencies. Congress prefers earmarks, while agencies would like greater flexibility to determine how to allocate the funds.[91] There seems to be a disconnect between Congress and federal agencies in terms of how agencies should best allocate resources. Perhaps because of underlying issues with their respective constituents, Congress seems to have a fixed understanding of how agency funds should be spent without taking shifting agency priorities into account.

Our previous research on federally sponsored grant programs had indicated that the executive branch has put a number of mechanisms into place designed to coordinate preparedness activities into a coherent homeland security strategy.[92] The interview data both supported and brought into question the effectiveness of these programs and policies. Taken together, the respondents' positive and negative positions, sometimes held by the same people, suggest that respondents know about and support federal efforts to harmonize preparedness activities, but that concerns remain and continued vigilance and determined effort are needed to overcome "silos of perceived authority."[93] As one respondent appropriately noted, any expectations of increased harmonization should be tempered by the reality that the relevant federal programs are relatively new and are still being fine-tuned.

89. *See, e.g.*, *Public Health Law Program*, *supra* note 58 ("The CDC Public Health Law Program supports and encourages applied research on the impact of law on public health and related issues at the intersection of public health law and policy.").

90. *See* SARAH A. LISTER, CONG. RESEARCH SERV., RL 31719, AN OVERVIEW OF THE U.S. PUBLIC HEALTH SYSTEM IN THE CONTEXT OF EMERGENCY PREPAREDNESS 5 (2005).

91. *See* Gene M. Grossman & Elhanan Helpman, *Separation of Powers and the Budget Process*, 92 J. PUB. ECON. 407, 408 (2008); Salinsky & Gursky, *supra* note 75, at 1020.

92. *See* NRP, *supra* note 6, at 2.

93. *See* discussion *supra* Part IV.B.2.

3. Unanticipated Barriers Imposed by Federal Funding Mechanisms

For many years, the federal government has provided funding and guidance for disaster preparedness and recovery through its power to spend for the general welfare and its power to regulate interstate commerce.[94] Following the terrorist attacks of 2001 and 2002 and outbreaks of emerging and reemerging infectious diseases, however, the federal government began to take a more proactive role in the prevention of, preparedness for, and response to biological weapons attacks and infectious disease outbreaks under the auspices of providing for national security.[95] In particular, the passage of PAHPA, PREP, the creation of the Biomedical Advanced Research and Development Authority (BARDA),[96] and the advent of numerous grant programs[97] has increased the percentage of state and local emergency preparedness dollars provided by the federal government.[98] Since 2002, billions in federal funds have been distributed to federal, state, and local authorities to enhance emergency preparedness and response capabilities.[99] Federal grants to state and local governments relevant to biosecurity preparedness are primarily administered by DHS and DHHS (primarily through CDC and ASPR).[100] Our findings suggest that the specific implementation of these federal funding mechanisms has created a number of unanticipated effects on state preparedness activities.

First, a number of these programs (including those established by PAHPA[101]) require states to commit matching or maintenance funds as a condition of receiving certain federal grants. As the economy and property values have declined, state revenue has followed, creating huge budgetary shortfalls in all sectors.[102] As states are unable to meet their matching or maintenance obligations, federal law will require that federal grant dollars be withheld or withdrawn.[103] Perversely, this federally imposed grant condition, which was designed to encourage states to prioritize preparedness activities in their budgetary allocations, may actually lead to decreased funding for preparedness at the state level. Loss of access to vital federal funds will simply compound preparedness challenges in an already

94. *See* David P. Fidler, *Constitutional Outlines of Public Health's "New World Order,"* 77 TEMP. L. REV. 247, 256 (2004).

95. BUSH, *supra* note 9.

96. Pandemic and All-Hazards Preparedness Act § 401, 42 U.S.C. § 247d-7e (2006).

97. LISTER, ISSUES IN THE 110TH CONGRESS, *supra* note 82, at 2-3.

98. *See* David Markenson & Robert G. Westphal, Editorial, *Public Health Preparedness Training: Resources Are There*, 11 J. PUB. HEALTH MGMT. & PRAC. S1-2 (2005).

99. *See* LISTER, ISSUES IN THE 110TH CONGRESS, *supra* note 82, at 2-3.

100. SALINSKY, *supra* note 8, at 20; Markenson & Westphal, *supra* note 98.

101. Pandemic and All-Hazards Preparedness Act § 201(2).

102. *See* Nuzzo, Mair & Franco, *supra* note 79, at 1.

103. Pandemic and All-Hazards Preparedness Act § 201(2).

difficult state budgetary environment. Unfortunately, it is unclear the extent to which there is any discretion in the implementation of this punitive provision. Further analysis is required to ascertain the magnitude and scope of this problem, but if the views of these respondents are accurate, Congress and the relevant federal agencies should consider working together to create a procedure for suspending or waiving matching or maintenance requirements.

Second, federal policy-makers perceived there to be a lack of synchronization between their grant-making processes and state budgetary cycles. According to their report, prospective information about funding availability and magnitude can be limited, giving states very little time to prepare an application. Magnifying this concern, states are often unable to take advantage of federal grant programs because their fiscal years do not line up. Thus, state budgetary planning can happen well before or well after a federal funding window, effectively precluding participation, even when such funding would have been desirable. Similarly, some states require that their legislative body pass an act in order to participate in a federal grant program,[104] but some state legislatures meet infrequently, or only at certain times of the year.[105] It will be interesting to compare these findings with the state policymaker reports, but assuming consistent accounts, federal grant programs should strive to provide states with a longer timeframe in which to develop and apply for funding.

Finally, respondents also identified problems related to the short duration and unpredictability of federal preparedness programs. Specifically, most grants have been written one year at a time, with uncertainty about prospects for continuation or renewal.[106] This aspect of the federal funding process increases the challenge of hiring, training, and retaining talented people.[107] Preparedness efforts do not simply entail the purchase of supplies, and the construction of infrastructure; preparedness requires trained, competent people to fulfill the necessary functions.[108] Uncertain funding creates a lack of job stability, which makes it difficult to recruit talented and dedicated staff.

Additionally, inconsistent, single-year grants impose a significant administrative burden on states.[109] Under the current model, state officials

104. *See* George D. Brown, *Federal Funds and National Supremacy: The Role of State Legislatures in Federal Grant Programs*, 28 AM. U. L. REV. 279, 280 (1979).

105. *See 2010 State Legislative Session Calendar*, NATIONAL CONFERENCE OF STATE LEGISLATURES (Aug. 4, 2010), http://www.ncsl.org/?tabid=18630.

106. *See* Nuzzo, Mair & Franco, *supra* note 79, at 2.

107. *Id*. at 1-2.

108. *Id*. at 2.

109. *Id.*

are spending a disproportionate amount of time applying for grants each year, rather than actually implementing programs.[110] Potential momentum is lost by always having to focus on finding and obtaining the next source of funding. This administrative burden is particularly exacerbated for states whose budgetary and appropriations processes do not match federal cycles.[111] As discussed above, some states must balance the tension between their own internal budgetary processes and out-of-phase federal requirements;[112] negotiating this fault line year after year can impede attempts to think about and implement long term, comprehensive preparedness strategies. This barrier could be mitigated if federal preparedness grant programs focused on increasing the availability of multiple-year grants, and clarifying whenever possible the long-term funding prospects for specific preparedness programs.

4. Evolving Accountability and Performance Evaluation Procedures

Respondent comments indicated that there has been an evolution in the way that grant guidance is developed. In the early years post 9/11, grant requirements and guidance came directly from the departmental level, with very little state and local involvement.[113] Because of ensuing confusion about how this guidance could be interpreted, federal policymakers began reaching out to state and local public health officials [often through national associations such as the Association of State and Territorial Health Officials (ASTHO) or National Association of County and City Health Officials (NACCHO)] to create a shared understanding of the meaning and intent of grant guidance requirements.[114] This cooperative decision-making arrangement lasted until DHS stepped into a coordinating role and began to implement top-down explanations of grant guidance requirements, including articulation of specific target capabilities and preparedness metrics.[115] CDC has continued to create a looser grant guidance system that provides more generalized instructions, delegating more flexibility to the states.[116] These competing models continue to exist in parallel, but

110. *Id*.

111. Nuzzo, Mair & Franco, *supra* note 79, at 2.

112. *See id*. *See also* discussion *supra* Part IV.C.3.

113. *See generally* U.S. DEP'T OF HOMELAND SEC., FINANCIAL MANAGEMENT GUIDE 2 (2006) [hereinafter FINANCIAL MANAGEMENT GUIDE], *available at* http://www.dhs.gov/xlibrary/assets/Grants_FinancialManagementGuide.pdf (setting out guidelines for DHS grant recipients).

114. *See* SALINSKY, *supra* note 8, at 17-22; Kathleen Sebelius, Sec'y, Dep't of Health & Human Servs., Address at Public Health Preparedness Summit (Feb. 16, 2010), *available at* http://www.hhs.gov/secretary/about/speeches/sp20100216.html.

115. *See generally* FINANCIAL MANAGEMENT GUIDE, *supra* note 113, at 1-49 (laying out specific federal grant guidelines).

116. *See* discussion *supra* Part IV.B.4.

respondents seemed to indicate that there is a prevailing trend away from top-down, explicitly directive grant guidance.

This finding was reinforced by several respondent comments discussing the role of grant guidance. Most argued that states should be given wide flexibility to act within a broad framework articulated by the federal government. While respondents articulated different models for the specific role of federal guidelines (i.e., goals, objectives, expectations, "allowable-type costs," "programmatic priorities") the majority were consistent in stating that they preferred not to see grant guidance as an imposition of requirements.

Progress reporting and monitoring were frequently mentioned mechanisms for determining whether states are achieving the federal government's articulated goals. Consistent with the notion of grant guidance as a flexible framework, there seemed to be more interest in measuring overall capacity-building, rather than specific steps along the way. In other words, according to the respondents, progress reporting was designed to be outcomes-oriented, rather than process-based. As long as the state goals are consistent with federal guidance and policy, most specific activities will be allowed (as long as they are not grossly wasteful).

Consistent with this paradigm are select grant programs that require states to articulate a periodic work plan, outlining what progress was made with the previous allotment of resources, and what they intend to do with the next segment of funds.[117] These plans are not intended to lay out specific intermediate steps, but rather should lay out the state's preparedness goals in a narrative form. These narrative reports provide a contextual base for federal project officers to collaboratively work with states that are not achieving their goals; given federal technical expertise, project officers can help states understand what their needs are and can help them construct strategies for filling those gaps. This collaborative strategy has been extremely helpful in engaging states as co-creators in the process, thus encouraging state buy-in and enthusiastic cooperation.

All of these findings point towards a federal conception of accountability and performance evaluation that stresses flexibility and state autonomy. Even with a trend towards more flexible grant guidance, however, there was concern that the high volume of grant guidance documents can still pose a significant barrier. Competing agency requirements and inconsistent language can create a complicated web of overlapping administrative, accounting, and reporting obligations, which can ultimately become an impediment to actual programmatic accomplishments. Furthermore, according to federal policymakers, it seems as if states are sometimes

117. *See, e.g.*, N.C. Gen. Stat. §§ 143-16, 341 (1983).

confused about the content of various requirements, and spend unnecessary time attempting to ascertain what is required of them.

Given the complexity and volume of these preparedness grant programs, respondents were asked to discuss enforcement mechanisms and punitive measures at their disposal for worst-case scenarios where states repeatedly fail to advance preparedness goals. Interestingly, respondents described a fairly non-draconian view of penalties for non-compliance. According to one respondent, prior to recent legislation, there was no requirement, or even ability to penalize states for non-compliance. Federal grant makers could of course always have chosen to reduce or eliminate a state's funding for a given project, but that would have been a prospective action, rather than retrospective punishment.

This does not mean that there is no willingness to lean on states when necessary. There was limited discussion of ways to encourage specific state action short of using the threat of explicit punishment. For example, one respondent described a grant review process technique called "restriction" which involves actively working with states that have a good idea for spending federal money, but have not yet amassed sufficient information to justify implementation. A restriction would be placed on the targeted money in the state accounts that would not be removed until a mutual agreement has been reached.

Nevertheless, there was widespread concern about the ramifications of new statutorily mandated withhold requirements that are going into effect soon. While there is some limited discretion at the secretary level to relax these penalties, the fear is that once this provision goes into effect, federal grant programs will be forced to start pulling back funds. For example, PAHPA mandates a ten percent withhold per year, with the percentage of withheld funds increasing by an additional five percent for each consecutive failure.[118] The prospect of these penalties was universally expressed as an extremely undesirable outcome. Respondents hoped that senior officials will either grant waivers (in the case of mandatory withhold provisions) or will choose not to implement (in the case of authorized, but non-mandatory withhold powers). In the meantime, federal grants programs are working closely with states in danger of failing, with the aim of helping them understand and meet the performance metrics.[119]

118. Pandemic and All-Hazards Preparedness Act § 201(2), 42 U.S.C. § 247d-3a (2006).

119. *See generally* U.S. GOV'T ACCOUNTING OFFICE, GAO-01-915, BIOTERRORISM: FEDERAL RESEARCH AND PREPAREDNESS ACTIVITIES 2, 13-65 (2001) (discussing previous instances of federal guidance for states' expenditures of grant funds).

5. Respondent Knowledge of Objective Legal Environment

An earlier phase of this project involved a detailed description of the objective legal environment. To examine how law affects the structure of the public health system and its ability to respond more effectively to the threat of emerging infectious disease threats and other public health preparedness needs, we first described, categorized, and analyzed current federal mandates and funding arrangements affecting state and local public health systems. This work was based on the premise that federal law provides a general structure and framework for public health activities, while state and local law provides parameters for the implementation and delivery of specific programs and services. Our research in federal law focused on identifying specific topical mandates, as well as analyzing funding mechanisms provided to achieve those mandates.

Throughout the analysis of the federal policymaker interviews, we cross-referenced their statements with our earlier research on the objective legal environment. We felt that it was important to ascertain the extent to which respondents had knowledge of the broad legal environment and the degree to which their understanding of federal preparedness laws and policies was consistent with our objective legal findings. In general, this analysis was very positive. Across all agencies and levels of seniority, respondents generally had a strong and accurate understanding of federal preparedness laws. Respondents were universally able to describe a wide range of detailed programs and were capable of discussing broad legal themes.

Nevertheless, two potential discrepancies emerged. First, while respondents possessed a detailed and accurate understanding of the federal preparedness environment, their comments seemed to focus on laws and programs related to their agency and specific area of emphasis. It is understandable, and even predictable, that policymakers would have a tendency to discuss the topics with which they are most comfortable. It does not necessarily follow from a lack of comment breadth that they are unfamiliar with federal grant programs outside of their jurisdiction. Further research could be conducted to determine whether federal policymakers, in fact, do only focus on the most immediately relevant aspects of federal preparedness laws, and whether this has any ramifications for harmonization of federal preparedness efforts.

Second, federal policymakers did not extensively discuss the possibility that the federal legal environment could be causing confusion at the state and local levels. Our early research highlighted the complexity and ambiguity in federal grant programs. We hypothesized that state and local public health officials could be experiencing significant difficulty distinguishing between the actions that the federal government requires them to perform as a condition of funding, versus those actions that are

merely suggested or encouraged. Federal policymakers were quite frank in articulating the numerous barriers imposed by federal funding mechanisms, but did not include lack of clarity as a potential difficulty that states might face.

D. Conclusion

Engaging in public health preparedness involves a monumental and constantly shifting set of interwoven activities. The goal of these interviews was to explore how federal policymakers see their role in the array of preparedness endeavors. Unsurprisingly, more work needs to be done to define the line between federal and state roles and to coordinate priorities. Nevertheless, there are many hopeful signs that federal policymakers are at least aware of these challenges and are actively trying to improve the collaborative relationships vital to preparedness efforts.

More surprising was the articulated view that federal preparedness funding mechanisms should be seen as driving priorities, rather than imposing specific requirements. One of the project's original core research questions concerned the extent to which the federal government was using its spending power to mandate certain state preparedness actions. At least according to the federal policymaker data, federal law is affecting state preparedness activities less through mandates and more through unanticipated barriers created by federal funding mechanisms. Additional research needs to be done to establish the nature and scope of these barriers, and to develop specific policy solutions, particularly after analyzing the state and local case studies in light of these findings.