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Recommended Citation

John D. Blum & Jordan Paradise, *Public Health Preparedness & Response: An Exercise in Administrative Law*, 20 DePaul J. Health Care L. (2019)
Available at: <https://via.library.depaul.edu/jhcl/vol20/iss2/1>

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Cover Page Footnote

The authors are grateful to Loyola University Chicago School of Law student Seema Imam for helpful research assistance. This article was developed from author presentations at DePaul University College of Law's Jaharis Symposium on Health Law and Intellectual Property held on February 22, 2018.

Public Health Preparedness & Response: An Exercise in Administrative Law

John D. Blum^α & Jordan Paradise^β

Responses to epidemics, pandemics, and other biological disasters require multiple coordinated initiatives that combine sophisticated planning, sound emergency management, effective stockpiles, solid geographic information systems, well-developed laboratory surveillance and response, and effective management capabilities. Critical to the noted elements of planning and response is the existence of a legal structure, which underpins the operations of necessary programs. While the law may not be the first public health tool considered in a disaster, it is fundamental to the effective functioning of multiple actors and must be harmonized across jurisdictional lines. This article explores the role of law in pandemics and other biological catastrophes, highlighting broad developments in public health law that have been sparked by recent events. The piece will consider general responses and trends in health disaster management in the context of administrative law with a particular focus on agency responses. Background discussion will also offer a broad overview of the evolution of federal and state laws, highlighting core areas where parallel legal frameworks have developed. The second half of this essay will paint a more detailed portrait of administrative law responses to public health disasters focusing on the Food and Drug Administration (“FDA”), exploring medical countermeasures pursued by this agency to enhance preparedness and response. Key FDA legislation and recent guidance, as well as emergency use authorization (“EUA”) policies, will be analyzed, as a case study of how a pivotal agency has been shaped through law to deal with public health crises.

I. EVOLVING LAW AND BIOLOGICAL CATASTROPHES

In the winter of 2018, a moderately severe strain of influenza swept across the United States. The 2017-18 flu outbreak moved rapidly, forcing school closures, overtaxing hospital emergency rooms and causing shortages in necessary supplies and drugs.¹ While a serious public health event, this recent flu outbreak was less severe than influenza episodes in 2009 and 2015; it nonetheless served as a stark reminder of how challenging infectious disease outbreaks can be to public health agencies and the medical delivery system.² The complexities of annual flu, added to a growing list of other natural and man-made biological catastrophes, from anthrax to Zika, in turn joined with other emergencies such as hurricanes and fires, incentivize governments at all levels

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¹ Centers for Disease Control and Prevention, *Summary of the 2017-2018 Influenza Season*, <https://www.cdc.gov/flu/about/season/flu-season-2017-2018.htm> (last updated Oct. 11, 2018).

² *Outbreaks, Attacks, and Accidents: Combatting Biological Threats: Hearing Before the Subcomm. on Oversight and Investigations* (Feb. 12, 2016) (opening statement of the Honorable Tim Murphy) (“At the same time, pandemic and other highly pathogenic diseases are occurring with greater frequency and spreading more quickly throughout the world. As human populations put increasing pressure on remote areas and with ease of global travel, we will see more and more infectious diseases emerge. Since 2002, the world has seen outbreaks of SARS, Chikungunya, cholera, influenza, measles, Ebola, MERS, and now Zika.”)

to direct their focus toward building infrastructures that facilitate disaster planning, preparation, response and recovery.³

Effective responses to both physical and biological emergencies have been fueled by greater sophistication in surveillance, advancements in molecular detection and concerted efforts to promote vaccine development to address both emerging viruses, as well as antimicrobial resistant pathogens.⁴ In addition, lessons learned from prior health related disasters serve as helpful guideposts for moving toward molding policies that are more effective in the face of future biological stressors. For example, it was noted that the Ebola epidemic demonstrated the need to strengthen health systems generally; bolster disease surveillance and laboratory testing; increase availability of trained on- ground personnel and necessary equipment and supplies; develop better data capabilities; and accelerate drug testing.⁵

While public health experts are not able to pinpoint the time and nature of the next “big event,” there is a consensus that it is not a matter of “if” but “when.” Analyses of past epidemics, and other biological disasters, demonstrate that although scientific understanding of pathogens is central to efficient responses, numerous other variables come into play to insure that key actors pursue impactful responses. Catastrophic biological events require commitments that are economically, politically, and legally feasible.⁶ The reality is that overall public health resources are strained, and necessary long term planning for biohazard responses is challenging in environments that are being driven by the crises, and where long-term strategies are difficult to sustain.⁷ Recent Congressional hearings concerning the reauthorization of Pandemic and All-Hazards Preparations Act (“PAHPA”) of 2006, highlighted numerous shortcomings in federal agency coordination and funding, underscoring current and long-standing failures in disaster response preparation.⁸ In a 2018 report, by the Blue Ribbon Panel on Biodefense concerning budgeting, it was noted that although in recent years the U.S. has developed a large biodefense enterprise, involving an array of public and private actors, spending in this area tends to be opaque and activities uncoordinated.⁹ It has been noted that while millions of dollars have been devoted to preparedness research, response systems, infrastructures, and procedures and practices, there is no national level comprehensive, systematic review and grading of public health emergency preparedness as there are in other areas of public health.¹⁰ Without such review and grading

³ Adam Jeffrey & Marty Steinberg, *2017 – A Year of Disasters*, CNBC (Dec. 26, 2017, 11:41 AM), <https://www.cnbc.com/2017/12/26/2017--a-year-of-disaster.html>. See also Monica Schoch-Spana, et al., *Global Catastrophic Biological Risk: Toward a Working Definition*, 15 HEALTH SECURITY 323 (2017).

⁴ Marta Gwinn, Duncan R. MacCannell & Rima F. Khabbaz, *Integrating Advanced Molecular Techniques into Public Health*, 55 J. CLIN. MICROBIOLOGY 703 (2017).

⁵ Bill Gates, *The Next Epidemic-Lessons from Ebola*, 372 NEJM 1381 (2015).

⁶ The Johns Hopkins Center for Health Security, *The Characteristics of Pandemic Pathogens*, http://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2018/180510-pandemic-pathogens-report.pdf (2018).

⁷ Seth Berkeley, *Do We Keep Waiting for the Next Pandemic or Try to Prevent It?*, STAT (June 14, 2018), <https://www.statnews.com/2018/06/14/pandemic-prevention-ebola-drc-vaccines/>.

⁸ *Examining the Reauthorization of the Pandemic and All-Hazards Preparedness Act: Hearing Before the Subcomm. on Health* (May 30, 2018), <https://energycommerce.house.gov/hearings/examining-the-reauthorization-of-the-pandemic-and-all-hazards-preparedness-act/>.

⁹ Bipartisan Report of the Blue Ribbon Study Panel on Biodefense, *Budget Reform for Biodefense* (2018), <https://www.biodefensestudy.org/Budget-Reform-for-Biodefense-Feb-2018.htm> (last accessed Feb. 26, 2019).

¹⁰ Nat'l Acad. of Scis., *Evidence-Based Practices for Public Health Emergency Preparedness and Response: Assessment of and Recommendations for the Field*,

procedures, the development of “best practices” by agency responders at all levels of government is frustrated.

Effective responses to catastrophic biological threats involve numerous strategies that necessitate a clear understanding of the tools available to address potential threats. The core of the public health enterprise resides in traditional functions such as prevention, planning, research, communication, and enforcement, and the underlying mechanisms that drive those activities have special applications during large-scale events such as a pandemic.¹¹ Of the various tools available to address public health disasters, law emerges as a necessary element in both empowering key actors and in providing detailed mandates that become guideposts for agency functioning during, pre and post stages of disasters. Unlike other elements of response, the law has only recently been viewed as a foundational tool in public health disaster management.¹² Sparked by the tragedy of 9/11 and a series of major disease outbreaks, a growing awareness has developed about the inadequacies of law to provide a clear and comprehensive framework for dealing with catastrophic events.¹³ Disjointed and archaic directives at all levels of government have evolved in siloed fashion over many years, and the inadequacies in public health laws often are highlighted in the face of ever present, and seemingly more serious, population health threats.

Legal principles responsible for responding to catastrophic biological events can be classified into three primary areas: statutory and administrative laws, including regulations and Executive Orders touching on the full spectrum of disaster prevention and response; common law principles that deal with an array of legal liability considerations that emerge in catastrophic events; and considerations about rights and social justice issues arising in the face of government efforts that impinge on individual liberties in the face of community needs. Understanding the general contexts within which the law impacts public health disasters is helpful, but it is only the first step in deciphering how to utilize legal tools to be more impactful in this area. It has been observed that although the law is fundamental to addressing catastrophic biological occurrences, there has been limited attention on how best to develop comprehensive legal frameworks.¹⁴

One noteworthy attempt to craft comprehensive public health disaster legislation was the 2001 Model State Emergency Powers Act (“The Model”). It was drafted as a template in an effort to encourage state and local governments to update and harmonize their law. The Model, and other related reform efforts was based on four objectives: to (1) rebuild legal infrastructure capabilities; (2) update public health emergency classifications; (3) rebalance individual liberty considerations with community needs; and (4) clarify public and private responsibilities in disaster contexts. While comprehensive legal reforms in local and state public health law are the exception, a range of individual reform initiatives in areas such as emergency declarations and social distancing has occurred.¹⁵ In addition, state and local public health officials, on the front lines of response, have developed a far more comprehensive awareness of the scope and operation of

<http://nationalacademies.org/hmd/Activities/PublicHealth/PublicHealthPreparedness.aspx> (last accessed Feb. 26, 2019).

¹¹ See Hugh Tilson & Bobbie Berkowitz, *The Public Health Enterprise: Examining our Twenty-First Century Policy Challenges*, 25 HEALTH AFFAIRS 900 (2006).

¹² James Hodge, Jr. et al., *From [A]nthrax to [Z]ika: Key Lessons in Legal Public Health Preparedness*, 15 IND. HEALTH L. REV. 23, 24 (2018).

¹³ *Id.* at 25.

¹⁴ *See id.* at 26, 29.

¹⁵ *Id.* at 25.

relevant law, and notable attempts have been made to better aggregate this body of law.¹⁶ For example, a number of states have drafted public health bench books designed as judicial references to merge relevant disaster law provisions. These books offer one-stop compilations of procedural frameworks, statutory texts, relevant case law, and model orders to provide helpful guidance for judicial proceedings and policy making.¹⁷ In the 21st century, natural and man-made disasters, individually and collectively have shifted public health legal and regulatory development to Washington, resulting in an avalanche of new federal statutory and administrative laws. The dominance of public health federalism has given way to a large expansion of national laws in this area, underpinned by regulatory authority garnered under the commerce clause.¹⁸ A number of broad-based federal laws have been enacted to cover an array of matters dealing with public health disasters; a strong focus in this area concerns national security.¹⁹ While the heart of biological hazard response at the federal level is rooted in the Department of Health & Human Services, numerous administrative agencies and Congressional committees are active in this area because a biological catastrophe implicates virtually all facets of public and private endeavors.

A pivotal federal law in this area is the PAHPA of 2006.²⁰ PAHPA amends the Public Health Services Act to revise the organization of public health emergency preparedness and response activities which impacts a number of key federal agencies.²¹ PAHPA sets out a wide federal foundation for an array of preparedness activities including matters touching on leadership, organization and planning, preparedness capability, and all –hazards medical surge capacity. A key element of the law includes the creation of the Office of the Assistant Secretary for Preparedness (“ASPR”) in the Department of Health and Human Services (“DHHS”). Also within DHHS, PAHPA established the Biomedical Advanced Research and Development Authority (“BARDA”) to foster the rapid development of drugs and vaccines against highly infectious pathogens.²² The ASPR and BARDA joined the Centers for Disease Control and Prevention (“CDC”), the National Institutes of Health (“NIH”), and the FDA, which represent the core agencies involved in pandemic preparation and response. Within this five-agency framework, advanced research, development and procurement of medical counter measures (vaccines, medicines, diagnostics, supplies), and the stockpiling of these measures occurs. The ASPR leads federal efforts in public health and medical preparedness, response and recovery, and is tasked with working toward the development of a national disaster healthcare system.²³

The scale of pandemic planning and response is akin to a massive military operation requiring many parallel components including information, human resources capabilities, and logistical expertise. It is clear that no one agency at any level of government possesses the necessary capabilities to cope with the resulting complexities of a biological catastrophe. Rather,

¹⁶ See Heather A. McCabe et al., *Expanding the Base: A Case for Increased Interprofessional Collaboration in Public Health Law and Policy*, 14 IND. HEALTH L. REV. 99, 101-2 (2017).

¹⁷ See Public Health Bench Book for Michigan Courts (2016), https://www.michigan.gov/documents/ag/PHLBB_2016_Edition_532659_7.pdf.

¹⁸ See 42 U.S.C. § 264 (2018).

¹⁹ Hodge et al., *supra* note 12, at 30-2.

²⁰ 42 U.S.C. 6A § 201 et seq. (2018).

²¹ *Id.*

²² Office of the Assistant Secretary for Preparedness, 42 U.S.C. §300hh-10 (2016); Biomedical Advanced Research and Development, 42 USC §247d-7e (2016).

²³ U.S. Dept. Health & Human Services, *Testimony from Robert Kadlec Before Comm. On Health, Education, Labor & Pensions on Facing 21st Century Public Health Threats*, <https://www.hhs.gov/about/agencies/asl/testimony/2018-01/aspr-facing-21st-century-public-health-threats-our-nations-prepared.html> (last revised Mar. 6, 2018).

disaster response must be developed internally within a given agency and, in turn, coordinate across relevant agencies at all levels of government, as well as with private sector actors. As the bureaucratic infrastructure in this area has evolved, federal law has been geared toward coordinating agency operations that are national in character, involving activities that require large-scale resources and capabilities that don't exist at other governmental levels. On the other hand, the traditional and well-established roles of state and local governments are vital components of on-ground public health response, and federal laws must be developed in ways that complement and support such efforts. Particularly challenging in the biological disaster context is crafting laws that maximize inter-agency cooperation while simultaneously minimizing potential conflicts. These matters are further complicated by the fact that legal frameworks will be applied in circumstances that are extreme and unpredictable which require considerable agility on the part of regulators.²⁴

II. PARALLEL LEGAL SCHEMES

Historically, state and local governments have been the principle actors in public health disasters, and while more of the burden in disaster management shifts to the federal level, effective, real-time response occurs first and foremost at local levels. As such, the legal framework applied in a biological catastrophe will still be heavily influenced by the dictates of state and local laws. This body of state and local law that impacts public health disasters has been developed over a long period of time and can be characterized as both broad and eclectic.²⁵ Like federal law, state and local law has been heavily affected by ongoing disasters and a heightened need to address inadequacies in planning and response. State laws traditionally address a number of fundamental elements in public health disaster response such as isolation and quarantine, examination, treatment, searches, and seizure.²⁶ Core state and local provisions are often found in sanitary codes dealing with communicable disease. While state and local public health law has been revised regularly, this body of law suffers from coverage gaps and raises matters in enforcement that have civil liberty implications.²⁷ In addition, the expanding presence of federal law in the all-hazards preparedness area has added greater complexities in deciphering the boundaries and roles of the respective government actors. A distinction between policy-making and response that may easily separate the federal role from that of state and local authorities is increasingly more difficult to draw as many areas in the public health disaster area are layered with multiple levels of regulation.

An area illustrative of the nature of state law in biological catastrophe situations concerns policies involving use of isolation and quarantine. Perhaps some of the oldest medical countermeasures, isolation and quarantine, are strategies still used in the face of highly communicable disease agents and entail varying considerations depending on the nature of the

²⁴ Federal Emergency Management Agency, *FEMA Approves Another \$140 Million for Recovery in Puerto Rico*, (July 16, 2018), <https://www.fema.gov/news-release/2018/07/16/fema-approves-another-140-million-recovery-puerto-rico>.

²⁵ *See generally*, State of Michigan Attorney General, *Public Health Law Bench Book for Michigan Courts*, 2016. *See also*, *Grossman v. Baumgartner*, 17 NY2d 345 (1966).

²⁶ Institute of Medicine, *Crisis Standards of Care: A Systems Frameworks for Catastrophic Disaster Response* Vol. 2, Chapter 5 State and Local Government (2012).

²⁷ *New York State Public Health Legal Manual*, Michael Colodner Ed. 2011, <https://www.nycourts.gov/whatsnew/pdf/PublicHealthLegalManual.pdf>.

contagion and site of implementation.²⁸ The two areas, isolation and quarantine, are closely related but the former affects individuals who have a given communicable disease, and the latter concerns individuals who have been exposed to a given contagion.²⁹ Typically state and local sanitary laws include detailed provisions concerning the definitions, authority, and processes necessary to follow when such measures are invoked on either a voluntary or involuntary basis.³⁰ As isolation and quarantine entail a deprivation of liberty, authorities mandating such measures must demonstrate that a substantial government interest is being protected and that this action is the least restrictive measure to protect that interest.³¹ The area typifies the nexus public health regulation has to matters of individual liberties, a strong legal theme in this area that emerges in multiple contexts involving intricacies of balancing the common good against individual liberties.³²

Sparked by growing concerns over increased threats from global communicable diseases, new regulations were issued in 2012 under the Public Health Service Act which expanded the scope of federal authority in the quarantine area.³³ Federal authority to implement quarantine measures is directed toward preventing the spread of disease into the United States from foreign countries, as well as across state lines. While federal quarantine jurisdiction exists outside the bounds of individual state authority, this dual track of regulation allows for variations in approaches to biological hazards that could weaken the larger goal of a coordinated response. The federal posture regarding quarantine has been characterized as more conservative than policies followed by some state and local authorities.³⁴ While federal and state laws in the quarantine area

²⁸ Lawrence Gostin & Lindsay Wiley, *Public Health Law: Duty, Power, and Restraint* 3rd Ed. (2016), at 417-429. Quarantine can involve home, institutions, work and travel settings. Historically regulatory authorities could invoke mass quarantines in geographical areas but while the power to apply large-scale quarantine may still exist, the logistical, political and legal challenges raised by this strategy would be daunting, rendering this type of quarantine impractical.

²⁹ U.S. Dept. Health & Human Services, *What is the Difference Between Isolation and Quarantine?*, <https://www.hhs.gov/answers/public-health-and-safety/what-is-the-difference-between-isolation-and-quarantine/index.html> (last reviewed Sept. 4, 2009).

³⁰ 10 NYCRR § 2.25 (d)-(e).

³¹ *Joyner v. Dumpson*, 712 F.2d 770 (2nd Cir.1983).

³² The tensions between individual rights and the needs of society to be protected, serve as the backdrop of many disputes in public health law (Charles Henderson, *The Social Duty of Cities*, 1908). In the well-known case of *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), the U.S. Supreme Court was faced with balancing the individual rights of a citizen to decide not to be vaccinated against a public health authority that mandated smallpox inoculation to protect community health. Jacobson argued that mandatory vaccination violated his individual rights to liberty; the local health department, in turn, argued that it had a social responsibility to mandate smallpox vaccines. The Supreme Court crafted an opinion that struck a balance between individual liberty and state police power, recognizing broad regulatory authority in public health, provided the regulation in question was necessary, reasonable, proportional, non-injurious and fundamentally fair. While the 1905 balancing test, created in Jacobson, has been modified by changes in constitutional jurisprudence, the case typifies frequent disputes in public health that pit individuals against public authorities. For example, see *Matter of Spence v. Shah*, 136 A.D.3d 1242 (App. Div. 2016), in which a challenge was brought against a New York State Department of Health requirement that non-vaccinated health workers be required to wear masks alleging that this directive was arbitrary, capricious and unwarranted. Another typical public health law challenge is evidenced in *Webster v. Moquin*, 175 F.Supp.2d 315 (D. Conn. 2001) in which a poultry farmer who was required to destroy his birds due to the presence of avian flu argued that he was deprived of property without due process in violation of the Connecticut constitution, as well as the U.S. 5th and 14th amendments.

³³ 79 Fed. Reg. 45671 (2014), further updated in 2017 in 82 Fed. Reg. 6890 (2017).

³⁴ Gostin & Wiley, *supra* note 28, at 426.

don't necessarily clash, the duality of law here typifies the complexities faced in achieving harmonization efforts.

Another basic issue in the all-hazards response sector, requiring traditional state law policies be approached in conjunction with federal law, concerns the issuance of disaster declarations. Disaster declarations at both federal and state and local levels are essential legal tools in facilitating efficient agency operations in crisis situations. An emergency (disaster) declaration determines the legal and operational resources available to public and private actors and is critical to mobilizing timely responses to public health catastrophes.³⁵ This area is yet another demonstration of the duality of authority in responding to disasters, as both federal and state and local law contain detailed directives specifying the parties and powers that can be evoked in crises situations. Generally, at the state level, governors have sufficient power to declare disasters, but in some instances legislative bodies must approve such decrees. Gubernatorial directives (and those made by other empowered officials), detail the dates and durations of a given emergency declaration, the locations impacted, and the agencies charged with carrying out the orders. In some cases, state declarations may waive or suspend state rules and regulations and provide liability protection or civil immunity to certain responders. Typical state powers flowing from emergency declarations may include activation of special emergency plans and command centers, authority to spend funds, access supply stockpiles, and personnel deployment.

Emergency declarations are not the sole purview of state and local governments, and such authority exists at the federal level to address biological hazards that have national implications. There is also an economic reality in play here as states often turn to the federal government for financial assistance in disaster situations since state fiscal resources are limited.³⁶ Under the auspices of several federal statutes, the President and the Secretary of DHHS also have the power to declare emergencies.³⁷ Akin to state law, federal emergency declarations trigger various types of assistance including: financial and technical, the waiver of certain laws, the provision of immunity and liability protections, as well as activation of emergency response protocols and systems. While federal law in the public health emergency context has preemptive power, it is an area where the respective parties are able to co-regulate with a reasonable degree of efficiency. Nonetheless, in crisis situations, public health authorities operating under multiple disaster declarations, will be confronted with a confusing landscape and will require a sophisticated understanding of the implications of specific declarations.

A major consideration in emergency response involves the development of strategies that insure an adequate supply of medical responders will be available. To facilitate human resource adequacy, a number of state and federal laws have been enacted that offer various waivers of liability and immunity protections to both licensed health care workers and volunteers. Under state laws, emergency declarations trigger various types of protections against legal liability for health care workers and volunteers alike. In many jurisdictions, states treat medical responders as agents, thereby extending sovereign immunity safeguards to these individuals during periods in which emergency declarations are in force.³⁸ State Good Samaritan laws have been expanded to

³⁵ Association of State and Territorial Health Officials, *Emergency Declarations and Authorities Fact Sheet*, (2012), <http://www.astho.org/Programs/Preparedness/Public-Health-Emergency-Law/Emergency-Authority-and-Immunity-Toolkit/Emergency-Declarations-and-Authorities-Fact-Sheet/>.

³⁶ Federal Emergency Management Agency, *Grants*, <https://www.fema.gov/grants> (last updated Aug. 24, 2018).

³⁷ Association of State and Territorial Health Officials, *supra* note 35.

³⁸ The Network for Public Health Law, *State Laws Providing Liability Protections for Healthcare Workers During Emergencies, Emerging Legal Preparedness & Response Memorandum* (June 29, 2011).

safeguard medical responders provided they act in a professionally responsible manner.³⁹ State protections against liability have also been extended to institutional health providers and state agencies.⁴⁰ Here too, like other areas previously discussed in the biological hazard context, state laws concerning liability and immunity protections are accompanied with a somewhat parallel set of measures at the federal level. Under the Public Readiness and Emergency Preparedness (“PREP”) Act of 2006, the Secretary of DHHS has the power to issue a declaration that extends immunity from tort liability for claims of loss that result from the application of medical countermeasures against diseases and other public health threats. The immunity reach of the PREP Act is broad, covering persons and entities involved in the manufacture, testing, distribution, administration, and use of covered countermeasures. Other grants of federal immunity are provided to volunteers who, together with federal employees, are protected against liability suits under the umbrella of the Federal Tort Claims Act.⁴¹

The massive amount of coordination across public and private actors in the face of biological catastrophes makes preparation and response planning a critical regulatory function. There is no single national biological hazards plan that acts as a unifying document in hazard preparation, but the National Incident Management System (“NIMS”) under the auspices of the Department of Homeland Security, and the DHHS Pandemic Influenza Plan collectively serve as broad guidance instruments that can be used to shape more uniform approaches across public and private actors.⁴² The NIMS details shared vocabularies, structures, and processes to be utilized in all-hazard responses as part of a National Preparedness System directed by the Federal Emergency Management Agency (“FEMA”). Originally published in 2005 the DHHS pandemic plan recently has been expanded by the CDC to cover these noted domains: surveillance, epidemiology laboratory activities, community mitigation, medical countermeasures, health care system preparedness and response, communications and public outreach, scientific infrastructure and preparedness, and domestic and international response.⁴³ While the domains noted are quite broad, they provide a framework that can be used by actors at all levels to craft plans targeted to particular needs. In addition to large scale planning models, DHHS has developed guidance documents for state and local planning, as well as a checklist of elements that need to be considered in individual hazard plans.⁴⁴ The availability of significant funding to bolster these efforts have incentivized the use of federal planning tools at state and local levels of government.⁴⁵

Individual state and local government hazard plans must cover administrative and fiscal processes such as procurement, contracting, hiring, funding allocation, and place considerable

³⁹ See Dechert LLP, Save Life Foundation, and Thomson Reuters Foundation, *Good Samaritan Laws: A Comparative Study of Laws that Protect First Responders Who Assist Accident Victims*, (May 2014), <https://www.trust.org/contentAsset/raw-data/7be34cce-ea0d-4c90-8b39-53427acf4c43/file>.

⁴⁰ The Network for Public Health Law, *Table-Legal Liability Protections for Emergency Medical/Public Health Responses* (Feb. 20, 2017).

⁴¹ Association of State and Territorial Health Officials, *supra* note 35.

⁴² U.S Dept. Health & Human Services, *Pandemic Influenza Plan*, 2017.

⁴³ *Id.*

⁴⁴ U.S. Dept. Health & Human Services, *Public Health Preparedness Capabilities: National Standards for State and Local Planning*, https://www.cdc.gov/cpr/readiness/00_docs/CDC_PreparednesResponseCapabilities_October2018_Final_508.pdf.

⁴⁵ Federal Emergency Management Agency, *The Stafford Act*, <https://emilms.fema.gov/IS318/MP0102020.htm> (last accessed Feb. 26, 2019); Lucien G. Canton, *Who Should Pay for Emergency Management?*, EMERGENCY MANAGEMENT, (July 1, 2013), <http://www.govtech.com/em/emergency-blogs/managing-crisis/Who-Should-Pay-for-070113.html>.

emphasis on maintaining continuity of operations during and after a biological catastrophe.⁴⁶ Plans need to be drafted in recognition of the fact that hazards evolve through phases and so responses to such events must be scalable to the magnitude and severity of the threat and available resources. Planning all levels of response is an ongoing process that evolves with expanding knowledge of biological hazards and changing resource capabilities.⁴⁷ A strong benefit derived from government disaster plans is the opportunity to explicitly delineate a given planner's understanding of the parameters of authority of all involved parties, mitigating operational roadblocks and promoting more harmonized responses.⁴⁸

III. PRIVATE SECTOR HAZARD PREPARATION

The complexities of biological hazard mandates that exist at federal and state levels are felt outside the realm of government bureaucracies in a wide array of private sector settings. No organizations are affected more directly by this area of law than health care providers, particularly acute care hospitals. As critical responders in emergency situations, hospitals operate under multiple mandates required by parallel regulatory schemes. Under federal law, hospitals and other health care entities and suppliers must meet the requirements of Medicare/Medicaid Conditions of Participation ("COP") issued by the Centers for Medicare and Medicaid Services ("CMS") that are designed to ensure that emergency management is integrated into daily operations.⁴⁹ Recently the COPs were amended with a focus on risk assessment and planning, improving institutional plans and procedures, updating communication plans to comply with federal and state requirements, and developing a staff training and testing program for hazard response.⁵⁰

While CMS regulations are noteworthy in their attempt to provide a broad institutional framework for health care entity planning and response, the reality is that COP requirements are only one category of mandates that must be adhered to in the biological hazard arena. An important component of federal law impacting hospitals concerns situations when key statutory requirements are suspended.⁵¹ The Secretary of DHHS has the authority to temporarily waive or modify an array of regulations affecting health providers including Medicare/Medicaid coverage requirements, emergency treatment mandates and privacy protection obligations under HIPAA.⁵²

⁴⁶ See U.S. Centers for Disease Control & Prevention, *Guide for All-Hazard Emergency Operations Planning*, (Sept. 1996), https://www.cdc.gov/nceh/ehs/docs/state_and_local_guide_101_heop.pdf.

⁴⁷ On September 8, 2018, the White House released the National Biodefense Strategy, an all-encompassing set of principles covering response strategies to biological risks, across public and private sectors. The White House plan was directed toward meeting biological threats that are naturally occurring, accidental or deliberate in origin. The new strategy identified DHHS as the lead regulatory actor in biodefense, and as might be expected, the focus of this policy directive rests more on national security considerations than on traditional public health responses. White House, *National Biodefense Strategy*, Sept. 11, 2018, <https://www.whitehouse.gov/wp-content/.../2018/09/National-Biodefense-Strategy.pdf>

⁴⁸ Leslie E. Gerwin, *Planning For Pandemic: A New Model for Governing Public Health Emergencies*, 37 AM. J. L. & MED. 126 (2011).

⁴⁹ Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 81 Fed. Reg. 63,860 (Sept. 16, 2016).

⁵⁰ *Id.*

⁵¹ U.S. Dep't Health & Human Serv., *Health Information Privacy*, HHS.GOV (last updated July 26, 2013), <https://www.hhs.gov/hipaa/for-professionals/faq/1068/is-hipaa-suspended-during-a-national-or-public-health-emergency/index.html>); Centers for Medicare & Medicaid Services, *1135 Waivers*, CMS.GOV, (last updated Dec. 12, 2017). <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers.html>.

⁵² 42 U.S.C. § 1320b-5 (2018).

At the state level, licensing laws regulate hospitals which must adhere to various provisions dealing with emergency management. For example, under Illinois law, hospitals are required to have a disaster and mass casualty plan in place; the plan must be coordinated with other hospitals and local health agencies.⁵³ In other states, such as Colorado, hospitals are required to have an emergency epidemic plan in place, specifying twelve elements to be included in the plan; some of which include developing an operations center, ensuring adequate supplies, and maintaining operational security.⁵⁴

In addition to federal and state law requirements, The Joint Commission (“TJC”), which accredits a significant number of hospitals, has additional emergency standards. Under TJC requirements, acute care facilities must meet specific obligations for maintaining safe and effective patient care measures during emergencies. The Joint Commission has identified six focus areas for planning and response purposes including communications, supplies, security, staff, utilities, and clinical activities.⁵⁵ Three areas of particular concern to TJC are: maintaining frail patients in a disaster; keeping hospital beds open and available; and maintaining scarce resources (pharmaceuticals, ventilators, oxygen, dialysis supplies).⁵⁶ As part of the emergency preparedness mandates, accredited facilities are required to conduct emergency disaster exercises to test an organization’s capabilities and make necessary changes.⁵⁷

Beyond the special considerations that need to be considered for health care provider entities, employers of all types need to develop policies and procedures for dealing with the possibility of a biological catastrophe. Under federal and related state occupational health and safety laws, there is a general obligation requiring employers to provide a healthy and safe work environment that takes on special import in a pandemic type situation. Generally, however, there are no all-encompassing occupational health and safety regulations that cover pandemic-type events. Rather, a number of narrower directives are germane, like those that mandate plans and specific actions to reduce employee contacts with blood borne pathogens, or special requirements concerning use of respirators and other protective equipment. While specific regulatory obligations under occupational health and safety laws may be limited, there is wide recognition by regulators of the centrality of the workplace in disaster response, evidenced from an extensive employer guidance first issued by the Occupational Health and Safety Administration (“OSHA”) in 2007.⁵⁸ Under the dictates of the OSHA guidance, businesses and organizations are provided with a template to assist them in continuity planning for a pandemic situation with a particular focus on critical industries and key resources. Numerous items are suggested by OSHA as elements that need to be incorporated into employer plans, including in part, downsizing workforces, stockpiling infection control supplies, and managing stressors related to pandemics.⁵⁹ It is clear from the OSHA guidance that pandemic planning needs to be ongoing and must be complimented by regular training and onsite disaster simulation exercises. In addition to OSHA health and safety considerations, there are an array of employment law matters that need special attention in

⁵³ Ill. Admin Code tit.77 §250.740(a) (2018).

⁵⁴ 6 COLO. CODE REGS. § 1009-5:2 (2018).

⁵⁵ Response Systems, *JCAHO Compliance*, RESPONSE SYSTEMS, <http://www.disasterpreparation.net/resources.html> (last accessed Feb. 26, 2019).

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ U.S. DEP’T OF LABOR, Occupational Health & Safety Admin., *Guidance on Preparing Workplaces for an Influenza Pandemic*, OSGA 3327-02N (2007), revised and updated in OSGA 3327-05R (2009).

⁵⁹ *Id.*

biological catastrophes including employee leave and benefit issues, telecommuting policies, workers' compensation, and disability law protections.⁶⁰

This article has thus far explored public health preparedness and response from a 50,000-foot view, discussing state and local activities, as well as the broader federal governmental legal infrastructure, including select issues regarding Medicare and OSHA, and relationships to local efforts. As noted earlier, there is a spectrum of domains involved in the federal pandemic plan developed by the DHHS. The next section will explore a select number of these domains utilizing the FDA as a case study in administrative implementation in the face of a pandemic that occurs in the form of a chemical, biological, radiological, or nuclear ("CBRN") emergency. In such an event, the FDA acts chiefly within the domain of medical countermeasures, preparedness of medical products and response activities, and scientific infrastructure at both the domestic and international level. FDA activities in this realm are closely intertwined with DHHS, other federal agencies, and state and local agencies and entities.

IV. THE FDA AS A CASE STUDY IN ADMINISTRATIVE PREPAREDNESS & RESPONSE

The FDA is a specialized agency within the DHHS, tasked with review and approval of medical products, as well as the regulation of food, cosmetics, tobacco products, and products that emit radiation. In all, the FDA oversees about 25% of consumer products on the market in the U.S.⁶¹ and is responsible for ensuring the safety and efficacy of medical products. There are three routes to market for FDA regulated medical products, depicted in Figure 1. Two federal statutes – the Food Drug and Cosmetic Act ("FDCA")⁶² and the PHSA⁶³ – set forth legal requirements. The traditional new drug approval process involves one of two statutory mechanisms.⁶⁴ The first is an investigational new drug ("IND") application, which triggers the clinical trial process, followed by a new drug application ("NDA") demonstrating that the product is safe and effective for a particular intended use, indication, and patient population.⁶⁵ The touchstone regulatory review measures include substantial evidence of safety and efficacy based on adequate and well-controlled studies.⁶⁶ The second is the abbreviated new drug application ("ANDA") process, also termed the generic drug approval process, premised on measures of bioequivalence to a reference drug product already approved by the FDA.⁶⁷

Similarly, biologic products have two general pathways to market. Like drugs, biologics are therapeutic products but rather than being chemically synthesized, they are derived from natural sources. Examples include vaccines, proteins, blood components, antitoxins, and gene therapy products.⁶⁸ The natural origin of biologics introduces novel challenges with manufacturing

⁶⁰ Donald Benson & Gina M. Cook, *Don't Just Wing It: Follow This Guide to Prepare Your Business Clients for a Possible Avian Flu Pandemic*, 44 TENN. B. J. 12 (2008).

⁶¹ U.S. FOOD & DRUG ADMIN., GLOBAL ENGAGEMENT, (May 2013), p. 2, https://www.ipqpubs.com/wp-content/uploads/2013/05/FDA_Global-Engagement.pdf.

⁶² Food, Drug & Cosmetic Act, FDCA §1 et seq.; 21 U.S.C. §101 et seq. (2016).

⁶³ Public Health Service Act §262 (2016).

⁶⁴ There is also a third route to market for new drugs, termed the "505(b)(2)" pathway, in reference to the statutory section describing it. This route is hybrid, in that drug sponsors may rely on published data to support a showing of safety and efficacy, but must provide some level of independently conducted studies as part of the NDA. FDCA §505(b)(2); 21 U.S.C. §355(b)(2).

⁶⁵ FDCA §505(b)(1); 21 U.S.C. §355(b)(1).

⁶⁶ *Id.*

⁶⁷ FDCA §505(j); 21 U.S.C. §355(j).

⁶⁸ 42 U.S.C. §262(i).

practices, handling, storage and patient response, requiring additional safeguards for safe use. The first route to market for biologics is an IND application which allows the initiation of clinical trials, followed by a biologics license application (“BLA”) to demonstrate that the product is safe, pure, and potent.⁶⁹ Given efforts to streamline the biologic approval process, the FDA applies general concepts of safety and efficacy to biologics, though the regulations are highly specific to biologics. Amendments to the PHSa in 2010 added an abbreviated route to market for biologics (“ABLA”), based on biosimilarity or interchangeability with a reference product.⁷⁰

The FDA regulates medical devices according to their level of risk, with a premarket approval process for high-risk products and a pre-market notification (“PMN”, or “clearance”) process for lower risk products.⁷¹ Pre-market approval involves the filing of an investigational new device application (“IDE”)⁷² followed by a pre-market application (“PMA”) demonstrating substantial evidence of safety and efficacy based on adequate and well-controlled studies.⁷³ The PMN process requires an application to the FDA establishing substantial equivalence to a predicate device.⁷⁴

Figure 1: Traditional FDA Routes to Market

<u>Product</u>	<u>Type</u>	<u>Statute</u>	<u>Requirements</u>	<u>Measures</u>
<u>New Drug</u>	IND, NDA	FDCA §505(b)(1); 21 USC §355(b)(1)	Safe & effective	Substantial evidence; well-controlled studies Phase I-III clinical trials
	ANDA	FDCA §505(j); 21 USC §355(j)	Bioequivalence	Therapeutic and pharmacologic equivalence to a reference listed drug
<u>Biologic</u>	IND, BLA	PHSA §351(j); 42 USC §262(j)	Safe, pure, potent	Substantial evidence; well-controlled studies Phase I-III clinical trials
	ABLA	PHSA §351(k); 42 USC §262(k)	Biosimilar/interchangeable	Highly similar/may be substituted for reference product
<u>Device</u>	IDE, PMA	FDCA §§514, 515; 21 USC §§360d, 360e	Safe & effective	Substantial evidence; well-controlled studies Phase I-III clinical trials
	PMN	FDCA §§510, 513; 21 USC §§360, 360c	Substantial equivalence	Comparison to predicate device

⁶⁹ 42 U.S.C. §262(j).

⁷⁰ 42 U.S.C. §262(k).

⁷¹ FDCA §513; 21 U.S.C. §360c.

⁷² Unlike the drug context, the IDE is not always required depending on the level of risk to human subjects involved in clinical trials.

⁷³ FDCA §§513-515; 21 U.S.C. §§360c-e.

⁷⁴ *Id.*

Each of these three product areas are also subject to expedited routes to market, periods of exclusivity, and specialized product status that alter the traditional mechanisms to market. For example, breakthrough therapy status and priority review are available for products that treat serious or life-threatening diseases or address an unmet medical need. Orphan drugs, new molecular entities, pediatric drugs, and humanitarian use devices are afforded additional exclusivity once on the market. Priority review vouchers are available for tropical disease drugs and expanded access mechanisms for IND and IDE may also be utilized by the FDA for use in emergency situations.

While the FDA has primary jurisdiction to regulate the regular review and approval of these three medical product areas, the FDA does not, and cannot, work alone in the face of a pandemic or national emergency. The FDA regularly coordinates with ASPA, BARDA, CDC, and NIH within DHHS well as the Departments of Agriculture, Defense, and Veterans Affairs during such an event. Within the FDA itself, the Center for Drug Evaluation and Research (“CDER”), the Center for Biologic Evaluation and Research (“CBER”), the Center for Devices and Radiological Health (“CDRH”), the Office of Counterterrorism and Emerging Threats (“OCET”) and the Office of Crisis Management all play vital roles. This network of agencies epitomizes a learning system, where legal and policy frameworks are adapted to a particular situation that arises. There is no “one-size-fits-all” approach, but there are established legal frameworks in place to inform and guide agency action.

In the event of a CBRN emergency, emerging infectious disease, or natural disaster that threatens health and safety, the FDA’s role is one of both preparedness and response, including advance measures to incentivize and support product development, a key role to secure the product supply, and to ensure that safe and appropriate medical countermeasures (“MCMs”) are available. MCMs are medical products that include drugs, biologics, medical devices, and specific respiratory protective devices.⁷⁵ The FDA’s purview extends across a broad life cycle spectrum, including product development, regulatory review, exclusivities and incentives, stockpiling, emergency use authorizations, dispensing to populations, adverse event monitoring, post market reporting, and requirements, and expiration date extensions.

Following the terrorist attacks on September 11, 2001, several foundational pieces of federal legislation were enacted by Congress to address coordination efforts across federal agencies: the Public Health Security and Bioterrorism Preparedness and Response Act (“Bioterrorism Act”) of 2002,⁷⁶ the Project BioShield Act of 2004,⁷⁷ the PREP Act of 2006,⁷⁸ the PAHPA of 2006,⁷⁹ and, most recently, the Pandemic and All-Hazards Preparedness Reauthorization Act (“PAHPRA”) of 2013.⁸⁰ Figure 2 highlights a number of core provisions within each piece of legislation between 2002 and 2006 relevant to the FDA.

⁷⁵ U.S. Food & Drug Admin., *Guidance for Industry & Other Stakeholders: Emergency Use Authorization of Medical Products & Related Authorities*, p. 2 (Jan. 2017).

⁷⁶ Pub. L. 107-188 (2002).

⁷⁷ Pub. L. 108-276 (2004).

⁷⁸ Pub. L. 109-148 (2006).

⁷⁹ Pub. L. 109-417 (2006).

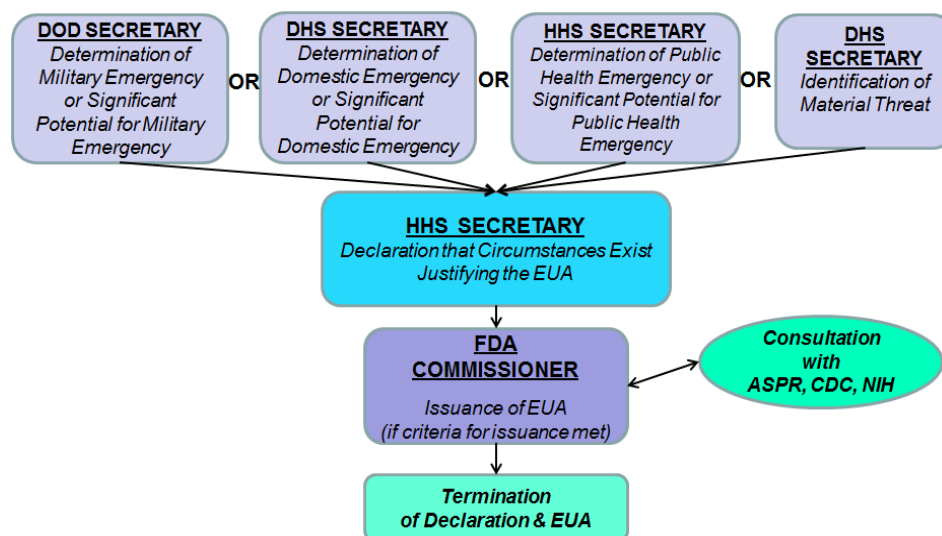
⁸⁰ Pub. L. 113-5 (2013).

Figure 2: Post 9-11 Legislation Relevant to FDA Authority, 2002-2006

Bioterrorism Act, 2002 <ul style="list-style-type: none">- Additional measures for the protection of food & drug supplies- Introduction of accelerated approval mechanisms for priority MCMs- Allowance of the use of animal models for measures of efficacy where unethical or infeasible for human study (“Animal Rule”)- Creation of a Strategic National Stockpile (SNS) system
Project BioShield Act, 2004 <ul style="list-style-type: none">- Infusion of funding and flexibility to support MCM development- Introduced process for Emergency Use Authorizations (EUAs) for MCMs during emergencies.- Creation of a special reserve fund for MCMs in development
Public Readiness & Emergency Preparedness Act, 2005 <ul style="list-style-type: none">- Immunity from liability for covered MCMs following PREP Act declaration by DHHS- Creation of an injury compensation program
Pandemic & All Hazards Preparedness Act, 2006 <ul style="list-style-type: none">- Creation of BARDA with DHHS- Expansion of preparedness and response authorities- Introduction and availability of FDA good manufacturing practices expert team for technical assistance to MCMs manufacturers

The emergency use authorization (“EUA”) procedure was first introduced in the Project BioShield Act of 2004 and subsequently amended through legislation. Figure 3 depicts the EUA process among the Secretaries of Defense, Health and Human Services, and Homeland Security, as well as the FDA Commissioner and ASPR, CDC, and NIH.

Figure 3: Emergency Use Authorization Procedure⁸¹



In 2013, PAHPRA introduced significant revisions and additions to the FDA’s procedural mandate as set forth in the FDCA §564, originally introduced in the Project Bioshield Act. Section 564 of the FDCA addresses the EUA procedure, depicted above in Figure 3, with respect to the authority and issuance by the FDA. Each of the Secretaries of Defense, Health and Human Services, and Homeland Security have the authority to make a determination of emergency or significant potential for emergency or identification of a material threat (“DHS”), at which point the DHHS Secretary may declare that circumstances exist justifying an EUA. If the criteria for issuance are met, the FDA Commissioner will issue an EUA. In its current form within the statute and outlined in FDA guidance, an EUA may be instituted for an unapproved medical product where there is a:

1. Serious or life-threatening illness or condition caused by CBRN agent as set forth in DHHS declaration;
2. Reasonable belief that the product may be effective in diagnosing, treating, or preventing the illness or condition caused by the agent (based on totality of scientific data);
3. The product’s known and potential benefits outweigh known and potential risks when used for disease or condition; and
4. There is no adequate approved, available alternative.⁸²

An EUA may be terminated by the DHHS, in conference with DHS and DOD, when the earlier of a determination by the DHHS Secretary that circumstances necessitating an EUA have ceased, or a change in the approval status of the medical product such that the medical product is

⁸¹ Image from U.S. Food & Drug Admin., Emergency Preparedness, <https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm411445.htm> (last accessed Oct. 25, 2018).

⁸² FDCA §564(c); *see also*, U.S. Food & Drug Admin., *Guidance for Industry & Other Stakeholders*, *supra* note 76, at 7-8.

not unapproved.⁸³ Also, under section 564(g)(2), the Secretary may revoke an EUA if “the criteria for issuance are longer met or other circumstances make such revocation appropriate to protect the public health or safety.”⁸⁴

General amendments introduced by PAHPRA included instructions to provide special protocol assessment meetings to address efficacy; the inclusion of pediatric populations in MCM development, where appropriate; a requirement for interagency training and involvement with MCMs; a command to finalize the Animal Rule guidance; and changes to the EUA process, both with regard to unapproved use of approved product and use of unapproved product. These changes to the EUA process directly under the control of the FDA are significant. For unapproved products, Section 564B now allows for governmental pre-positioning (including purchase, shipment, or stockpile) of MCMs prior to approval or clearance by the FDA or the declaration of an EUA without violating the statute in order to enable rapid deployment in the event of a CBRN emergency. This pre-positioning requires adherence to explicit processes, recordkeeping, and monitoring contained within the statute and implementing regulations.

Where the FDA has approved or cleared a medical product for a specific intended use, Section 564A grants the FDA the authority to allow for emergency use for a different intended use without an EUA declaration and issuance. For example, where the FDA has approved a particular drug for the treatment of exposure to an aerosolized toxin, such as *Bacillus anthracis*, the FDA may provide for emergency use of that drug for treatment of exposure to a different strain of aerosolized toxin. Eliminating the requirement for an EUA declaration from the DHHS allows quicker access to assist victims in the event of exposure. Section 564A also provides for expiration date extensions, where safe and appropriate, to allow longer use of approved medicines and products. It requires the development of emergency use instructions (EUIs) through coordination between DHHS, FDA and the CDC. It also gives authority for emergency dispensing in the absence of a prescription and provides waivers for deviation from manufacturing standards and FDA-imposed risk evaluation and mitigation strategies.

A January 2017 guidance document gives procedural instruction to industry on the operation of each of the statutory provisions.⁸⁵ As the FDA guidance document explains, an EUA may be requested or it may be initiated by the federal government. Once issued, there are conditions imposed on EUAs, including that the applicant develop detailed information about the product for health care professionals and authorized dispensers, as well as information for the recipients of the medical product. Manufacturers of a medical product with an EUA must actively monitor and report adverse events, maintain records, and comply with all FDA-imposed requirements and limitations. DHHS must publish notice of a declaration in the Federal Register, and the FDA must publish the issuance of an EUA in the Federal Register. The FDA may also revise or revoke an EUA, also through publication in the Federal Register. The guidance also addresses issues of federal preemption, protection from liability, importing and exporting medical products under an EUA, and pre-positioning of MCMs.

⁸³ U.S. Food & Drug Admin., *Guidance for Industry & Other Stakeholders*, *supra* note 76.

⁸⁴ FDCA §564(g)(2).

⁸⁵ U.S. Food & Drug Admin., *Guidance for Industry & Other Stakeholders*, *supra* note 76.

V. EUAS IN PRACTICE

As of August 2018, the FDA website identifies eight categories of medical products with an active EUA: the drug doxycycline for treatment after inhalational anthrax exposure; medical assays for detection of the conditions of Ebola, enterovirus D68 (“EV-D68”), H7N9 influenza, Middle East respiratory syndrome coronavirus (“MERS”), and Zika; an atropine auto injector for nerve agent exposure; and freeze dried plasma for use in military combat.⁸⁶ The most recent EUA declaration came from the Department of Defense in June 2018, followed by the FDA’s issuance on July 9, 2018, of the EUA for freeze dried plasma. The letter from the FDA to the French manufacturer authorizes an EUA for “Pathogen-Reduced Leukocyte-Depleted Freeze Dried Plasma ... for U.S. military forces for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical, pursuant to section 564.”⁸⁷ The FDA website provides documents associated with active EUAs, including the full authorization letter, the Federal Register notice, any Facts Sheets or manufacturer instructions, the emergency use determination and declaration, the EUA effective date, and the PREP Act declaration if there was one associated with the EUA.⁸⁸

One prime example of the EUA process is that of the response to the threat of the Zika virus, which grabbed national and international attention beginning in 2015.⁸⁹ The transmission of the Zika virus to humans occurs through bites from infected *Aedes* genus of mosquito, with symptoms manifesting as fever, headache, rash, joint pain, and conjunctivitis.⁹⁰ The virus is a type of flavivirus, related to other pathogenic vectors such as West Nile and the Dengue virus.⁹¹ Symptoms last anywhere from several days to a week and the illness is typically mild in nature.⁹² However, the effects can be severe in pregnant women due to the ability of the virus to transfer to the fetus, causing devastating neurological birth defects in offspring. These defects can include microcephaly, which is a condition in which the brain and head are malformed and decreased in

⁸⁶ See FDA, *Emergency Use Authorization*,

<https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm182568.htm#doxy> (last updated Feb. 8, 2018).

⁸⁷ U.S. Food & Drug Admin., Letter to Robert E. Miller, (July 9, 2018); see also U.S. Department of Health & Human Services, *Declaration of Emergency Use of Treatment for Uncontrolled Hemorrhage Due to Agents of Military Combat*, 83 Fed. Reg. 32884 (2018).

⁸⁸ A PREP Act determination and publication in the Federal Register relates to the granting of liability immunity to the manufacturer for providing a medical countermeasure. Pub. L. 109-148 (2005), sections codified in 42 U.S.C. 247d-6d and 42 U.S.C. 247d-6e (pertaining to compensation).

⁸⁹ For discussion of Zika see Thomas R. Friedman, et al., *Zika Virus 6 Months Later*, 316 JAMA 1443 (2016); Neelima Arora et al., *Zika Virus: An Emerging Arboviral Disease*, 11 FUTURE VIROL. 395 (2016); Braira Qahid et al., *Zika: As an Emergent Epidemic*, 9 ASIAN PACIFIC J. TROP. MED. 723 (2016); Lawrence Gostin & James G. Hodge, *Is the United States Prepared for a Major Zika Outbreak?*, 315 JAMA 2395 (2016); Chris Fellner, *Zika Virus: Anatomy of a Global Health Crisis*, 41 P&T 242 (2016).

⁹⁰ K.A. Galan-Huerta, et al., *The Zika Virus Disease: An Overview*, 18 MEDICINA UNIVERSITARIA 115, 118-19 (2016).

⁹¹ *Id.* at 116.

⁹² *Id.* at 119.

size.⁹³ Other effects on the fetus include severe brain defects and Guillain-Barre Syndrome, a disorder in which the immune system attacks the nervous system.⁹⁴

Although isolated reports of Zika infection existed prior to 2015, the virus became a significant area of concern in 2015 and early 2016. In May 2015, a case of Zika virus infection was confirmed in northern Brazil with skin rash as a key symptom.⁹⁵ Based on accumulating information, the World Health Organization (“WHO”) declared a Public Health Emergency of International Concern (“PHEIC”) on February 1, 2016, in response to clusters of microcephaly and Guillain-Barre Syndrome in French Polynesia and Brazil.⁹⁶ The disorders were believed to be linked to Zika. One week later, the CDC elevated Zika response efforts to Level 1, the highest response level. That same day, the Obama administration requested \$1.9 billion in emergency appropriations from Congress for Zika preparedness and resources.⁹⁷ On April 6, 2016, the White House reallocated \$589 million of Ebola appropriations for Zika preparedness and response.⁹⁸ Three months later, at the end of July 2016, the CDC reported that Florida had diagnosed Zika infections in four individuals as a result of a local infected mosquito. Until that date, confirmed cases of Zika involved people who had traveled to affected areas returning with the virus. Subsequently, cases inflicted from local mosquitos were reported in the U.S. territories of Puerto Rico, the US Virgin Islands, American Samoa, Florida, and Texas.⁹⁹

Public education and the availability of detection assays through issuance of emergency use authorizations have triggered an international decline in the incidence of Zika. In the U.S., there were 5,168 reported cases in 2016 (4,897 were travelers; 224 were result of bites from local mosquitoes in Florida and Texas); there were 452 reported cases in 2017 (437 were travelers; 7 were the result of mosquito bites in Florida); and in 2018, there have been 34 reported cases as of August 1, 2018, all of which were travelers returning from affected areas.¹⁰⁰

The FDA has not yet approved any vaccines or treatments for the Zika virus, and there are no commercially available diagnostic tests for the detection of Zika.¹⁰¹ However, the FDA has issued nineteen EUAs to address assays to be used to detect Zika. Figure 4 lists the FDA-issued EUAs for Zika.

⁹³ *Id.* at 119.

⁹⁴ U.S. FOOD & DRUG ADMIN., ZIKA VIRUS RESPONSE UPDATES FROM FDA, <https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm485199.htm> (last updated Aug. 13, 2018).

⁹⁵ Galan-Huerta, *supra* note 91, at 116.

⁹⁶ Arlene Chua, et al., *Update on Zika Diagnostic Tests and WHO’s Related Activities*, 11 PLOS NEGL. TROP. DIS. E0005269 (2017)(DOI:10.1371/journal.pntd.0005269).

⁹⁷ White House, Letter from the President, (Feb. 22, 2016), <https://obamawhitehouse.archives.gov/the-press-office/2016/02/22/letter-president-zika-virus>.

⁹⁸ Juliet Eilperin & Kelsey Snell, *White House to Divert Ebola Funds in \$589M Push to Fight Zika*, WASHINGTON POST, (Apr. 6, 2016), https://www.washingtonpost.com/news/powerpost/wp/2016/04/06/white-house-to-spend-589m-in-ebola-funds-to-fight-zika/?utm_term=.f8d21c23264e.

⁹⁹ U.S. Centers for Disease Control and Prevention, Media Release, *Florida Investigation Links Four Recent Zika Cases to Local Mosquito-Borne Virus Transmission*, (July 29, 2016), <https://www.cdc.gov/media/releases/2016/p0729-florida-zika-cases.html>.

¹⁰⁰ U.S. Centers for Disease Control and Prevention, *Zika Case Counts*, <https://www.cdc.gov/zika/reporting/case-counts.html> (last updated Aug.2, 2018).

¹⁰¹ U.S. FOOD & DRUG ADMIN., ZIKA VIRUS RESPONSE UPDATES FROM FDA, <https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm485199.htm> (last updated Aug. 13, 2018). In 2018, the FDA has cleared two assays for the detection of the Zika virus in blood donations. *Id.*

Figure 4: FDA Emergency Use Authorization Issuances for Zika¹⁰²

EUA Date	Product	Manufacturer
2/26/2016	Zika MAC-ELISA	CDC
3/17/2016	Trioplex rRT-PCR	CDC
4/28/2016	Zika Virus RNA Qualitative RT-PCR	Quest Diagnostics Infectious Disease, Inc.
5/13/2016	RealStar Zika Virus RT-PCR Kit U.S.	Altona Diagnostics
6/17/2016	Aptima Zika Virus assay	Hologic, Inc.
7/19/2016	Zika Virus Real-Time RT-PCR Test	Viracor Eurofins
7/29/2016	VERSANT Zika RNA 1.0 Assay (kPCR)	Siemens Healthcare Diagnostics Inc.
8/4/2016	xMAP MultiFLEX Zika RNA Assay	Luminex Corporation
8/17/2016	ZIKV Detect 2.0 IgM Capture ELISA	InBios International, Inc.
9/23/2016	Sentosa SA ZIKV RT-PCR Test	Vela Diagnostics USA, Inc.
9/28/2016	Zika Virus Detection by RT-PCR Test	ARUP Laboratories
11/21/2016	Abbott RealTime Zika	Abbott Molecular Inc.
12/9/2016	Zika ELITe MGB Kit U.S.	ELI TechGroup Inc. Molecular Diagnostics
3/10/2017	Gene-RADAR Zika Virus Test	Nanobiosym Diagnostics, Inc.
4/5/2017	LIASION XL Zika Capture IgM Assay	DiaSorin Incorporated
8/2/2017	TaqPath Zika Virus Kit (ZIKV)	Thermo Fisher
8/11/2017	CII-ArboViroPlex rRT-PCR Assay	Columbia University
9/18/2017	ADVIA Centaur Zika test	Siemens Healthcare Diagnostics Inc.
9/27/2017	DPP Zika IgM Assay System	Chembo Diagnostic Systems, Inc.

The CDC's Zika MAC-ELISA is the first diagnostic test authorized for use in the U.S. through an DHHS declaration and the FDA's subsequent EUA issuance on February 26, 2016. Following the WHO's declaration of PHEIC in February 2016, the CDC requested on February 22, 2016 that the FDA issue an EUA for select *in vitro* diagnostic tests for the detection and/or diagnosis of Zika. On February 26, 2016, the Secretary of DHHS declared that circumstances existed to justify the authorization of emergency use of the Zika Immunoglobulin M (IgM) Antibody Capture Enzyme-Linked Immunosorbent Assay (Zika MAC-ELISA) for the presumptive detection of Zika virus-specific IgM in human sera or cerebrospinal fluid. The Secretary issued a notice pursuant to FDCA §564, which was published in the Federal Register on March 2, 2016.¹⁰³ In the notice, the Secretary determined that there is significant potential for a public health emergency that may affect national security or the health and security of US citizens living abroad due to the Zika virus.¹⁰⁴ On February 26, 2016, the FDA Commissioner authorized the EUA for Zika MAC-ELISA, which was later officially published in the Federal Register on March 28, 2016.¹⁰⁵

¹⁰² All information in the chart was derived from the Food and Drug Administration's website. U.S. FOOD & DRUG ADMIN., ZIKA VIRUS RESPONSE UPDATES FROM FDA, <https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm485199.htm> (last updated Aug. 13, 2018).

¹⁰³ U.S. Dept. Health & Hum. Services, *Determination and Declaration Regarding Emergency Use of in Vitro Diagnostic Tests for Detection of Zika Virus and/or Diagnosis of Zika Virus Infection*, 81 Fed. Reg. 10878 (2016).

¹⁰⁴ *Id.*

¹⁰⁵ U.S. Food & Drug Admin., *Authorization of Emergency Use of an In Vitro Diagnostic Device for Diagnosis of Zika Virus Infection; Availability*, 81 Fed. Reg. 17170 (2016).

The test is intended for use in the detection of antibodies that fight a Zika virus infection.¹⁰⁶ The antibody immunoglobulin M, or IgM, is one basic antibody produced by B cells within the body to fight infection. It appears in the blood of an infected person four to five days after transmission.¹⁰⁷ The test is directed to populations either with a history of symptoms linked to Zika or those who recently traveled to an affected area. For patients with a history of prior flavivirus infection, there is potential for false positive results, thus additional testing may be required to confirm Zika virus infection.¹⁰⁸ Many issues regarding proper testing and interpretation are described in supplemental materials for users and patients. The Zika MAC-ELISA has several fact sheets: one for patients,¹⁰⁹ one healthcare providers,¹¹⁰ and general instructions for use.¹¹¹

The authorization letter from the FDA waives current good manufacturing practice requirements with respect to design, manufacture, packaging, labeling, storage, and distribution of the Zika MAC-ELISA.¹¹² Also waived are several labeling requirements, except for the intended use statement, adequate directions for use, limitations on the use of the device, and information regarding performance of the device.¹¹³ The letter also establishes conditions on the EUA, including that the test is only to be administered in qualified laboratories, not in hospitals or other primary care settings.¹¹⁴ The letter also stipulates that all advertising and promotional descriptive material related to the use of the product shall clearly state: that test has not been FDA cleared or approved; the test has been authorized by FDA under an EUA for use by authorized laboratories only; the test has been authorized only for the diagnosis of Zika virus infection and not for any other viruses or pathogens; and the test is only authorized for the duration of the declaration.¹¹⁵ These notices are all present in the patient and health care fact sheets. The EUA remains effective until a declaration that circumstances exist to justify the termination or revocation under section 564(g) of the Act.

On June 29, 2016, the FDA reissued the February 26, 2016, EUA with amendments requested by the CDC.¹¹⁶ The amendments included updating the language of the clinical and epidemiological criteria, updating the language related to additional testing of positive or equivocal test results using the CDC algorithm, and adding an additional antigen for use with the test.¹¹⁷ The

¹⁰⁶ U.S. Centers for Disease Control and Prevention, *New CDC Laboratory Test for Zika Virus Authorized for Emergency Use by FDA*, (Feb. 26, 2016), <https://www.cdc.gov/media/releases/2016/s0226-laboratory-test-for-zika-virus.html>.

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ U.S. Centers for Disease Control and Prevention, *Zika MAC-ELISA Fact Sheet for Patients*, (Dec. 6, 2016), <https://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM488042.pdf>.

¹¹⁰ U.S. Centers for Disease Control and Prevention, *Zika MAC-ELISA Fact Sheet for Health Care Providers*, (May 7, 2017), <https://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM488041.pdf>.

¹¹¹ U.S. Centers for Disease Control and Prevention, *Zika MAC-ELISA Instructions for Use*, (Apr. 16, 2018), <https://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM488044.pdf>.

¹¹² U.S. Food & Drug Admin., *Letter of Emergency Use Authorization for Zika MAC-ELISA*, (July 26, 2016), <https://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM488040.pdf>. This letter is the reissue of the original EUA; the original letter is not available on the website.

¹¹³ *Id.*

¹¹⁴ *Id.* Guidance further describes these requirements for conduct in a CLIA-certified laboratory. Centers for Disease Control, *Guidance for U.S. Laboratories Testing for Zika Virus Infection*, (July 24, 2017), <https://www.cdc.gov/zika/pdfs/laboratory-guidance-zika.pdf>.

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ *Id.*

EUA has been amended several other times: on November 15, 2016; December 6, 2016; May 3, 2017; July 31, 2017; and April 16, 2018.

CONCLUSION

There is a growing realization in the public health law community that the linear structure underlying a detailed command and control response to biological disasters may not adequately meet future challenges.¹¹⁸ Furthermore, it has been argued that complex systems behave in ways that fall outside the silos of legal response, demanding more fluid and adaptable approaches, driven by the unique nature of a given threat.¹¹⁹ Long term, fundamental changes to public health law may be warranted, but within the confines of this piece, the focus has been on using the law with its current structures, as a necessary element in effectuating better responses to disasters. The core of this piece details generally how the law has evolved to respond to biological disasters at federal and state levels, and in turn the essay presents a more detailed portrait of how one key agency, the federal FDA, has forged a regulatory response to the critical need to identify the Zika virus through the use of EUAs.

It is the underlying premise of this article that laws that are current and well-designed can play a defining role in shaping critical responses to public health emergencies and should be thought as an elemental tool of this field. Based on the general discussion about public health law and the more detailed FDA case discussion, several observations can be made. First, as law exists in this area across levels of government and jurisdictions, there is a need to harmonize this often-disparate body of jurisprudence on an ongoing basis. Legislators and regulators alike must be broadly aware of existing mandates, and in crafting new laws must strive for transparency and hierarchical clarity. While all relevant hands of government need to be engaged in biological disaster response, certain matters, particularly dealing with science policy, need to be the primary purview of specialized federal agencies, like the FDA, CDC and NIH. On the other hand, federal authorities must recognize and support local and state actors in their roles as first responders whose performance has the most import on the ground level.

The second observation that can be drawn from this essay is that laws and regulations concerning biological disasters must be regularly revisited to ensure that current “best practices” underpin legal responses, as public health science rapidly evolves and changes. Third, difficult balances will need to be made in forging policies in disaster prevention and response which are respectful of individual rights. The imperative of public authorities to confront the challenges of a biological catastrophe cannot be successfully met if they fail to be rooted in respect for individual liberties. Finally, in adopting legal responses to biological disasters, the most effective strategies will allow for flexible approaches that optimize necessary partnerships with non-government actors and can be readily tailored to a given event. While law is an essential tool of public health, it is a means to an end. Thus, it should be subject to ongoing revision and reform, based on careful assessment, post disaster, of its application to given events. As noted early in this piece, there is a high likelihood of a catastrophic biological event occurring in the near future, and while the exact nature of a potential threat may be unpredictable, failure to create necessary legal and administrative structures for prevention and response is unacceptable public policy. Our law plays a critical role in biological disaster preparedness and demands clear articulation and ongoing development at all levels of government.

¹¹⁸ Scott Burris, et al., *A Transdisciplinary Approach to Public Health Law: The Emerging Practice of Legal Epidemiology*, 37 ANNUAL REV. PUB. HEALTH 135-148 (2016).

¹¹⁹ Lewis A. Lipsitz, *Understanding Health Care as a Complex System*, 308 JAMA 243-244 (2012).