FDA Emergency Use Authorization From 9/11 to COVID-19: Historical Lessons and Ethical Challenges

JONATHAN L. IWRY[*†]

ABSTRACT

Emergency use authorization (EUA) is a power granted by Congress to FDA to expedite the availability and distribution of medical countermeasures during public health emergencies. This Article reviews the history of FDA's EUA authority from its inception in the post-9/11 era to its present-day use in response to COVID-19 in order to better understand and anticipate the limitations, potential, and risks of EUAs. We offer several reflections on the history of EUAs and ethical considerations relevant to their use in connection with COVID-19 (including a potential vaccine) and future emergencies. This history and analysis center around four main themes: 1) the effects that post-9/11 counterterrorist concerns have had on FDA's ability to deal with naturally occurring threats to public health and safety; 2) political interference in efforts to defend the country against those threats; 3) the question of where the risks posed by emergency countermeasures should fall, including with respect to legal liability for vaccine-related injuries; and 4) the key ethical and policy issues confronting FDA in public health emergencies.

I. INTRODUCTION

Emergency use authorization (EUA) is a statutory emergency power granted to the Food and Drug Administration (FDA) by Congress to ensure the timely availability and distribution of medical countermeasures during public health emergencies. Under Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA), the FDA Commissioner may authorize unapproved medical products (such as diagnostic tests, drugs, or vaccines) or unapproved uses of approved products for use in emergency circumstances.[1] Such products can be used to diagnose, treat, or prevent serious health conditions caused by a chemical, biological, radiological, or nuclear (CBRN) agent under certain statutory conditions.[2]

---

[*] Incoming Associate, Ropes & Gray LLP; B.A., University of Pennsylvania; J.D., Harvard Law School. I am indebted to Peter Barton Hutt for his invaluable guidance and encouragement. Joseph Page and Nathan Brown provided essential feedback. This Article has also benefited from extensive commentary and discussion while being presented at the *Food & Drug Law Journal* 2020 Symposium, "This Teachable Moment: How COVID-19 Provides Lessons from FDA's Past and Present that Will Benefit its Future Preparedness."

[†] This Article summarizes and discusses events pertaining to the COVID-19 pandemic that are still unfolding. The information presented here may be outdated by the time of publication.

[1] 21 U.S.C. § 360bbb-3 (2011).

[2] *Id.*

Issuance of an EUA by FDA for medical countermeasures requires a declaration by the Secretary of Health and Human Services (HHS) justifying the authorization. This in turn depends on a declaration of the existence of a public health emergency, or a potential public health emergency, that could affect national security or threaten the health and security of U.S. citizens abroad.[3] FDA then consults with the HHS Assistant Secretary for Preparedness and Response, the National Institutes of Health, and the Centers for Disease Control and Prevention (CDC) in deciding whether to issue an EUA.[4] Unlike the strict standard of safety and efficacy used by FDA for ordinary product approvals,[5] an EUA for a given product requires only a finding that "it is reasonable to believe that the product may be effective for the specified use,"[6] combined with a determination that there are no formally approved alternatives to the product in question and that the "known and potential benefits" of issuing an EUA for that product outweigh the risks.[7] Each issuance of an EUA requires a public notice in the Federal Register.[8] EUAs limit the informed consent process normally used by FDA for human research while requiring that patients be adequately informed to the fullest extent possible given the circumstances of the emergency.[9] EUAs also give considerable discretion to the FDA Commissioner in regulating the distribution of EUA products.[10] According to CDC, this power of authorization "fills the need for timely and practical medical treatment when the relevant product has not already been approved or approved for this specific use by FDA."[11]

EUAs are playing a critical role in responding to the current COVID-19 pandemic, a situation developing constantly with near-daily emergency authorizations of medical countermeasures. In the past fifteen months, FDA has issued an unprecedented number of EUAs for the use of protective equipment, medical equipment, diagnostic tests, and treatments that have yet to run the gauntlet of FDA's extensive ordinary approval process.[12] However, we have yet to chronicle the evolution of this important power

---

3 *Id*.

4 *Summary of Process for EUA Issuance*, U.S. FOOD & DRUG ADMIN. (Feb. 7, 2020), https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/summary-process-eua-issuance [https://perma.cc/3H8N-XWVS].

5 For a thorough review of FDA's generally applicable approval process, see chapters on "Human Drugs," "Biological Products: Vaccines, Blood, Tissue Transplants, and Cellular Therapies," and "Medical Devices" in PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, FOOD AND DRUG LAW: CASES AND MATERIALS (4th ed. 2014).

6 *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders*, U.S. FOOD & DRUG ADMIN. (Oct. 17, 2018), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities [https://perma.cc/6MFK-KEE8].

7 *Id.*

8 *Summary of Process for EUA Issuance*, U.S. FOOD & DRUG ADMIN. (Feb. 7, 2020), https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/summary-process-eua-issuance [https://perma.cc/3H8N-XWVS].

9 Stewart L. Nightingale, Joanna M. Prasher & Stewart Simonson, *Emergency Use Authorization (EUA) to Enable Use of Needed Products in Civilian and Military Emergencies, United States*, 13 EMERGING INFECTIOUS DISEASES 1046, 1049 (2007).

10 *Id.*

11 *Id.* at 1050.

12 U.S. FOOD & DRUG ADMIN., COVID-19 RESPONSE: AT-A-GLANCE SUMMARY (July 19, 2021), https://www.fda.gov/media/137005/download [https://perma.cc/BY89-UH3P].

from its inception through its use against COVID-19, the most consequential public health emergency since the 1918 Spanish flu.

This Article reviews the history of FDA's EUA authority to better understand and anticipate EUAs' limitations, potential, and risks. Together, this history and accompanying analysis of EUAs center around four main themes: 1) the effects that counterterrorist concerns in the post-9/11 era have had on the United States' ability to deal with naturally occurring threats to public health and safety; 2) the inevitable specter of political interference in efforts to defend the country against those threats; 3) the question of where the risks posed by emergency countermeasures should fall, including with respect to legal liability for vaccine-related injuries; and 4) the key ethical and policy issues that confront FDA in responding to public health emergencies.

Part II of the Article starts by considering four events that set the stage for the inception of EUAs: 1) the swine flu affair of 1976; 2) FDA's response to the AIDS crisis in 1990; 3) the controversy over administering the DryVax smallpox vaccine to first responders in 2001; and 4) the SARS outbreak of 2002. Part III then details the establishment and early use of EUA authority in the wake of 9/11, focusing on its enactment under Project BioShield in 2004 and enhancement by the Public Readiness and Emergency Preparedness (PREP) Act in 2005. Part IV reviews early uses of EUAs, including during the H1N1 crisis of 2009. Part V reviews the use of EUAs in response to COVID-19. Parts VI and VII reflect on the history of EUAs and consider ethical questions relevant to their use in connection with COVID-19 and emergencies to come.

II. SETTING THE STAGE: THE PRE-EUA PERIOD

A. 1976: Swine Flu Vaccine Liability

The swine flu affair of 1976 is widely remembered as a health policy disaster.[13] Although an outbreak of swine flu did not materialize, the government's preemptive course of action was a major event that set the stage both for diminished widespread vigilance against pandemics and for conflicts over manufacturing and distribution of medical countermeasures in crises to come—issues that would converge decades later in the development and use of EUAs.

In 1976, a soldier in New Jersey contracted a fatal case of influenza.[14] CDC acquired viral samples and feared that Influenza A, the class of influenza viruses responsible for all historic flu pandemics, might have undergone an antigenic shift—a convergence of separate strains into a new and deadlier form—that could be as significant as the form that caused the Spanish flu of 1918.[15] The federal government quickly developed an unprecedented plan to manufacture and administer a "swine flu" vaccine and immunize the entire country. While the World Health Organization (WHO) advocated a more cautious approach, President Gerald Ford, who was running for reelection in

[13] For a thorough chronology of the swine flu affair of 1976, see RICHARD NEUSTADT & HARVEY V. FINEBERG, THE SWINE FLU AFFAIR: DECISION-MAKING ON A SLIPPERY DISEASE (1978).

[14] *Id.*

[15] *Id.*

1976, was reportedly pushing hard for rapid implementation of a national immunization program.[16]

Major vaccine providers were willing to cooperate with the federal government to address the threat of swine flu, but they were skittish about the risks involved in preparing a vaccine for use on a national scale. The vaccine industry had not been completely without incident. For example, Wyeth Labs, a major vaccine provider, had recently been brought to court after their polio vaccine resulted in a child contracting the disease; Judge Wisdom had found the company liable even though it had no power to warn vaccinated persons about the risk of contracting polio.[17] Vaccines are not guaranteed to work exactly as planned in every case, and the prospect of a nationwide vaccination program entailed considerable risk for private-sector entities tasked with producing those vaccines.

What resulted was a compromise between government actors insisting on a rapid response and manufacturers reluctant to supply a vaccine without economic protection. The legislation, the National Swine Flu Immunization Program, was enacted in August 1976.[18] The program precluded liability against manufacturers, requiring that any related suits be brought against the federal government under the Federal Tort Claims Act (FTCA).[19] In other words, parties claiming to have been injured as a result of the national vaccination program would be able to file suit only against the federal government—and only through the standard process for any other tort claim against a federal employee acting within the scope of employment, subject to the same exceptions and limitations on damages. The government in turn would have a right against manufacturers for indemnification, but only upon a finding that the government's liability had arisen from manufacturers' failure to meet their contractual obligations to manufacture the vaccine properly.[20]

Unfortunately, the vaccine developed against swine flu had considerable side effects, and the government's effort to immunize the general public resulted in widespread personal injury claims over cases of Guillain-Barré syndrome.[21] The next several years saw extensive litigation against the government and vaccine manufacturers, with a generous compensation system offering plaintiffs a second stream of payment in addition to court-awarded damages. The tort claims branch of the Department of Justice decided to settle cases where there was reasonable evidence

---

16 *See* Rebecca Kreston, *The Public Health Legacy of the 1976 Swine Flu Outbreak*, DISCOVER MAG. (Sept. 30, 2013), https://www.discovermagazine.com/health/the-public-health-legacy-of-the-1976-swine-flu-outbreak [https://perma.cc/EU87-QWF6].

17 *See* Reyes v. Wyeth Labs., 498 F.2d 1264 (5th Cir. 1974).

18 42 U.S.C. § 201 note (2010).

19 The Federal Tort Claims Act (FTCA) is a federal statute providing limited exceptions to 11th Amendment sovereign immunity under which potential plaintiffs can file suits against the United States, and potentially receive compensation, for tortious misconduct committed by federal employees within the scope of their employment (specifically *excluding* independent contractors such as private-sector vaccine manufacturers). *See* 28 U.S.C. § 1346 (2011).

20 *See* 42 U.S.C. § 201 note (2010).

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

of vaccination having resulted in Guillain-Barré syndrome, creating an hoc settlement scheme.[22]

This led to an increase in general litigation against vaccine manufacturers, including for mishaps involving other vaccines.[23] Mandatory vaccination for children against polio, measles, tetanus, and other illnesses had been a public health success, though not without accompanying risks. Polio vaccines could occasionally cause polio in children, and vaccines for whooping cough were later reported to result in occasional incidents of encephalopathy.[24] The resulting product liability cases ballooned alongside settlement claims for the swine flu vaccine. Wyeth Labs, still reeling from the unfavorable ruling over its polio vaccine in 1974, was one of several major manufacturers that began pulling out of the vaccine market; it ceased production of its tetanus vaccine in 1984, citing "extreme liability exposure, cost of litigation and the difficulty of continuing to obtain adequate insurance."[25] Between 1963 and 1986, seven of the eight drug companies manufacturing diphtheria-pertussis-tetanus (DPT) vaccines ceased to do so.[26]

Fearing that massive losses would drive companies out of the vaccine market altogether, Congress responded by enacting the National Childhood Vaccine Injury Compensation (NCVIC) Act in 1986.[27] The NCVIC Act created a no-fault compensation system funded by an excise tax and administered in a Court of Federal Claims.[28] Potential plaintiffs would have to go through the compensation system before they would be able to turn their compensation offers down and proceed to litigation, rather than pursuing both remedies simultaneously.[29] The NCVIC Act also ensured a strong legal presumption that FDA warnings were adequate, precluded strict liability under conditions of proper manufacturing and adequate warning, offered a strong defense against punitive damages, and specified civil procedural requirements in vaccine injury suits to ensure dispassionate jury findings.[30] Finally, the NCVIC Act limited the recovery of damages for vaccine-related deaths and pain, suffering, and emotional distress to $250,000.[31] The National Childhood Vaccine Injury Compensation Act thereby offered compensation for children who may have suffered adverse side effects from vaccination while offering vaccine manufacturers protection from liability.

---

[22] For more on the history of swine flu litigation, see Paul D. Rheingold & Clifford J. Shoemaker, *The Swine Flu Litigation*, 8 LITIGATING WITH THE GOV'T 28, 29 (1981).

[23] *See* Arnold W. Reitze, Jr., *Federal Compensation for Vaccination Induced Injuries*, 13 B.C. ENV'T AFF. L. REV. 169, 192 (1986) (reviewing the history of litigation against vaccine manufacturers for vaccination-related injuries and its effects on the vaccine market).

[24] *Id.* at 169.

[25] *Vaccine Injury Compensation: Hearings on H.R. 5810 Before the Subcomm. on Health & the Env't of the H. Comm. on Energy & Commerce*, 98th Cong. 295 (1984) (statement of Dr. Daniel L. Shaw, Jr., Vice-President, Medical Affairs, Wyeth Laboratories).

[26] Reitze, Jr., *supra* note 23, at 194.

[27] 42 U.S.C. §§ 300aa-1–34 (2010).

[28] *Id.*

[29] *Id.*

[30] *Id.*

[31] 42 U.S.C.A. § 300aa-15(a)(2),(4) (West, Westlaw through PL 117-12 with the exception of PL 116-283).

Looking back, the swine flu affair of 1976 resulted in a system that largely eliminated vaccine injury litigation while still compensating injured parties. These efforts to incentivize FDA and industry to pursue better new vaccines appear to have revitalized the vaccine development industry, which had been threatening to become moribund in the 1970s and 1980s; many more entrepreneurial companies have since entered into the vaccine development and manufacturing business. While the means of protection offered to manufacturers could have provided greater compensation to injured parties, they appear to have succeeded in addressing economic risks so as to ensure a sizable vaccine market for future emergencies.

B. 1990: Emergency Use During the AIDS Crisis

Before emergency use authorization was enacted in 2004, no formal mechanism existed for bringing promising drugs to market in a large-scale public health crisis. A variety of pathways could be and had been used before, but none laid out a sufficiently clear or official path to compel more risk-averse regulators within FDA to take bold measures in times of emergency.

One notable counterexample involves FDA's efforts to respond to the AIDS crisis of the 1980s. In 1989, FDA announced its intention to allow dideoxynosine (DDI), an experimental AIDS treatment drug, to be sent to market while continuing to put it through clinical trials, having not yet approved the drug for safety and efficacy.[32] DDI had only completed Phase I review—the first of three phases—and had been found to occasionally cause swelling and pancreatic pain, albeit at high doses.[33]

Because of the observed side effects, the drug's provider, Bristol Myers Squibb, ultimately agreed with FDA to distribute DDI only to patients unable to take AZT—the only AIDS treatment drug on the market at the time—while FDA proceeded to put the drug though the next two phases of testing.[34] This "Parallel Track" process would make an exception to standard protocol to allow simultaneous distribution and testing given the dire circumstances.[35] FDA's decision was considered an unprecedented departure from its typical mode of conduct; a *New York Times* article called it "the first step toward the F.D.A.'s much-heralded fast track in delivering drugs to people with fatal diseases, a policy that has been called the 'parallel track' because testing and wide distribution go on simultaneously."[36]

FDA's longstanding conservative approach to approving new drugs was at least partly a reaction to tragic historical mishaps resulting from hasty distribution of dangerous pharmaceutical drugs. Perhaps the most notorious was the thalidomide incident of the 1960s, when a treatment for nausea administered to pregnant women

---

[32] *See* Eve Nichols, *Expanding Access to Investigational Therapies for HIV Infection and AIDS: March 12–13, 1990 Conference Summary* (1991), https://www.ncbi.nlm.nih.gov/books/NBK234129/ [https://perma.cc/V8XV-VA4Y]. For a related policy proposal by HHS, see Expanded Availability of Investigational New Drugs Through a Parallel Track Mechanism for People with AIDS and HIV-related Disease, 55 Fed. Reg. 20858 (May 21, 1990).

[33] Philip J. Hilts, *F.D.A., in Big Shift, Will Permit Use of Experimental Aids Drug*, N.Y. TIMES (Sept. 29, 1989), https://www.nytimes.com/1989/09/29/us/fda-in-big-shift-will-permit-use-of-experimental-aids-drug.html [https://perma.cc/NJG9-XDAN].

[34] *Id.*

[35] *Id.*

[36] *Id.*

in West Germany resulted in widespread birth defects.[37] In recent years, however, advocates for AIDS victims had been putting considerable pressure on FDA to find faster ways of bringing new drugs to market, arguing that many of those infected with HIV could not afford to wait years for a promising drug to gain full approval, and would rather take their chances with an unknown drug that might have a chance of saving their lives.[38]

It is debatable to what extent public pressure to relax (or bypass) FDA's usual standards of vigilance reflected a rational and disinterested cost–benefit analysis of the associated risk, and to what extent it reflected an exceptional sense of desperation amid an ongoing crisis claiming thousands of lives. Some, such as former FDA commissioner Dr. Jere Goyan, expressed serious uncertainty, predicting that:

> "we will see some late-arriving side effects, and some price will be paid. The question is how high a price will society have to pay? . . . Maybe this is the right experiment to do, but I hope in doing it we don't destroy the clinical trials, and lose the information that will tell us whether this drug works."[39]

Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases (NIAID), was more emphatic about getting the treatment to market and allowing patients to weigh the costs and benefits for themselves, though he too expressed concern that patients might not appreciate the risks involved:

> "It is clear from a humanitarian point of view that when there are practically no alternative treatments, we cannot say to patients, 'If you are not eligible for clinical trials, too bad, you cannot get this drug. . . .' 'People who take the drug under this program do have to understand that there is a real risk here . . . . There could be toxic side effects. But as long as it is an informed choice, it is worth trying this.'"[40]

This unease on the part of public health officials included an urgent practical concern. Ordinarily, the only way for members of the public to get access to a new and uncertain drug like DDI was to volunteer for clinical trials. Making it easier for people to obtain the drug without entering trials would disincentivize people from volunteering for those trials and thus could make it harder to find enough subjects to test the drug in the first place. In addition, setting a precedent with one drug could bring about a future in which members of the public were generally less willing to participate in trials before bringing other drugs to market, undermining the testing and evaluation process generally.

What results is an ethical dilemma with an added wrinkle: putting an uncertain drug on the market would not only invite sick patients to take risks they might not be in a position to weigh objectively, but could also make it harder to gain more accurate information about the risks involved for countless future patients. How should

---

[37] *See* Morton Mintz, *"Heroine" of FDA Keeps Bad Drug Off Market*, WASH. POST (July 15, 1962), https://www.washingtonpost.com/wp-srv/washtech/longterm/thalidomide/keystories/071598drug.htm [https://perma.cc/7FCN-DNZW]. *See also* Max Sherman & Steven Strauss, *Thalidomide: A Twenty-Five Year Perspective*, 41 FOOD DRUG COSM. L.J. 458, 460 (1986).

[38] *See* Hilts, *supra* note 33.

[39] *Id.*

[40] *Id.*

regulators weigh these concerns against the value of getting potentially useful drugs to market quickly?

In October 1991, FDA granted approval for distribution of DDI to patients who had not used AZT extensively.[41] Two years later, a study overseen by NIAID found common reports of neuropathy and pancreatitis at high doses.[42] FDA would later issue a 2010 finding that DDI put patients at higher risk of non-cirrhotic portal hypertension, a rare but deadly liver disorder.[43]

FDA already had other means to distribute DDI; if a drug company wanted to allow for expanded use, there were already ways of doing so. FDA had a variety of expanded access programs for "investigational new drugs" (INDs) at its disposal, some of which dated back decades.[44] Emergency Use INDs, for instance, authorized access to INDs in times of emergency and dated back to 1962.[45] Treatment IND was yet another formal mechanism to get FDA approval and give patients access to an IND.[46] Orphan Drug, Tropical Drug, and Special Exception INDs abounded,[47] all of which FDA officials were reluctant to use. The general notion of "compassionate use" had also been used since the 1950s to justify informally giving unapproved drugs to patients who were unable to volunteer for clinical trials—effectively acting as a catchall for circumstances falling outside any particular expanded access IND program.[48]

These procedures all effectively amounted to the same thing: giving an investigational and unapproved drug to desperate patients who were unable to access that drug via clinical trials. If regulators in FDA had been so inclined, they could have found a way to put those measures to use for AIDS victims without any essential change in basic procedure.[49] Fauci and others introduced the concept of a "Parallel Track" IND to frame FDA's decision to authorize DDI as a new, salient, and independently legitimate authority.[50] A number of high-level FDA regulators strongly resisted the term until it was endorsed by President George H.W. Bush.[51] FDA's decision was unprecedented relative to its typical pattern of behavior, not to its formal capabilities.

---

41 *AIDS Drug DDI is More Useful*, WASH. POST (Sept. 29, 1992), https://www.washingtonpost.com/archive/lifestyle/wellness/1992/09/29/aids-drug-ddi-is-more-useful/0990f158-cc0d-4819-b7e9-a0007835ac28/ [https://perma.cc/A2YW-UEGM].

42 NAT'L INST. OF ALLERGY & INFECTIOUS DISEASES, CLINICAL ALERT: IMPORTANT THERAPEUTIC INFORMATION ON TREATMENT OF HIV INFECTION IN HIV-INFECTED PATIENTS WHO ARE INTOLERANT OF OR HAVE FAILED ZIDOVUDINE THERAPY (Feb. 1, 1993), https://www.nlm.nih.gov/databases/alerts/ddi_ddc.html [https://perma.cc/DL6Y-AD7T].

43 *FDA Drug Safety Communication: Serious Liver Disorder Associated with the Use of Videx/Videx EC (Didanosine)*, U.S. FOOD & DRUG ADMIN. (Jan. 19, 2010), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fda-drug-safety-communication-serious-liver-disorder-associated-use-videxvidex-ec-didanosine [https://perma.cc/C4TZ-WHVN].

44 *See* HUTT et al., *supra* note 5, at 765.

45 *Id.*

46 *Id.* at 766.

47 *Id.* at 769–70.

48 *Id.* at 769.

49 *See* Nichols, *supra* note 32.

50 *Id.*

51 Bill Snyder, *Anthony Fauci: Unfinished Business*, LENS MAG. (Apr. 2004), https://lens.newsarchive.vumc.org/article/?id=85&pg=4 [https://perma.cc/3LCE-9Z7R].

C. 2001: Smallpox Vaccine Liability

The events of September 11, 2001 had a significant impact on the development of U.S. public policy. With a wave of anthrax attacks occurring only weeks later,[52] the federal government grew even more concerned about defense against bioterrorism.[53] The next few years would see a wave of preemptive measures to protect the American military and citizenry against weaponized versions of infectious agents, focusing mainly on anthrax and smallpox.

In 2001, the government turned to an old smallpox vaccine—one that had been in storage since the 1970s—and administered it to first responders in case of a bioterror attack. The vaccine, known as DryVax, was considered to be unusually volatile, and this round of vaccination resulted in occasional cases of heart failure.[54]

Fearing another swine flu debacle, the government terminated the vaccination program in 2002 and followed up by adding a liability shield to the Homeland Security Act of 2002.[55] This amendment, Section 304 of the Homeland Security Act, gave legal coverage to smallpox vaccine manufacturers as employees of the Public Health Service.[56] This had two critical effects. First, in keeping with the swine flu liability shield of 1976, it rendered manufacturers immune to liability, prohibiting any injury claims from being brought against manufacturers directly. Second, it prohibited parties injured by the smallpox vaccine from bringing product liability claims related to the vaccine in state court, allowing them to bring claims only against the federal government under the FTCA in federal court. Manufacturers could be forced to pay for vaccine-related injuries only upon a finding that they had violated their contractual obligations or engaged in "gross misconduct" and were thus required to reimburse the government for losing a suit under the FTCA.[57] Some considered the government's measures to be excessive; the president of the National Vaccine Information Center worried that the bill "hands over unprecedented power to federal employees and does not preclude allowing them to use the military to strip citizens of informed consent rights and force them to risk their lives with highly reactive vaccines . . . that will injure or kill thousands of Americans if used on a mass basis."[58]

Anthrax and smallpox had by now permeated debates over health policy, joining (or, perhaps, eclipsing) concerns about naturally occurring pandemics to spur more

---

[52] U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-04-152, BIOTERRORISM: PUBLIC HEALTH RESPONSE TO ANTHRAX INCIDENTS OF 2001 (2003).

[53] *See, e.g.*, 150 CONG. REC. H5721, 5729 (2004) (statement of Rep. Turner) ("[I]n spite of this dire and clear warning, our biodefenses are no better than they were in September of 2001. No new medical treatments, vaccines, or lifesaving drugs have been approved for use. There is no antitoxin for ricin poisoning, no vaccine to protect against the plague, and no treatments of any kind against the deadly ebola virus.").

[54] CTRS. FOR DISEASE CONTROL & PREVENTION, *Cardiac Adverse Events Following Smallpox Vaccination*, MORBIDITY & MORTALITY WKLY. REP. (Mar. 28, 2003), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5212a2.htm [https://perma.cc/J8LS-F74E].

[55] *See* Homeland Security Act of 2002, Pub. L. No. 107-296, § 304, 116 Stat. 2135, 2165 (2002).

[56] *Id.* at § 304(c).

[57] 42 U.S.C. § 233(p)(6)(A).

[58] *Homeland Security Bill Could Allow DHHS to Force Smallpox Vaccination While No One is Liable for Harm*, INFECTION CONTROL TODAY (Nov. 18, 2002), https://www.infectioncontroltoday.com/vaccines-vaccination/homeland-security-bill-could-allow-dhhs-force-smallpox-vaccination-while-no-one [https://perma.cc/J4DK-AW9R].

extensive efforts at medical preparedness for a public health emergency. These events inured Congress to the idea that at least one prong of the solution to ensuring available countermeasures to infectious threats was to insulate vaccine providers from liability. The liability shield for smallpox vaccines echoed the swine flu liability shield from 1976; together they would ultimately inspire the liability shield inscribed in the PREP Act of 2005 for general countermeasures against health emergencies.

D. 2002: SARS

In late 2002, an outbreak of a virus causing severe acute respiratory syndrome (SARS) infected 5,300 people in China.[59] WHO declared SARS a "worldwide health threat."[60] SARS spread across the globe and claimed 774 lives before vanishing abruptly in 2004.[61] Unlike other looming threats to public health that dominated policy discussions in this area, this infectious disease was of natural origin. The United States experienced only a handful of infections and no deaths, though the event led public health experts to question the federal government's readiness for naturally occurring infectious disease outbreaks in the future—an issue that would resurface time and again in congressional hearings for years to come and play a background role in prompting the PREP Act of 2005.

III. THE GENESIS OF THE EUA

A. 2004: Project BioShield

FDA's emergency use authorization powers officially came into being in 2004 in the wake of the September 11 terror attacks of 2001. Concerns about anthrax and smallpox were continuing to play a prominent role in the federal government's response, as fear of bioterror attacks prompted massive increases in funding for research into biological warfare and countermeasures. In 2003, for example, Congress increased funding by $1.5 billion for research related to bioterrorism at NIAID. HHS began preparing for the prospect of a national terrorism-related health crisis requiring widespread use of unapproved products or unapproved use of approved products. Pursuing FDA approval would take years (if it would be granted at all), and regulators at FDA had proven reluctant to break protocol in the past without express permission and even pressure from the President. The only available procedure for making such products available during a national emergency was an Investigational Device Exemption or an exemption for IND, and even those protocols were too cumbersome to respond to a rapidly developing national emergency. According to the CDC, HHS needed "something short of licensure that included specific safety, efficacy, and quality requirements in a manner less administratively burdensome . . . . The country

---

[59] Yanzhong Huang, *The SARS Epidemic and its Aftermath in China: A Political Perspective*, *in* LEARNING FROM SARS: PREPARING FOR THE NEXT DISEASE OUTBREAK 116 (Stacey Knobler et al. eds., 2004).

[60] *Id.*

[61] Jim Yardley, *After Its Epidemic Arrival, SARS Vanishes*, N.Y. TIMES (May 15, 2005), https://www.nytimes.com/2005/05/15/health/after-its-epidemic-arrival-sars-vanishes.html [https://perma.cc/VJ3D-N7XE].

needed an emergency mechanism built not on a clinical research model, but on a public health model."[62]

In 2004, Congress passed the Project BioShield Act,[63] a bipartisan effort to defend the United States against bioterrorism and related threats to national security and public safety. President George W. Bush explicitly identified counterterrorism as the impetus for Project BioShield, asserting that the statute would "transform our ability to defend the nation" by providing the means "to fight anthrax, smallpox and other potential agents of bioterror."[64]

The Project BioShield Act prescribed a multipronged strategy to prepare the United States for large-scale national security and public health emergencies. This included authorizing $5.6 billion for the government to purchase and stockpile vaccines and treatments against likely candidates for a bioterror attack.[65] The Project BioShield Act's primary functions were to expedite government funding and procurements, provide for private-sector development and public-sector acquisition of medical countermeasures, and authorize use of those countermeasures under emergency circumstances.

Accordingly, Project BioShield amended the FDCA to allow FDA to grant emergency use authorization (EUA) to drugs, devices, or biological products that could serve as emergency countermeasures despite lacking formal approval. Any issuance of an EUA required a declaration of emergency by the Secretary of HHS, on the condition that 1) the Secretary of Homeland Security identifies a "domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiologic, or nuclear agent or agents;"[66] 2) the Secretary of Defense identifies a similar type of military emergency or potential military emergency;[67] or 3) the Secretary of HHS identifies a similar public health emergency "that affects, or has a significant potential to affect, national security."[68]

B. 2005: The First EUA

The first EUA issued under Project BioShield met with controversy. Since 1998, the military had made receipt of an anthrax vaccine called Anthrax Vaccine Absorbed (AVA) mandatory for personnel serving in regions considered high risk for anthrax attacks. AVA had been developed in the 1970s for cases of exposure to anthrax not involving inhalation—for which it had been repurposed by the military without being thoroughly tested. More than 1.3 million soldiers had been vaccinated under the mandate, though some had faced disciplinary measures for refusing the vaccine out of

---

62 Nightingale et al., *supra* note 9, at 1047.

63 Project BioShield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835 (2004).

64 *President Bush Signs Project Bioshield Act of 2004*, WHITE HOUSE (July 21, 2004), https://georgewbush-whitehouse.archives.gov/news/releases/2004/07/20040721-2.html [https://perma.cc/DG9C-TE6Y].

65 *See* Project BioShield Act § 510.

66 21 U.S.C. § 360bbb-3(b)(1) (2011).

67 *Id.*

68 *Id.*

concern about potential side effects.[69] A group of military personnel and civilian contractors filed suit in federal court, and in 2004, a U.S. district judge found that FDA had wrongly authorized AVA for a different intended use than that for which it had been approved and had failed to obtain public comments.[70] The judge pointed to FDA's own regulations for approving drugs and vaccines, including independent reviews by expert panels and a standard notice-and-comment procedure, and found that FDA had relied on insufficient data to infer that AVA was effective against all forms of anthrax and had failed to offer a public comment period.[71] The decision effectively rendered the military's use of AVA an unapproved use of an approved drug, leading the Department of Defense to suspend the program.[72]

Military officials were eager to restore vaccinations for military personnel serving abroad—to address what they "considered to be the adverse effect of the injunction on military readiness."[73] In December 2004, they asked HHS to allow FDA to reauthorize administration of AVA, despite the lack of a basis for approval, for emergency use. Then-HHS Secretary Tommy G. Thompson declared a public health emergency on January 14, 2005, finding significant potential for a military emergency involving anthrax. FDA issued its first EUA on January 27, 2005, five weeks after the request, on the condition that vaccination of military personnel remained voluntary.[74] The EUA expired in January 2006, not long after FDA cleared AVA as safe and effective for its intended use.[75]

C. 2005: The PREP Act

Despite the extensive latitude granted to FDA under Project BioShield, the Project BioShield Act made no mention of protection against liability. This was cause for concern among providers of emergency countermeasures, who feared having to bear the risk of developing or administering medical products with potential side effects that could result in litigation.

These liability concerns became more salient in light of discussions surrounding the possible need to develop a vaccine against "avian flu," an emerging possible threat.[76] The specter of avian flu would affect discussions of manufacturing liability in particular, and the trajectory of the federal government's public health emergency

---

[69] *DoD to Resume Giving Anthrax Shots*, CTR. FOR INFECTIOUS DISEASE RES. & POL'Y (May 4, 2005), https://www.cidrap.umn.edu/news-perspective/2005/05/dod-resume-giving-anthrax-shots [https://perma.cc/474S-TU5S].

[70] Doe v. Rumsfeld, 297 F. Supp. 2d 119 (D.D.C. 2003), *and* 341 F. Supp. 2d 1 (D.D.C. 2004).

[71] *Id.*

[72] Robert Roos, *FDA Seeks Comments on Controversial Anthrax Vaccine*, CTR. FOR INFECTIOUS DISEASE RES. & POL'Y (Jan. 13, 2005), https://www.cidrap.umn.edu/news-perspective/2005/01/fda-seeks-comments-controversial-anthrax-vaccine [https://perma.cc/WYS5-YYAP].

[73] Nightingale et al., *supra* note 9, at 1050.

[74] Doe v. Rumsfeld, Civil Action No. 03-707 (EGS), 2 (D.D.C. Apr. 6, 2005) ("This injunction, however, shall not preclude defendants from administering AVA, on a voluntary basis, pursuant to the terms of a lawful emergency use authorization ["EUA"] pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act, without prejudice to a future challenge to the validity of any such EUA.").

[75] *See* Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review; Anthrax Vaccine Adsorbed; Final Order, 70 Fed. Reg. 75,180, 75,186 (Dec. 19, 2005).

[76] In 2004, for example, Senate Democrats introduced S. 1821, the Pandemic Preparedness and Response Act, in anticipation of an avian influenza outbreak, citing avian flu as a looming public health threat. *See* Pandemic Preparedness and Response Act, S. 1821, 109th Cong. (2005).

readiness in general. Public health experts had already been concerned about the United States' ability to combat infectious diseases given the SARS outbreak of 2002 when reports arrived of a new strain of influenza appearing in domestic poultry in Asia in 2005. Despite its low rate of transmission to humans—the only people known to have been infected lived in close proximity to birds—the strain showed 60–80% lethality, and like the Spanish flu, it was mostly killing healthy young people, including eighteen-year-olds with no pre-existing conditions.[77]

EUAs had by now existed for over a year, and the threat of an avian flu pandemic only underscored the apparent need for a strong liability shield to accompany EUAs (as well as New Drug Applications and other measures under FDA protocol). There were two strands to this issue: one involved bioterror, the other natural pandemics. Both required 1) a fast process to approve products in an emergency; and 2) adequate guarantees of protection for providers of risky countermeasures for which there was no time to conduct ordinary testing.

Although avian flu did not become the global pandemic that health experts worried it would, it nonetheless triggered a massive preemptive push to develop a new vaccine and immunize the public. With the Vaccine Injury Compensation Program already in place and being applied to seasonal flus, the question was raised whether to include an avian flu vaccine under the program. The resulting legislation left open the possibility of compensation but offered no funding; Congress would have to appropriate compensation money in the event of a vaccine injury debacle.[78]

This proposed legislation, called the Public Readiness and Emergency Preparedness (PREP) Act, was proposed as a follow up to Project BioShield bolstering private-sector investment in emergency readiness. The PREP Act would direct $3.8 billion to preparation for a pandemic scenario,[79] but its most distinctive feature was its extensive liability shield. Injured parties would be denied a right to sue in any state court.[80] Any case brought in federal court would have no discovery until the court had considered a motion for summary judgment.[81] Suits could only be brought in cases of "willful misconduct" by providers, for which plaintiffs would bear the burden of proof.[82] If the defendant was protected under the FTCA, willful misconduct could be shown only by proving the existence of an ongoing investigation against that provider by FDA or the Department of Justice.[83] Moreover, any provider of a drug approved for clinical trials during an emergency, whether issued through an EUA or not, would enjoy immunity from suit.[84]

---

[77] Matt Phillips, *A Closer Look at Bird Flu's Victims*, WALL ST. J. (Jan. 8, 2007), https://online.wsj.com/public/resources/documents/retro06-avfludeaths-date_desc.html [https://perma.cc/RXS7-J8LH].

[78] DEP'T OF HEALTH & HUM. SERVS., PREP ACT Q&AS (Sept. 5, 2019), https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx [https://perma.cc/B3TW-AJ3H].

[79] *See* DEP'T OF STATE, FACT SHEET: ADVANCING THE NATION'S PREPAREDNESS FOR PANDEMIC INFLUENZA (May 3, 2006), https://www.presidency.ucsb.edu/documents/fact-sheet-advancing-the-nations-preparedness-for-pandemic-influenza [https://perma.cc/H85R-7SH9]; *see also* H.R. REP. NO. 109-359 (2005).

[80] *See* Public Readiness and Emergency Preparedness Act., Pub. L. No. 109-148, Division C, § 2 (2005).

[81] *See id.*

[82] *Id.*

[83] *See id.*

[84] *Id.*

The proposal proved controversial. While some viewed the PREP Act as necessary to incentivize the private sector to produce needed countermeasures for a public health emergency, others viewed it as favoring the drug industry at the expense of injured parties and their right to seek damages. Democrats in the Senate characterized the PREP Act's liability shield as a "Christmas present to the drug industry and a bag of coal to everyday Americans."[85]

The debate surrounding the PREP Act's enactment pointed back to the same fundamental question raised in earlier debates over liability shields: where should the loss fall in times of crisis? Emergency countermeasures are practically bound to have adverse consequences for at least a small number of unlucky individuals; mounting a rapid and effective response to a public health emergency requires policymakers and providers of countermeasures to take risks that will almost surely be imposed on the public. In such cases, a decision must be made as to who will (and who should) bear the loss when parties are forced to confront those risks by engaging in conduct that benefits both themselves and the general public.

The PREP Act was signed into law as P.L. 109-148 on December 30, 2005. The PREP Act was first applied on January 6, 2007, when HHS declared that "there is a credible risk that the spread of avian influenza viruses and resulting disease could in the future constitute a public health emergency."[86] The declaration triggered a liability shield for anyone involved in producing or distributing a vaccine for avian flu.[87] A vaccine was never developed, so no EUAs were triggered under the declaration.

The next two years would be a period of relative calm. Only one other EUA would be issued during this time, responding to continuing concerns over the threat of anthrax mail attacks. A declaration by HHS led FDA to authorize the use of antibiotic emergency kits containing doxycycline hyclate tablets in response to anthrax exposure in October 2008; the authorization would be renewed repeatedly and is still in effect.[88]

D. 2009: The H1N1 Crisis

The first national health emergency to occur after the enactment of Project BioShield turned out to be a form of influenza other than avian flu. The culprit, a "swine flu" called H1N1, was also a new strain of Influenza A—the same category of virus that had caused the Spanish flu of 1918. The outbreak began in Mexico in March 2009 and spread to the United States in the course of a month; swine flu cases began to appear in the United States in April 2009.[89]

---

[85] *Pandemic Funding, Liability Shield Clear Congress*, CTR. FOR INFECTIOUS DISEASE RES. & POL'Y (Dec. 28, 2005), https://www.cidrap.umn.edu/news-perspective/2005/12/pandemic-funding-liability-shield-clear-congress [https://perma.cc/NF6B-DEBQ].

[86] Pandemic Countermeasures; Declaration Under the Public Readiness and Emergency Preparedness Act, 72 Fed. Reg. 4710 (Feb. 1, 2007).

[87] 42 U.S.C. § 247d-6d (2012).

[88] Authorization of Emergency Use of Doxycycline Hyclate Tablet Emergency Kits for Eligible United States Postal Service Participants in the Cities Readiness Initiative and Their Household Members, 73 Fed. Reg. 62507 (Oct. 21, 2008).

[89] Sarah A. Lister & C. Stephen Redhead, CONG. RSCH. SERV., R40554, THE 2009 INFLUENZA PANDEMIC: AN OVERVIEW (Sept. 10, 2009), https://fas.org/sgp/crs/misc/R40554.pdf [https://perma.cc/HY7E-RLPZ].

Only a handful of cases had been reported across the country when HHS declared an emergency on April 26, 2009, and FDA began issuing EUAs the next day.[90] One EUA was issued for N95 respirators, three for antiviral drugs, and eighteen for diagnostic tests.[91] Almost all were issued during a single year-long period between May 2009 and May 2010, making this the most active period of EUA use as of that time and the second-most active in FDA's history.[92]

FDA's EUA authority enabled a rapid and largely effective response to the outbreak. As with the anthrax vaccine years before, it facilitated unapproved uses of approved drugs. It also enabled FDA to address medical shortages across the country: FDA both authorized use of Tamiflu (an antiviral medicine used to treat influenza) for infants and severely ill patients and expanded access by testing and authorizing expired Tamiflu lots, making Tamiflu more widely available to fight the virus.[93] FDA then authorized expanded use of Relenza and authorized certain expired lots of the drug.[94]

This was also the first time that FDA authorized emergency use of an unapproved product: an antiviral drug called peramivir, which was authorized in October 2009 on the condition that practitioners and patients were given emergency use information pertaining to its use.[95] In doing so, FDA compiled an extensive and transparent collection of information to advise practitioners on the drug's known risks and benefits.[96]

The HHS declaration of emergency in response to swine flu expired in June 2010, and the resulting EUAs were terminated accordingly.

IV. EUAS AFTER H1N1

The period after swine flu saw a return to relatively low levels of EUA activity. In July 2011, a prior EUA issued for anthrax exposure was reauthorized with amendments to include all forms of oral doxycycline and enable mass dispensing of doxycycline kits through the National Postal Model in the event of an anthrax attack.[97] Another EUA would not be issued until April 2013.

A. 2013: PAHPRA

On March 13, 2013, the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) was signed into law by President Barack Obama, reauthorizing the

---

[90] *Id.* at 11.

[91] *Historical Information about Device Emergency Use Authorizations*, U.S. FOOD & DRUG ADMIN. (Oct. 28, 2019), https://www.fda.gov/medical-devices/emergency-situations-medical-devices/historical-information-about-device-emergency-use-authorizations [https://perma.cc/3L7S-BB42].

[92] *Id.*

[93] *See* Letter from Joshua M. Sharfstein, Principal Deputy Commissioner, U.S. Food & Drug Admin., to Richard E. Besser, Acting Director, Ctrs. for Disease Control & Prevention (Apr. 27, 2009), https://www.cdc.gov/swineflu/eua/pdf/fda_letter_tamiflu.pdf [https://perma.cc/E625-4PC8].

[94] *Id.*

[95] Debra Birkrant & Edward Cox, *The Emergency Use Authorization of Peramivir for Treatment of 2009 H1N1 Influenza*, 361 NEW ENG. J. MED. 2204, 2204 (2009).

[96] *Id.*

[97] DEP'T OF HEALTH & HUM. SERVS., *HHS Preparedness Grants Help Cities Plan for Anthrax Attacks*, HHS NEWS (Aug. 1, 2011), https://www.phe.gov/Preparedness/news/Pages/postalgrants-110801.aspx [https://perma.cc/8Y6C-YDBL].

Pandemic and All-Hazards Preparedness Act of 2006 with new additions to enhance emergency readiness. PAHPRA was partly intended to address stockpiling issues faced during the H1N1 affair of 2009.[98] PAHPRA thus signified an expansion in the federal government's scope of awareness to include natural pandemics alongside bioterror, reflecting their experiences with swine flu several years prior.

PAHPRA included a number of revisions to FDA's EUA provisions under the FDCA, several of which made EUA protocol more flexible. For example, PAHPRA removed the word "specified" before "biological, chemical, radiological, or nuclear agent" under § 564(b)(1), allowing even broader grounds for determining the presence or possibility of an emergency warranting an EUA. PAHPRA also added a new and fourth basis on which the Secretary of HHS can make an emergency declaration toward an EUA, grounded in the "identification of a material threat" by the DHS Secretary "sufficient to affect national security or the health and security of U.S. citizens living abroad."[99]

PAHPRA also provided clearer authorization for FDA to issue an EUA in advance of a possible emergency. Authority to issue an EUA originally required a declaration of emergency, often limiting EUAs to an actual emergency; PAHPRA explicitly allowed the Secretary of HHS to declare that "circumstances exist justifying the authorization" of emergency use, offering more discretion in issuing EUAs.[100] These provisions were intended to promote better coordination in the event of a possible crisis by giving time for relevant parties to mobilize and prepare for countermeasures under an EUA.[101] Before PAHPRA, HHS declarations would expire after one year; PAHPRA replaced the time limit with a set of conditions that would significantly extend the duration of EUAs' applicability.[102] PAHPRA also facilitated more efficient execution of emergency countermeasures by permitting FDA to waive standard manufacturing requirements under emergency circumstances[103] and by permitting emergency dispensing of emergency medical products without requiring individual prescriptions for each recipient.[104]

B. 2013–2019: A Long Calm with Six False Starts

By clarifying FDA's scope of authority, PAHPRA enabled FDA to authorize emergency countermeasures in advance of actual emergencies. FDA issued a limited number of EUAs later in 2013 for preparedness purposes to respond to events that emerged in other countries. As described below, the next few years would see an assortment of potential health threats, none of which ultimately materialized in the United States, and the resulting EUAs were few.

---

98 U.S. FOOD & DRUG ADMIN., PANDEMIC AND ALL-HAZARDS PREPAREDNESS REAUTHORIZATION ACT OF 2013 (PAHPRA) MEDICAL COUNTERMEASURE (MCM) AUTHORITIES: FDA QUESTIONS AND ANSWERS FOR PUBLIC HEALTH PREPAREDNESS AND RESPONSE STAKEHOLDERS (Jan. 2014), https://www.fda.gov/media/87718/download [hereinafter PAHPRA MEDICAL COUNTERMEASURE AUTHORITIES] [https://perma.cc/XDW5-AJSX].

99 Federal Food, Drug, and Cosmetic Act § 564(b)(1)(D).

100 *Id.* § 564(b)(1).

101 PAHPRA MEDICAL COUNTERMEASURE AUTHORITIES, *supra* note 100.

102 Federal Food, Drug, and Cosmetic Act § 564(b)(2).

103 *Id.* § 564A(c). *See also* Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders, 82 Fed. Reg. 4362 (Jan. 13, 2017).

104 Federal Food, Drug, and Cosmetic Act § 564A(d).

1. 2013: H7N9

In 2013, a number of cases of H7N9, a novel strain of influenza, were identified in China without sustained human-to-human transmission.[105] The federal government nonetheless took proactive steps in declaring significant potential for an emergency under PAHPRA on April 19, 2013.[106] FDA issued two EUAs for diagnostic tests in February and April 2014[107] and would later issue a third in March 2018.[108] There were limited infections in the United States and few deaths worldwide.

2. 2013: MERS

In 2012, Saudi Arabia experienced an outbreak of MERS-Cov-2, a coronavirus with low rates of human-to-human transmission but a high fatality rate.[109] HHS Secretary Kathleen Sebelius found MERS to have significant potential for a public health emergency justifying EUAs for diagnostic testing on May 29, 2013.[110] FDA issued EUAs for diagnostic tests in June 2013[111] and July 2015.[112] MERS spread across the world over the course of 2014 and 2015, but caused only a handful of cases in the United States.

3. 2014: Enterovirus D68

In August 2014, North America experienced an outbreak of Enterovirus D68. The virus had first been identified in the United States in California in 1962, producing only a handful of cases between 1970 and 2006. The 2014 wave started in Kansas and soon spread across the continent. Approximately 700 people had been infected, and five children had died, by October 2014.[113] HHS Secretary Sylvia Burwell declared

---

[105] CTRS. FOR DISEASE CONTROL & PREVENTION, *H7N9 Update* (Oct. 28, 2013), https://www.cdc.gov/flu/spotlights/h7n9-oct2013-update.htm [https://perma.cc/RPB2-8U6X].

[106] Determination and Declaration Regarding Emergency Use of In Vitro Diagnostics for Detection of the Avian Influenza A (H7N9) Virus, 78 Fed. Reg. 25273 (Apr. 30, 2013).

[107] Letter from Margaret A. Hamburg, Commissioner of Food and Drugs, U.S. Food & Drug Admin., to John Tamerius, Quidel Corp. (Feb. 14, 2014), https://www.fda.gov/media/87767/download [https://perma.cc/V8XD-YJHZ]; letter from Margaret A. Hamburg, Commissioner of Food and Drugs, U.S. Food & Drug Admin., to Peter Lu, Arbor Vita Corp. (Apr. 25, 2014), https://www.fda.gov/medical-devices/emergency-situations-medical-devices/ah7n9-influenza-rapid-test-letter-authorization [https://perma.cc/B982-ZQ38].

[108] Letter from Rachel Sherman, Principal Deputy Commissioner, U.S. Food & Drug Admin., to Anne Schuchat, Acting Director, Ctrs. For Disease Control & Prevention (Mar. 27, 2018), https://www.fda.gov/media/85910/download [https://perma.cc/98AS-JDYA].

[109] Alimuddin Zumla, David S. Hui & Stanley Perlman, *Middle East Respiratory Syndrome*, 386 LANCET 995, 995 (2015).

[110] Determination and Declaration Regarding Emergency Use of In Vitro Diagnostics for Detection of Middle East Respiratory Syndrome Coronavirus (MERS-CoV), 78 Fed. Reg. 33842 (June 5, 2013).

[111] Letter from Margaret A. Hamburg, Commissioner of Food and Drugs, U.S. Food & Drug Admin., to Thomas R. Frieden, Director, Ctrs. For Disease Control & Prevention (June 10, 2014), https://www.fda.gov/media/88518/download [https://perma.cc/PJL9-DKLS].

[112] Letter from Stephen M. Ostroff, Acting Commissioner of Food and Drugs, U.S. Food & Drug Admin., to Sven Cramer, altona Diagnostics GmbH (Feb. 12, 2016), https://www.fda.gov/media/93040/download [https://perma.cc/4FYX-X7FW].

[113] CTRS. FOR DISEASE CONTROL & PREVENTION, *States with Lab-Confirmed Enterovirus D68* (Oct. 10, 2014), https://web.archive.org/web/20141012094650/http://www.cdc.gov/non-polio-enterovirus/outbreaks/EV-D68-states.html [https://perma.cc/YW8C-UTYR].

significant potential for a public health emergency on February 6, 2015.[114] FDA issued one EUA for a diagnostic test on May 12, 2015.[115]

4. 2014: Ebola

In March 2014, West Africa experienced a significant outbreak of Ebola virus.[116] The outbreak had caused over 27,000 infections and 11,000 deaths by late 2015.[117] The federal government took preemptive steps to prevent the outbreak from reaching the United States: HHS declared a potential emergency on August 4, 2014,[118] and FDA issued EUAs for ten in vitro diagnostic tests.[119] The United States experienced only a handful of cases and no deaths.

5. 2016: Zika

Although the Zika virus had existed for decades, a 2016 epidemic of the virus began in Brazil and spread across South and North America.[120] While not typically fatal, the disease was found to cause microcephaly in children of infected mothers, leading WHO to declare a Public Health Emergency of International Concern in February 2016.[121] HHS subsequently declared a potential emergency on February 26, 2016,[122] and FDA issued EUAs for fifteen diagnostic tests from February 2016 through September 2017.[123] Despite considerable panic both at home and abroad, an epidemic never materialized in the United States.

---

[114] Determination and Declaration Regarding Emergency Use of In Vitro Diagnostics for Detection of Enterovirus D68, 80 Fed. Reg. 10685 (Feb. 27, 2015).

[115] Letter from Stephen M. Ostroff, Acting Commissioner of Food and Drugs, U.S. Food & Drug Admin., to Thomas R. Frieden, Director, Ctrs. For Disease Control & Prevention (May 12, 2015), https://www.fda.gov/media/120425/download [https://perma.cc/U3SR-7M73].

[116] CTRS. FOR DISEASE CONTROL & PREVENTION, GUIDELINES FOR EVALUATION OF US PATIENTS SUSPECTED OF HAVING EBOLA VIRUS DISEASE (Aug. 1, 2014), https://stacks.cdc.gov/view/cdc/24830 [https://perma.cc/Z3TR-58Z].

[117] INT'L ORG. FOR MIGRATION, REGIONAL RESPONSE TO EBOLA CRISIS: EXTERNAL SITUATION REPORT (May 29, 2015), https://www.iom.int/sites/default/files/situation_reports/file/IOM_Ebola_Crisis_Response_Programme_External_SitRep_2015-05-29.pdf [https://perma.cc/9N3Y-28UB].

[118] Determination and Declaration Regarding Emergency Use of In Vitro Diagnostics for Detection of Ebola Virus, 79 Fed. Reg. 47141 (Aug. 12, 2014).

[119] *See Emergency Use Authorizations for Medical Devices*, U.S. FOOD & DRUG ADMIN. (Mar. 1, 2021), https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices [https://perma.cc/9NAY-TTDZ].

[120] Tom Miles & Kevin Liffey, *WHO Sees Zika Outbreak Spreading Through the Americas*, REUTERS (Jan. 25, 2016), https://www.reuters.com/article/health-zika/who-sees-zika-outbreak-spreading-through-the-americas-idUSL8N15917Z [https://perma.cc/CMJ9-MR7B].

[121] Sabrina Tavernise & Donald G. McNeil, Jr., *Zika Virus a Global Health Emergency, W.H.O. Says*, N.Y. TIMES (Feb. 1, 2016), https://www.nytimes.com/2016/02/02/health/zika-virus-world-health-organization.html [https://perma.cc/YL8Q-W6YF].

[122] 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 (Mar. 2, 2015).

[123] *See Emergency Use Authorizations for Medical Devices*, U.S. FOOD & DRUG ADMIN. (Mar. 1, 2021), https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices [https://perma.cc/9NAY-TTDZ].

6. 2017: Nerve Agents

On April 11, 2017, HHS declared the potential for an emergency in response to the prospect of poisoning by organophosphorus nerve agents and certain related insecticides.[124] FDA immediately issued an EUA for an autoinjector for delivering treatment upon exposure to organophosphorus substances, which would be reauthorized periodically until the autoinjector gained approval in 2018.[125]

7. 2018: Frozen Plasma

On July 9, 2018, HHS declared that circumstances justified the potential need for freeze-dried plasma in response to emergencies involving weapons used in military combat.[126] FDA issued an EUA on July 16, 2018 for freeze-dried plasma to treat hemorrhage and coagulopathy in emergency situations in which plasma is unavailable or impractical.[127]

***

A series of other bills were signed into law over this period to further facilitate research and development of medical countermeasures in the private sector: 1) the 21st-Century Cures Act of 2016;[128] 2) Public Law 115-92 (2017); and 3) the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA).[129] Public Law 115-92 amended FDCA to allow FDA to issue EUAs in response to an attack involving any agents (as opposed to CBRN agents in particular) that "may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces."[130]

V. EUAS IN RESPONSE TO COVID-19

FDA's response to the COVID-19 pandemic has made the most significant use of EUA authorization since its inception in 2004. H1N1 resulted in twenty-two EUAs over a two-year period; COVID-19 has resulted in over 500 EUAs over the 1.5-year period since WHO declared the outbreak a pandemic and cases first emerged in the United States.

COVID-19 is widely considered the most serious public health emergency in FDA's history. As of August 3, 2021, over 35.2 million cases and 614,000 deaths due to

---

[124] Determination and Declaration Regarding Emergency Use of Injectable Treatments for Nerve Agent or Certain Insecticide (Organophosphorus and/or Carbamate) Poisoning, 82 Fed. Reg. 18152 (Apr. 17, 2017).

[125] *Emergency Use Authorizations*, U.S. FOOD & DRUG ADMIN. (May 16, 2020), https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#nerveagents [https://perma.cc/3B2Z-NLB5].

[126] Emergency Use of Treatment for Uncontrolled Hemorrhage Due to Agents of Military Combat, 83 Fed. Reg. 32884 (July 16, 2018).

[127] Press Release, U.S. Food & Drug Admin., FDA Takes Action to Support American Military Personnel by Granting an Authorization for Freeze-dried Plasma Product to Enable Broader Access While the Agency Works Toward Approval of the Product (July 10, 2018), https://www.fda.gov/news-events/press-announcements/fda-takes-action-support-american-military-personnel-granting-authorization-freeze-dried-plasma [https://perma.cc/K9D9-7A7H].

[128] 21st Century Cures Act, Pub. L. 114-255.

[129] Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, Pub. L. 116-22.

[130] 21 U.S.C. § 360bbb-3(b)(1)(B).

COVID-19 have been reported in the United States.[131] The Secretary of HHS declared the COVID-19 pandemic a public health emergency on February 4, 2020, asserting that the circumstances of the outbreak justified authorization of EUAs for in vitro diagnostic devices.[132] On March 17, 2020, HHS followed up with a notice of declaration under the PREP Act to provide a liability shield for those responding to COVID-19: immunity would extend to "any claim of loss . . . resulting from the manufacture, distribution, administration, or use of medical countermeasures," excluding cases of willful misconduct.[133] FDA also announced its preparedness to implement guidance documents related to COVID-19 without an opportunity for public comment, explaining that "prior public participation will not be feasible or appropriate" in responding quickly to a developing emergency.[134]

A. Categories of EUAs Issued for COVID-19

FDA has since issued what its website describes as three general categories of EUAs: 1) vaccines; 2) drug and biological therapeutic products; and 3) medical devices. Of particular interest are general categories 1) and 2), as well as the subcategories involving in vitro diagnostic products and personal protective equipment:[135]

EUAs Issued in Response to COVID-19[136]

	In vitro diagnostic products	***Personal protective equipment and related devices***	***Other medical devices***	***Drug and biological therapeutic products***	***Vaccines***	***Total***
Date of HHS authorization	February 4, 2020	March 2, 2020	Misc.	March 27, 2020	March 27, 2021	

131 CTR. FOR SYS. SCI. & ENG'G AT JOHNS HOPKINS UNIV., *COVID-19 Map*, JOHNS HOPKINS UNIV., https://coronavirus.jhu.edu/map.html (last updated Aug. 11, 2021) [https://perma.cc/2PEJ-SNNP].

132 Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the FDCA, 85 Fed. Reg. 7316 (Feb. 4, 2020).

133 Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020).

134 Process for Making Available Guidance Documents Related to Coronavirus Disease 2019, 85 Fed. Reg. 16949 (Mar. 25, 2020).

135 Six categories were originally listed on FDA's EUA webpage. As of Aug. 3, 2021, several of those categories appear to have been collapsed into medical devices. *See Emergency Use Authorization*, U.S. FOOD & DRUG ADMIN. (July 30, 2021), https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization [https://perma.cc/ZN39-FNE9].

136 These estimates are derived from multiple FDA webpages spanning FDA's EUA database. *See id. See also* Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: July 30, 2021, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-july-30-2021 [https://perma.cc/2BVD-VDK2].

Number of EUAs in effect as of August 3, 2021 (as reported on FDA's website)[137]	395	50	65	11	3	524

1. In Vitro Diagnostic Products

A steady stream of authorizations for diagnostic products, laboratory tests, and medical and protective devices has continued since the declaration of emergency. Since the first EUA on February 4 for a CDC-developed in vitro diagnostic test for SARS-CoV-2,[138] new in vitro diagnostic products have received EUAs on a daily basis. HHS granted FDA permission to issue EUAs for laboratory tests under certain conditions on March 31, 2020.[139] Rather than wait to give each individual diagnostic provider an EUA, FDA authorized providers to proceed with distributing diagnostic products while FDA reviews those products on a case-by-case basis for individual authorization.[140] FDA announced on March 16 that it would allow serology tests "to be marketed with notification to FDA and certain labeling information, but without submission of an EUA . . . based on the considerations that serology tests are not meant to diagnose active SARS-CoV-2 infection and that early availability and use of these tests could help answer critical questions about the prevalence of COVID-19 infections in different communities."[141]

On April 28, 2020, FDA issued an "umbrella" EUA for antibody tests conducted by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 and validated by the National Institutes of Health's National Cancer Institute (NIH/NCI).[142] FDA followed up with an expanded policy on May 11 "for commercial manufacturers to more rapidly distribute their SARS-CoV-2 diagnostic tests to laboratories for specimen testing after validation, while an EUA is being prepared for submission to FDA."[143] FDA revoked this umbrella policy on July 21, 2020,

---

[137] *Id.*

[138] Letter from Denise M. Hilton, Chief Scientist, U.S. Food & Drug Admin., to Robert R. Redfield, Director, Ctrs. for Disease Control & Prevention (Mar. 15, 2020), https://www.fda.gov/media/134919/download [https://perma.cc/5654-CF4Y].

[139] Authorization of Emergency Use of Certain Medical Devices During COVID-19; Availability, 85 Fed. Reg. 34638 (June 5, 2020).

[140] U.S. FOOD & DRUG ADMIN., POLICY FOR CORONAVIRUS DISEASE-19 TESTS DURING THE PUBLIC HEALTH EMERGENCY (May 4, 2020), https://www.fda.gov/media/135659/download [https://perma.cc/QU6P-XYDL].

[141] *Id.*

[142] U.S. FOOD & DRUG ADMIN., SARS-COV-2 ANTIBODY TESTS (Apr. 28, 2020), https://www.fda.gov/media/137470/download [https://perma.cc/J7EZ-MAGY]; U.S. FOOD & DRUG ADMIN., POLICY FOR CORONAVIRUS DISEASE-19 TESTS DURING THE PUBLIC HEALTH EMERGENCY (May 4, 2020), https://www.fda.gov/media/135659/download [https://perma.cc/2QGM-X4TC] [hereinafter U.S. FOOD & DRUG ADMIN., POLICY FOR CORONAVIRUS DISEASE-19 TESTS].

[143] U.S. FOOD & DRUG ADMIN., POLICY FOR CORONAVIRUS DISEASE-19 TESTS, *supra* note 144.

announcing that it would begin reviewing individual requests for EUAs for antibody tests on a case-by-case basis to ensure compliance with statutory EUA requirements.[144]

2. Personal Protective Equipment and Related Devices

FDA issued an EUA on March 2, 2020 for protective devices such as protective barriers, face shields, decontamination systems, and respirators.[145] Manufacturers and stockpilers of authorized respirators have been exempted from the standard requirement that they submit a formal request for authorization from FDA, due to the urgent need to address widespread shortages.[146]

On April 3, 2020, FDA issued an umbrella EUA for filtering face-piece respirators manufactured in China that lack approval by the National Institutes of Occupational Safety and Health (NIOSH).[147] FDA later found some of the authorized respirators not to meet performance standards, leading them to issue revised versions of the EUA on May 7, 2020 and June 6, 2020 to include new and stricter eligibility criteria.[148] On October 15, 2020, FDA reinstated the original EUA for non-NIOSH-approved facepiece respirators manufactured in China and revoked the added criteria, citing the need to address shortages of respirators.[149]

On May 1, 2020, FDA issued an umbrella EUA for protective barrier devices in the context of treating patients with COVID-19,[150] but revoked it on August 20, 2020.[151] Citing findings that protective barrier devices might not be effective at decreasing exposure to airborne particles and might even pose additional risks with respect to intubation procedures, FDA concluded that the known and potential benefits of such devices no longer outweighed the known and potential risks, and that it would instead consider individual EUA requests for protective barrier devices on a case-by-case basis.[152]

---

[144] *See* Letter from Denise M. Hilton, Chief Scientist, U.S. Food & Drug Admin., to Manufacturers and Other Stakeholders (July 21, 2020), https://www.fda.gov/media/140351/download [https://perma.cc/9YHC-9XWB].

[145] *See* Letter from Denise M. Hilton, Chief Scientist, U.S. Food & Drug Admin., to Robert R. Redfield, Director, Ctrs. for Disease Control & Prevention (Mar. 11, 2020), https://www.fda.gov/media/136023/download [https://perma.cc/7W3B-QM4Q].

[146] *See id.*

[147] *Personal Protective Equipment EUAs*, U.S. FOOD & DRUG ADMIN. (Oct. 21, 2020), https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#nonniosh [https://perma.cc/8XDY-27DW].

[148] *Id.*

[149] Press Release, U.S. Food & Drug Admin., FDA Reissues Emergency Use Authorization for Certain Non-NIOSH-Approved Filtering Face-Piece Respirators Manufactured in China (Oct. 15, 2020), https://www.fda.gov/news-events/press-announcements/fda-reissues-emergency-use-authorization-certain-non-niosh-approved-filtering-face-piece-respirators [https://perma.cc/FW5B-GRY4].

[150] Press Release, U.S. Food & Drug Admin., FDA In Brief: FDA Revokes Emergency Use Authorization for Protective Barrier Enclosures Without Negative Pressure Due to Potential Risks (Aug. 21, 2020), https://www.fda.gov/news-events/fda-brief/fda-brief-fda-revokes-emergency-use-authorization-protective-barrier-enclosures-without-negative [https://perma.cc/E3RA-PVGK].

[151] *See* Letter from Denise M. Hilton, Chief Scientist, U.S. Food & Drug Admin., to Manufacturers of Protective Barrier Enclosures; Health Care Providers; Hospital Purchasing Departments and Distributors; and Any Other Stakeholders (Aug. 20, 2020), https://www.fda.gov/media/141415/download [https://perma.cc/S8QQ-25J5].

[152] *Id.*

3. Drug and Biological Therapeutic Products

Emergency use authorizations for drug products have been considerably more limited. This is unsurprising; whereas tests are relatively non-invasive and medical devices are fairly predictable in their design, manufacture, and application, drugs that enter the body carry a substantially higher risk of unintended adverse effects on the patient. A total of eleven EUAs have been issued for drug treatments since the pandemic began—most notably, one on March 28, 2020 for both chloroquine phosphate and hydroxychloroquine sulfate; one on May 1, 2020 for remdesivir; and one on August 23, 2020 for convalescent plasma containing antibodies against SARS-CoV-2.[153] In all cases, FDA concluded that the drug in question "may be effective" in combating COVID-19 or its respiratory effects and that its "known and potential benefits . . . outweigh the known and potential risks,"[154] finding that "there is no adequate, approved, and available alternative to [emergency use] due to shortages of FDA-approved alternatives during the COVID-19 pandemic."[155] As detailed below, two of those drug products have had their EUA revoked, leaving only five with continued authorization.

4. Vaccines

The development and manufacture of COVID-19 vaccines with unprecedented speed is widely considered one of the United States' few decisive victories against SARS-CoV-2. On December 11, 2020, FDA granted an EUA for the Pfizer-BioNTech COVID-19 vaccine for individuals sixteen years of age and older.[156] FDA then granted an EUA for the Moderna COVID-19 vaccine on December 18, 2021,[157] followed by an EUA for the Janssen COVID-19 vaccine on February 27, 2021.[158] FDA amended the authorizations for the Pfizer-BioNTech and Moderna vaccines on August 12, 2021 to permit a third dose in solid organ recipients and others who are immunocompromised to a comparable degree.[159]

---

[153] *See Emergency Use Authorization*, U.S. FOOD & DRUG ADMIN. (Oct. 22, 2020), https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization [https://perma.cc/8T6G-DJHP].

[154] *See, e.g.*, U.S. FOOD & DRUG ADMIN., REMDESIVIR EUA LETTER OF AUTHORIZATION (May 1, 2020), https://www.fda.gov/media/137564/download [https://perma.cc/B2DQ-C35B].

[155] *See, e.g.*, *id.*

[156] Letter from Denise M. Hilton, Chief Scientist, U.S. Food & Drug Admin., to Elisa Harkins, Pfizer Inc. (Feb. 25, 2021), https://www.fda.gov/media/144412/download [https://perma.cc/3P6V-4UUL].

[157] Letter from Denise M. Hilton, Chief Scientist, U.S. Food & Drug Admin., to Carla Vinals, ModernaTX, Inc. (Feb. 25, 2021), https://www.fda.gov/media/144636/download [https://perma.cc/9X2N-WL7W].

[158] Letter from Denise M. Hilton, Chief Scientist, U.S. Food & Drug Admin., to Ruta Walawalkar, Janssen Biotech, Inc. (Feb. 25, 2021), https://www.fda.gov/media/146303/download [https://perma.cc/K4UV-ND23].

[159] Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Authorizes Additional Vaccine Dose for Certain Immunocompromised Individuals (Aug. 12, 2021), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised [https://perma.cc/42YN-DPQV].

B. Major Developments and Controversies

Unreliable tests and misleading information about testing have posed a problem throughout the pandemic, especially given the prevalence of fraudulent products and unreliable marketing claims by private entities.[160] FDA initially proceeded by issuing umbrella EUAs to address widespread shortages in medical supplies and testing, encouraging providers to bring products to market while FDA reviewed those products on a case-by-case basis. FDA has since revoked several of those umbrella policies and revoked individual EUAs for numerous products found to be unreliable. On May 14, 2020, for instance, FDA reported that a molecular test by Abbott Laboratories was recently reported to demonstrate a high rate of negative results.[161] Regarding antibody tests, FDA acknowledged that "a concerning number of commercial serology tests are being promoted inappropriately . . . or are performing poorly based on an independent evaluation by the NIH."[162] FDA reaffirmed that the agency does "not intend to object as described below where commercial manufacturers develop and distribute their serology tests after validation, for a limited period of time, while an EUA is being prepared for submission to FDA."[163] On June 16, 2020, FDA revoked an EUA granted to Chembio Diagnostic Systems for its DPP antibody test for COVID-19 under Section 654(g)(2)(B) & (C) of the FDCA.[164] FDA explained that upon reviewing the test, it had determined that "it is not reasonable to believe the product may be effective in detecting antibodies against SARS-CoV2 or that the known and potential benefits of the device . . . outweigh its known and potential risks."[165] FDA concluded that "based on the risk to public health from false test results, revocation is appropriate to protect the public health or safety."[166]

---

[160] According to a July 30 report, FDA had received over 1,486 reports of fraudulent products related to COVID-19 as of July 15. *See FDA COVID-19 Response: At-A-Glace Summary as of July 30, 2021*, U.S. FOOD & DRUG ADMIN. (July 30, 2020), https://www.fda.gov/media/137005/download [https://perma.cc/2X8V-MQYD]. FDA has issued over 180 warning letters to entities believed to have been selling fraudulent products related to COVID-19. *See Fraudulent Coronavirus Disease 2019 (COVID-19) Products*, U.S. FOOD & DRUG ADMIN. (July 22, 2021), https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products#Warning%20Letter%20Table [https://perma.cc/Y6N9-KRHE].

[161] Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Informs Public About Possible Accuracy Concerns with Abbott ID NOW Point-of-Care Test (May 14, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-informs-public-about-possible-accuracy-concerns-abbott-id-now-point [https://perma.cc/VKM4-HM5G].

[162] Anand Shah & Jeff Shuren, *Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy*, U.S. FOOD & DRUG ADMIN. (May 4, 2020), https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy [https://perma.cc/3MQT-SPPF].

[163] U.S. FOOD & DRUG ADMIN., POLICY FOR CORONAVIRUS DISEASE-19 TESTS DURING THE PUBLIC HEALTH EMERGENCY (May 4, 2020), https://www.fda.gov/media/135659/download [https://perma.cc/YWQ6-2X7Y].

[164] *See* Letter from Denise M. Hilton Chief Scientist, U.S. Food & Drug Admin., to Dr. Louise M. Sigismondi, Chembio Diagnostic Systems, Inc. (June 16, 2020), https://www.fda.gov/media/139109/download [https://perma.cc/GH3X-47MU].

[165] Press Release, U.S. Food & Drug Admin., FDA Revokes Emergency Use Authorization for Chembio Antibody Test (June 16, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chembio-antibody-test [https://perma.cc/TBV3-UY66].

[166] *Id.*

A number of politically newsworthy events have subjected FDA's EUA power to criticism. One was FDA's June 15, 2020 decision to revoke the EUA it had issued for chloroquine and hydroxychloroquine on March 29, 2020.[167] The EUA for those unapproved antimalarial drugs had come only eight days after President Donald J. Trump's personal and widely publicized endorsement of those drugs on March 21, 2020,[168] with one whistleblower stating that the White House had pressured federal scientists at FDA to prepare the authorization.[169] Yet when clinical trials showed no antiviral effect—and continued research even suggested risks of serious health complications—FDA concluded that it was not reasonable to believe that the drugs' benefits outweighed the risks of authorized use.[170] President Trump responded by publicly urging FDA to reinstate the EUA, calling on them to "Act now" on Twitter.[171] The president made these statements around the same time that he publicly criticized CDC for its stringent guidelines for reopening schools; Vice President Mike Pence announced hours later that CDC would be required to issue new guidelines in response to the president's criticism, stating a refusal to allow "the guidance from CDC to be a reason why schools don't open."[172] Their statements did not go unacknowledged: the CDC Director responded with a public statement assuring the president and vice president that CDC's guidelines were not meant as a "rationale to keep schools closed."[173]

Equally striking was the timing of FDA's decision to grant an EUA for COVID-19 convalescent plasma. Although FDA offered a comprehensive memorandum outlining the evidence they used in deciding to grant the EUA, many were unable to ignore that the EUA arrived the night before the Republican National Convention.[174] The timing

---

[167] *See* Letter from Denise M. Hilton, Chief Scientist, U.S. Food & Drug Admin., to Gary L. Disbrow, Deputy Assistant Secretary, Biomedical Advanced Research & Dev. Auth. (June 15, 2020), https://www.fda.gov/media/138945/download [https://perma.cc/4PB4-TX2D].

[168] Elyse Samuels & Meg Kelly, *How False Hope Spread About Hydroxychloroquine to Treat COVID-19—and the Consequences that Followed*, WASH. POST (April 13, 2020, 3:00 AM), https://www.washingtonpost.com/politics/2020/04/13/how-false-hope-spread-about-hydroxychloroquine-its-consequences/ [https://perma.cc/RYQ9-Y5Z6]; Andrew Solender, *All the Times Trump has Promoted Hydroxychloroquine*, FORBES (May 22, 2020, 5:01 PM), https://www.forbes.com/sites/andrewsolender/2020/05/22/all-the-times-trump-promoted-hydroxychloroquine/#402ed75c4643 [https://perma.cc/TR7F-2XFP].

[169] Toluse Olorunnipa, Eunjung Cha & Laurie McGinley, *Drug Promoted by Trump as Coronavirus "Game Changer" Increasingly Linked to Deaths*, WASH. POST (May 15, 2020, 6:41 PM), https://www.washingtonpost.com/politics/drug-promoted-by-trump-as-coronavirus-game-changer-increasingly-linked-to-deaths/2020/05/15/85d024fe-96bd-11ea-9f5e-56d8239bf9ad_story.html [https://perma.cc/D29W-VNVJ].

[170] *See* Letter from Denise M. Hilton, Chief Scientist, U.S. Food & Drug Admin., to Gary L. Disbrow, Deputy Assistant Secretary, Biomedical Advanced Research & Dev. Auth. (June 15, 2020), https://www.fda.gov/media/138945/download [https://perma.cc/CHJ7-6R6G].

[171] Aaron Blake, *Trump is Making it Harder and Harder to Escape Blame on the Coronavirus*, WASH. POST (July 8, 2020, 3:42 PM), https://www.washingtonpost.com/politics/2020/07/08/trump-is-making-it-harder-harder-escape-blame-coronavirus/ [https://perma.cc/5FJT-AKUY].

[172] John Wagner, *CDC Will Issue New Guidance on School Openings, Pence Says, After Criticism from Trump*, WASH. POST (July 8, 2020), https://www.washingtonpost.com/politics/trump-administration-officials-downplay-guidance-from-health-experts-as-they-push-to-reopen-schools/2020/07/08/236a6c5e-c13b-11ea-b178-bb7b05b94af1_story.html [https://perma.cc/A35W-P6J4].

[173] *Id.*

[174] Paige Winfield Cunningham, *Health 202: Trump Played Up a Coronavirus Treatment on the Eve of the Republican National Convention*, WASH. POST (Aug. 24, 2020), https://www.washingtonpost.

of these events led to widespread concern by scientific experts over apparent political interference in public health policy.[175]

The question of whether, and how, to grant emergency authorization to a potential COVID-19 vaccine also proved controversial. With the health industry racing to develop a vaccine with breakneck speed, the federal government pledged $500 million to biotechnology company, Moderna, to produce a vaccine.[176] Moderna in turn partnered with Lonza, a foreign manufacturing company, in the hope of manufacturing one billion doses.[177] President Trump announced his appointment of several new vaccine-related expert officials on May 15, 2020, one of whom claimed to have "very recently seen early data from a clinical trial" that made him "feel even more confident" about the possibility of preparing a vaccine by the end of 2020.[178] In September of 2020, FDA issued a list of topics for which it intended to offer clearer guidance, including EUAs for vaccines.[179] FDA officials separately announced their intent to provide stricter standards—or "EUA-plus"—in deciding whether to grant emergency authorization to a potential COVID-19 vaccine.[180] President Trump responded by stating that he "may or may not approve" such guidelines, consistent with other statements by the president calling for a vaccine to be ready in time for the upcoming presidential election.[181] These clashes and reversals of policy have engendered criticism among policy experts and scientists alike, raising concerns over health agencies' insulation from political pressure by interested parties and nonexperts in authorizing products whose efficacy and safety have not been confirmed at the usual standard of review.[182]

---

com/politics/2020/08/24/health-202-trump-played-up-coronavirus-treatment-eve-republican-convention/ [https://perma.cc/BD37-W2QH].

[175] *See, e.g.*, Rachel Sachs, *Understanding the FDA's Controversial Convalescent Plasma Authorization*, HEALTH AFF. BLOG (Aug. 27, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200827.190308/full/ [https://perma.cc/T25Q-DUSK].

[176] Jonathan Salzman, *Federal Government Pledges Up to $483m to Speed Moderna's Coronavirus Vaccine*, BOSTON GLOBE (Apr. 16, 2020, 10:08 PM), https://www.bostonglobe.com/2020/04/16/business/federal-government-pledges-up-nearly-500m-speed-modernas-coronavirus-vaccine/ [https://perma.cc/FB5C-AW7G].

[177] *See* Leah Rosenbaum, *Fueled by $500 Million of Federal Cash, Moderna Races to Make Billion Doses of an Unproven Cure*, FORBES (May 8, 2020, 6:30 AM), https://www.forbes.com/sites/leahrosenbaum/2020/05/08/fueled-by-500-million-in-federal-cash-moderna-races-to-make-1-billion-doses-of-an-unproven-cure/#13af72b479dc. [https://perma.cc/2ZRQ-58V3].

[178] David Smith, *Trump Unveils "Warp-Speed" Effort to Create Coronavirus Vaccine by Year's End*, THE GUARDIAN (May 16, 2020, 11:45 PM), https://www.theguardian.com/us-news/2020/may/15/trump-coronavirus-warp-speed-vaccine-white-house [https://perma.cc/S4NQ-MHJ5].

[179] *See* U.S. FOOD & DRUG ADMIN., GUIDANCE AGENDA: GUIDANCE DOCUMENTS CBER IS PLANNING TO PUBLISH DURING CALENDAR YEAR 2020 (Sept. 2020), https://www.fda.gov/media/120341/download [https://perma.cc/4V5L-2SGN].

[180] Sarah Owermohle, *Marks: Prepare for "EUA-Plus" for Covid Vaccines*, POLITICO (Sept. 11, 2020, 12:06 PM), https://www.politico.com/newsletters/prescription-pulse/2020/09/11/marks-prepare-for-eua-plus-for-covid-vaccines-790343 [https://perma.cc/XG5R-4YEM].

[181] *See* Sheryl Gay Stohlberg, *Trump May Reject Tougher F.D.A. Standards, Calling them "Political,"* N.Y. TIMES (Sept. 23, 2020), https://www.nytimes.com/2020/09/23/us/politics/coronavirus-science.html [https://perma.cc/3V58-LYME].

[182] *See* Robert P. Baird, *Can Trump Really Speed Approval of Covid Treatments?*, N.Y. TIMES (Oct. 10, 2020), https://www.nytimes.com/2020/10/10/health/covid-vaccine-treatment-fda-emergency.html [https://perma.cc/AN7S-3D8Y]; *see also* Kyle Thompson & Herschel Nachlis, *Emergency Use*

VI. REFLECTIONS

A. The Legacy of the War on Terror

The first two decades of the 21st Century have seen a shift toward swifter measures for getting urgently needed drugs and medical devices to market. The impetus within the federal government to prepare for the risk of infectious diseases largely reflected a broader anxiety about public health and safety emergencies in light of the September 11 terror attacks. The 2001 attacks had a tremendous effect on the federal government's health policy outlook, resulting in comprehensive changes oriented to the threat of a bioterror attack. NIAID divided pathogens into three priority categories, with pathogens such as anthrax, smallpox, and plague—all prime suspects for being weaponized into bioterror agents—being given highest priority under Category A.[183] Prospects of an anthrax attack in particular were on the American mind. Anthrax was considered such a pressing concern that NIAID director Anthony Fauci was reported to have taken an active role since 9/11 in funding startup companies' efforts to develop an anthrax vaccine—even drawing some criticism for his aggressive efforts at funding rival companies to compete with one another.[184]

Discussing Project BioShield on the House floor, Representative Billy Tauzin made clear how thoroughly rooted these proposals were in concerns about terrorism:

> As my colleagues will recall, right after 9/11 it became clear to us as a Nation that we were under serious threat of attacks from agents like anthrax or perhaps even such horrible agents as botulism toxin or ebola or other similar viruses and that we were so unprepared in this country for that kind of attack that we got together . . . and immediately passed an act to bolster the competence and the ability of the Center for Disease Control and of agents across the country to better respond to an attack of that nature.
>
> Since the passage of those two very important actions that have better armed our country for this danger that we face perhaps even more increasingly as years go by, it has come to our attention that there were some holes even in that great act. The most important hole which this act seeks to fill is the concern we have that when it comes to some of these agents, whether they be a botulism toxin agent, ebola, or whether it is a radioactive type of attack we have to deal with in this country, that we have not done enough research and development into the antidotes, the vaccines, the treatments that victims of these attacks might find are critically necessary to save lives and prevent injury.[185]

Authorization During the COVID-19 Pandemic: Lessons From Hydroxychloroquine for Vaccine Authorization and Approval, 324 JAMA 1282, 1282 (2020).

[183] *See* Bernard Wysocki, Jr., *Agency Chief Spurs Bioterror Research—and Controversy*, WALL STREET J. (Dec. 6, 2005, 12:01 AM), https://www.wsj.com/articles/SB113383825463714813 [https://perma.cc/MX38-GD46].

[184] *See id.*

[185] 150 CONG. REC. H5730 (daily ed. July 14, 2004) (statement of Rep. Tauzin).

Tauzin characterizes Project BioShield as a follow-up on and revision to prior legislation focused exclusively on the threat of bioterrorism. By describing BioShield as one component of a more comprehensive legislative response to the September 11 terror attacks, he places BioShield and its underlying legislative intent firmly within the post-9/11 paradigm of the War on Terror. His appeal to the importance of medical responses to infectious diseases, by phrasing them in terms of "attacks" akin to "a radioactive type of attack," further underscores Congress's counterterrorist mindset.

Even a liberal Democrat like then-Representative Sherrod Brown, in calling for caution, referred to Project BioShield as a "promising weapon in the battle against terrorism" and commended the legislation on the basis that "[t]he United States, and the global community, can only benefit from the development of bioterrorism countermeasures."[186] However, Brown went on to warn against devoting excessive funding to bioterrorism at the expense of research areas such as cancer and Parkinson's Disease, asserting that "bioterrorism . . . is just one enemy in a much broader war against disease and disability."[187] By associating Project BioShield with bioterrorism in contrast to a "much broader war against disease," Brown seemed to portray Project BioShield as a counterterrorism measure specifically, rather than a general-purpose protection against public health emergencies that included pandemics of both human and natural origin.[188] This phrasing suggests that even among more skeptical reviewers, the emergency measures comprising Project BioShield were viewed primarily, if not exclusively, through the counterterror lens of the time.

Other legislators also saw the prospect of future infectious disease outbreaks through the lens of bioterrorism. Representative Joe Barton, for example, stated that the bill was intended "to deal with those . . . agents that pose a material threat to our national security. This list includes anthrax, the plague, ebola and other similar viruses, many of which lack any effective treatment or antidote today."[189] To the extent that Congress considered infectious outbreaks, their foresight was limited to viruses being deliberately weaponized for acts of terrorism, as opposed to influenza or other naturally occurring viruses with a more extensive history of destruction. (Even Representative Brown's reference to diseases of non-terrorist origin made no mention of viral pandemics—only chronic diseases.) It is striking to look back from our current place in epidemiological history at Representative Tauzin's statement that "[w]e know the attack may come in a place we do not know, in a place we are unprepared for, and it might involve . . . some horrible virus or some agent the likes of which we are unprepared to deal with."[190]

Meanwhile, testimony by government scientists at congressional hearings demonstrated how concerned the public health community had become about the threat of a global pandemic, particularly in light of a steady international rise in avian flu cases. Some argued that the United States' emphasis on combating bioterrorism specifically—and its focus on the War on Terror—had distracted the federal government from taking a broader and more realistic stance on national emergencies of natural origin. In the words of Dr. Martin Blaser, President of the Infectious

---

186 150 CONG. REC. H5730 (daily ed. July 14, 2004) (statement of Rep. Brown).

187 *Id.*

188 *Id.*

189 150 CONG. REC. H5729 (daily ed. July 14, 2004) (statement of Rep. Barton).

190 150 CONG. REC. H5730 (daily ed. July 14, 2004) (statement of Rep. Tauzin).

Diseases Society of America, in testimony before the Subcommittee on Health of the House Committee on Energy and Commerce:

> Policymakers have recognized the urgent need to spur biodefense R&D, which led to the establishment of Project BioShield. While concern about bioterrorism is appropriate, it is important to keep things in perspective. Not one American has died from bioterrorism since President Bush first announced Project BioShield in February of 2003, but drug-resistant bacterial and other infections have killed hundreds of thousands of Americans in hospitals and communities across the United States and millions of people across the world during that same short period of time.[191]

In 2005, President George W. Bush called on Congress to direct $7.1 billion dollars in appropriations toward preparing for an influenza pandemic, almost all of which would be directed to HHS to research and stockpile drugs and vaccines.[192] Many health experts praised the President's generally proactive stance, though Democrats in the Senate argued that more spending would be needed to address the threat.[193]

In March 2006, the Council of State and Territorial Epidemiologists testified before the Subcommittee on Labor, Health and Human Services, Education, and Related Agencies of the House Committee on Appropriations. Urging the Committee to direct more extensive funding to research on influenza pandemics, they asserted that they were not alone in their concerns. In his 2006 testimony, Dr. Blaser urged the Committee "to extend [Project BioShield's] scope beyond products intended to address bioterrorism-related pathogens and apply current incentives to products to be used against naturally occurring infectious diseases," and to update Project BioShield to "eliminate disincentives and to spur infectious diseases product development both related to naturally occurring infections and biodefense."[194]

Turning to the risk of pandemics in particular, Dr. Blaser went on to explain that "vaccines and diagnostics are needed across the spectrum of infectious disease medicines, including to address the growing threat of pandemic flu."[195] He offered a grim and prescient warning about the rise of pandemics—and about the United States' level of readiness:

> The impact of an influenza pandemic cannot be overstated. The CDC estimates that between 100,000 and 250,000 U.S. deaths would result from a "mild" pandemic, and that 900,000—2 million Americans will die

---

[191] *Project Bioshield Reauthorization Issues: Hearing Before the J. Comm. on Energy & Commerce*, 109th Cong. 60 (Apr. 6, 2006) (statement of Dr. Martin Blaser, President, Infectious Diseases Society of America).

[192] Gardiner Harris, *Bush Announces Plan to Prepare for Flu Epidemic*, N.Y. TIMES (Nov 2, 2005), https://www.nytimes.com/2005/11/02/politics/bush-announces-plan-to-prepare-for-flu-epidemic.html [https://perma.cc/GEH9-XQWR].

[193] *Id.*

[194] *Project Bioshield Reauthorization Issues: Hearing Before the J. Comm. on Energy & Commerce*, 109th Cong. 59 (Apr. 6, 2006) (statement of Dr. Martin Blaser, President, Infectious Diseases Society of America).

[195] *Id.*

> from a virus as bad as the 1918 virus. . . . H5N1 avian influenza has spread rapidly in the past few months to more than 40 countries in Asia, Africa, the Middle East and Europe. Experts agree that it is only a matter of time before it appears among birds in North America. . . . Fortunately, the virus is not yet capable of easily spreading from person to person; should this happen, a dramatic pandemic will occur. Despite the increased attention and progress that has been made in preparing for an influenza pandemic, the Institute of Medicine and virtually all experts conclude that the United States is woefully unprepared to sufficiently respond to pandemic flu and many gaps and challenges remain.[196]

***

In 1978, Harvey Feinberg and Richard Neustadt reflected on the federal government's missteps in 1976 in preparing for a swine flu epidemic that never materialized. They worried that because of both the government's reaction to the threat and the ensuing backlash, "the lessons of the crash program [were] learned too well—too literally—producing stalemate in the face of the next out-of-routine threat from influenza. Someday there will be one."[197]

Is it possible that the United States overlearned the lessons of the apparent failure of the 1976 swine flu effort—becoming too complacent about the prospects of future pandemics—and that it had taken a different sort of national security crisis to mobilize the efforts needed to achieve an adequate level of readiness? One could argue that the government's focus on terrorism was a classic case of myopia and misguided attention, driven by jingoistic tropes of Western Judeo-Christian heroes versus Islamic villains, at the expense of scientifically informed preparedness for more credible health emergencies. Yet one also wonders whether, given the background lack of national attention to pandemics, adequate steps would have been taken without the response to 9/11—the anxiety about disasters in densely populated areas, the eagerness to reallocate money and create new legal authorizations, and indeed, the introduction of national emergencies as an organizing principle in foreign and domestic policy. It might well have taken this more sensational type of national emergency (one of human origin) to compel the federal government to ready itself for large-scale health-related emergencies of any kind.

It is hard to convince the general public of high-magnitude threats with low probabilities. The same arguably is true for their elected representatives—who, given the recency of the 9/11 attacks, were more focused on combating a salient specter of terrorism than on more plausible threats for which they lacked the relevant scientific expertise.[198] The United States had not confronted a pandemic since the Spanish flu of

---

[196] *Id.* at 61.

[197] RICHARD E. NEUSTADT & HARVEY V. FINEBERG, THE EPIDEMIC THAT NEVER WAS: POLICY-MAKING AND THE SWINE FLU SCARE AT XXVI (1st ed. 1983).

[198] This is especially striking when one tries to compare the number of lives lost during the terror attacks on 9/11 to that of COVID-19. By December 2020, the U.S. was averaging about as many COVID-19-related deaths per day as the total number of deaths related to 9/11: 3,124 deaths from COVID-19 on December 9, 2020, compared to 2,977 deaths on September 11, 2001. *See* Dylan Scott, *America's Failures Have Led to a New Daily Record in COVID-19 Deaths*, VOX (Dec. 30, 2020, 1:50 PM), https://www.vox.com/coronavirus-covid19/2020/12/3/22150299/us-covid-19-deaths-yesterday-record-9-11 [https://perma.cc/6VGK-W5EH]; Heather Hollingsworth, *One-Day US Deaths Top 3,000, More than D-Day or 9/11*, U.S. NEWS & WORLD REP. (Dec. 10, 2020), https://www.usnews.com/news/health-news/

1918, but it had just suffered a violent terrorist attack claiming thousands of lives. In Fineberg's words, "the public, like many experts, has a hard time separating likelihood from severity. Estimation of risk is difficult when the observable instances are widely separated in time, as with pandemic influenza."[199] That became less of an issue for pandemic influenza in light of the swine flu crisis of 2009; only then does governmental rhetoric appear to have ramped up its focus on combating infectious diseases of natural origin.

B. The Legacy of H1N1

There is reason to think that H1N1, as the first U.S. public health emergency since the emergence of EUA authority, altered the federal government's outlook on the range of threats to public health and the associated framework of emergency laws tracing back to Project BioShield. Public health officials had been keeping a watchful eye on avian flu (H5N1) developments abroad for years; one CDC official described the appearance of H5N1 in China as a "wake-up call" that galvanized the U.S. government to prepare for a similar outbreak.[200] Even so, the difficulties faced by the United States in responding swiftly to H1N1 in 2009 might have helped to shift the government's view of threats to public health away from bioterrorism and toward naturally occurring infectious diseases.

One prominent example comes from the Biomedical Advanced Research and Development Authority (BARDA). Congress had established BARDA as part of the 2006 Pandemic and All-Hazards Preparedness Act (PAHPA) to coordinate private-sector production of medical countermeasures in preparation for public health emergencies.[201] Years later, BARDA offered a reflection on the federal government's efforts to address the swine flu crisis:

> The recent response to 2009 H1N1 shows that we are still hampered by the limits of current technology. The first domestic cases of 2009 H1N1 influenza were identified in April and the pandemic peaked about six months later, in late October. Despite an intensive effort to develop a pandemic vaccine, the 2009 H1N1 vaccine arrived too late to have a significant effect on the dynamics of the fall disease wave. Influenza vaccines licensed in the United States use egg-based technology that is more than 50 years old and a substantial portion of the manufacturing capacity is based overseas.[202]

---

articles/2020-12-10/one-day-us-deaths-top-3-000-more-than-d-day-or-9-11 [https://perma.cc/WY23-Z9GM].

[199] Harvey V. Feinberg, *Preparing for Avian Influenza: Lessons from the "Swine Flu Affair,"* 197 J. INFECTIOUS DISEASES S14, S17 (2008).

[200] Donald G. McNeil, Jr., *Avian Flu Fears Said to Help U.S. Prepare for Swine Flu*, N.Y. TIMES (June 4, 2009), https://www.nytimes.com/2009/06/05/health/policy/05flu.html [https://perma.cc/WQ48-BZ5R].

[201] P.L. 109-417 (2006); 42 U.S.C. § 247d-7e(c) (2012).

[202] BIOMEDICAL ADVANCED RESEARCH & DEV. AUTH., BARDA STRATEGIC PLAN 2011–2016 (2011), http://www.phe.gov/about/barda/Documents/barda-strategic-plan.pdf [https://perma.cc/6YYZ-P77K] [hereinafter BARDA, BARDA STRATEGIC PLAN 2011–2016].

BARDA states on its website that its overall approach to combating infectious diseases is informed by, among other things, "the many lessons learned from the 2009 H1N1 influenza pandemic response."[203] And the introductory message to BARDA's Strategic Plan 2011–2016, written by director Robin A. Robinson, indicates a shift in national health policy outlook away from focusing primarily on bioterrorism: his message reflects on the country's ten-year effort to prepare for "catastrophic events such as bioterrorist events and pandemic influenza," as well as BARDA's vision of offering "medical countermeasures for Chemical, Biological, Radiological, and Nuclear threats, pandemic influenza, and emerging infectious diseases."[204] Similarly, the document's introduction reflects on a decade of "naturally emerging outbreaks of high-consequence infectious diseases, including pandemic influenza and SARS," as well as "the dramatic spread of antimicrobial resistance and community outbreaks of multidrug-resistant bacteria that had previously been confined to hospitals."[205] If BARDA's overarching language offers any indication, the federal government—or, at least, crucial constituent agencies—had begun by 2011 to shift its general focus away from the strictly counterterrorist mindset of the post-9/11 decade toward a more watchful emphasis on the prospect of a microbial war on multiple fronts.

VII. THE FUTURE OF EMERGENCY USE AUTHORIZATION

Having reviewed the history of EUAs, what lessons can we learn regarding the ethical and political context of EUA authority? And what are the ethical implications of deciding whether—and, if so, on what conditions—to implement an EUA for a high-stakes medical product, such as a vaccine?

A. The Fog of War

It is hard not to look back at the counterterror origins of FDA emergency authority and wonder whether traces of that mindset live on today. EUA legislation had its origins in the threat of bioterrorism. The introductory language of Project BioShield states that the statute's purpose is "to provide protections and countermeasures against chemical, radiological, or nuclear agents that may be used in a terrorist attack against the United States . . . ."[206] The surrounding rhetoric likewise reflects a pervasive association of public health emergencies with terror attacks. The most consistent issuance and renewal of EUAs has been for countermeasures against bioterror and military emergencies. Furthermore, the enactment of the PREP Act in 2005 points to a Congress that appears to have been more interested in shielding providers of emergency countermeasures from liability than in ensuring a well-funded compensation system for injured parties. One might wonder whether any of those members of Congress, steeped in the counterterror mindset of the time, might have justified a diminished concern for injured parties by viewing those parties as "casualties of war."

---

[203] *BARDA Strategic Plan 2011–2016*, U.S. DEP'T HEALTH & HUM. SERVS., http://www.phe.gov/about/barda/Pages/2011barda-stratplan.aspx [https://perma.cc/3TKF-DT8Y] (last visited June 5, 2021).

[204] BARDA, BARDA STRATEGIC PLAN 2011–2016, *supra* note 205.

[205] *Id.*

[206] Pub. L. No. 108-276, 118 Stat. 835 (2004).

Put differently, does the historical context of EUA authority point to a preoccupation with terrorism and an analogy to war that could affect the way policymakers conceptualize public health crises? While the notion of the "fog of war" might indeed apply to the difficulty and uncertainty involved in making public health decisions during an emergency, could it also lend hasty justification to unnecessary sacrifices made in the interest of a quick victory? Framing national emergencies in the language of war, enemies, and victory should not lead to an excessively cavalier handling of the risks involved in combatting a pandemic. It is important that the logic of war not lead policymakers to strike a regrettable tradeoff between conquering the enemy (e.g., a virus) and minimizing collateral damage (adverse side effects of a drug treatment or vaccine and lack of access to compensation).

B. Increasing Regularization of EUAs

Issuances of EUAs were significant in the early years of Project BioShield and the PREP Act. PAHPRA significantly enhanced EUA protocol to make it easier and more powerful to use, and issuance of repeated EUAs preemptively and during proto-emergencies began to develop a precedent of more regular use. With the explosion of EUAs during the current COVID-19 crisis, EUAs might well become standard practice, especially if pandemics grow increasingly common or severe in the future.[207]

It is worth considering how best to regulate these channels once the current crisis ends. Having the option to authorize emergency uses might well come in handy in times of crisis. If it is increasingly relied on, however, regulators and private parties might grow too accustomed to its use—and too relaxed about applying it in situations that only questionably fit the bill. The worry is that emergency use might offer too tempting an opportunity for future parties to cut corners in bringing their products to market, either in the absence of an emergency or in the name of one.[208] Requiring a declaration of emergency from HHS—a different agency—should in theory help to keep EUA power in check. Even so, one is reminded of the old saying that "whatever can happen, will happen." An attractive passageway seldom stays hidden from passing ships. History might rarely offer direct lessons, but if it teaches us anything, it might be that short-term solutions tend to have long-lasting effects—specifically, that people rarely underuse a known shortcut, and such channels, once opened, tend to invite exploitation.

C. Protecting Against Political Pressure

Examples of such exploitation require little imagination. We have already witnessed two presidents who pushed hard during their reelection campaigns for quick fixes to

---

[207] Helen Regan, *Future Pandemics Will Be Deadlier If We Don't Change Our Behavior, Scientists Say*, CNN (Apr. 28, 2020, 3:31 AM), https://www.cnn.com/world/live-news/coronavirus-pandemic-04-28-20-intl/h_61c2b7cb27f1154b533d41bab08dfb48 [https://perma.cc/6KFU-6DHX].

[208] As an analogy, some worry that FDA's "generally recognized as safe" policy for food additives has morphed from an occasional exception to standard protocol into a common shortcut through an overburdened/backlogged system. *See, e.g.*, Ctr. for Pub. Integrity, *Why the FDA Has Never Looked at Some of the Additives in Our Food*, NPR (April 14, 2015, 3:28 PM), https://www.npr.org/sections/thesalt/2015/04/14/399591292/why-the-fda-is-clueless-about-some-of-the-additives-in-our-food [https://perma.cc/7HZJ-XJY2]. Others have complained that loopholes in the Orphan Drug Act similarly have allowed pharmaceutical companies to take advantage of provisions that supposedly apply only to drugs meant to treat rare diseases. *See, e.g.*, GERALD POSNER, PHARMA: GREED, LIES, AND THE POISONING OF AMERICA 520 (2010).

real or anticipated public health emergencies. Gerald Ford insisted on preparing a national swine flu vaccine on the eve of an election. Donald Trump initially refused to acknowledge the existence of a major public health threat and refused to make use of available administrative resources to address COVID-19—out of apparent concern that doing so might depress a rising stock market[209]—yet later made aggressive efforts to use certain of those resources in time for an upcoming election. His call to authorize chloroquine and hydroxychloroquine was particularly public and forceful,[210] as was his pushback against FDA's proposed "EUA-plus." Given these experiences, Congress might consider whether further measures could be used to insulate the process from political influence and hold decisionmakers accountable without compromising the streamlined nature of the EUA process. Additional safeguards might help to prioritize scientific expert authority and protect the integrity of FDA's decision making against political pressure, including from the White House.[211]

D. The Limits of EUA Efficacy

Although the United States' response to COVID-19 has been weighed down by shortages of supplies such as masks and ventilators, the federal government had in place a statute capable of mobilizing a significant effort against a pandemic. From a strictly regulatory standpoint, the federal government, and FDA in particular, was remarkably well-prepared for the current crisis. Whether government officials as a whole were adequately coordinated or took the threat seriously enough—whether they made the best and earliest possible use of the available resources—is a separate question.[212] If the pre-EUA past has taught us the value of having emergency shortcuts, the present is teaching us a pointed and somber lesson of equal magnitude. It might be true that responsible and well-intentioned government actors can be only as effective as the law enables them to be. Yet the reverse is also true: the existing mechanisms of rapid response, emergency powers included, are only as effective as the government actors putting them to use. Authorization to distribute drugs and devices from a national stockpile can succeed only if policymakers are willing to build and maintain that stockpile and deploy it prudently. A successful emergency response depends on several variables, including funding, time to prepare, and, crucially, willingness among public officials to take action. FDA's EUA authority, rather than being sufficient to handle a health crisis, is one among a panoply of necessary conditions.

---

[209] *See generally* BOB WOODWARD, RAGE (2020).

[210] President Trump tweeted on March 21 that "HYDROXYCHLOROQUINE & AZITHROMYCIN, taken together, have a real chance to be one of the biggest game changers in the history of medicine" and that they should be "put in use IMMEDIATELY. PEOPLE ARE DYING, MOVE FAST, and GOD BLESS EVERYONE!" The President's tweet tagged the Twitter handles for FDA Commissioner Stephen M. Hahn, FDA, CDC, and the Department of Homeland Security. Andrew Solender, *All the Times Trump has Promoted Hydroxychloroquine*, FORBES (May 22, 2020, 5:01 PM), https://www.forbes.com/sites/andrewsolender/2020/05/22/all-the-times-trump-promoted-hydroxychloroquine/#402ed75c4643 [https://perma.cc/8AWS-E446].

[211] Lest the risk of political pressure seem remote, see Laurie McGinley, Josh Dawsey, Yasmeen Abutaleb & Carolyn Y. Johnson, *Trump Rails Against 'Medical Deep State' After Pfizer Vaccine News Comes After Election Day*, WASH. POST (Nov. 12, 2020, 12:08 AM), https://www.washingtonpost.com/politics/2020/11/11/trump-angry-about-pfizer-vaccine/ [https://perma.cc/PQY6-F7Y4].

[212] *See, e.g.*, Garrett M. Graff, *An Oral History of the Warnings Trump Ignored*, WIRED MAG. (Apr. 17, 2020, 6:00 AM), https://www.wired.com/story/an-oral-history-of-the-pandemic-warnings-trump-ignored/ [https://perma.cc/HQT4-YH8L].

One cannot ignore the context in which EUAs were developed and are being applied. They are part of an overarching policy scheme toward pandemics that involves multiple interrelated components—not only prevention, diagnosis, and treatment, but also arrangements to compensate those affected by unintended consequences, and incentives and protections for suppliers of countermeasures. Congress must decide what its policy will be. One related question is whether FDA will be given permission to strike tradeoffs different from those it usually strikes between caution and speed. Other concerns, such as those involving vaccine liability and compensation, do not directly address EUA authority but do interact with it. If companies are shielded from liability against injured parties, that eliminates a natural incentive to ensure high standards of care to minimize the risk of damaging side effects; there may accordingly be greater reason for caution in reducing the stringency of review when testing those products for safety and efficacy. One cannot evaluate the proper use of FDA's emergency authorization powers without considering the broader policy ecosystem in which they operate.

E. Policy and Ethical Issues for COVID-19 and Beyond

The controversy over DDI during the AIDS crisis exemplified a core ethical dilemma: when do the circumstances justify taking risks in times of emergency, especially when the nature, magnitude, and likelihood of those risks are unknown? This incident embodied the clash between cautious restraint on the one hand, and pragmatism driven by urgency and desperation on the other—between following protocol and saving lives faster. Some would channel the famous phrase, "better the devil you know than the devil you don't." Others might argue that when the stakes are high enough, the opposite becomes true.

This applies to FDA's response to COVID-19 as well. Antimalarial drugs that were initially granted EUAs for COVID-19 patients are now believed to have considerable side effects.[213] Although FDA ultimately revoked its EUA for chloroquine and hydroxychloroquine, the decision to do so was unexpected and by no means certain to happen. Even when FDA revokes an EUA for a given drug, countless patients could receive that drug and experience adverse side effects in the time it takes FDA to implement the revocation. Other drugs with their own possible risks are likely to come under consideration as the COVID-19 pandemic continues and will surely come under consideration in emergencies to come. They will pose similar questions as to how best to evaluate tradeoffs in uncertain and high-stakes situations.

1. Essential Policy and Ethical Considerations

FDA's EUA authority raises a number of fundamental and challenging policy and ethical questions. How to weigh the practical efficiency of emergency powers against the possibility that reduced safeguards would increase the risk of harm to individuals? How to weigh the value of using emergency powers against the risk that they will open the door to undue political influence? And if the risks of harm or abuse are sufficiently real, should such emergency powers even be available to the agency in the first place?

The history of EUA authority raises several key considerations bearing on these questions. Debates over the administration of DDI during the AIDS crisis reflected the

---

[213] U.S. FOOD & DRUG ADMIN., FACT SHEET FOR PATIENTS AND PARENT/CAREGIVERS: EMERGENCY USE AUTHORIZATION (EUA) OF REMDESIVIR FOR CORONAVIRUS DISEASE 2019 (COVID-19) (June 2020), https://www.fda.gov/media/137565/download [https://perma.cc/DDH8-T79P].

sense of urgency posed by public health emergencies in light of the apparent value of bringing unapproved products to market for practical reasons.[214] Yet instances of governmental haste in seeking to vaccinate the public in time for a presidential reelection underscore the need to proceed with caution, because the risk of undue political influence on agency scientists' decision-making process is not merely theoretical. In addition, past efforts at mandatory vaccination among the military in the case of AVA point to thorny questions about personal autonomy.

It may be helpful to consider three alternative frameworks or approaches through which to analyze the ethics of EUAs, taking into account the EUA experience to date. These approaches apply both with respect to the possible issuance of EUAs for specific products in specific circumstances and with respect to the broader question of whether to allow EUAs at all:

- *Outcome-oriented:* The first approach would maintain that FDA should weigh the total benefits and risks of making the product in question available on an accelerated basis against the benefits and risks of waiting for formal approval. This entails a cost-benefit analysis of the sort typically employed in social and economic policy debates.[215] Under this approach, FDA would assess the nature of the emergency and how much is known about the product, assess the feasibility of any alternatives to granting the EUA, and weigh the known and unknown risks of administering the product against the risks of letting the emergency continue, and potentially worsen, while waiting for formal approval.
- *Principle-oriented:* The second approach endorses the principle that government has a duty to protect citizens from undue risks to health and safety by adhering to rigorous and traditional procedures and practices—and that this duty to protect should have unconditional primacy. History has already demonstrated how easily the rush to address emergencies can lead to judgments that prove regrettable in hindsight. It would be one thing if the nature, probability, and magnitude of risks posed by a given product were reasonably known; in many such cases, FDA would already have been in a position to decide whether or not to grant formal approval. But when dealing with far greater uncertainty, one could argue that FDA should instead avoid compromising its usual standards of integrity in the interest of expediency.
- *Autonomy-oriented:* The third approach would prioritize individual autonomy. Under this approach, FDA should make products available to the public more readily than under current standards, with full and ample disclosure of the relevant data.

---

[214] *See supra* Section II.B.

[215] *See, e.g.*, CASS R. SUNSTEIN, THE COST-BENEFIT REVOLUTION (2018) (arguing for a quantitative cost-benefit approach to analyzing policy issues rather than reliance on intuition or ideological values).

> Individuals are then free, at least in theory, to make an informed choice for themselves and their families.

Whichever framework one chooses to adopt, history points to several other considerations for decision makers to apply in deciding whether to grant an EUA. These involve the institutional context of EUA authority and should be considered alongside more straightforward medical and epidemiological questions:

- Should the product be made available on a limited or conditional basis to a specific population or sub-population?
- Would granting an EUA interfere with FDA's ability to complete its ordinary investigative protocol—for example, by eliminating individuals' incentive to volunteer for clinical trials?
- What is the risk of political interference with the EUA process, both in deciding whether to grant an EUA and in determining how that EUA would be applied?
- What precedent would that EUA set for future FDA decision making?
- What effect would the circumstances surrounding that EUA have on public trust in FDA and willingness to comply with public health guidance, regarding both the emergency at issue and future emergencies?

Keeping these factors in mind might help to ensure that decisions regarding EUAs are made with an eye not just to practical and epidemiological considerations, but also to the long-term integrity and reliability of the EUA and larger FDA process in general.[216] Although the short history of EUA authority might not point to any clear-cut conclusions, it suggests a variety of ethical dimensions and causes for potential concern that can warn and inform policy makers, regardless of what specific approach they adopt.

2. Granting EUAs for Vaccines

These considerations might be useful in evaluating whether and how to grant an EUA for a vaccine in future emergencies. Vaccines are especially hard to evaluate: rather than being used on already-sick patients with perhaps somewhat less to lose, they impose new risks on the majority of the public who have yet to contract the illness and who, in many cases, might be expected to remain healthy otherwise. When we face the next pandemic, FDA will be required to confront several key ethical questions:

i. Should FDA Grant an EUA for a Vaccine at All?

After analyzing the nature of a potential vaccine and the state of a given public health crisis as of that time, FDA might well conclude that the benefits of authorizing a vaccine with reasonable effectiveness potentially outweigh the costs of waiting if

---

[216] For more on the importance of maintaining FDA's credibility and perceived legitimacy in ensuring widespread compliance with public health measures, see DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA 33 (2010).

alternative means of preventing further infection are unsuccessful. Accordingly, one might also argue that alternative measures are not effective enough. Consider the COVID-19 pandemic: while many people have followed social distancing and masking protocol, others have not, and consequently the virus has continued to spread. (Those who disobeyed protocol arguably did so at their own risk and accepted the potential consequences; the problem, however, is that their behavior put others at risk, even when those third parties acted reasonably by wearing masks and practicing social distancing.) Alternatively, FDA might conclude that the risk of widespread side effects is too great, both in probability and magnitude, to proceed with an uncertain vaccine.

FDA might also channel the autonomy-based approach: an EUA should be granted so that members of the public can freely decide whether or not to take a vaccine, and as long as informed consent is provided, those that choose to take the vaccine accept the risk. Of course, one could respond that those individuals might then abandon health precautions (such as social distancing) prematurely—and risk exposing third parties to the pathogen at hand in the event a vaccine proves ineffective. This is a serious possibility when dealing with a vaccine that has not met FDA's traditional approval standards, and the risk posed to third parties might be deemed sufficiently hard to justify that it overcomes the argument for autonomy.

Each of these arguments in turn depends on various institutional considerations, which appeal to administrative and political issues involving the EUA process itself. One institutional argument against granting an EUA for a vaccine is the risk of political interference with the quality or safety of such a vaccine. Highly publicized statements by the Trump White House endorsing a speedy COVID-19 vaccine development process have raised widespread concern that political pressure could compromise the vaccine manufacturing and distribution process. On the other hand, several high-profile vaccine manufacturers pledged not to release a vaccine without adhering to rigorous testing standards and demonstrating safety and efficacy in large clinical trials, suggesting that in some cases, private-sector parties might comport with good practices and follow protocol.[217]

A second institutional argument against a vaccine EUA is that granting an EUA could interference with FDA scientists' ability to assess such a vaccine over the long term. As raised in the case of DDI during the AIDS crisis, offering short-term access to an investigational medical product removes an incentive for individuals to volunteer for clinical trials. This limits scientists' ability to collect information about that product for purposes of evaluating its efficacy and safety under the formal approval process. When facing the next pandemic, FDA will have to analyze the circumstances of the spread of the pathogen and weigh the risk of allowing it to spread in the short term against the risk of exposing the public to a vaccine about which relatively little is known.

A third institutional argument is that a hasty and controversial vaccine deployment program—especially one that appears to the public to be tainted by political interests—would weaken FDA's credibility and further erode public trust in health organizations. For one thing, people might not take such a vaccine at all, in which case the program would backfire; that might even make members of the public unnecessarily hesitant to take a subsequent vaccine that receives formal FDA approval. Lack of public trust in

[217] Bill Chappell, *Nine Drugmakers Sign Safety Pledge in Rush to Develop Covid Vaccine*, NPR (Sept. 8, 2020, 12:37 PM), https://www.npr.org/sections/coronavirus-live-updates/2020/09/08/910671322/9-drugmakers-sign-safety-pledge-in-race-to-develop-covid-19-vaccine [https://perma.cc/L48W-3M3R].

FDA's independence and integrity can make the public generally more skeptical of health agencies—and could risk doing even further damage to health advocates' efforts to raise public awareness of the benefits of vaccines—beyond COVID-19 and into the next public health crisis.

ii. How Quickly Should an EUA Be Administered?

Were FDA to go forward with granting an EUA for a new vaccine, the next question would be at what point to do so. How long a follow-up period should FDA require to assess efficacy and safety before granting the EUA? Given the extensive existing precedent with respect to vaccine trials, scientists would be in a particularly authoritative position to answer this question. For example, a number of medical experts have recommended that FDA require a median two-month follow up with trial participants before granting an EUA for a COVID-19 vaccine, given that vaccine side effects usually take approximately six weeks to manifest.[218]

iii. Who Should Receive the Vaccine First Under an EUA?

There is also the question of whether FDA should narrow the scope of a vaccine EUA, either based on limited supply or based on weighing prudence against exceptional need. One pragmatic form of a solution would be to start by first administering a vaccine only to medical practitioners involved in treating patients directly (who therefore are at greater risk of both contracting and spreading the disease). Given FDA's latitude in issuing and defining the scope of EUAs, it would be possible for FDA to impose such a limitation, which might be a reasonable compromise between using EUAs unconditionally and not at all.

One argument in favor of granting an EUA to health practitioners (especially first responders) takes an outcome-oriented approach: health practitioners are at particular risk both of being infected by patients and of infecting new patients, so giving them the vaccine would protect them and limit the spread of a dangerous pathogen to others. Doing so would have the added benefit of providing field data on potential side effects among vaccinated practitioners. One could also argue as a matter of principle that they deserve extra protection for putting their lives at risk.

Arguments that take the outcome-oriented approach and autonomy-oriented approach could also cut the other way. Health practitioners typically are young and healthy, arguably having a lower level of underlying risk of complications from illnesses such as COVID-19 than do other members of the public. This means that the risk of suffering health complications from the vaccine might not be as valuable a tradeoff for them as it would for others who are at greater underlying risk due to illnesses such as COVID-19. Furthermore, health practitioners arguably have a duty—and have made an autonomous choice—to risk their health in serving others, and so limited supplies of an effective vaccine should go to those whom they have committed to serving. (On the other hand, as argued above, the fact that such a vaccine would come with great uncertainty might itself be a reason to administer it to health practitioners first—effectively putting them on the "front lines" of uncertainty about the vaccine.)

---

[218] *See, e.g.*, Philip R. Krause & Marion F. Gruber, *Emergency Use Authorization of Covid Vaccines—Safety and Efficacy Follow-Up Considerations*, NEW ENG. J. MED. (Nov. 5, 2020), https://www.nejm.org/doi/full/10.1056/NEJMp2031373 [https://perma.cc/LB3N-2W2B].

iv. Should Vaccination Under an EUA Be Mandatory or Voluntary?

That in turn would raise further ethical questions: if a new vaccine were to be granted an EUA for use among medical practitioners, should vaccination be made mandatory, as was initially done with military personnel receiving AVA in 2005? Or should vaccination simply be voluntary? Should a middle ground again be struck by making vaccination a default with the ability to opt out, or should it merely be made available on an opt-in basis? These questions are equally relevant whether applied to health practitioners or to members of the public in general.

Whether someone prefers mandatory or voluntary vaccination with respect to an EUA might depend on the threshold question of whether they believe in mandatory vaccination in general—with respect to vaccines with formal approval. For those who believe that ordinary vaccines ought to be mandatory, an argument could be made that the grounds are weaker, at least in theory, for a vaccine that has been subjected to anything other than the standard process of formal approval—all the more so for those who oppose making even formally approved vaccines mandatory. On the other hand, it might be that much more urgent to give people a vaccine given the stakes of the emergency at hand.

Whether to make a vaccine voluntary or mandatory depends at least partly on the nature of the risks to the individual and to the collective. These include the risk of a given pathogen infecting fewer or more people, the risk of harm resulting from the vaccine, and the risk that people would not vaccinate themselves voluntarily. Each pandemic likely will entail a different set of risks (such as rate of transmission and degree of severity), and answering this question thus requires looking to the particular circumstances of each public health emergency rather than relying too heavily on principles in the abstract.

Recent events relating to mandatory countermeasures point to another possible consideration bearing on the issuance of EUAs. As of August 2021, a public debate has erupted in the United States over whether to mandate vaccination against COVID-19 with the three vaccines that have received EUAs.[219] Opponents of mandatory vaccination have attempted to support their positions by appealing to the fact that the three vaccines have been granted only emergency authorization rather than full formal approval.[220] A number of organizations suggested that they intended to wait until the vaccines are fully approved before making vaccination mandatory for their members.[221]

---

[219] The debate over vaccine mandates is taking place against a backdrop of vaccine hesitancy among a substantial minority of the American public. In March 2021, 28% of surveyed American adults expressed hesitation about receiving a COVID-19 vaccine; that number has dropped to 15%, though 13% remained opposed to receiving the vaccine. *See* Alexa Lardieri, *Vaccine Hesitancy Declines, But Barriers Prevent Some Americans from Receiving Shot: Survey*, U.S. NEWS & WORLD REP. (July 28, 2021), https://www.usnews.com/news/health-news/articles/2021-07-28/vaccine-hesitancy-declines-but-barriers-prevent-some-americans-from-receiving-shot-survey.

[220] *See* David Leonhart, *Why Aren't the Vaccines Approved?*, N.Y. TIMES (July 21, 2021), https://www.nytimes.com/2021/07/21/briefing/covid-vaccines-fda-approval.html (summarizing how some might view the lack of formal approval for COVID-19 vaccines as indicating that FDA has not collected enough data to guarantee the safety of those vaccines) [https://perma.cc/UCK6-HCBJ].

[221] *See* Shannon Pettypiece, *Vaccine Mandates More Likely Once FDA Grants Full Approvals, Health Experts Say*, NBC NEWS (July 20, 2021), https://www.nbcnews.com/politics/white-house/vaccine-mandates-more-likely-once-fda-grants-full-approvals-health-n1274288 (reporting that even organizations

This raises the question of whether FDA's decision-making pertaining to the issuance of EUAs should factor in the risk of lower public take-up if a given countermeasure receives an EUA rather than full formal approval. Some might argue that the potential impact on public trust in those countermeasures could be a valid concern in deciding whether to issue an EUA while simultaneously pursuing the formal approval process. Others might object that, if the EUA process is as reliable as formal approval, FDA should not dignify unfounded and politically motivated arguments to the contrary by taking them into account. The answer depends in part on whether the emergency at hand involves third-party risks, as in the case of an infectious disease. It might also depend in large part on whether issuing an EUA is deemed likely to expedite, delay, or not affect the timing of a subsequent formal approval. If issuance of EUAs would otherwise be appropriate and not delay formal approval, then should FDA take into account a concern that attacks on the credibility of EUAs by vaccine skeptics might permanently taint public attitudes toward the vaccine even after it has been fully approved? It would be hard to argue that such a concern could possibly justify withholding from others the benefits of EUAs that were otherwise determined to meet EUA standards.

One hopes that future public health emergencies will not be subjected to the same exceptional degree of politization as COVID-19 and that the current pandemic will prove to have been an outlier. Still, the debate over EUA status and vaccine mandates exemplifies the range of institutional considerations potentially in play, such as EUAs' and FDA's credibility with the general public and the public's understanding of FDA procedures.

***

EUAs for vaccines largely remain uncharted territory. AVA was the only vaccine ever granted an EUA prior to the three vaccines authorized for use against COVID-19, but it had already received formal approval for use against anthrax in other contexts.[222] By contrast, the vaccines currently authorized against COVID-19 have yet to be formally approved at all. There is reason to worry that in the event of a future pandemic, there would be tremendous public and political pressure to authorize a vaccine with even a chance of being effective—even though relatively little might be known about any such vaccine. As noted earlier, it is hard to ignore that FDA initially authorized chloroquine and hydroxychloroquine only weeks after an unusual endorsement of those drugs by President Trump.[223] The White House's highly publicized pushback against FDA for promising to apply stricter standards before granting an EUA for a vaccine has done little to assuage health policy experts' concerns.

One might be concerned that political pressure might unduly influence FDA officials' judgement—or already has had that effect. If so, the stakes would be especially high with respect to a vaccine intended for otherwise-healthy individuals. Issuing an EUA for an unapproved vaccine could set a precedent with the potential to influence future EUAs in uncertain ways. Whether a vaccine succeeds or fails—and whether it causes serious adverse side effects—could also have extensive ramifications

---

that might support vaccine mandates face legal and public relations hurdles regarding mandates for vaccines lacking formal approval) [https://perma.cc/4YA6-H3BY].

[222] *See supra* Section III.B.

[223] *See supra* Section V.B.

for the public's trust in public health officials, including willingness to comply with governmental directives in public health emergencies.

3. Liability Shields and Compensation

The intense political clashes over vaccine liability described earlier reveal a parallel dilemma: how to weigh the interest in swift access to countermeasures against the interest in preventing injury and ensuring compensation to individuals in cases of injury. Low-risk side effects of a given vaccine will predictably result in occasional injury; such incidents are almost inevitable when administering a vaccine on a national scale. Solutions to large-scale emergencies often can be viewed as a sort of lottery, and whether subjecting individual members of the public to such a lottery is justified depends on whether one is willing to engage in outcome-oriented cost–benefit analysis.

The historical back-and-forth over liability immunity and no-fault compensation has resulted in an imperfect system—one that has left potential injured parties at a disadvantage while also enabling vaccines to be made available on the scale needed to address a public health emergency. This speaks to an essential tradeoff between maximally safeguarding the rights of those who might suffer harm and taking imperfect steps toward better outcomes for the greater good.

Although other nations offer more extensive compensation schemes, none offers the extent of immunity from liability enjoyed by providers in the United States. That said, one could argue that the extensive protection from liability is one of the reasons so many companies have stepped up to invest hundreds of millions into developing vaccines and drug products. In the event of another pandemic, any vaccines that survive initial clinical trials will potentially need to be readied to produce enough doses for a population of hundreds of millions. Of the various economic risks involved for vaccine providers, one from which they are almost entirely safe is ruinous liability.

4. Testing Tests

After first resolving to address widespread testing shortages by authorizing whole "umbrella" categories of diagnostic products without individual EUAs, FDA faced the task of going back through the available products to evaluate them. Some of those tests, as documented earlier, have been found to be unreliable: offering either false positives that make people believe incorrectly that they are infected, or false negatives that fail to disclose the infection.[224] It presumably can be hard to know how to weigh the need for speed against the need for prudence, especially in the fog of war. Although FDA's decision risks allowing faulty or fraudulent tests to come to market, that might simply be an unavoidable consequence of taking a pragmatically permissive approach to emergency response. How one views FDA's decision, both during this pandemic and in emergencies to come, will reflect one's views on the balance of costs and benefits—and on the tradeoff between carefully following protocol on the one hand and responding quickly with a solution that entails a risk of adverse side effects on the other.

[224] *See supra* Section V.B.

5. Two Categories of EUAs: "High-Downside" and "Low-Downside"

The history of EUAs (including similar approaches prior to Project BioShield) points to two general scenarios. First, there are those in which products such as DDI, DryVax, and hydroxychloroquine come with conspicuous downsides involving a risk of potentially serious adverse health effects. Second, there are those in which products such as AVA are reasonably certain not to pose a risk of serious side effects—based on prior experience or formal approval for other uses—yet might prove ineffective. Arguably there is some degree of indirect or second-order risk associated even with countermeasures that are merely ineffective—for example, creating a false sense of safety or crowding out alternative measures that might prove more effective. However, we might view this form of risk as being either less important than or qualitatively different from the more direct risk of damage to patients' health caused by taking a given product.

It might be useful for regulators to consider how to more clearly distinguish and weigh these two types of risks as part of the EUA decision-making process. For example, one can imagine creating two subcategories of EUAs: "high-downside" EUAs, for which there is reason to suspect a direct risk of adverse effects, and "low-downside" EUAs, for which the only tangible risk is lack of effectiveness. (A "moderate-downside" category may also be appropriate.)

This difference would usefully improve the decision-making calculus when considering a product for emergency authorization. In situations involving low-downside countermeasures—potentially including a vaccine—regulators might set a lower bar for granting an EUA, being more inclined to authorize use of a countermeasure where, at least as a first approximation, there is little or nothing to lose. By contrast, health officials might take a more cautious approach to high-downside countermeasures—and might consider them only when the stakes of the underlying emergency and the efficacy of the given countermeasure are both sufficiently high. Regulators might, among other things, include additional safeguards or investigative steps in cases involving downside risks, and perhaps even make the process simpler and faster for products that appear to have low downsides on first impression.

Does the public debate over the credibility of COVID-19 vaccine EUAs in contrast to FDA's formal approval process suggest that FDA and Congress should consider the possibility of a broader restructuring of those processes? For example, would it help ameliorate public concern—and make it harder to raise unfounded doubts about the EUA process—if EUAs were nominally assimilated into the formal approval process? One could imagine stratifying the formal approval process into multiple categories along a spectrum, including replacement of the separate "EUA" designation with something along the lines of an "Approval Category A" (the "emergency category," or highest level of urgency) that would preserve the EUA process. Such a restructuring might be challenged as a purely cosmetic move, though that would depend on whether it also entailed desirable substantive reforms. And some would maintain that even a cosmetic change could be justified if it helped shore up the public credibility and positive impact of emergency authorizations.

VIII. CONCLUSION

Tracing the development of FDA's emergency use power from counterterrorism to today's pandemic, one might be left with the impression that the current law regarding EUAs is being used fairly differently now from the way it was first imagined. The history of EUAs reflects a gradual shift from counterterrorism in the post-9/11 period to naturally occurring infectious diseases in the wake of the H1N1 crisis of 2009. Equally interesting is how the federal government's emphasis on bioterror threats helped prepare us, at least from a legal standpoint, to confront the current crisis over a decade later; it appears as though Project BioShield ultimately protected us against a different type of biosword. One wonders whether an emphasis on pandemics would have garnered the same amount of support among legislators or the public. At the same time, statutory developments and background deliberation across the federal government took influence, at least on occasion, from a community of health experts who consistently tried to draw the nation's attention to infectious diseases—who warned that pandemics would arrive sooner or later, and that we ignore them at our peril.

One might worry that the early counterterror mindset of Project BioShield, if relied on too heavily, might lead policymakers to not be careful enough in balancing all the relevant public health risks, and that unnecessary sacrifices will be made in the interest of a quick "victory." All the more so when political motivations and pressure are involved. To some, the origins of FDA's EUA authority might serve as a reminder not to draw facile analogies to war that threaten to erode a more cautious mindset of proceeding as quickly as possible, but not more quickly.

Perhaps the clearest takeaway from the history of FDA emergency authorization is the relative leanness of that history. EUAs have never been used as frequently or played as prominent a role in a public health emergency as they are today in battling COVID-19. There is hardly any precedent to refer to in making EUA-related decisions; even the use of EUAs in the H1N1 crisis of 2009 pales in comparison. The United States has not faced a public health emergency of this magnitude in over a century, yet the emergency powers FDA is relying upon in doing so have existed for fewer than twenty years and have been used sparingly until now.

Whether the sheer quantity of emergency authorizations issued during COVID-19, compared to previous emergencies, will cause EUAs to become normalized in the future remains to be seen—as do the implications of a federal agency using its emergency powers both pursuant to and in spite of orders that appear to be tinged by political considerations. Every decision involving EUAs that is made during this crisis will influence how FDA's emergency powers are evaluated and applied in crises to come. FDA's policy in using its EUA authority has already involved, and may well continue to involve, some of the weightiest public health decisions FDA will ever make. Emergency use authorization has existed for two decades, but the bulk of its history is currently being written.