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Cover Page Footnote

J.D. Candidate, 2022, University of Georgia School of Law; B.S., 2015, Emory University. This Note is dedicated to my family and roommates, whose support made completing this Note possible.

AGENTS OF BIOSHIELD: THE FDA, EMERGENCY USE AUTHORIZATIONS, AND PUBLIC TRUST

Kirstiana Perryman[*]

The SARS-CoV-2 pandemic spurred the U.S. Food & Drug Administration (FDA) to utilize the Emergency Use Authorization (EUA) procedure more than ever before. The pandemic pushed the relatively obscure procedure into public consciousness, making it a frequent topic of discussion and debate. The EUA procedure permits the FDA Commissioner to authorize the introduction of drugs, devices, or biological products into interstate commerce for use in an actual or potential emergency. To issue an authorization, the FDA Commissioner must determine that it is "reasonable to believe," based on the "totality of the evidence," that the product "may be effective." This standard creates a lower evidentiary burden than the traditional pathways to market for drugs and vaccines in the United States, allowing the FDA to respond quickly and effectively during public health emergencies (PHEs).

While the flexibility provided by the EUA procedure can and has saved lives, aspects of the procedure can also exacerbate public mistrust in the safety, rigor, and objectivity of FDA review and authorization. Focusing solely on drugs and vaccine EUAs, this Note builds off of existing scholarship to propose three modifications to the EUA procedure: (1) the EUA procedure should mandate that the FDA create and disseminate guidance as soon as practicable after the declaration of a PHE; (2) Congress should modify the evidentiary standard for vaccine EUAs; (3) the EUA procedure should mandate that the FDA cite, in the authorization letter, the evidence it relies upon when deciding to issue an EUA and publicly release any data and studies that underlie its decision. These modifications could yield pragmatic and positive reform without unduly sacrificing the speed and centralized authority the FDA needs to respond effectively to a PHE.

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I. INTRODUCTION

The 2019 coronavirus (COVID-19) pandemic[1] put the U.S. Food and Drug Administration's (FDA) Emergency Use Authorization (EUA) power to the test. During the coronavirus pandemic, the FDA issued more EUAs than ever before,[2] causing EUAs to become a frequent topic of public discussion and debate.[3] The pandemic both highlighted the immense benefits of the EUA power and revealed some of its flaws. The EUA process provides the FDA the essential

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[1] The strain of virus that caused the pandemic is called SARS-CoV-2, and the name of the disease caused by SARS-Cov-2 is called coronavirus disease 2019. *See Coronavirus Disease 2019 (COVID-19)*, MAYO CLINIC (Nov. 5, 2021), https://www.mayoclinic.org/diseases-conditions/coronavirus/symptoms-causes/syc-20479963 ("Infection with the new coronavirus (severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2) causes coronavirus disease 2019 (COVID-19)."). COVID-19 is the acronym for coronavirus disease 2019. *Id.*

[2] As of this writing, the FDA has issued three vaccine EUAs and nine drug and non-vaccine biological therapeutic EUAs. *See Emergency Use Authorization*, U.S. FOOD & DRUG ADMIN. [hereinafter *Current EUA Information*], https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization (last updated Dec. 28, 2021) (listing three coronavirus vaccines and fourteen drug and biological therapeutics for treatment of COVID-19 that have EUA status as of the writing this Note); *Emergency Use Authorization—Archived Information*, U.S. FOOD & DRUG ADMIN. [hereinafter *Archived EUAs*], https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information (last updated Dec. 21, 2021) (noting that the chloroquine and hydroxychloroquine EUA and the bamlanivimab EUA have been revoked, while an EUA for bamlanivimab administered with estevimab remains effective). By contrast, the FDA issued three antiviral EUAs for H1N1 and one vaccine EUA for anthrax. *Archived EUAs*, *supra*.

[3] *Compare* Edmund DeMarche, *FDA OKs Emergency Authorization of Drugs Touted by Trump to Fight Coronavirus*, FOX NEWS (Mar. 29, 2020), https://www.foxnews.com/health/fda-oks-emergency-authorization-of-drugs-touted-by-trump-to-fight-coronavirus ("[President Trump] has touted drugs used in malaria cases as a possible response to the coronavirus and now the Food and Drug Administration put in place an emergency use authorization to try these drugs despite clear evidence of their effectiveness."), *with* Charles Piller, *Former FDA Leaders Decry Emergency Authorization of Malaria Drugs for Coronavirus*, SCI. (Apr. 7, 2020), https://www.sciencemag.org/news/2020/04/former-fda-leaders-decry-emergency-authorization-malaria-drugs-coronavirus ("The recent Food and Drug Administration (FDA) emergency use authorization (EUA) for two malaria drugs to treat COVID-19, based on thin evidence of efficacy, has jeopardized research to learn the drugs' real value against the pandemic coronavirus, say former agency executives under President Donald Trump and former President Barack Obama.").

ability to respond quickly to a public health emergency,[4] but aspects of the process can undermine public trust, confuse health authorities, stymie important data collection efforts, and potentially put individuals at unnecessary risk. These flaws are unlikely to dissipate when the COVID-19 pandemic ends because scientists predict that we will face more outbreaks like COVID-19 in the coming years.[5]

This Note proposes three modifications that would improve the EUA power while retaining its effective elements. First, the EUA procedure should mandate that the FDA create and disseminate guidance as soon as practicable after the declaration of a public health emergency (PHE). Second, Congress should modify the evidentiary standard for vaccine EUAs.[6] Third, the EUA procedure should mandate that the FDA specifically cite which evidence it relies upon when deciding to issue an EUA and publicly release any data underlying its decision.

Part II of this Note contrasts traditional FDA approval procedures for drugs and vaccines with the EUA procedure.[7] Part

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[4] *See* Patricia J. Zettler, Micah L. Berman & Efthimios Parasidis, *Drug and Vaccine Development and Access*, *in* ASSESSING LEGAL RESPONSES TO COVID-19 163, 165 (Scott Burris et al. eds., 2020) ("The addition of the EUA mechanism . . . arguably reflects a societal decision that FDA ought to have flexibility to lower standards of safety and effectiveness during public health emergencies to speed access to promising, but unproven, products.").

[5] *See* Victoria Gill, *Coronavirus: This Is Not the Last Pandemic*, BBC (June 6, 2020), https://www.bbc.com/news/science-environment-52775386 (describing how and why the world will likely face more pandemics in the future); John D. Blum & Jordan Paradise, *Public Health Preparedness & Response: An Exercise in Administrative Law*, DEPAUL J. HEALTH CARE L., Spring 2018, at 1, 2 ("While public health experts are not able to pinpoint the time and nature of the next 'big event,' there is a consensus that it is not a matter of 'if' but 'when.'").

[6] While this Note critically discusses vaccine EUAs, it in no way questions the safety or effectiveness of modern vaccines. As another J.D. candidate has noted in his insightful Note regarding EUAs, "[v]accines are one of the safest and most effective public health interventions ever invented." Daniel Walsh, Note, *COVID-19: A Crisis and an Opportunity to Improve the Emergency Use Authorization Process*, 22 MINN. J.L. SCI. & TECH. 169, 171 n.8 (2021).

[7] Although the EUA procedure also allows the FDA Commissioner to issue EUAs for medical devices, personal protective equipment (PPE), and diagnostic tests, this aspect of the FDA's powers is beyond the scope of this Note. For a comprehensive discussion of EUAs and diagnostic tests, see Barbara J. Evans & Ellen Wright Clayton, *Deadly Delay: The FDA's Role in America's COVID-Testing Debacle*, 130 YALE L.J.F. 78 (2020), arguing that the FDA does not have the power to issue EUAs for COVID-related laboratory-developed diagnostic tests.

III presents an overview of chemical, biological, radiological, or nuclear (CBRN) emergencies during which the FDA has issued EUAs for drugs or vaccines. Part IV first analyzes the benefits and pitfalls of the EUA procedure as applied to drugs and vaccines and then suggests possibilities for reform. Finally, Part V briefly concludes.

II. OVERVIEW OF EMERGENCY USE AUTHORIZATIONS

This Part describes the EUA procedure through comparison with the traditional pathways for obtaining FDA approval or licensing. This comparison elucidates the unique aspects of the EUA procedure, highlights its potential benefits, and indicates its potential weaknesses.

A. THE ENABLING ACTS

The Federal Food, Drug, and Cosmetic Act (FDCA) and the Public Health Service Act (PHSA) grant the FDA the power to approve, license, or authorize drugs and biologics.[8] Section 505(a) of the FDCA requires that the FDA approve drugs prior to their introduction into interstate commerce, stating that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed . . . is effective with respect to such drug."[9] Similarly, Section 351 of the PHSA requires that the FDA issue a biologics license prior to a biologic's "introduction into interstate commerce."[10] The statute states that "[n]o person shall introduce or deliver for introduction into interstate commerce any biological product unless . . . a

[8] *See* 21 U.S.C. § 355(a) (requiring approval of an application before the introduction of any new drug into interstate commerce under the FDCA); 42 U.S.C. § 262(a) (requiring a biologics license before the introduction of any biological product into interstate commerce under the PHSA); 21 U.S.C. § 360bbb-3 (permitting the FDA to authorize the introduction of a drug or biologic into interstate commerce "for use in an actual or potential emergency (referred to . . . as an 'emergency use')" under the FDCA). The HHS Secretary—granted authority under these statutes—has delegated the EUA decision-making authority to the FDA Commissioner. *See infra* notes 47–48 and accompanying text.

[9] 21 U.S.C. § 355(a).

[10] 46 U.S.C. § 262(a).

biologics license . . . is in effect for the biological product."[11] These two statutory sections provide the "traditional new drug approval process[es]," or the "general pathways to market," for drugs and biologics.[12] By contrast, the EUA procedure is a newer and faster pathway to market for drugs and biologics with vastly different requirements.[13] Section 564 of the FDCA empowers the FDA to issue EUAs for both drugs and biologics, stating that "the Secretary [of Health and Human Services] may authorize the introduction into interstate commerce . . . of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this section as an 'emergency use')."[14]

The most obvious difference between the EUA procedure and the traditional pathways to market is clear from the language of the statutes: the EUA procedure is solely an emergency response,[15] while the traditional pathways have no emergency requirement.[16] An emergency situation drastically alters the FDA's priorities, requiring fast and decisive action.[17] The differences between the processes for obtaining FDA approval or licensing and the process for obtaining an EUA further demonstrate this change in priorities.

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[11] *Id.*

[12] Blum & Paradise, *supra* note 5, at 11.

[13] *See id.* at 14–16 (describing the establishment of the EUA procedure in the Project Bioshield Act of 2004, the "significant revisions and additions" the Pandemic and All-Hazards Preparedness Reauthorization Act made to the procedure in 2013, and the key aspects of the EUA procedure); Zettler et al., *supra* note 4 at 163–64 (explaining the FDA approval and pre-approval access then elaborating upon the EUA procedure).

[14] 21 U.S.C. § 360bbb-3(a)(1).

[15] *See id.* (conditioning authorization on intended "use in an actual or potential emergency").

[16] 21 U.S.C. § 355; 42 U.S.C. § 262.

[17] *See, e.g.*, Zettler et al., *supra* note 4, at 165 (recognizing that, during a PHE, the FDA still faces the need to develop "rigorous evidence of products' safety and effectiveness" but with "an urgent need to move as quickly as possible"); OFF. OF COUNTERTERRORISM & EMERGING THREATS, U.S. DEP'T HEALTH & HUM. SERVS., EMERGENCY USE AUTHORIZATION OF MEDICAL PRODUCTS AND RELATED AUTHORITIES 8 (2017) [hereinafter 2017 FDA GUIDANCE], https://www.fda.gov/media/97321/download ("FDA intends to assess the potential effectiveness of a possible EUA product on a case-by-case basis using a risk-benefit analysis . . . .").

B. FDA APPROVAL AND LICENSING

Under the traditional pathways for approval or licensing, drug developers must first submit an Investigational New Drug (IND) application to the FDA.[18] An IND application requests authorization from the FDA to begin clinical research testing of a drug on humans.[19] The IND must include animal study and toxicity data, manufacturing information, clinical protocols, any data from prior human research, and information about the developer.[20] The FDA approves the IND, delays the IND, or prohibits further investigation of the drug or vaccine.[21] After IND approval, the developer can begin clinical trials.[22] Clinical trials usually proceed in four phases, and the FDA requires completion of Phase 3 trials—which typically involve a significantly larger number of study participants than the previous phases—before a developer can apply for approval.[23] Developers typically take several years to complete Phase 1 through Phase 3.[24]

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[18] *See, e.g.*, *Investigational New Drug (IND) Application*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application (last updated Feb. 24, 2021) ("Current Federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. . . . The IND is the means through which the sponsor technically obtains this exemption from the FDA."); Blum & Paradise, *supra* note 5, at 11 ("[A]n investigational new drug ('IND') application . . . triggers the clinical trial process . . . .").

[19] *Development & Approval Process (CBER)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber (last updated Jan. 27, 2021); *see also Step 3: Clinical Research*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/patients/drug-development-process/step-3-clinical-research (last updated Jan. 4, 2018) (describing IND design, review, and approval).

[20] *Step 3: Clinical Research*, *supra* note 19.

[21] *Id.* ("FDA responds to IND applications in one of two ways: [a]pproval to begin clinical trials [or] [c]linical hold to delay or stop the investigation.").

[22] *Id.*

[23] *See* Natalie M. Kase, Commentary, *Do Right to Try Laws Undermine the FDA's Authority? An Examination of the Consequences of Unlimited Access to Unapproved Drugs*, 36 J. LEGAL MED. 420, 422 (2015) (noting that a drug sponsor must complete three pre-market phases of clinical trials before submitting a New Drug Application).

[24] *Step 3: Clinical Research*, *supra* note 19. In Phase 1, the investigator tests varying dosages to determine how great of a dosage trial participants can tolerate and whether the drug or vaccine has any side effects. *Id.* In Phase 2, researchers test the drug's efficacy and obtain additional safety data. *Id.* Phase 3 trials typically involve a much larger number of study participants than prior phases, and researchers continue to test the drug for efficacy

After a drug developer has completed Phase 3 clinical trials, the developer can submit a New Drug Application (NDA).[25] The NDA includes data gathered through the clinical trials and pre-clinical animal studies.[26] The Center for Drug Evaluation and Research (CDER), a division of the FDA, then reviews the NDA.[27] To obtain approval for a new drug, a developer must show evidence of *safety* and *effectiveness* based on "substantial evidence" derived from well-controlled clinical trials.[28] If a developer demonstrates that the drug is "safe and effective for [its] particular intended use, indication, and patient population"[29] and that the benefits of the drug outweigh the risks, the FDA will approve the drug.[30]

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and adverse reactions. *Id.* Phase 4, also known as post-marketing surveillance, occurs after FDA approval. *Id.* During Phase 4, the investigator continues to monitor the safety of the product, determine optimal dosages, or study populations underrepresented in the previous phases. Stuart R. Cohn & Erin M. Swick, *The Sitting Ducks of Securities Class Action Litigation: Bio-Pharmas and the Need for Improved Evaluation of Scientific Data*, 35 DEL. J. CORP. L. 911, 922 (2010).

[25] *See Step 4: FDA Drug Review,* U.S. FOOD & DRUG ADMIN., https://www.fda.gov/patients/drug-development-process/step-4-fda-drug-review (last updated Jan. 4, 2018) ("A drug developer must include everything about a drug—from preclinical data to Phase 3 trial data—in an NDA.").

[26] *New Drug Application (NDA)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/types-applications/new-drug-application-nda (last updated June 10, 2019) ("The data gathered during the animal studies and human clinical trials of an Investigational New Drug (IND) become part of the NDA.").

[27] *See Development & Approval Process | Drugs*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/development-approval-process-drugs (last updated Oct. 28, 2019) ("FDA approval of a drug means that data on the drug's effects have been reviewed by CDER.").

[28] *See* 21 U.S.C. § 355(b) (requiring safety and effectiveness of drugs for approval); 21 U.S.C. § 355(d) ("[T]he term 'substantial evidence' means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved . . . .").

[29] Blum & Paradise, *supra* note 5, at 11; *see also* Maureen C. Kelley & Samuel J. Tilden, *Ethical and Legal Oversight of Human Subjects Research in Emerging Infections and Biodefense Research: A Review of Recent Changes and Call for Policy Reform*, 8 HOUS. J. HEALTH L. & POL'Y 1, 19 (2007) ("[FDA] [a]pprovals are based on clinical investigations of the drug demonstrating its safety and effectiveness for the intended use.").

[30] *See* 21 U.S.C. § 355(b) (requiring that an NDA demonstrate that the drug is "safe" and "effective"); *Development & Approval Process | Drugs*, *supra* note 27 ("FDA approval of a drug means that data on the drug's effects have been reviewed[,] . . . and the drug is determined to provide benefits that outweigh its known and potential risks for the intended population."). A developer can also obtain FDA approval by submitting an Abbreviated New Drug Application (ANDA). *See* 21 U.S.C. 355(j) ("Any person may file with the Secretary [of Health

To obtain a biologics license, vaccine developers must submit a Biologics License Application (BLA), which also includes data from pre-clinical trials and clinical trials.[31] The Center for Biologics Evaluations and Research (CBER), a division of the FDA, evaluates the BLA.[32] To obtain a biologics license, the developer must show that the biologic is *safe, pure, and potent*.[33] Through the safe, pure, and potent standard, "the FDA applies general concepts of safety

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and Human Services] an abbreviated application for the approval of a new drug."). The FDA will approve the ANDA if the developer shows bioequivalence to a drug that already has FDA approval, meaning that its active ingredients and conditions for use match those of an approved drug. *Id.*; Blum & Paradise, *supra* note 5, at 11 ("[T]he abbreviated new drug application ('ANDA') process, also termed the generic drug approval process [is] premised on measures of bioequivalence to a reference drug product already approved by the FDA."). This is commonly referred to as the generic drug approval process. *Id.*

[31] *See Biologics License Application (BLA) Process (CBER)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber (last updated Jan. 27, 2021) (describing the BLA process and requirements). Like the ANDA, biologics developers can also seek approval through the Abbreviated Biologics Approval License Application (ABLA). *See* 46 U.S.C. § 262(k) (outlining the requirements for licensure of a biosimilar or interchangeable biological product); Blum & Paradise, *supra* note 5, at 12 (listing the ABLA as a route to FDA approval).

[32] *See Development & Approval Process (CBER)*, *supra* note 19 (listing applications that CBER is responsible for reviewing, including the BLA). BLAs for certain other biological products are reviewed by CDER, including, for example, monoclonal antibodies, proteins intended for therapies, and growth factors. Scientific Writing Team, *What are the Regulatory Differences Between an NDA and BLA?*, NUVENTRA PHARMA SCIS. (Apr. 15, 2020), https://www.nuventra.com/resources/blog/regulatory-differences-between-an-nda-bla/.

[33] *See* 42 U.S.C. § 262(a) ("The Secretary [of Health and Human Services] shall approve a biologics license application . . . on the basis of a demonstration that . . . the biological product that is the subject of the application is safe, pure, and potent . . . ."); 21 C.F.R. § 601.2(a) (2021) ("To obtain a biologics license under section 351 of the Public Health Service Act for any biological product, the manufacturer . . . shall submit data derived from nonclinical laboratory and clinical studies which demonstrate that the manufactured product meets prescribed requirements of safety, purity, and potency . . . ."); *id.* § 600.3(p) ("The word *safety* means the relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time."); *id.* § 600.3(r) ("*Purity* means relative freedom from extraneous matter in the finished product, whether or not harmful to the recipient or deleterious to the product."); *id.* § 600.3(s) ("The word *potency* is interpreted to mean the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result.").

and efficacy to biologics, though the regulations are highly specific to biologics."[34]

C. EMERGENCY USE AUTHORIZATION

Before Congress empowered the FDA to use the EUA procedure,[35] the FDA could only authorize the large-scale administration of unapproved products, or unapproved use of approved products, under the IND treatment protocol.[36] The IND treatment protocol requires, in part, "Institutional Review Board (IRB) approval of the investigational protocol, documented informed consent from all patients describing, among other things, the research purposes of the protocol, substantial record keeping, and patient follow-up requirements."[37] While the IND protocol works

[34] Blum & Paradise, *supra* note 5, at 12. For example, "potency" includes substantial evidence of effectiveness. *See* CTR. FOR DRUG EVALUATION & RSCH., U.S. DEP'T HEALTH & HUM. SERVS., DEMONSTRATING SUBSTANTIAL EVIDENCE OF EFFECTIVENESS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS 3–4 (2019) ("Potency has long been interpreted to include effectiveness. FDA has also generally considered 'substantial evidence' of effectiveness to be necessary to support licensure of a biological product under section 351 of the PHS Act." (citation omitted)).

[35] The EUA process was first authorized in 2004 by the Project BioShield Act. *See* Blum & Paradise, *supra* note 5, at 14 (describing legislation relevant to FDA authority).

[36] *See* 21 C.F.R. § 312.34(b) (2003) ("FDA shall permit an investigational drug to be used for a treatment use under a treatment protocol or treatment IND if: (i) The drug is intended to treat a serious or immediately life-threatening disease; (ii) There is no comparable or satisfactory alternative drug or other therapy available to treat that stage of the disease in the intended patient population; (iii) The drug is under investigation in a controlled clinical trial under an IND in effect for the trial, or all clinical trials have been completed; and (iv) The sponsor of the controlled clinical trial is actively pursuing marketing approval of the investigational drug with due diligence."); Gail H. Javitt, *Old Legacies and New Paradigms: Confusing "Research" and "Treatment" and Its Consequences in Responding to Emergent Health Threats*, 8 J. HEALTH CARE L. & POL'Y 38, 41 (2005) ("FDA had . . . authorized the administration of IND products for treatment purposes . . . .").

[37] Stuart 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, 1046–47 (2007). An IRB is a committee tasked with reviewing and approving scientific study protocols for research on humans. *See, e.g.*, Sharona Hoffman & Jessica Wilen Berg, *The Suitability of IRB Liability*, 67 U. PITT. L. REV. 365, 372 (2005) ("Federal regulations mandate that all research that is conducted, supported, or regulated by HHS, the FDA, or another federal agency must be overseen by an IRB, a committee constituted to provide initial approval and periodic monitoring for biomedical research studies." (footnote omitted)).

well for clinical trials or individual authorizations, it is too rigorous to allow fast, large-scale action during an emergency.[38]

As part of its response to the 2001 terrorist and anthrax attacks, Congress introduced the EUA pathway in the Project BioShield Act of 2004.[39] Congress then amended the EUA process several times.[40] EUAs provide a mechanism to grant rapid access to medical countermeasures during an emergency, particularly when the benefits of a product might outweigh the costs of following traditional approval procedures.[41] By removing some of the procedural safeguards in the traditional approval and licensing pathway, the EUA process empowers qualified actors to make judgment calls and respond quickly to an emergency.[42]

The FDA can issue an EUA for "an unapproved medical product or an unapproved use of an approved medical product."[43] Before the

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[38] For example, the FDA utilized the IND protocol to offer emergency access to drugs and an anthrax vaccine during the 2001 anthrax attacks. Nightingale et al., *supra* note 37, at 1047. The IND use of the anthrax vaccine "highlighted substantial shortcomings with [the IND] approach" for emergency authorizations because its focus on controlled clinical research and its administrative burdens could not adequately address the needs of a population during a CBRN emergency. *See id.* ("The country needed an emergency mechanism built not on a clinical research model, but on a public health model.").

[39] *See* Project BioShield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835; Megan O'Reilly, Case Brief, *The Failures of Project BioShield & Congressional Attempts to Remedy It*, 10 DEPAUL J. HEALTH CARE L. 503, 503 (2007) ("In response to the 2001 terrorist attacks, the United States government began a crash program to develop drugs, vaccine and diagnostic tests to protect the nation from biological terrorism."); 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 ("In the wake of the Sept. 11 terrorist attacks, and especially the anthrax mailings later that year, it was widely acknowledged that even the agency's fastest approval mechanisms were too slow and inflexible to handle a true emergency.").

[40] *See, e.g.*, Blum & Paradise, *supra* note 5, at 14–16 (noting that "[t]he emergency use authorization ('EUA') procedure was first introduced in the Project Bioshield Act of 2004 and subsequently amended through legislation" and describing the amendments).

[41] *See, e.g.*, Kelley & Tilden, *supra* note 29, at 18–20 (describing how EUAs allow the FDA to bypass traditional measures for protecting human subjects through IRBs).

[42] *See, e.g.*, Zettler et al., supra note 4, at 165 ("The addition of the EUA mechanism to the FDCA arguably reflects a societal decision that FDA ought to have flexibility to lower standards of safety and effectiveness during public health emergencies to speed access to promising, but unproven, products.").

[43] OFF. OF COUNTERTERRORISM & EMERGING THREATS, U.S. DEP'T HEALTH & HUM. SERVS., EMERGENCY USE AUTHORIZATION OF MEDICAL PRODUCTS AND RELATED AUTHORITIES 3 (2017)

FDA Commissioner issues an EUA, two actions must occur.[44] First, either the Secretary of Defense, the Secretary of Health and Human Services (HHS), or the Secretary of Homeland Security must determine that an emergency, or the significant potential for an emergency, exists.[45] Second, upon such a determination, the HHS Secretary must declare that circumstances exist that justify emergency authorized use of medical products.[46] Although Section 564 of the FDCA authorizes the Secretary of Health and Human Services to issue EUAs,[47] the Secretary has delegated the decision-making authority to the FDA.[48] The FDA Commissioner may then issue an EUA if, after consultation with the Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention, the Commissioner concludes that the product meets certain statutory criteria.[49] The HHS Secretary retains the power to override an FDA EUA decision, but this has yet to occur.[50]

To issue an EUA, the following criteria must be satisfied: (1) the CBRN agent referred to in the emergency declaration must be capable of causing "a serious or life-threatening disease or condition"; (2) the FDA Commissioner must find that *it is reasonable,* "*based on the totality of scientific evidence*," to believe that "the product *may be effective* in diagnosing, treating, or preventing" the disease or condition and that the benefits of using the product outweigh the risks; (3) there must be "no adequate,

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[hereinafter 2017 FDA GUIDANCE] (footnote omitted), https://www.fda.gov/media/97321/download.

[44] *See* 21 U.S.C § 360bbb-3 (specifying the prerequisites for EUA issuance); 2017 FDA GUIDANCE, *supra* note 43, at 5–6 (elaborating on the EUA procedure).

[45] 2017 FDA GUIDANCE, *supra* note 43, at 5.

[46] 21 U.S.C. § 360bbb-3(b)–(c).

[47] 21 U.S.C § 360bbb-3(b)(1).

[48] *See* 2017 FDA GUIDANCE*, supra* note 43, at 3 n.6 ("[T]he Secretary of Health and Human Services (HHS Secretary or Secretary of HHS) has delegated most of the authorities under sections 564, 564A, and 564B to the Commissioner of FDA (Commissioner).").

[49] 21 U.S.C. § 360bbb-3(c). The FDA Commissioner must only consult with the Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention "to the extent feasible and appropriate given the applicable circumstances." *Id.*

[50] *See* Zettler et al., *supra* note 4, at 164 (noting that because "the FDA is an agency within HHS," the HHS secretary can override FDA decisions but rarely does).

approved" alternative product; and (4) any additional criteria imposed by applicable regulations must be satisfied.[51]

Upon issuance of an EUA, the HHS Secretary must "promptly publish in the Federal Register a notice of each authorization . . . and an explanation of the reasons therefor."[52] Additionally, the FDA must make "any revisions to an authorization under this section available on the Internet Web site of the Food and Drug Administration."[53] The FDA must periodically review the authorization and retains the power to revoke or terminate the EUA whenever it determines that it is no longer reasonable to believe that the product may be effective.[54] A notice of a termination or revocation must also be published in the Federal Register.[55] Upon a determination that the CBRN emergency is over, all EUAs will terminate.[56]

D. COMPARISON

While there are many differences between the traditional pathways and the EUA pathway, the most important differences relate to evidentiary requirements, decision-making, and speed of authorization. First, the EUA procedure presents a significantly lower evidentiary burden than the traditional pathways do.[57] While developers must show that a drug *is* safe and effective or a vaccine "*is* safe, pure, and potent" to obtain FDA approval or licensing,[58] a developer must only show that a drug or vaccine "*may* be effective"

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[51] 21 U.S.C. § 360bbb-3(c) (emphasis added); *see also* 2017 FDA GUIDANCE, *supra* note 43, at 7–8 (describing the criteria as (1) serious or life-threatening disease or condition, (2) evidence of effectiveness, (3) risk-benefit analysis, and (4) no alternatives).

[52] 21 U.S.C § 360bbb-3(h)(1).

[53] *Id.*

[54] 21 U.S.C. § 360bbb-3(b)(2), (g)(1)–(2).

[55] *See* 2017 FDA GUIDANCE, *supra* note 43, at 29–30 (describing the publication protocol for EUAs).

[56] *See id.* at 6 ("The HHS Secretary's EUA declaration will terminate on . . . a determination by the HHS Secretary that the circumstances that precipitated the declaration have ceased . . . .").

[57] *See* Kelley & Tilden, *supra* note 29, at 12 (noting that the legal standards for emergency use authorizations "are less stringent than provided by the investigational new drug regulations").

[58] 21 U.S.C. § 355(b); 42 U.S.C. § 262(a) (emphasis added).

to obtain an EUA.[59] FDA approval and licensing also require "*substantial* evidence" of safety and effectiveness, which includes completion of Phase 3 clinical trials.[60] Clinical investigations, as required by NDAs and BLAs, must have IRB review and approved informed consent procedures.[61] By contrast, the FDA Commissioner must only find that "it is *reasonable* to believe" that the product "*may* be effective,"[62] and EUAs do not require completion of clinical trials prior to issuance.[63] No IRB review of the EUA trials is required, but the FDA can seek IRB review if it desires.[64]

Additionally, unlike the traditional approval pathways, where CDER or CBER evaluates the drug or vaccine based on clinical and pre-clinical trial results, the FDA Commissioner can consult a variety of additional sources when evaluating the drug or vaccine for EUA.[65] These sources do not have to be well-controlled scientific trials and can include incomplete studies or guidelines from other countries.[66] As some commentators have noted, "[t]he addition of

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[59] 21 U.S.C. § 360bbb-3(c) (emphasis added).

[60] *See supra* notes 24, 28.

[61] *See* Kelley & Tilden, *supra* note 29, at 19–20 (describing the typical IRB procedure for FDA drug approval).

[62] 21 U.S.C. § 360bbb-3(c)(2) (emphasis added); *see also* Zettler et al., *supra* note 4, at 164 (commenting that the bar for EUA is lower than that of traditional FDA approval).

[63] *See* 21 U.S.C. § 360bbb-3(k) ("If a product is the subject of an authorization under this section, the use of such product within the scope of the authorization shall not be considered to constitute a clinical investigation . . . ."); Kelley & Tilden, *supra* note 29, at 19 ("[O]ne can surmise that [through EUAs] unapproved products and unapproved uses of approved products, which clearly are experimental in nature, have effectively been removed from traditional review by institutional review boards.").

[64] *See* Kelley & Tilden, *supra* note 29, at 20 (emphasizing that IRB review is discretionary for EUAs).

[65] *See* 2017 FDA Guidance, *supra* note 43, at 14–15 (listing examples of the types of evidence the FDA Commissioner may consider); *see also, e.g.*, CTR. FOR DRUG EVALUATION AND RSCH., (CDER) REVIEW, EMERGENCY USE AUTHORIZATION (EUA) FOR CHLOROQUINE PHOSPHATE, AN UNAPPROVED PRODUCT AND HYDROXYCHLOROQUINE SULFATE, AN UNAPPROVED USE OF AN APPROVED PRODUCT 6 (2020) [hereinafter CHLOROQUINE & HYDROXYCHLOROQUINE CDER REVIEW], https://www.documentcloud.org/documents/6933189-LEOPOLD-FDA-FOIA-Hydroxychloroquine-study.html (citing Chinese and Korean guidelines recommending chloroquine or hydroxychloroquine for coronavirus treatment).

[66] *See* 21 U.S.C. § 360bbb-3(c) (allowing the HHS Secretary to issue an authorization "based on the totality of scientific evidence available"); *see also* 2017 FDA Guidance, *supra* note 43, at 8 ("FDA intends to look at the totality of the scientific evidence to make an overall risk-benefit determination. Such evidence, which could arise from a variety of sources, may

the EUA mechanism to the FDCA arguably reflects a societal decision that FDA ought to have flexibility to lower standards of safety and effectiveness during public health emergencies to speed access to promising, but unproven, products."[67]

These differing evidentiary requirements and decision-making standards support one of the EUA procedure's key benefits: the speed of authorization.[68] The FDA typically requires at least a few months to review an NDA or BLA prior to issuing its decision on approval or licensing, and the process of completing Phase 3 clinical trials takes years.[69] By contrast, the FDA typically decides whether to issue EUAs within weeks.[70] As mentioned, developers seeking authorization do not need to complete clinical trials and can instead submit preliminary data from clinical trials or data from other trials.[71] This expedited decision-making process is critical during a CBRN emergency when time is of the essence, but removing safeguards and granting more discretionary power to key players raises concerns with safety, ethics, and political influence.[72]

Last, EUAs differ from the traditional processes because they must be used during CBRN emergencies, are limited in time and scope, and are easily revocable.[73] The EUA procedure allows the FDA to respond quickly and flexibly to a CBRN emergency in a way that would be impossible with only the traditional routes for FDA approval, but it sacrifices some of the traditional routes' scientific

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include (but is not limited to): results of domestic and foreign clinical trials, *in vivo* efficacy data from animal models, and *in vitro* data, available for FDA consideration.").

[67] Zettler et al., *supra* note 4, at 165.

[68] *See id.* (noting that EUAs increase the speed at which access to products is granted).

[69] *See, e.g.*, JAMA Network, *Coronavirus Vaccine Update from the FDA – October 5, 2020*, YOUTUBE (Oct. 5, 2020), https://www.youtube.com/watch?v=43XAc5iDN9k (discussing the differences between EUAs and traditional FDA approval with the director of the FDA's CBER).

[70] *See id.* at 23:35–23:54 ("It's probably going to take a matter of weeks [to issue an EUA] . . . . [W]e're talking about weeks as opposed to months. A biologics license application, even a very well put together one, will take us a few months at least . . . .").

[71] *See supra* notes 63–66 and accompanying text.

[72] *See* Zettler et al., *supra* note 4, at 165 (mentioning concerns surrounding the EUA procedure and "developing rigorous evidence of products' safety and effectiveness," "tremendous political pressure," and "providing equitable access to COVID-19 countermeasures").

[73] *See supra* notes 52–55 and accompanying text.

and ethical safeguards to achieve this goal.[74] The EUAs issued by the FDA since the creation of the EUA pathway in 2004 illustrate the strengths and weakness of the EUA procedure. Part III examines these EUAs.

III. EUAS IN PRACTICE

Since 2011, the FDA has issued various EUAs for emergencies and potential emergencies including H1N1 (swine flu), Middle East Respiratory Syndrome Coronavirus (MERS-CoV), Ebola virus, Zika virus, and, most recently, COVID-19.[75] The COVID-19 pandemic, however, put the EUA power to the ultimate test, presenting the greatest CBRN emergency since the procedure was established and spurring the FDA to issue more EUAs than for any other CBRN emergency.[76] This Part provides a brief synopsis of various CBRN emergencies during which the FDA has issued EUAs for drugs or vaccines. Examining these CBRN emergencies demonstrates the strengths and weaknesses of the EUA procedure and illuminates a path for effective reform.

A. ANTHRAX

In 2005, the FDA issued the first EUA for Anthrax Vaccine Adsorbed (AVA).[77] Before the 2005 EUA, in response to the 2001 anthrax attacks, the FDA offered emergency access to the anthrax vaccine through the IND process.[78] Few people opted to receive the

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[74] *See supra* notes 60–67 and accompanying text.

[75] *See Archived EUAs*, *supra* note 2 (listing CBRN emergencies for which EUAs have been issued).

[76] *Id.* (illustrating the numerous EUAs issued for COVID-19 in comparison to previous CBRN emergencies).

[77] *See* Authorization of Emergency Use of Anthrax Vaccine Adsorbed for Prevention of Inhalation Anthrax by Individuals at Heightened Risk of Exposure Due to Attack with Anthrax; Availability, 70 Fed. Reg. 5452 (Feb. 2, 2005) (announcing the EUA for AVA); Sarah Zhang, *What the 'Emergency' Blood-Plasma Debacle Reveals*, ATLANTIC (Aug. 26, 2020), https://www.theatlantic.com/health/archive/2020/08/the-emergency-use-loophole/615679/ ("[T]he FDA ended up issuing an EUA before reaffirming the vaccine's safety and efficacy in a formal review.").

[78] *See* Sandra Crouse Quinn, Tammy Thomas & Supriya Kumar, *The Anthrax Vaccine and Research: Reactions from Postal Workers and Public Health Professionals*, 6 BIOSECURITY &

vaccine due to factors such as reduced trust in public health agencies, public controversy and debate surrounding the vaccine's safety and necessity, differing levels of risk perception, and "mixed and changing messages" from public health agencies.[79] The Department of Defense (DoD) also vaccinated a number of military personnel with AVA prior to the 2005 EUA issuance.[80] As a result of AVA's unapproved status, the DoD faced substantial litigation and criticism of its vaccination program.[81] In 2004, a federal court issued an injunction against the DoD vaccination program.[82] In response, the Deputy Defense Secretary requested an EUA,[83] which the FDA Commissioner granted after following the EUA procedure and consulting with the directors of the National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC).[84]

The AVA EUA required, among other things, that the DoD advise military members of their right to refuse the vaccine without facing adverse consequences, thereby addressing some of the objections brought in the litigation.[85] The EUA allowed the DoD to continue vaccinations by providing a legal pathway for the FDA to grant

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BIOTERRORISM: BIODEFENSE STRATEGY, PRAC. & SCI. 321, 321–22 (2008) (discussing the CDC's plan to offer certain at-risk groups the anthrax vaccine through the IND).

[79] *Id.* at 323, 325; *see also id.* at 330 ("In 2001, public health professionals were unprepared for the vaccine recommendation, and agencies did not have consensus about its use, which contributed to further distrust and suspicion among postal workers [offered the vaccine].").

[80] *See* Nightingale et al., *supra* note 37, at 1050 ("Since 1998, to protect against the threat of anthrax attack, the armed forces have vaccinated a substantial number of their members with AVA . . . .").

[81] *See id.* (noting that the military AVA vaccination program "has had detractors and has been the subject of litigation" and detailing the litigation); Quinn et al., *supra* note 78, at 326 (discussing negative reactions by postal workers to the military's use of AVA).

[82] *See* Nightingale et al., *supra* note 37, at 1050 ("In late 2004, a federal court issued an injunction against the DoD program on the grounds that the FDA should have obtained public comments before issuing a determination confirming that the AVA license included use for prevention of inhalation anthrax.").

[83] *See id.* ("Then Deputy Defense Secretary Paul Wolfowitz . . . determined . . . that there was a significant potential for a military emergency involving anthrax and requested that an EUA be issued for AVA.").

[84] *Id.*

[85] *See id.* ("[T]he EUA . . . required DoD to inform military members that they had an option to refuse the vaccine and that no adverse action would be taken against those who declined the vaccine under the EUA.").

access to the vaccine.[86] The EUA terminated on January 14, 2006, when the FDA pronounced the AVA safe and effective for people at high risk of anthrax exposure in a formal review.[87] Ultimately, the EUA process provided the government with a pathway to respond quickly to the anthrax emergency, rather than face the additional administrative burdens of an IND.[88]

B. H1N1

On April 26, 2009, HHS declared the H1N1 pandemic, colloquially referred to as the swine flu pandemic, a public health emergency.[89] The FDA issued EUAs for two antivirals in August of 2009,[90] followed by a third EUA for another antiviral in November of 2009.[91] These EUAs likely helped to mitigate the morbidity and mortality of H1N1.[92] However, some local health departments

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[86] *See id.* ("The issuance of this EUA cleared the way for DoD to resume anthrax vaccinations to protect military personnel assigned to certain higher threat areas.").

[87] *See* Termination, By Expiration, of Declaration of Emergency Justifying Emergency Use Authorization of Anthrax Vaccine Adsorbed, 71 Fed. Reg. 5341 (Feb. 1, 2006) (announcing the termination of the AVA EUA).

[88] Using the EUA specifically to require military vaccination or to circumvent court orders presents serious ethical issues that are beyond the scope of this note. *See* Kelley & Tilden, *supra* note 29, at 22 ("[The AVA EUA] foreshadows the serious ethical and legal issues that would arise in the event of a public health emergency due to a naturally occurring outbreak or bioterrorist attack.").

[89] *See* Wendy E. Parmet, *Pandemics, Populism and the Role of Law in the H1N1 Vaccine Campaign*, 4 ST. LOUIS U. J. HEALTH L. & POL'Y 113, 120–23 (2010) (detailing the governmental response to the H1N1 pandemic). H1N1 was a novel type of influenza, so few young people had existing immunity. *See 2009 H1N1 Pandemic (H1N1pdm09 virus)*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/flu/pandemic-resources/2009-h1n1-pandemic.html (last updated June 11, 2019) (providing an overview of the 2009 H1N1 pandemic statistics). From April 2009 to March 2010, there were about 60 million cases of H1N1, resulting in about 270,000 hospitalizations and about 12,270 deaths in the United States. Michael A. Jhung et al., *Epidemiology of 2009 Pandemic Influenza A (H1N1) in the United States*, 52 CLINICAL INFECTIOUS DISEASES 13, 23 (2011).

[90] *See Archived EUAs*, *supra* note 2 (listing EUAs issued by the FDA for Tamiflu and Relenza in response to H1N1).

[91] *See id.* (denoting an EUA issued by the FDA for Peramivir to treat H1N1).

[92] *See* Brooke Courtney, *Five Legal Preparedness Challenges for Responding to Future Public Health Emergencies*, 39 J.L. MED. & ETHICS 60, 60 (2011) ("These authorizations gave public health and medical practitioners additional, important tools to mitigate H1N1-related morbidity and mortality."). A 2014 study later indicated that Peramivir may not be effective,

struggled to obtain the EUA drugs and accompanying literature that specified the EUA conditions and content.[93] Although a company eventually produced a vaccine and received full FDA approval—not an EUA—in mid-September of 2009, the vaccine was not widely available until the second wave of infection had begun to recede.[94] The FDA approved the H1N1 vaccine without full clinical trials, stating that the vaccine did not differ fundamentally from the seasonal flu vaccine.[95] One study concluded that if H1N1 vaccinations had begun two weeks earlier, the vaccine would have prevented 59% more cases than the base estimate.[96] The vaccine faced public fears that it was untested or unsafe, which were possibly exacerbated by the vaccine's lack of full clinical trials and

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but the study had to be terminated due to lack of a sufficient sample size. *See* Menno D. de Jong et al., *Evaluation of Intravenous Peramivir for Treatment of Influenza in Hospitalized Patients*, 59 CLINICAL INFECTIOUS DISEASES 172, 172 (2014) ("A significant clinical benefit was not demonstrated for peramivir plus [Standard of Care] compared with placebo plus [Standard of Care]. Peramivir was generally safe and well tolerated. These findings highlight the challenges in designing studies to evaluate influenza antiviral agents in a hospitalized setting."); Zhang, *supra* note 77 ("The [FDA] learned a lesson—better to do the trial *during* the pandemic. That way, [a former acting chief scientist for the FDA] said, 'we can actually learn quickly enough which drugs have merit and which ones don't that we can actually alter the course of the pandemic.'").

[93] *See* Courtney, *supra* note 92, at 60–61 ("[S]ome health departments have noted that they do not have advance access to EUA content and conditions because EUAs are issued at the time of the emergency.").

[94] *See* Parmet, *supra* note 89, at 119–23 ("[M]ost people who wanted to be vaccinated could not be [in early November 2009]. . . . [I]n December 2009, as supplies picked up, the CDC announced two voluntary 'non-safety' recalls of H1N1 vaccine. Meanwhile, worries about the pandemic abated, as the dreaded second wave appeared no more virulent than the first." (footnotes omitted)); *see also* Rebekah H. Borse et al., *Effects of Vaccine Program Against Pandemic Influenza A(H1N1) Virus, United States, 2009–2010*, 19 EMERGING INFECTIOUS DISEASES 439, 447 (2013) ("The major factor influencing the effects of the 2009 subtype H1N1 vaccination program was that the amount of vaccine available early in the epidemic (when the effects of vaccination would be greatest) was limited.").

[95] *See* Parmet, *supra* note 89, at 131 ("[T]he FDA licensed the H1N1 vaccine . . . without waiting for full clinical trials, reasoning that the vaccine was not fundamentally different than the seasonal flu vaccine.").

[96] *See* Borse et al., *supra* note 94, at 444–45 ("If [the vaccinations] had begun 2 weeks earlier than the actual date, the number of cases prevented would have been ≈59% greater than the base estimate; moving the program ahead by 8 weeks would have resulted in a ≈306% increase in cases prevented compared with the base estimate.").

public discussions regarding whether the FDA should grant an H1N1 vaccine EUA.[97]

C. SARS-COV-2

On January 31, 2020, the HHS Secretary declared the coronavirus pandemic a PHE.[98] While the FDA faced criticism for its slow issuance of EUAs for diagnostics following the declaration,[99] the EUAs for drugs and biological products garnered particular media attention and criticism.[100]

1. Chloroquine and Hydroxychloroquine. On March 19, 2020, President Trump directed the FDA to expedite testing of certain medicines to treat COVID-19, mentioning the drugs chloroquine and hydroxychloroquine, as well as remdesivir.[101] Less than ten days later, the FDA issued an EUA for chloroquine and

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[97] *See* Parmet, *supra* note 89, at 131–32 ("[T]he discussion of a possible EUA, and the decision to license the vaccine without full testing, may have helped to fuel a public perception that the vaccine was rushed and untested.").

[98] *Public Health Emergency Declarations*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx (last visited Nov. 2, 2021).

[99] *See* Evans & Clayton, *supra* note 7, at 78–79 ("When a contaminated reagent slowed deployment of a COVID-19 test from the Centers for Disease Control and Prevention (CDC), other entities such as diagnostic test manufacturers and research, clinical, and public health laboratories were poised to fill the void. Actions by the FDA [using the EUA procedure] allegedly delayed or even halted some of their efforts.").

[100] *See, e.g.*, Dorit Rubinstein Reiss, *Institutionalizing the Centers for Disease Control and Prevention's Independence*, 12 CONLAWNOW 107, 120 (2020) ("The concern that the administration will directly intervene in CDC's professional decisions is not a hypothetical concern: there is strong evidence that influence by the administration had a role in the FDA's choice to give an emergency use authorization (EUA) to hydroxychloroquine."); Piller, *supra* note 3 (describing criticism by former FDA officials of the hydroxychloroquine EUA).

[101] *See* Thomas M. Burton, Andrew Restuccia & Jared S. Hopkins, *U.S. Moves to Expand Array of Drug Therapies Deployed Against Coronavirus*, WALL ST. J. (Mar. 19, 2020, 3:00 PM), https://www.wsj.com/articles/trump-expected-to-detail-new-virus-therapies-but-expansion-could-be-controversial-11584629965 ("Mr. Trump specifically mentioned two drugs, chloroquine and hydroxychloroquine, that have long been used for malaria but aren't approved for the coronavirus, as well as an antiviral drug, remdesivir, that is currently being tested in clinical research on Covid-19, the coronavirus disease.").

hydroxychloroquine.[102] In the EUA letter, the FDA cited to "limited in-vitro and anecdotal clinical data in case series" and noted that "a number of national guidelines report incorporating recommendations regarding use of chloroquine phosphate or hydroxychloroquine sulfate in the setting of COVID-19."[103] The EUA letter did not state which specific studies or guidelines the FDA examined when reaching its decision.[104]

A subsequent review, released at a later date in response to a Freedom of Information Act request, indicated that the EUA relied upon a French study, a Chinese study, Chinese and Korean guidelines, sixteen ongoing clinical trials, and the clinical community's "substantial interest" in trying the drugs for COVID-19 treatment.[105] The French study that the FDA utilized was controversial; it involved only thirty-six patients and was open-label and nonrandomized.[106] The journal that published the French study later issued a statement explaining that the study did not meet the

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[102] Letter from Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin., to Rick Bright, Dir., Biomed. Advanced Rsch. & Dev. Auth. 2 (Mar. 28, 2020) [hereinafter Chloroquine and Hydroxychloroquine EUA], https://www.fda.gov/media/136534/download.

[103] *Id.*

[104] *Id.*

[105] CHLOROQUINE & HYDROXYCHLOROQUINE CDER REVIEW, *supra* note 65; *see* Kyle Thomson & Herschel Nachlis, *Emergency Use Authorizations During the COVID-19 Pandemic: Lessons from Hydroxychloroquine for Vaccine Authorization and Approval*, 324 JAMA 1282, 1282–83 (2020) (criticizing the evidence relied upon for the hydroxychloroquine EUA). The EUA did recognize, however, that "[b]ecause of the limitations and inconsistencies of the available data, continuation and expansion of assessment in well-designed clinical trials is considered to be highly important, at the same time that emergency uses of these products in carefully selected crisis settings might be considered." CHLOROQUINE & HYDROXYCHLOROQUINE CDER REVIEW, *supra* note 65.

[106] *See* Philippe Gautret, et al., *Hydroxychloroquine and Azithromycin as a Treatment of COVID-19: Results of an Open-Label Non-Randomized Clinical Trial*, INT'L J. ANTIMICROBIAL AGENTS, July 2020, at 1, 3 (describing the study methods). An open-label study is a study in which participants are aware of whether or not they receive treatment, as compared to a placebo study in which participants are unaware. *Open Label Study*, NIH, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/open-label-study (last visited Nov. 2, 2021); *Placebos in Clinical Trials*, NIH, https://www.nia.nih.gov/health/placebos-clinical-trials (last visited Nov. 2, 2021). A nonrandomized study is a study in which participants are not assigned by random chance to different treatments. *See Nonrandomized Clinical Trial*, NIH, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/nonrandomized-clinical-trial (last visited Nov. 2, 2021).

journal's publication standard.[107] The FDA also referred to a "brief report"—not data or preliminary findings—"from a Chinese study of 100 COVID-19 patients [that] reported clinical improvement with chloroquine or hydroxychloroquine treatment versus an unspecified control."[108]

A variety of former FDA officials criticized the EUA, saying that it fell far below the evidentiary standards used for other therapeutic EUAs.[109] Further political controversy emerged when the former director of the Biomedical Advanced Research Development Authority (BARDA), Rick Bright, claimed that he was pressured into approving the EUA.[110] On June 15, 2020, the FDA revoked the authorization after a number of studies indicated that chloroquine and hydroxychloroquine were not effective in reducing the mortality or morbidity of COVID-19 and that the drug increased risks for a variety of adverse health consequences, including serious cardiac adverse events.[111] Subsequently, President Trump continued to advocate publicly in favor of using the drug.[112]

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[107] *See* Andreas Voss, *Official Statement from International Society of Antimicrobial Chemotherapy (ISAC)*, INT'L SOC'Y ANTIMICROBIAL CHEMOTHERAPY (Apr. 3, 2020), https://www.isac.world/news-and-publications/official-isac-statement ("The ISAC Board believes the [Gautret et al.] article does not meet the Society's expected standard, especially relating to the lack of better explanations of the inclusion criteria and the triage of patients to ensure patient safety.").

[108] CHLOROQUINE & HYDROXYCHLOROQUINE CDER REVIEW, *supra* note 65. For the original report cited, see Jianjun Gao, Zhenxue Tian & Xu Yang, *Breakthrough: Chloroquine Phosphate Has Shown Apparent Efficacy in Treatment of COVID-19 Associated Pneumonia in Clinical Studies*, 14 BIOSCIENCE TRENDS 72 (2020), https://www.jstage.jst.go.jp/article/bst/14/1/14_2020.01047/_pdf/-char/en.

[109] *See, e.g.*, Piller, *supra* note 3 (noting that former FDA executives criticized the hydroxychloroquine EUA for weak evidence of efficacy and for appearing to bow to political influence).

[110] *See* Zettler et al., *supra* note 4, at 165 ("FDA issued the [hydroxychloroquine and chloroquine] EUAs only nine days after the president publicly touted the drugs as COVID-19 countermeasures and, according to a whistleblower complaint from the former director of [BARDA], at the secretary of HHS's direction—raising significant concerns about political interference in public health decision making.").

[111] *See* Letter from Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin., to Gary L. Disbrow, Deputy Assistant Sec'y, BARDA, U.S. Food & Drug Admin. (June 15, 2020), https://www.fda.gov/media/138945/download (revoking the EUA for hydroxychloroquine).

[112] *See* Ben Gittleson, Jordyn Phelps & Libby Cathey, *Trump Doubles Down on Defense of Hydroxychloroquine to Treat COVID-19 Despite Efficacy Concerns*, ABC NEWS, (July 28, 2020, 7:06 PM), https://abcnews.go.com/Politics/trump-doubles-defense-hydroxychloroquine-treat-

2. Remdesivir. On May 1, 2020, the FDA issued an EUA for remdesivir (also known as Veklury) for the treatment of hospitalized adult and pediatric patients with severe COVID-19.[113] The FDA issued this EUA following preliminary results from a randomized, double-blinded, placebo-controlled trial conducted by the National Institute of Allergy and Infectious Disease (NIAID) and an open-label trial by the pharmaceutical company Gilead, which indicated that remdesivir shortened hospital stays by 31% in some patient populations.[114] Remdesivir had IND status but was not previously approved by the FDA for any indication.[115] On the day of the EUA issuance, the FDA did not release the data underlying the relevant efficacy statistics referred to in its authorization letter.[116] A variety of doctors in the United States called for the FDA to release the data so that they could treat the right patients properly.[117] A preliminary version of the peer-

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covid-19-efficacy/story?id=72039824 (quoting several statements President Trump made in support of hydroxychloroquine).

[113] Letter from Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin., to Ashley Rhoades, Regulatory Affairs Manager, Gilead Sciences, Inc. 1 (Oct. 22, 2020) [hereinafter Remdesivir EUA], https://www.fda.gov/media/137564/download.

[114] *See* Deena Beasley, *U.S. Doctors Call for Remdesivir Data to Guide Coronavirus Treatment*, REUTERS (May 21, 2020, 5:16 PM), https://www.reuters.com/article/us-health-coronavirus-gilead-sciences/u-s-doctors-call-for-remdesivir-data-to-guide-coronavirus-treatment-idUSKBN22X2Q3 ("The FDA approved emergency use of remdesivir on May 1 based on preliminary results from a National Institute of Allergy and Infectious Diseases (NIAID) trial showing that the drug cut hospital stays by 31%, or about four days, compared with a placebo.").

[115] *See* Remdesivir EUA, *supra* note 113, at 1 (granting an emergency use authorization for remdesivir and noting that remdesivir "was an investigational drug and not approved for any indication").

[116] *See* Beasley, *supra* note 114 (noting that the FDA did not release the data it referred to in the EUA); *NIH Clinical Trial Shows Remdesivir Accelerates Recovery from Advanced COVID-19*, NIH (Apr. 29, 2020), https://www.niaid.nih.gov/news-events/nih-clinical-trial-shows-remdesivir-accelerates-recovery-advanced-covid-19 ("More detailed information about the trial results, including more comprehensive data, will be available in a forthcoming report.").

[117] *See* Beasley, *supra* note 114 ("U.S. doctors and others in the scientific community are calling for the release of data that convinced health regulators to authorize emergency use of . . . remdesivir to treat COVID-19 . . . .").

reviewed findings was published three weeks later, and a final version was published six months later.[118]

In August of 2020, the FDA expanded the EUA to include treatment of all hospitalized adult and pediatric patients with COVID-19 after the results of two clinical trials indicated that the drug improved recovery times for all patients, including those with mild to moderate disease.[119] Two months later, the FDA approved remdesivir for a large patient population based on the results of "three randomized, controlled clinical trials," but the EUA continued for those populations not covered by the approval.[120]

3. Convalescent Plasma. On August 23, 2020, the FDA issued an EUA for COVID-19 convalescent plasma.[121] COVID-19 convalescent plasma had IND status and was not previously licensed or approved for any indication.[122] The EUA letter cited data demonstrating clinical benefits but noted that the data was not obtained from well-

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[118] John H. Beigel et al., *Remdesivir for the Treatment of COVID-19*, 383 NEW ENG. J. MED. 1813, 1813 (2020) (noting that "[a] preliminary version of this article was published on May 22, 2020" and that the "data show that remdesivir was superior to placebo in shortening the time to recovery in adults who were hospitalized with Covid-19 and had evidence of lower respiratory tract infection").

[119] *See* Press Release, U.S. Food & Drug Admin., COVID-19 Update: FDA Broadens Emergency Use Authorization for Veklury (Remdesivir) to Include All Hospitalized Patients for Treatment of COVID-19 (Aug. 28, 2020), https://www.fda.gov/news-events/press-announcements/covid-19-update-fda-broadens-emergency-use-authorization-veklury-remdesivir-include-all-hospitalized ("The expansion of the scope of the EUA to include hospitalized patients with mild or moderate COVID-19 is supported by the Agency's analysis of additional data from two randomized, controlled clinical trials that included patients with mild or moderate disease.").

[120] Press Release, U.S. Food & Drug Admin., FDA Approves First Treatment for COVID-19 (Oct. 22, 2020), https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19. Remdesivir was approved for adults and pediatric patients at least twelve years of age and weighing at least forty kilograms. *Id.*

[121] Letter from Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin., to Robert P. Kadlec, Assistant Sec'y for Preparedness and Response, U.S. Dep't Health & Hum. Servs. (Aug. 23, 2020) [hereinafter Convalescent Plasma EUA], https://web.archive.org/web/20200922235943/https://www.fda.gov/media/141477/download. Convalescent plasma "is the acellular component of blood that contains antibodies," which is collected from patients who have recovered from COVID-19. Sean T. H. Liu, et al., *Convalescent Plasma Treatment of Severe COVID-19: A Propensity Score-Matched Control Study*, 26 NATURE MED. 1708, 1708 (2020). The plasma is then transfused into patients currently infected with SARS-CoV-2. *Id.*

[122] Convalescent Plasma EUA, *supra* note 121.

controlled randomized clinical trials.[123] Rather, the data was derived from a nationwide expanded access program (also known as "compassionate use")[124] run by the Mayo Clinic, which treated more than 70,000 people.[125] The FDA initially intended to conduct well-controlled, randomized trials of convalescent plasma, but as the expanded access program grew, the trials struggled to enroll patients.[126] Following publicized reports of disagreement between FDA scientists and the Trump Administration about whether to issue the authorization[127] and controversial statements made at the press conference announcing the authorization,[128] fears of political influence on the EUA issuance emerged.[129] The COVID-19 Treatment Panel at the NIH issued a statement explaining that there was not enough evidence for the panel to recommend the use of convalescent plasma for treatment of COVID-19 but recognizing that the FDA could argue that the data met the "may be effective"

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[123] *See id.* ("Given that the clinical evidence supporting this EUA was not obtained from prospective, well-controlled randomized clinical trials (RCTs), additional RCTs are needed.").

[124] *See* James T. O'Reilly & Katharine A. Van Tassel, 1 FOOD AND DRUG ADMIN. § 13:90, Westlaw (database updated June 2021) ("The FDA allows for *individual* access to investigational therapies for terminally ill patients *outside* of a clinical trial under expanded or 'compassionate' use on a case-by-case basis pursuant to The Food and Drug Administration Modernization Act of 1997 (FDAMA).").

[125] *See* Rachel Sachs, *Understanding the FDA's Controversial Convalescent Plasma Authorization*, HEALTH AFFS.: BLOG (Aug. 27, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200827.190308/full/ ("[T]he FDA has faced serious questions about the expanded access program, which has now grown to treat more than 70,000 patients while the randomized clinical trials struggle to enroll enough patients to determine whether plasma is truly effective against COVID-19.").

[126] *See id.* (explaining how the FDA had to put plans "on hold" after the issuance of the EUA because of various challenges, including low enrollment).

[127] *See id.* ("The manner in which the EUA was granted raised a series of questions about the agency's independence from political pressure.").

[128] *See, e.g.*, Kai Kupferschmidt & Jon Cohen, *In Plasma OK, Critics See Politics, Not Science*, 369 SCI. 1038, 1038–39 (2020) (describing fears over political interference in the issuance of EUAs for convalescent plasma based on the press conference announcement, which "represented as much political theater as science").

[129] *See* Noah Wieland, Sharon LaFraniere & Sheri Fink, *F.D.A.'s Emergency Approval of Blood Plasma Is Now on Hold*, N.Y. TIMES (Jan. 6, 2021), https://www.nytimes.com/2020/08/19/us/politics/blood-plasma-covid-19.html ("[A] group of top federal health officials including Dr. Francis S. Collins and Dr. Anthony S. Fauci intervened [in the issuance of the EUA for convalescent plasma], arguing that emerging data on the treatment was too weak, according to two senior administration officials.").

criteria for EUA issuance.[130] On February 4, 2021, the FDA revised the EUA to authorize "only the use of high titer COVID-19 convalescent plasma, for the treatment of hospitalized patients with COVID-19, early in the disease course" after "additional studies, including randomized, controlled trials . . . provided data to further inform the safety and efficacy of COVID-19 convalescent plasma."[131]

4. Vaccines. As of this writing, the FDA has issued EUAs for three COVID-19 vaccines.[132] Rampant speculation and concern about the possibility of a vaccine EUA marked the months preceding the vaccine EUAs.[133] Comments from various politicians, the

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[130] *Convalescent Plasma*, NIH, https://web.archive.org/web/20201011025339/https://www.covid19treatmentguidelines.nih.gov/immune-based-therapy/blood-derived-products/convalescent-plasma/ (last updated Oct. 9, 2021) ("There are insufficient data for the COVID-19 Treatment Guidelines Panel (the Panel) to recommend either for or against the use of COVID-19 convalescent plasma for the treatment of COVID-19.").

[131] Letter from Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin, to Nikki Bratcher-Bowman, Acting Assistant Sec'y for Preparedness and Response, U.S. Dep't Health & Hum. Servs. (Feb. 4, 2021), https://web.archive.org/web/20210216050215/https://www.fda.gov/media/141477/download. "Titer" refers to the concentration of antibodies. *Titer*, MEDLINEPLUS, https://medlineplus.gov/ency/article/002328.htm (last visited Nov. 6, 2021).

[132] *Emergency Use Authorization*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization (last updated Nov. 9, 2021) (listing the EUAs for the Janssen, Moderna, and Pfizer-BioNTech COVID-19 vaccines). The FDA also issued revised EUAs authorizing booster shots for each of the vaccines. Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Takes Additional Actions on the Use of a Booster Dose for COVID-19 Vaccines (Oct. 20, 2021) [hereinafter Vaccine Booster Press Release], https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines.

[133] *See, e.g.*, Philip Rucker, Josh Dawsey & Yasmeen Abutaleb, *Trump Fixates on the Promise of a Vaccine — Real or Not — as Key to Reelection Bid*, WASH. POST (Sept. 5, 2020, 5:02 PM), https://www.washingtonpost.com/politics/trump-vaccine-election/2020/09/05/c0da86d6-edf5-11ea-99a1-71343d03bc29_story.html ("There is intense disagreement over whether the FDA should use its emergency authority to clear a vaccine before it is formally approved, which some in the scientific community say could be dangerous."); Jon Cohen, *"There's Only One Chance to Do This Right"—FDA Panel Wrestles with COVID-19 Vaccine Issues*, SCI. (Oct. 23, 2020, 3:45 PM), https://www.sciencemag.org/news/2020/10/there-s-only-one-chance-do-right-fda-panel-wrestles-covid-19-vaccine-issues (discussing disagreement among the Vaccine and Related Biological Products Advisory Committee (VRBPAC) members about whether the FDA should issue vaccine EUAs).

impending 2020 presidential election,[134] and widely publicized controversies surrounding other EUAs all increased public concern about the safety of a possible vaccine EUA—in addition to concerns about political motivations influencing the authorization process.[135]

In response to mounting public pressure, in early September 2020, the chief executives of nine pharmaceutical companies pledged that the companies would "only submit for approval or emergency use authorization after demonstrating safety and efficacy through a Phase 3 clinical study that is designed and conducted to meet requirements of expert regulatory authorities such as FDA."[136] Then, in October 2020, the FDA released more stringent guidelines for EUAs of vaccines.[137] Although these guidelines were nonbinding,[138] they made it unlikely that a vaccine would be authorized prior to Election Day—November 3, 2020—

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[134] *See, e.g.*, Cohen, *supra* note 133 ("President Donald Trump repeatedly pushed for a COVID-19 vaccine EUA before the 3 November elections . . . .").

[135] *See, e.g.*, *id.* ("Several VRBPAC members worried an EUA could contribute to the public's growing hesitancy toward COVID-19 vaccines by fueling the perception that FDA was compromising its famously high standards."); Rucker et al., *supra* note 133 (describing the pressure that President Trump placed on health officials to approve a coronavirus vaccine); Zettler et al., *supra* note 4, at 165–66 (noting that "although FDA has not yet faced the question of whether to issue an EUA for a COVID-19 vaccine, concerns about political interference in such a decision have been raised, particularly if an EUA application is under review shortly before the November 2020 election," and "developing rigorous evidence of safety and effectiveness . . . will be particularly critical before distributing a COVID-19 vaccine").

[136] *See* Press Release, Pfizer, Inc., Biopharma Leaders Unite to Stand with Science (Sept. 8, 2020), https://www.pfizer.com/news/press-release/press-release-detail/biopharma-leaders-unite-stand-science (stating that the CEOs "want[ed] to make clear [their] on-going commitment to developing and testing potential vaccines for COVID-19 in accordance with high ethical standards and sound scientific principles").

[137] *See* CTR. FOR BIOLOGICS EVALUATION & RSCH., U.S. DEP'T HEALTH & HUM. SERVS., EMERGENCY USE AUTHORIZATION FOR VACCINES TO PREVENT COVID-19 (2020) [hereinafter 2020 VACCINE GUIDANCE], https://web.archive.org/web/20201223081724/https://www.fda.gov/media/142749/download ("[F]or a COVID-19 vaccine for which there is adequate manufacturing information to ensure its quality and consistency, issuance of an EUA would require a determination by FDA that the vaccine's benefits outweigh its risks based on data from at least one well-designed Phase 3 clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner.").

[138] *Id.* (noting that the document contains "nonbinding recommendations").

contrary to the pressure from the President.[139] Among other requirements, the new guidelines required that data from Phase 3 studies "include a median follow-up duration of at least two months after" the completion of the vaccination regimen.[140] Vaccine developers were also required to collect data in "ongoing trials for as long as feasible" after EUA issuance and to work towards receiving full FDA approval.[141] The new guidelines strongly recommended that vaccine developers monitor "a high proportion" of enrolled subjects," "numbering well over 3,000," for serious adverse events and "adverse events of special interest for at least one month after" completing the vaccine regimen.[142]

The FDA eventually issued EUAs for three vaccines: the Pfizer-BioNTech vaccine (the Pfizer vaccine) and the Moderna TX, Inc. vaccine (the Moderna vaccine) in December of 2020[143] and the Janssen Biotech, Inc. vaccine (the Johnson & Johnson vaccine) in February of 2021.[144] In its press releases describing the December EUAs, the FDA assured high levels of scientific rigor and independent decision-making during the EUA process.[145] All EUAs

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[139] *See* Zachary Brennan, *White House Lifts Block on FDA's Stricter Vaccine Requirements*, POLITICO (Oct. 6, 2020, 9:21 PM), https://www.politico.com/news/2020/10/06/fda-vaccine-guidelines-white-house-426764 (describing the impact of the FDA's EUA vaccine guidance and President Trump's reaction).

[140] 2020 VACCINE GUIDANCE*, supra* note 137, at 10.

[141] *Id.* at 4.

[142] *Id.* at 10.

[143] Press Release, U.S. Food & Drug Admin., FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine (Dec. 11, 2020) [hereinafter Pfizer Press Release], https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19; Press Release, U.S. Food & Drug Admin., FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine (Dec. 18, 2020) [hereinafter Moderna Press Release], https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid.

[144] Press Release, U.S. Food & Drug Admin., FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine (Feb. 27, 2021) [hereinafter J&J Press Release], https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine.

[145] *See* Pfizer Press Release, *supra* note 143 ("Today's action follows an open and transparent review process that included input from independent scientific and public health experts and a thorough evaluation by the agency's career scientists to ensure this vaccine met FDA's rigorous, scientific standards for safety, effectiveness, and manufacturing quality

were based on data derived from ongoing randomized, placebo-controlled studies with over 30,000 participants.[146] Participants in the Moderna study were followed for a median of seven weeks with additional safety data reviewed after nine weeks,[147] while Pfizer and Janssen study participants were followed for medians of two months and eight weeks respectively.[148] At the time of approval, the preliminary data indicated that the Moderna "vaccine was 94.1% effective . . . in preventing COVID-19 at least 14 days after the second dose,"[149] and the Pfizer vaccine was 95% effective in preventing COVID-19.[150] The preliminary data from the Janssen study indicated that the vaccine was 66.9% effective at least fourteen days after vaccination[151] and 66.1% effective at least twenty-eight days after vaccination.[152]

The FDA issued the EUAs with various conditions, including that vaccine manufacturers report all vaccine administration errors, any serious adverse events, any cases of Multisystem Inflammatory Syndrome in adults, and any cases of COVID-19 that

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needed to support emergency use authorization."); Moderna Press Release, *supra* note 143 ("Today's authorization demonstrates our steadfast commitment to the health of the American people, with the assurance that our scientific standards and the integrity of our review process have been maintained. This achievement is yet another testament to the dedication of FDA's career scientists and physicians, who have been working urgently to conduct comprehensive and rigorous evaluations of the data submitted for vaccines to prevent COVID-19.").

[146] Pfizer Press Release, *supra* note 143 (stating the trial included 37,586 participants); Moderna Press Release, *supra* note 143 (stating the trial included 30,351 participants); J&J Press Release, *supra* note 144 (stating the trial involved 43,783 participants).

[147] Letter from Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin., to Carlota Vinals, ModernaTX, Inc. 1–2 (Dec. 18, 2020) [hereinafter Moderna EUA], https://web.archive.org/web/20201231160643/https://www.fda.gov/media/144636/download.

[148] Letter from Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin., to Elisa Harkins, Pfizer, Inc. 2 (Dec. 23, 2020) [hereinafter Pfizer EUA], https://web.archive.org/web/20210102082132/https://www.fda.gov/media/144412/download; Letter from Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin., to Ruta Walawalkar, Janssen Biotech, Inc. 1–2 (Feb. 27, 2021) [hereinafter J&J EUA], https://web.archive.org/web/20210411075651/https://www.fda.gov/media/146303/download.

[149] 95% Confidence Interval: 89.3, 96.8. Moderna EUA, *supra* note 147, at 2. The preliminary results indicated that the vaccine was 94.5% effective seven weeks after the second dose (95% Confidence Interval: 86.5, 97.8). *Id.*

[150] 95% Credible Interval: 90.3, 97.6. Pfizer EUA, *supra* note 148, at 2.

[151] 95% Confidence Interval: 59.0, 73.4. J&J EUA, *supra* note 148, at 2.

[152] 95% Confidence Interval: 55.0, 74.8. *Id.*

result in hospitalization or death that are reported to the company to the Vaccine Adverse Event Reporting System (VAERS).[153] The EUA also required the companies to submit monthly safety reports and conduct post-authorization observational studies.[154] Additionally, the FDA required Moderna to continue its ongoing clinical studies[155] and Moderna, Pfizer, and Janssen to conduct post-authorization observational studies to evaluate the association between the vaccines and "a pre-specified list of adverse events of special interest, along with deaths and hospitalizations, and severe COVID-19."[156]

In April of 2021, the FDA ordered a pause of the Janssen vaccine—but did not revoke the EUA—in response to six cases of blood clots, including one death, reported to VAERS.[157] In late April, the EUA vaccine fact sheets were revised to reflect the risk of blood clots, but the FDA determined that Janssen vaccinations should resume because the data indicated that blood clots were extremely rare.[158] Even after lifting the pause, public distrust regarding the safety of the vaccine EUAs, especially the Janssen vaccine, continued.[159] Despite this, the vaccine EUAs achieved significant success. For example, in May of 2021, the FDA expanded the Pfizer vaccine EUA, which had previously applied only to individuals

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[153] Pfizer EUA, *supra* note 148, at 6; Moderna EUA, *supra* note 147, at 6; J&J EUA, *supra* note 148, at 6.

[154] Moderna EUA, *supra* note 147, at 7–8; Pfizer EUA, *supra* note 148, at 7–8; J&J EUA *supra* note 148, at 6–7.

[155] Moderna EUA, *supra* note 147, at 7.

[156] *Id.* at 7; Pfizer EUA, *supra* note 148, at 7; J&J EUA *supra* note 148, at 7.

[157] *See* Press Release, U.S. Food & Drug Admin., FDA and CDC Lift Recommended Pause on Johnson & Johnson (Janssen) COVID-19 Vaccine Use Following Thorough Safety Review (Apr. 23, 2021), https://www.fda.gov/news-events/press-announcements/fda-and-cdc-lift-recommended-pause-johnson-johnson-janssen-covid-19-vaccine-use-following-thorough (describing the rationale behind the recommended pause and resumption of vaccinations).

[158] *Id.* (encouraging healthcare providers, as well as recipients and caregivers, to review relevant changes to the new Janssen vaccine fact sheets, reflecting the latest information and guidance).

[159] *See, e.g.*, Mia Sato, *The J&J Vaccine Is Back. Next Comes Trust*, MIT TECH. REV. (Apr. 29, 2021), https://www.technologyreview.com/2021/04/29/1024205/jj-johnson-and-johnson-vaccine-trust/ ("[E]ven though the pause lasted just 11 days, it raised new concerns about whether Americans will trust vaccinations. Recent polling shows that confidence in the Johnson & Johnson shot in particular is very low, with 73% of unvaccinated people saying they wouldn't accept a dose if offered.").

sixteen years and older, to include those twelve years and older.[160] Then, in August of 2021, the FDA granted the Pfizer vaccine full approval for individuals sixteen years and older, while the EUA continued to cover children ages twelve through sixteen.[161] In late October of 2021, the FDA re-issued the Pfizer EUA for children ages five through eleven.[162] Despite these successes, the Biden Administration was unable to meet its initial vaccination goals by July of 2021.[163] Nevertheless, in the following months, vaccine rates continued to increase.[164] By October of 2021, the FDA expanded the

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[160] Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Adolescents in Another Important Action in Fight Against Pandemic (May 10, 2021), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use.

[161] *See* Press Release, U.S. Food & Drug Admin., FDA Approves First COVID-19 Vaccine (Aug. 21, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine ("The FDA's approval of this vaccine is a milestone as we continue to battle the COVID-19 pandemic. While this and other vaccines have met the FDA's rigorous, scientific standards for emergency use authorization, as the first FDA-approved COVID-19 vaccine, the public can be very confident that this vaccine meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product.").

[162] Press Release, U.S. Food & Drug Admin., FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Children 5 through 11 Years of Age (Oct. 29, 2021), https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age; Letter from Jacqueline A. O'Shaughnessy, Acting Chief Scientist, U.S. Food & Drug Admin., to Amit Patel, Pfizer, Inc. 3 (Oct. 29, 2021), https://www.fda.gov/media/150386/download. The EUA was granted based on data from "an ongoing randomized, placebo-controlled study that has enrolled approximately 4,700 children 5 through 11 years of age." Press Release, *supra*. "The vaccine was found to be 90.7% effective in preventing COVID-19 in children 5 through 11" and "no serious side effects" were detected in a study that involved "approximately 3,100 children age 5 through 11." *Id.*

[163] *See* Richard Luscombe, *US Reaches Biden's 70% First-Shot Goal as Threat to Unvaccinated People Grows*, GUARDIAN (Aug. 2, 2021, 8:41 PM), https://www.theguardian.com/us-news/2021/aug/02/us-vaccination-rate-covid-coronavirus-biden-white-house ("The president had said he wanted the country to reach 70% at least partially vaccinated by the early July holiday, but the White House coronavirus response coordinator . . . admitted in June that the country would need 'a few extra weeks' because of reluctance by those aged 18 to 26 to get a shot.").

[164] *See, e.g.*, Jeff Mason & Ahmed Aboulenein, *U.S. COVID-19 Vaccine Rates up Thanks to Mandates; Cases and Deaths Down – Officials*, REUTERS (Oct. 13, 2021, 10:48 PM), https://www.reuters.com/world/us/vaccine-requirements-raised-covid-19-vaccination-rates-by-20-percentage-points-2021-10-13/ (discussing the rising vaccination rates and attributing the increase to vaccine mandates).

three vaccine EUAs to include booster doses for specific patient populations.[165] As of this writing, however, vaccine hesitancy continues to pose a challenge to public health authorities seeking to increase vaccination rates.[166]

While not an exhaustive summary, this Part has described various important EUAs that demonstrate how the procedure works in practice.[167] These EUAs represent the benefits of the EUA

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[165] *See* Vaccine Booster Press Release, *supra* note 132.

[166] *See, e.g.*, Alison Durkee, *Here's How Covid-19 Vaccine Hesitancy Has (and Hasn't) Changed over 2021*, FORBES (Dec. 26, 2021, 2:56 PM), https://www.forbes.com/sites/alisondurkee/2021/12/26/heres-how-covid-19-vaccine-hesitancy-has-and-hasnt-changed-over-2021/ ("More than 25% of U.S. adults are still not fully vaccinated against Covid-19 as 2021 comes to an end . . . ."); *Covid News: Omicron Hasn't Swayed the Least Vaccinated U.S. Counties*, N.Y. TIMES (Dec. 31, 2021, 5:11 AM), https://www.nytimes.com/live/2021/12/27/world/cdc-quarantine-isolation-guidelines ("In the United States, over 204 million people are fully vaccinated, but that's still only 62 percent of the population, much lower than in most other wealthy countries.").

[167] This Note summarizes EUAs that impacted the largest population groups for each PHE discussed. For more details about every drug and biological therapeutic product issued, see *Emergency Use Authorization, supra* note 132. At the time of this writing, the FDA authorized two pills, molnupiravir and Paxlovid, for treatment of mild-to-moderate COVID-19 in adults. Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Authorizes Additional Oral Antiviral for Treatment of COVID-19 in Certain Adults (Dec. 23, 2021), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-oral-antiviral-treatment-covid-19-certain; Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Authorizes First Oral Antiviral for Treatment of COVID-19 (Dec. 22, 2021), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-oral-antiviral-treatment-covid-19. Examining the issuances and progression of these EUAs in the following months may provide important insight into the importance of rapid authorization once sufficient data is gathered and the benefits and pitfalls of utilizing advisory committees is ascertained. *See, e.g.*, Celine Castronuovo & Jeannie Baumann, *Pfizer Covid Pill's Fast Signoff Spurs Row Over Skipped Step (1)*, BLOOMBERG L. (Dec. 22, 2021, 4:29 PM), https://news.bloomberglaw.com/health-law-and-business/pfizer-covid-pill-clearance-sparks-calls-for-more-transparency ("The FDA authorized Pfizer Inc.'s pill to treat Covid-19 without first getting input from a panel of clinical advisers, a move public health professionals say could further undermine trust in an agency already facing scrutiny over its rapid decision-making during the pandemic."); David Lim & Lauren Gardner, *FDA Weighs Molnupiravir After Narrow Advisory Committee Vote*, POLITICO (Dec. 3, 2021, 12:00 PM), https://www.politico.com/newsletters/prescription-pulse/2021/12/03/fda-weighs-molnupiravir-after-narrow-advisory-committee-vote-799245 ("[T]he 13–10 [advisory committee] vote was a squeaker, signaling the drug is not the panacea many would like to see on the market.").

procedure and illustrate possibilities for reform, further discussed in Part IV.

IV. ANALYSIS AND POSSIBILITIES FOR REFORM

Any emergency situation in which the government grants a few people the power to make quick, executive decisions will likely elicit criticisms of the decision-making, concerns about independence and objectivity, high levels of public scrutiny, and post-hoc analysis.[168] The EUA procedure is no exception. The FDA Commissioner's status as a presidential appointee has led critics to speculate whether political incentives, rather than health-oriented public policy, have influenced the EUA decision-making process.[169] Although scientific data is in one sense objective, reasonable minds can differ on issues such as the reliability of study protocol and sample size, the interpretation of data, and the outcome of the cost-benefit analysis throughout the various stages of the EUA process.[170] During the COVID-19 pandemic, many people—in both the public and private sectors, and within and outside of the scientific community—have closely scrutinized the data that the

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[168] *See, e.g.*, *supra* notes 3–5 and accompanying text.

[169] For instance, critics speculated about FDA Commissioner Stephen Hahn's ability to protect the FDA from President Trump's influence during the coronavirus pandemic. *See* Sheila Kaplan, *Stephen Hahn, F.D.A. Chief, Is Caught Between Scientists and the President*, N.Y. TIMES (Aug. 28, 2020), https://www.nytimes.com/2020/08/10/health/stephen-hahn-fda.html ("Many medical experts—including members of his own staff—worry about whether Dr. Hahn, despite his good intentions, has the fortitude and political savvy to protect the scientific integrity of the F.D.A. from the president."). The President has the power to remove the FDA Commissioner. *See, e.g.*, PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, FOOD AND DRUG LAW: CASES AND MATERIALS 17 (Robert C. Clark et al. eds., 4th ed. 2013) ("A Commissioner of Food and Drugs is subject to direction and may be removed . . . for any or no reason."). Some have argued in favor of making the FDA an independent agency, a topic beyond the scope of this Note. *E.g.*, Robert M. Califf, Margaret Hamburg, Jane E. Henney, David A. Kessler, Mark McClellan, Andrew C. von Eschenbach & Frank Young, *Seven Former FDA Commissioners: The FDA Should Be an Independent Federal Agency*, 38 HEALTH AFFS. 84, 84 (2019) ("Seven former commissioners of the Food and Drug Administration (FDA) from both sides of the political aisle recommend that the FDA be moved out of the Department of Health and Human Services and reconfigured as an independent federal agency.").

[170] *See, e.g.*, Peter Kosso, *Science and Objectivity*, 86 J. PHIL. 245, 245–47 (1989) (discussing various characterizations of objectivity in science); *supra* Part III.

FDA relied upon when issuing EUAs for drugs and vaccines.[171] This public monitoring can hold the FDA accountable during a CBRN emergency, but it can also contribute to confusion and distrust surrounding EUAs.[172] Furthermore, the media and public have consistently demonstrated confusion about differences between EUA and traditional routes to market, fueling false or confusing narratives about the safety of EUA products.[173] All of these factors combine to further heighten public scrutiny and concern surrounding EUAs during an emergency. Overall, the criticisms of the EUA procedure fall into two broad, overlapping categories: (1) concern with scientific rigor and (2) concern with the independence of the FDA's decision-making.

Critical examination of past EUAs, especially the "stress test" that the COVID-19 pandemic posed, demonstrates the benefits of the EUA procedure more clearly. Ultimately, Congress took an important and effective step in improving the United States' PHE response procedure when it first established the EUA process through the Project BioShield Act of 2004.[174] The EUA process enables the FDA to quickly respond to a PHE and to provide the public with promising tests, medical devices, drugs, and biologics to help track and treat diseases.[175]

Despite continued controversy surrounding EUAs, the FDA has achieved significant success with the EUA procedure.[176] For example, the EUAs issued for two drugs during the H1N1 outbreak appeared to help reduce the number of deaths and the duration of the disease, and earlier authorization of a vaccine could have further reduced cases.[177] During the early stages of the COVID-19

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[171] *See supra* Section III.C.*4*.

[172] *See, e.g.*, *supra* notes 109–112 and accompanying text.

[173] *See* Zettler et al., *supra* note 4, at 165 ("[S]ome media reports continue to equate EUAs with FDA approval, including by reporting that FDA 'approved' the drugs for which it issued EUAs. It is critical that policymakers, health care professionals, and the public understand that . . . products issued EUAs are not necessarily safe or effective countermeasures for COVID-19.").

[174] *See supra* note 39.

[175] *See supra* notes 13–17 and accompanying text.

[176] For examples of EUA controversies, see *supra* notes 109–112, 117–118, 126–130 and accompanying text. For examples of EUA successes, see *supra* notes 86–89, 119–120, 143–152 and accompanying text.

[177] *See supra* notes 90–92, 96 and accompanying text.

pandemic, the FDA issued an EUA for remdesivir based on preliminary results from a randomized, double-blinded, placebo-controlled trial conducted by NIAID and an open-label trial by a pharmaceutical company.[178] Five months later, the FDA approved the drug for treatment of a specific population, and the drug has been used throughout the pandemic to treat people afflicted with COVID-19.[179] The FDA also issued EUAs for three COVID-19 vaccines based on preliminary results from Phase 3 clinical trials.[180] While the ultimate effects of these EUAs on the continued spread of the virus cannot be calculated currently, the EUA procedure granted the FDA the flexibility necessary to approve these much-needed vaccines at a faster rate than ever before.[181] Ultimately, the EUA procedure allows the FDA to respond quickly to a crisis in a way that it otherwise could not, and unduly hampering the EUA process could cost lives.[182]

It is important to note that any EUA revocation will likely result in heightened criticism and scrutiny of the process.[183] A revocation, however, does not automatically indicate that the process has failed.[184] Rather, a revocation indicates that the review procedures and flexibility provided by the EUA process function as they should.[185] An EUA does not function as an expedited process for NDA or BLA approval, but rather as a measure employed only during times of emergency when the cost-benefit analysis of issuing

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[178] *See supra* note 114 and accompanying text.

[179] *See supra* note 120 and accompanying text.

[180] *See supra* notes 143–152 and accompanying text.

[181] *See supra* Section III.C.*4*; notes 41–42 and accompanying text.

[182] *See supra* notes 57–64 and accompanying text.

[183] For example, the revocation of the hydroxychloroquine EUA spurred many journalists to re-examine the original EUA letter. *See* Thomson & Nachlis, *supra* note 105, at 1282–83 (examining the issuance and revocation of the hydroxychloroquine EUA, a "politically and scientifically contentious [process that] illustrates central problems that can arise with emergency drug authorizations during crises").

[184] While the Janssen EUA was not revoked, if the FDA had determined that the blood clots significantly altered the risk-benefit analysis, it could quickly and efficiently revoke the EUA to adapt to this knew knowledge and risk-benefit assessment. *See supra* note 53 and accompanying text.

[185] *See* Zettler et al., *supra* note 4, at 165 ("A revocation reflects the uncertainty surrounding safety and effectiveness of countermeasures that receive an EUA, along with the iterative nature of EUA issuance and oversight.").

an authorization differs markedly from non-emergency situations.[186]

The EUA procedure is not perfect, though. The EUA procedure grants the FDA Commissioner a vast amount of discretion and presents a low evidentiary burden.[187] While this discretion and low evidentiary burden empower the FDA to act quickly, the FDA Commissioner could misuse this discretion. The chloroquine and hydroxychloroquine EUA and the convalescent plasma EUA, for example, demonstrate some of the failures of the EUA process.[188] The FDA relied upon limited, and in some cases flawed, evidence when it issued the chloroquine and hydroxychloroquine EUA during the COVID-19 pandemic.[189] The FDA did not specifically cite which evidence it relied upon in its original authorization letter, creating additional public skepticism about the EUA.[190] Prior to the EUA issuance, President Trump made statements in support of authorization that contributed to public confusion about the drug's effectiveness.[191] The publicized revocation of the EUA undermined public trust in the independence of the FDA and in the safety of EUAs at an early stage in the pandemic when garnering public trust was critical.[192] The chloroquine and hydroxychloroquine EUA thus illustrated three potential flaws in the EUA procedure: (1) the very low evidentiary standard was fully utilized; (2) the FDA was not sufficiently transparent in its authorization letter; and (3) the lack of any clear evidentiary standard contributed to concerns that politics could have influenced the FDA's decision-making.[193]

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[186] *See* Zettler et al., *supra* note 4, at 163–65 (contrasting traditional FDA approval and emergency use authorization).

[187] The Commissioner must find that "is reasonable to believe" that the authorized product "may be effective." *See supra* note 62 and accompanying text.

[188] *See supra* Sections III.C.*1*, *3*.

[189] *See supra* notes 103–110 and accompanying text.

[190] *See supra* notes 102–103 and accompanying text. The FDA also did not release details about the NIAID trial that it relied upon when issuing the remdesivir EUA, leading to confusion and concern by prescribing doctors. *See supra* notes 115–117 and accompanying text.

[191] *See supra* note 100 and accompanying text.

[192] *See supra* notes 109–112 and accompanying text.

[193] *See supra* notes 103–112 and accompanying text.

EUAs can also hamper researchers' ability to recruit and conduct adequately controlled randomized trials.[194] This issue first arose in regard to the EUAs issued during the H1N1 pandemic, and researchers remain unable to conduct adequately controlled studies to determine the effectiveness of one of the drugs that was authorized to treat H1N1.[195] The convalescent plasma EUA raised similar concerns because it reduced access to participants for controlled clinical trials.[196] Granting an EUA may diminish scientists' ability to continue conducting research on the efficacy of the authorized product simply because fewer people will be willing to participate in randomized, controlled clinical trials.[197] In randomized, controlled clinical trials, participants risk falling into the control population where they receive a placebo instead of the drug or vaccine being tested.[198] By contrast, participants enjoy guaranteed access to the treatment through the compassionate use pathway or by obtaining a prescription under an EUA.[199] Adequate clinical trials are essential to properly evaluate the EUA and confirm that the EUA's preliminary risk-benefit analysis holds true, but requiring completion of clinical trials before EUA issuance could cause the FDA to deny people in need access to effective treatment.[200]

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[194] *See* s*upra* note 126 and accompanying text.

[195] *See, e.g.*, Jong et al., *supra* note 92, at 172, 181 (stating that "a significant clinical benefit was not demonstrated for peramivir," one of the H1N1 antivirals granted EUA, and noting that "[t]he study was terminated for futility after a planned interim analysis").

[196] *See supra* note 125 and accompanying text.

[197] *See* Sachs, *supra* note 125 (stating that "the grant of the EUA itself may make it more difficult for the FDA to obtain results from the randomized controlled trials it has stated will be needed to determine the product's efficacy" because patients are more likely to pick a guarantee of treatment instead of the chance of receiving a placebo).

[198] *Id.*

[199] *See id.* ("[F]or patients and their doctors, the choice is clear: why enroll in clinical trials in which you might be assigned to the placebo group, when you could be assured of receiving the treatment under the EUA?"); Helen Branswell, *FDA Shows Signs of Cold Feet over Emergency Authorization of Covid-19 Vaccines,* STAT (Oct. 23, 2020), https://www.statnews.com/2020/10/23/fda-shows-signs-of-cold-feet-over-emergency-authorization-of-covid-19-vaccines/ ("[T]he fear is that early authorization of vaccines could squander a one-time chance to determine how well the various vaccines work and which work best in whom.").

[200] Zettler et al., *supra* note 4, at 165 ("Pre-approval access, including via EUAs, has the potential to interfere with . . . necessary generation [of evidence of products' safety and effectiveness] by making it difficult to enroll participants in clinical trials.").

Last, vaccines raise special concerns surrounding public trust and compliance with public health interventions.[201] The prospect of an expedited process for vaccine development and authorization consistently raises fears about the safety and efficacy of authorized vaccines.[202] The possibility of the FDA granting an EUA for a vaccine elicited public concern and criticism during the government's anthrax response,[203] the H1N1 pandemic,[204] and the COVID-19 pandemic.[205] EUAs raise fears about the scientific rigor of the vaccine's testing and the safety of the ultimate product.[206] An ineffective or dangerous vaccine could unnecessarily endanger healthy people and further undermine public trust in vaccines.[207] Even if a vaccine is safe and effective, herd immunity requires widespread vaccine compliance in combination with natural immunity resulting from infection.[208] Distrust of a vaccine can render even the most effective vaccine a failure.[209]

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[201] *See* Efthimios Parasidis, *Public Health Law and Institutional Vaccine Skepticism*, 41 J. HEALTH POL., POL'Y & L. 1137, 1140 (2016) ("A common thread underlying vaccine hesitancy is a lack of trust in government and industry.").

[202] *See, e.g.*, *supra* notes 97, 135, 166.

[203] *See supra* notes 78–82 and accompanying text.

[204] *See supra* notes 94, 96 and accompanying text.

[205] *See, e.g.*, Alec Tyson, Courtney Johnson & Cary Funk, *U.S. Public Now Divided over Whether to Get COVID-19 Vaccine*, PEW RSCH. CTR. (Sept. 17, 2020), https://www.pewresearch.org/science/2020/09/17/u-s-public-now-divided-over-whether-to-get-covid-19-vaccine/ ("[T]he . . . survey finds three-quarters of Americans (77%) think it's very or somewhat likely a COVID-19 vaccine will be approved in the United States before its safety and effectiveness are fully understood.").

[206] *See, e.g.*, Parmet, *supra* note 89, at 131–32 ("[T]he discussion of a possible EUA [for an H1N1 vaccine], and the decision to license the vaccine without full testing, may have helped to fuel a public perception that the vaccine was rushed and untested."); Quinn et al., *supra* note 78, at 326 (detailing reports of feeling like "lab rats," "lab monkey[s]," and "guinea pigs" from people offered the AVA vaccine).

[207] *See* Zettler et al., *supra* note 4, at 166 (describing special considerations involved with EUAs for vaccines).

[208] *See* Lawrence O. Gostin, *Law, Ethics, and Public Health in the Vaccination Debates: Politics of the Measles Outbreak*, 313 JAMA 1099, 1099 (2015) ("Clustering [of unvaccinated people] erodes herd immunity, facilitating disease outbreaks that can spread.").

[209] *See id.* at 1099–1100 (describing the importance of vaccine compliance in fostering herd immunity).

Despite these valid concerns, the best solution is not to stop issuing EUA vaccines, as some critics suggested.[210] As demonstrated by the EUA for AVA, the EUA process can be a valuable tool for ensuring that particularly high-risk populations have access to the necessary protections.[211] Furthermore, the COVID-19 vaccines, particularly the eventual approval of the Pfizer vaccine for individuals sixteen years and older and the Pfizer EUA's re-issuances for those ages five through fifteen, demonstrate that the FDA can successfully integrate rigorous testing standards into the EUA process.[212]

In short, vaccines can be critical to ending CBRN emergencies so that society can return to normal life, and a blanket ban on EUAs for vaccines could extend the length of CBRNs unnecessarily, resulting in substantially greater loss of life.[213] Nevertheless, concerns about individual rights and safety of the approved vaccine should not be discounted, especially when widespread vaccine compliance is so critical to herd immunity.[214]

The crux of the controversy surrounding the EUA procedure stems from the fact that EUA requires a significantly lower degree of evidence than traditional routes for FDA approval.[215] The EUA procedure requires only that the FDA Commissioner determine that

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[210] *See, e.g.*, Zettler et al., *supra* note 4, at 167 ("FDA should decline to authorize EUAs for COVID-19 vaccines. . . . Issuance of an EUA for a vaccine that can be used across the entire population may create unnecessary risks to healthy individuals, and may delay or prevent completion of clinical trials on vaccine safety and efficacy."); Cohen, *supra* note 133 ("Sheldon Toubman, an attorney on the committee who represents consumers, flat out urged FDA not to issue an EUA for a COVID-19 vaccine, arguing that the agency should stick to the traditional approval process.").

[211] *See, e.g.*, Nightingale et al., *supra* note 37, at 1050 (approving of the AVA EUA for military use and concluding that "EUA is a critical new tool for the medical and public health communities and is applicable for both civilian and military use").

[212] *See supra* notes 137–145, 161–162 and accompanying text.

[213] For example, see the predictions made by Borse et al., *supra* note 94, at 443, regarding a vaccine's possible impact during the H1N1 pandemic.

[214] *See* Gostin, *supra* note 208, at 1099–1100 (discussing how lack of vaccine compliance can impair herd immunity); Emily Kopp, *Experts: Public Trust in Science, Data Key to COVID-19 Vaccine Credibility*, ROLL CALL (July 14, 2020, 5:49 PM), https://www.rollcall.com/2020/07/14/coronavirus-vaccine-update-experts-public-fda-hearings/ (recounting the emphasis placed by health experts on the importance of public trust in ensuring public compliance with COVID-19 vaccinations).

[215] *See supra* notes 56–66 and accompanying text.

it is "reasonable to believe" that the product "may be effective,"[216] unlike the traditional routes for approval that require "substantial evidence" that the product is "safe and effective" or "pure and potent."[217] This lower evidentiary burden provides significant benefits during a PHE when quick, decisive action can save lives and quell the spread of disease. In times of crisis, the cost-benefit analysis for FDA authorization shifts markedly from non-crisis situations; the benefits of authorizing a drug or vaccine with promising preliminary results can undoubtedly outweigh the risk when lives are on the line.[218] For example, the fast EUA procedure makes particular sense if the product is already approved for a different purpose because its potential adverse effects are mostly known already.[219] After EUA issuance, the FDA may find that an authorized product was ineffective or more harmful than beneficial.[220] The flexibility of the EUA process helps to address this issue; EUAs are consistently reviewed in light of new data and can be modified and revoked as needed.[221]

Issues with the EUA process emerge, however, when the decision-making process does not appear to be based on sufficient evidence.[222] A lower evidentiary burden provides necessary discretion to respond to the unique circumstances of a PHE, but some cognizable evidentiary burden must remain to ensure that the public is not put at risk without sufficient justification.[223] If the bar is set too low, authorization of a product could put people at significant risk simply based on anecdotal data and the hope that a

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[216] 21 U.S.C. § 360bbb(c)(2); *see supra* notes 59, 62 and accompanying text.

[217] 21 U.S.C. § 355(b), (d); 42 U.S.C. § 262(a); see supra notes 57, 59 and accompanying text.

[218] *See* 2017 FDA GUIDANCE, *supra* note 43, at 8 (describing the FDA's process for conducting risk-benefit analyses).

[219] *See supra* notes 29–30 and accompanying text; *infra* note 229. This same logic could also apply to the recently authorized vaccine booster doses, although perhaps to a lesser degree because the vaccines are currently only authorized rather than approved. *See supra* note 132 and accompanying text.

[220] *See, e.g.*, *supra* note 110 and accompanying text.

[221] *See* 21 U.S.C. § 360bbb-3(g)(2) (authorizing the Secretary of Health and Human Services to revise or revoke an EUA under certain circumstances).

[222] *See, e.g.*, *supra* note 108 and accompanying text.

[223] *Cf.* Zettler et al., *supra* note 4, at 165 (noting the dual pressures on the FDA during a PHE of generating rigorous evidence of safety and effectiveness while responding to the "urgent need to move as quickly as possible").

product may be effective. An evidentiary standard that is too low can cause the public to feel like test subjects, and the public may lose critical trust in the government for the duration of the PHE, and even after the PHE is over.[224]

Diagnostic tests, PPE, medical devices, drugs, and biological products all fall under the same broad EUA procedure, subject to specified guidance provided by the FDA.[225] However, these categories, especially drugs and biologics, present vastly different risk-benefit analyses and play clearly distinct roles within a robust pandemic or bioterror response. EUA drugs are typically acute treatments, given to people who are severely sick and hospitalized for a short amount of time.[226] Still, these acute treatments have the potential to do more harm than good to patients if their efficacy or adverse side effects are completely unknown.[227] EUAs of drugs for acute treatments also raise heightened ethical concerns about informed consent, access and distribution, and the ability to conduct further clinical trials.[228] EUAs of drugs that have been approved by the FDA for other purposes present lesser safety concerns,[229] but previously unknown side effects can emerge when a drug is used in

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[224] *See, e.g.*, Zettler et al., *supra* note 4, at 165 ("FDA . . . may lose public trust if the agency is viewed as unresponsive to patients' concerns."); Kopp, *supra* note 214, at 2 ("If a vaccine was granted emergency authorization and later discovered to have severe side effects and the authorization was revoked, in the way the emergency use authorization for hydroxychloroquine was granted and then revoked, experts worry it could not only reduce COVID-19 vaccination rates but damage vaccination rates for generations.").

[225] *See* 21 U.S.C. § 360bbb-3 (subjecting "drug[s], device[s], [and] biological product[s]" to the FDA's EUA powers).

[226] *See* Zettler et al., *supra* note 4, at 166 ("A drug that is issued an EUA is typically administered to a sick person with no other treatment options, whereas a vaccine is administered to a healthy person.").

[227] *See, e.g.*, Section III.C.*1*.

[228] *See* Lawrence O. Gostin, Eric A. Friedman & Sarah A. Wetter, *Responding to Covid-19: How to Navigate a Public Health Emergency Legally and Ethically*, 50 HASTINGS CTR. REP. 8, 8 (2020) (noting concerns whenever "the health system becomes stretched beyond capacity" with "ethical[] allocation [of] scarce health goods and services" needed to "ensure that marginalized populations can access the care they need," that "ethical duties . . . owe[d] to vulnerable people separated from their families and communities" are met, and that public health and civil liberties are "ethically and legally balance[d]"); Zettler et al., *supra* note 4, at 166 ("Yet another major concern is how to provide fair and equitable access to COVID-19 countermeasures once they are available under an EUA . . . .").

[229] These drugs will already have completed three phases of clinical trials and likely some post-marketing surveillance. *See supra* notes 22–24 and accompanying text.

a new circumstance.[230] Nevertheless, when faced with acute and severe need, the FDA can, and in many instances should, determine that the benefits of a drug EUA with promising safety data derived from reliable preliminary research outweigh the costs.

By contrast, vaccines are administered to people who are healthy in order to prevent infection.[231] This presents a drastically different set of circumstances and considerations from a drug administered to a severely ill patient or a diagnostic test that presents no direct dangers to a patient.[232] Vaccines must also be widely distributed and administered to have a net benefit to the general population.[233] A vaccine with low efficacy or unexpected adverse side effects may undermine public trust in the FDA or vaccines generally, hindering future public health efforts.[234] Vaccines' preventative effect, however, can play a key role in combating the spread of disease and returning society to normal pre-pandemic functioning.[235]

The FDA inherently recognizes the distinct cost-benefit analyses of various products when administering EUAs. For example, the FDA has issued guidance about EUA administration and delineated different requirements for drugs and biologics at various times.[236] However, during the COVID-19 pandemic, the FDA issued this type of guidance for vaccines too late, following months of speculation and criticism.[237]

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[230] Reflecting this understanding, the FDA approves or authorizes drugs or vaccines for specific indications and patient populations. *See, e.g.*, note 120 and accompanying text.

[231] *See* Zettler et al., *supra* note 4, at 166 (discussing the cost-benefit analysis that applies uniquely to vaccines).

[232] *See, e.g.*, Vincent Y. Ling, *Emerging Partially Effective Vaccines: Ethical and Policy Considerations*, 6 N.C. CENT. U. SCI. & INTELL. PROP. L. REV. 1, 10 (2013) (detailing ethical concerns around emergency vaccine authorizations).

[233] *See, e.g.*, Kopp, *supra* note 214 (noting that the spread of anti-vaccine disinformation negatively affected the distribution and administration of the measles, mumps, and rubella vaccinations).

[234] *See id.* ("'The emergence of a serious safety concern related to a COVID-19 vaccine, or even the perception by the public that corners were cut or political pressure was applied in a rush to approve it, would be greatly damaging not only to COVID-19 vaccination efforts, but also to public confidence in all recommended vaccines,' [one health expert] said.").

[235] *See, e.g.*, *supra* note 213.

[236] *See* 2017 FDA GUIDANCE, *supra* note 43, at 11–16 (discussing general types of evidence typically required for the issuance of an EUA); 2020 VACCINE GUIDANCE, *supra* note 137, at 3–4 (delineating specific requirements for EUAs for vaccines).

[237] *See supra* Section III.C.*4*.

Issuing EUAs for drugs and vaccines during a PHE is critical to a successful PHE response. Despite the controversies surrounding some EUAs, the overall procedure effectively achieves its goals by providing emergency access to potentially life-saving drugs and vaccines. Nevertheless, the procedure presents possibilities for positive reform. The following sections propose three possible reforms to the EUA procedure that would likely benefit the FDA, the public, and private industry: (1) the EUA procedure should mandate that the FDA create and disseminate guidance as soon as practicable after the declaration of a PHE; (2) Congress should modify the evidentiary standard for vaccine EUAs; and (3) the EUA procedure should require that the FDA specifically cite which studies or other evidence it relies upon when deciding to issue an EUA and release the data underlying its decision.

A. GUIDANCE

The EUA procedure should be modified by congressional lawmaking or agency rulemaking to require the FDA, upon the declaration of a PHE, to issue guidance delineating the different evidentiary standards that it will require companies to meet before it grants EUAs to vaccines or drugs.[238] This guidance should resemble the EUA guidance that the FDA issued for vaccines during the COVID-19 pandemic, where the FDA clearly stated the types of data it required and additional criteria it would impose upon vaccine manufacturers.[239] Although the FDA will face numerous responsibilities and pressures at the beginning of a pandemic, establishing these standards should occur as soon as practicable. These standards should remain non-binding and susceptible to amendment because the guidance will likely change as the FDA

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[238] *See* Herschel Nachlis, *The FDA's Evolving COVID-19 Emergency Use Authorizations: How the Convalescent Plasma Authorization Can Inform Future Vaccine and Therapeutic EUAs*, HEALTH AFFS. (Oct. 20, 2020), https://www.healthaffairs.org/do/10.1377/hblog20201016.659416/full/ ("The agency could consider providing greater clarity by updating the current EUA guidance or issuing additional new guidance outlining different evidentiary standards for different types of products, and perhaps different standards for therapeutics depending on the populations in which they will be used.").

[239] *See generally* 2020 VACCINE GUIDANCE, *supra* note 137.

learns more about the CBRN threat. Additionally, the EUA procedure should require the FDA to evaluate a drug or vaccine granted an EUA against the guidance and state its justification for any deviation in the EUA letter. Although the guidance will be nonbinding, it will provide a standard to which the FDA should adhere when issuing EUAs.

First, this change will improve the EUA process within the FDA. Like the FDA's adherence to the 2020 vaccine EUA guidelines, the FDA will likely be motivated to follow these guidelines because they provide consistent standards to pharmaceutical companies and assurance to the public.[240] The requirement will likely reduce the number of EUAs with low evidentiary support and provide a degree of protection from political influence because any unusually large deviation from procedure will be clear and will likely elicit substantial public pushback. Additionally, the guidance could accelerate the EUA procedure by clarifying that a drug has met certain objective minimum requirements, thus setting the parameters for a quicker and more uniform evaluation of similar products. The FDA could also use the guidance as a means of resisting political or public pressure, using the guidance to leverage and safeguard against attempts to influence the process for political, rather than health related, reasons.

Second, this requirement will also likely benefit other interested parties and further public health efforts. Investing in developing these standards early on will help to educate the public about the EUA process. This could foster trust in the EUA process because it will counter the false narrative that the FDA has unfettered discretion to authorize products.[241] Publishing the guidance as soon as possible after the declaration of an emergency may also reduce pundits' speculation about the safety or danger of EUAs generally because they will have concrete requirements to examine. Additionally, pharmaceutical companies will benefit from both the certainty and the increased public trust provided by the guidance. Public distrust can impact both pharmaceutical companies' revenue

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[240] *See supra* Section II.C.*4*.

[241] *See, e.g.*, Zettler et al., *supra* note 4, at 165–66 (describing the requirements of the EUA process and the importance of developing rigorous evidence).

and, in the case of vaccines, the efficacy of their products.[242] The guidance provides companies with a better explanation of the evidence that they must gather prior to seeking authorization and a better idea of their likelihood of successfully obtaining an EUA. Last, this modification may support more adequately controlled randomized trials prior to and following authorization because the guidance will delineate more clearly specified evidentiary requirements.

This change to the EUA procedure for drugs will ensure that the FDA retains the flexibility to respond to unforeseen circumstances while remaining faithful to its guidance in all other circumstances; however, this change does not adequately address the additional concerns raised by EUAs for vaccines. The following subsection addresses these concerns.

B. EUA EVIDENTIARY REQUIREMENTS

Congress should raise the standard for vaccine EUAs above the "reasonable to believe that . . . the product may be effective" standard currently used for EUAs[243] but below the "substantial evidence" standard used for traditional approvals.[244] An intermediate standard, such as one requiring the Secretary of Health and Human Services—and therefore, through delegated authority, the FDA Commissioner[245]—to determine that it is reasonable to believe that the product *is* effective, could solve this problem. This threshold imposes a notably higher evidentiary burden than "may be effective," but it falls short of requiring "substantial evidence" of effectiveness.

This change in standard would, from the outset, recognize a higher evidentiary standard for vaccines while simultaneously retaining the flexibility of EUAs as opposed to traditional approval. This change would also help the general public recognize that vaccine EUAs are held to a high standard and could increase public

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[242] For example, these concerns likely spurred pharmaceutical companies to pledge to meet specific evidentiary metrics before applying for a vaccine EUA. *See supra* notes 135, 207–208 and accompanying text.

[243] 21 U.S.C. § 360bbb-3(c).

[244] *Id.* § 355(d)–(e).

[245] *See supra* notes 48–50 and accompanying text.

trust in a potential vaccine.[246] This higher evidentiary burden simply reflects the truth tacitly recognized by the FDA, public health experts, and the public regarding vaccines: the relatively amorphous promise that they "may be effective" is not sufficient to justify their authorization.

Some might argue that this modification is too drastic and would place too large a burden on the FDA during a crisis when quick action is necessary. This modification, however, would not greatly change the higher burden that the FDA created for itself in the 2020 vaccine guidelines.[247] Rather, it would clearly indicate to the public that vaccines may go through an expedited review and development process during a PHE, but any authorized vaccine is still subject to rigorous safety and efficacy tests.

This change would also help to safeguard against any political pressure that the FDA might face to approve a vaccine before sufficient data is available. Under the current standard, the FDA Commissioner could authorize a vaccine based on a very small amount of evidence.[248] While this is unlikely to occur, the current standard creates an atmosphere ripe for speculation, influence, and public mistrust.[249] Explicitly requiring reasonable belief that the product is effective would remedy this problem without unduly impeding vaccine authorizations.

Both the AVA vaccine and the two coronavirus vaccines would pass this heightened evidentiary requirement. The AVA vaccine EUA was issued based on years of testing and development indicating that it would be effective,[250] and the coronavirus vaccines adhered to the FDA's vaccine guidance that required specific metrics of evidence beyond those required by the general EUA

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[246] Despite this improvement, some increased fear will likely always remain whenever a vaccine falls short of traditional FDA approval.

[247] *See* 2020 VACCINE GUIDANCE, *supra* note 137, at 9–11 (enumerating the various safety and effectiveness criteria that companies must meet prior to emergency use authorization).

[248] The FDA Commissioner must determine that it "is reasonable to believe" that the authorized product "may be effective" and can rely upon the "totality of scientific evidence," rather than only on clinical trials. 21 U.S.C. § 360bbb-3(c)(2); *see also supra* Section II.C.

[249] For example, President Trump's unwavering public support for hydroxychloroquine raised concerns about the FDA's independence. *See supra* notes 100–101 (listing comments made by President Trump and fears about the FDA succumbing to political influence).

[250] *See* Quinn et al., *supra* note 78, at 322 (providing a timeline of AVA vaccine research from 1999 to 2001).

standard.[251] Formally recognizing a heightened requirement for vaccines provides a number of benefits without unduly burdening the FDA or slowing public health efforts.

C. TRANSPARENCY

Unfortunately, any major EUA decision involving a drug or biologic is susceptible to politicization.[252] Although the FDA's focus is, rightly, on evaluating the data before issuing an EUA, the FDA should recognize its increased political salience during a pandemic or bioterror attack. Although it is always desirable to maintain public trust in governmental agencies, especially public health agencies, public trust during a pandemic can particularly impact public health outcomes.[253] While it is nearly impossible to fully explain all scientific procedures, trials, and analyses to the general public, continual and accurate public communication is critical. Two changes to FDA EUA operating procedures could improve transparency and public communication during EUA issuance.

First, when issuing an EUA, the FDA should be required to explicitly reference the evidence that it relied upon when deciding whether to issue the EUA. Unlike the hydroxychloroquine EUA, which vaguely referenced "limited in-vitro and anecdotal clinical data in case series" and "a number of national guidelines,"[254] EUAs should state the specific studies or guidelines to which they refer.[255] This requirement would increase transparency in the FDA's decision-making process and allow other public health experts to examine the evidence for themselves. This measure will give the public a better understanding of EUAs and allow the scientific

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[251] *See supra* Section III.C.*4*.

[252] *See, e.g.*, *supra* notes 133–135 and accompanying text.

[253] *See* Julie Henderson et al., *Developing and Maintaining Public Trust During and Post-COVID-19: Can We Apply a Model Developed for Responding to Food Scares?*, FRONTIERS PUB. HEALTH, July 2020, at 1–2 (highlighting the importance of trust in public health countermeasures during epidemics).

[254] Chloroquine and Hydroxychloroquine EUA, *supra* note 102, at 2.

[255] *See* Scott Burris et al., *Summary of Recommendations for Assuring Access to Medicines and Medical Supplies*, *in* ASSESSING LEGAL RESPONSES TO COVID-19, *supra* note 4, at 149, 150 ("Congress and FDA should consider creating specific processes to protect decision making during pandemics, such as requiring FDA to proactively release detailed information about the basis for its EUA decisions immediately after they are made.").

community to hold the FDA accountable, should it rely upon faulty data.

Second, the FDA should be required to release the data underlying its decision to grant the EUA if the data is not currently available. This will prevent another circumstance like the remdesivir EUA, which referenced a particular efficacy statistic but provided no further data to put the statistic into context.[256] This requirement will provide an additional incentive for the FDA to make certain that the data it uses are reliable, allow the scientific community to hold the FDA accountable, and ensure healthcare providers understand how to best administer the authorized product as soon as the product is authorized.

Third, making this information available may also decrease the amount of speculation about the FDA's political motivations or other factors that might influence its decision-making and may increase the public's confidence in the agency.[257] These changes recognize that during an emergency, governmental transparency is particularly important. Especially during a time of wild uncertainty like a PHE, the public should know what evidence the FDA relies upon in making its EUA decisions.

V. CONCLUSION

The COVID-19 pandemic has emphasized the important role that the EUA procedure plays in a comprehensive CBRN emergency response. The procedure has faced criticism, however, due to its low evidentiary burden and concerns with political interference.[258] This Note proposes modifications to Section 564 of the Federal Food, Drug, and Cosmetic Act; FDA regulations; and FDA operating procedure.

At the outset of a PHE response, the EUA procedure should require the FDA to draft guidance outlining the differing evidentiary burdens for the issuance of EUAs for drugs, vaccines, and other biologics. Additionally, Congress should alter the EUA

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[256] *See supra* notes 115–117 and accompanying text.

[257] *Cf.* Kopp, *supra* note 214 (noting that anti-vaccine conspiracy theories contributed to the rise in a number of diseases such as measles and mumps).

[258] *See, e.g.*, Piller, *supra* note 3 (describing criticism by former FDA officials of the hydroxychloroquine EUA).

evidentiary burden for vaccines from the "reasonable to believe that" the vaccine "may be effective" standard[259] to an intermediate "reasonable to believe" that the vaccine "is effective" standard. Furthermore, every EUA letter should specifically cite the data upon which it relies, and this data should be released as soon as practicable. These changes might not transform FDA officials into the crime-fighting agents of S.H.I.E.L.D.,[260] but the changes will enable them to more effectively become what we truly need during a PHE: agents of Bioshield.

[259] 21 U.S.C. § 360bbb-3(c).

[260] Like FDA officials during a PHE, the Agents of S.H.I.E.L.D. are a "small, highly trained, team of agents" who "tackle the cases that haven't been classified yet, the new, the strange and the unknown." *Agents of S.H.I.E.L.D.*, MARVEL CINEMATIC UNIVERSE WIKI, https://marvelcinematicuniverse.fandom.com/wiki/Agents_of_S.H.I.E.L.D. (last visited Nov. 2, 2021).

APPENDIX: ACRONYMS

AVA	Anthrax Vaccine Adsorbed
BARDA	Biomedical Advanced Research and Development Authority
BLA	Biologics License Application
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CBER	Center for Biologics Evaluation and Research
CBRN	Chemical, Biological, Radiological, and Nuclear
DoD	Department of Defense
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
HHS	Health and Human Services
IND	Investigational New Drug
IRB	Institutional Review Board
NDA	New Drug Application
NIAID	National Institute of Allergy and Infection Disease
NIH	National Institutes of Health
PHE	Public Health Emergency
PHSA	Public Health Service Act
PPE	Personal Protective Equipment
VRBPAC	Vaccines and Related Biological Products Advisory Committee
VAERS	Vaccine Adverse Event Reporting System