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Emergency Use Authorizations in the Time of Coronavirus

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EMERGENCY USE AUTHORIZATIONS IN THE TIME OF CORONAVIRUS

Laura Kent-Jensen *

Abstract

When COVID-19 first emerged in the United States, the pandemic sparked a rush to provide protective gear, develop tests to detect the disease, and implement effective containment strategies to stop the spread. The Food and Drug Administration (FDA) used its Emergency Use Authorization (EUA) process to facilitate the rapid market introduction of medical devices (authorized but unapproved) to combat the emergent public health threat. Unfortunately, performance problems with some medical devices stymied initial containment efforts, arguably resulting in greater spread and suggesting a need for improvement in the EUA process.

By reviewing the statutory requirements of the EUA process, this Note examines how the process is intended to function and where it came up short during the COVID-19 pandemic. The Note then identifies the medical devices (diagnostic tests and personal protective equipment) that are most likely to require EUAs during a potential future pandemic and reveals a regulatory gap in quality control procedures that enabled non-performing devices to reach the market during the current pandemic. Finally, the Note proposes a solution that would likely fill this regulatory gap and help the FDA achieve its goals in the event of another infectious disease emergency. The solution is to require an independent test of the manufactured product to ensure it meets its performance specifications before releasing the medical device to the market.

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I. INTRODUCTION

On January 31, 2020, the Secretary of Health and Human Services (HHS), Alex Azar, declared a national public health emergency and affirmed his department’s commitment to “protecting the health and safety of all Americans”¹ Just four days later, Secretary Azar determined “that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus (2019-nCoV)”² Through the Emergency Use Authorization (EUA) process, the Food and Drug Administration (FDA) enables companies to quickly bring important medical products to the market.³ Specifically, EUAs allow products aimed at protecting healthcare providers, diagnosing patients, and providing treatments or cures “to reach patients in need when there are no adequate, FDA-approved and available alternatives.”⁴ However, the product itself is

¹ Press Release, HHS Press Office, U.S. Dep’t Health & Hum. Servs., Secretary Azar Declares Public Health Emergency for United States for 2019 Novel Coronavirus U.S. Dep’t Health & Hum. Servs. (Jan. 31, 2020), <https://www.hhs.gov/about/news/2020/01/31/secretary-azar-declares-public-health-emergency-us-2019-novel-coronavirus.html> [<https://perma.cc/Z22U-NBG4>].

² Determination of Public Health Emergency, 85 Fed. Reg. 7,316-01 (Feb. 7, 2020).

³ *FDA Combating COVID-19 with Medical Devices*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/media/136702/download> [<https://perma.cc/65WQ-BFR3>] (last updated Nov. 24, 2020).

⁴ *See id.*

not “FDA approved”⁵ and does not necessarily meet the stringent regulations established by the FDA to assure efficacy and safety.⁶

By relying on companies to verify their own products, the FDA permitted products to reach the market much more swiftly, precisely as intended by the EUA process during a national emergency. Yet, problems with the medical devices and tests procured through this streamlined process have repeatedly required the FDA to issue warnings and clarifications regarding safety and accuracy,⁷ calling into question the adequacy of emergency regulations. This Note will briefly review the EUA process, examine how effectively the EUA regulations have met objectives during the coronavirus pandemic, and propose a legislative solution for improving the EUA process without impeding overall goals.

II. BACKGROUND

A. FDA Oversight of Medical Devices

The Federal Food Drug and Cosmetic Act, codified in 21 U.S.C. § 301 *et seq.*,⁸ did not include medical devices until the Medical Device Amendments of 1976.⁹

⁵ *Id.*

⁶ See, e.g., Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Informs Public About Possible Accuracy Concerns with Abbott ID NOW Point-of-Care Test (May 14, 2020), [hereinafter Abbott ID NOW Point-of-Care Test] <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-informs-public-about-possible-accuracy-concerns-abbott-id-now-point> [https://perma.cc/DHG4-82SC].

⁷ The FDA issued multiple updates each month during the COVID-19 pandemic, including warnings about specific medical device warnings and modifications to existing EUAs. See, e.g., Abbott ID NOW Point-of-Care Test, *supra* note 6; Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Reissues Emergency Use Authorizations Revising Which Types of Respirators Can Be Decontaminated for Reuse (June 7, 2020), <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-reissues-emergency-use-authorizations-revising-which-types> [https://perma.cc/M4ZK-RS27]; Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine (June 15, 2020), <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chloroquine-and> [https://perma.cc/AQS9-ZU92]; Press Release, Coronavirus (COVID-19) Update: FDA Warns of Newly Discovered Potential Drug Interaction That May Reduce Effectiveness of a COVID-19 Treatment Authorized for Emergency Use (June 15, 2020), <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-warns-newly-discovered-potential-drug-interaction-may-reduce> [https://perma.cc/44JB-7L6B].

⁸ Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (2018).

⁹ *A History of Medical Device Regulation & Oversight in the United States*, U.S. FOOD & DRUG ADMIN. (June 24, 2019), <https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states> [https://perma.cc/7QC G-8CWG].

The U.S. Code now defines medical devices to include any instrument, article, or part which is “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.”¹⁰ Specifically, *in vitro* diagnostic (IVD) tests¹¹ and personal protection equipment (PPE), such as filtering facepiece respirators, are regulated as medical devices.¹² The FDA has identified these devices as essential to the effort to control the spread of COVID-19 because IVD tests detect the coronavirus SARS-CoV-2, thus diagnosing disease, and PPE devices minimize transmission of the virus.¹³

B. Standard Regulations for Approval of Medical Devices

The Code of Federal Regulations (CFR) defines the standards a medical device must meet to receive FDA approval.¹⁴ To evaluate a product, the FDA relies upon scientific evidence, including well-controlled investigations, studies, case histories, and reports of experience, “from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use.”¹⁵ In addition, the FDA establishes performance standards for the medical device and rigorous requirements for quality control systems, including good manufacturing practices, to ensure ongoing safety and effectiveness.¹⁶ Together, these standards, controls, and practices provide assurance that when medical devices are marketed to and utilized by healthcare personnel or patients, they will work as intended without harming public health.

The FDA categorizes medical devices into three classes, requiring varying degrees of regulation for each class to provide reasonable assurance of safety and

¹⁰ 21 U.S.C. § 321(h)(1)(B).

¹¹ IVD tests are used to detect diseases or other conditions in “samples such as blood or tissue that have been taken from the human body.” *In Vitro Diagnostics*, U.S. FOOD & DRUG ADMIN. (Oct. 25, 2019), <https://www.fda.gov/medical-devices/products-and-medical-procedures/in-vitro-diagnostics> [<https://perma.cc/8KM5-EHW8>]. When a person is tested for COVID-19, a positive result means the IVD test detected the virus in the sample. *Coronavirus Disease 2019 Testing Basics*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/consumers/consumer-updates/coronavirus-disease-2019-testing-basics> [<https://perma.cc/7P8L-55X7>] (last updated Apr. 7, 2021).

¹² See *Coronavirus (COVID-19) and Medical Devices*, U.S. FOOD & DRUG ADMIN. (May 25, 2021), <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid-19-and-medical-devices> [<https://perma.cc/3FKX-JMB6>].

¹³ See *id.*

¹⁴ See Medical Devices, 21 C.F.R. §§ 801.1–820.250 (2020); see also *Overview of Device Regulation*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation> [<https://perma.cc/4Z6L-82BA>] (last visited Aug. 3, 2021) (outlining the basic regulatory requirements for manufacturers of medical devices).

¹⁵ Medical Device Classification Procedures, 21 C.F.R. § 860.7(c).

¹⁶ See Procedures for Performance Standards Development, 21 C.F.R. §§ 861.1–861.38 (2020); see also Quality System Regulation, 21 C.F.R. §§ 820.1–820.250 (2020).

effectiveness: Class I in which “general controls are sufficient”;¹⁷ Class II, which requires special controls to address particular concerns;¹⁸ and Class III for which “premarket approval is . . . required.”¹⁹ The FDA must consider “the probable benefit to health from the use of the device weighed against any probable injury or illness from such use” and “the reliability of the device” when classifying a medical product and determining which specific controls might be needed.²⁰ For example, non-surgical face masks are Class I medical devices with general controls, while surgical N95 respirators are Class II devices whose approval depends upon testing and certification by the National Institute of Occupational Safety and Health (NIOSH).²¹

C. Emergency Use Authorization (EUA)

Congress established the Emergency Use Authorization (EUA) program through the Project BioShield Act of 2004 “as part of a broader strategy to defend America against the threat of weapons of mass destruction.”²² The EUA program is a mechanism “to accelerate the research, development, acquisition, and availability . . . of safe and effective medical countermeasures to protect the United States” from chemical, biological, nuclear, and radiological threats.²³ By design, EUAs provide special authority for unapproved medical products to be used “in a public health emergency stemming from a terrorist attack with . . . a biological . . . agent, or a

¹⁷ 21 C.F.R. § 860.3(c)(1) (2020).

¹⁸ *Id.* § 860.3(c)(2). Special controls often address intended use, performance standards, and labeling requirements that are specific to the product. *See, e.g.,* Denise N. Johnson-Lyles, *What Does Having a FDA Cleared Pregnancy Test Mean?*, U.S. FOOD & DRUG ADMIN. (July 16, 2013) (illustrating the type of specific performance and labeling standards that may be required for regulatory clearance of a Class II device).

¹⁹ Medical Device Classification Procedures, 21 C.F.R. § 860.3 (2020).

²⁰ *Id.* § 860.7.

²¹ Surgical Devices, 21 C.F.R. § 878.4040 (2020). NIOSH verifies that an N95 mask filters at least 95% of airborne particles, while the FDA requires surgical masks to be fluid resistant and to protect against large droplets and sprays of hazardous fluids. A surgical N95 respirator must meet both requirements. *See Understanding the Difference*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/niosh/npptl/pdfs/UnderstandDifferenceInfographic-508.pdf> [<https://perma.cc/7E2D-ZF8V>] (last visited July 7, 2021). Standard N95 respirators are also Class II medical devices that meet only the NIOSH filtration standard. *See, e.g.,* 3M, *Surgical N95 vs. Standard N95 – Which to Consider?*, TECH. BULL. (June 2020), <https://multimedia.3m.com/mws/media/1794572O/surgical-n95-vs-standard-n95-which-to-consider.pdf> [<https://perma.cc/DB67-UHNW>].

²² U.S. Department of Health & Human Services, *Project BioShield Overview*, MEDICAL COUNTERMEASURES.GOV, <https://www.medicalcountermeasures.gov/barda/cbrn/project-bioshield-overview/> [<https://perma.cc/X7RS-KMUK>] (last visited July 7, 2021); *see also* Project BioShield Act of 2004, Pub. L. No. 108–276, 118 Stat. 835.

²³ HHS Public Health Emergency Medical Countermeasures Enterprise Strategy for Chemical, Biological, Radiological and Nuclear Threats, 72 Fed. Reg. 13109 (Mar. 20, 2007).

naturally occurring emerging infectious disease.”²⁴ Each EUA is intended to be a temporary measure that provides authorization only during the time of national emergency.²⁵ However, in practice, companies have marketed authorized, but FDA unapproved, products for years after the original EUA date of issuance.²⁶

Significantly, while non-emergency FDA rules are extensive and detailed in the CFR, the EUA process is governed only by the Authorization for Medical Products for Use in Emergency (Medical Products EUA) federal statute, 21 U.S.C § 360bbb-3.²⁷ The EUA process does not have corresponding FDA regulations. Under the Medical Products EUA statute, the HHS Secretary may authorize emergency use of a product that “is not approved, licensed, or cleared for commercial distribution” during a public health emergency.²⁸ The Secretary may also authorize an “unapproved use” of a product that has been previously approved for a different treatment or application.²⁹ Either type of authorization applies to medical products, which includes drugs, devices, or biological products.³⁰

To issue an EUA when public health is threatened by a serious disease, the Secretary must “conclude[] . . . that, based on the totality of scientific evidence available to the Secretary, . . . it is *reasonable to believe* that . . . the product *may be effective* in diagnosing, treating, or preventing” the disease.³¹ Because the process is

²⁴ What Are Medical Countermeasures, U.S. FOOD & DRUG ADMIN. (May 26, 2021), <https://www.fda.gov/emergency-preparedness-and-response/about-mcmi/what-are-medical-countermeasures> [<https://perma.cc/GA4Q-C798>].

²⁵ Project BioShield Act of 2004, Pub. L. No. 108–276, 118 Stat. 835, 854–58. Generally, the authorization terminates when the declaration of emergency terminates, upon the earlier of the emergency circumstances ceasing to exist or on the one-year anniversary of the declaration. *Id.*

²⁶ *FAQs on Emergency Use Authorizations (EUAs) for Medical Devices During the COVID-19 Pandemic*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/faqs-emergency-use-authorizations-euas-medical-devices-during-covid-19-pandemic> [<https://perma.cc/HSS8-8NKL>] (last updated Apr. 23, 2021). For example, fourteen Zika-related medical products that were authorized in 2016 or 2017 are still marketed under EUAs today. See *Emergency Use Authorizations for Medical Devices: Zika Virus Emergency Use Authorization*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices> [<https://perma.cc/DJY3-R76F>] (last visited Aug. 3, 2021) [hereinafter *Emergency Use Authorizations for Medical Devices*] (showing active EUAs for Zika testing).

²⁷ Authorization for Medical Products for Use in Emergencies, 21 U.S.C. § 360bbb-3 (2017).

²⁸ *Id.* § 360bbb-3(a)(2)(A).

²⁹ *Id.* § 360bbb-3(a)(2)(B).

³⁰ *Id.* § 360bbb-3(a)(1).

³¹ *Id.* § 360bbb-3(c) (emphasis added).

intended to be fast and flexible, there are very few conditions that the Secretary is required by statute to impose on the authorized product. Once the Secretary issues an EUA, the product may be legally introduced into interstate commerce for public use.³²

D. Regulations During the COVID-19 Pandemic

During the COVID-19 pandemic, the FDA has issued more than 250 EUAs applicable to IVD tests and PPE, an unprecedented number.³³ As during previous outbreaks of infectious diseases, such as Zika, the FDA has amended existing EUAs to allow expanded usage of, or improvements to, the devices in cooperation with companies and laboratories.³⁴ However, the FDA has also reversed its authorization policies based on new information, issued advisories against use, and removed manufacturers from its authorized list for specific medical devices.³⁵ Quality problems, in particular, have stymied some FDA efforts to rapidly deliver safe and effective products to the market for the benefit of public health.³⁶ These problems

³² *Id.* § 360bbb-3(a)(1).

³³ During the H1N1 pandemic, the FDA issued a total of nineteen EUAs for IVD tests and PPE, which was the pre-COVID-19 record. See *Historical Information About Device Emergency Use Authorizations: In Vitro Diagnostics (IVD) & Personal Protective Equipment (PPE)*, U.S. FOOD & DRUG ADMIN., [hereinafter *Historical Information About Device Emergency Use Authorizations*] <https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations#ivd> [<https://perma.cc/BQS2-FKF6>] (last visited Aug. 3, 2021) (listing all historical EUAs for IVD tests and PPE). In comparison, at least 249 EUAs have been given solely for COVID-19 molecular IVD tests. See *In Vitro Diagnostics EUAs - Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#individual-molecular> [<https://perma.cc/B4E7-AM6M>] (last visited Aug. 3, 2021).

³⁴ *Emergency Use Authorization: Coronavirus Disease 2019 (COVID-19) EUA Information*, U.S. FOOD & DRUG ADMIN., [hereinafter *Emergency Use Authorization: Coronavirus*] <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas> [<https://perma.cc/C5XQ-5P48>] (last visited Aug. 3, 2021).

³⁵ *Id.*

³⁶ *Id.*; see also *Emergency Use Authorization--Archived Information: Coronavirus Disease 2019 (COVID-19) EUA*, U.S. FOOD & DRUG ADMIN., [hereinafter *Emergency Use Authorization--Archived Information*] <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information#covid19> [<https://perma.cc/RE3Y-33R9>] (last visited Aug. 3, 2021); *supra* text accompanying note 7; *Coronavirus Disease 2019 (COVID-19)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19> [<https://perma.cc/YSJ5-M3ZN>] (last visited Aug. 3, 2021) (providing a summary of updates).

contributed to the undetected spread of COVID-19 in several U.S. communities, which seeded outbreaks and prevented the implementation of early containment strategies.³⁷

III. ANALYSIS

This section begins by identifying the types of products that since 2004 have been repeatedly authorized for emergency use under the EUA regulations. It then examines how the regulations have changed and become more flexible over time. A discussion of the key provisions of the EUA regulations lays the foundation for comparison to the standard FDA-approval process and reveals that discretionary measures are an important feature built into the EUA process. This flexibility is necessary to enable rapid response to unpredictable circumstances in an emergency; however, when compared with the standard FDA approval process, the EUA regulations leave a gap. The COVID-19 pandemic provides an illustration of problems that arise as a result of this regulatory gap and hinder the FDA's ability to protect public health. Finally, this section synthesizes a solution that can bridge the gap, reconcile the competing objectives, and help the FDA to fulfill its mission.

A. EUAs Are Frequently Issued for Certain Medical Devices

For protection against influenza, the Centers for Disease Control and Prevention (CDC) recommends a three-step plan: vaccination, preventive actions to stop spread, and treatment in the case of infection.³⁸ The preventive actions include avoiding close contact with those who are sick, covering the nose or mouth when coughing or sneezing, and staying home if infectious.³⁹ While these actions, aimed at the general public, are for a known threat, essentially the same preventive measures are recommended for any outbreak of disease, including COVID-19.⁴⁰ Moreover, these measures map to the types of medical devices that are similarly aimed at prevention: tests that identify who is infectious and respirators that cover the nose and mouth.

³⁷ See Michael D. Shear, Abby Goodnough, Sheila Kaplan, Sherry Fink, Katie Thomas & Noah Weiland, *The Lost Month: How a Failure to Test Blinded the U.S. to Covid-19*, N.Y. TIMES (Mar. 28, 2020), <https://www.nytimes.com/2020/03/28/us/testing-coronavirus-pandemic.html> [<https://perma.cc/R4RW-XM8D>].

³⁸ *Prevent Seasonal Flu*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/flu/prevent/index.html> [<https://perma.cc/D5TT-GW2K>] (last visited Oct. 22, 2020).

³⁹ *Id.*; see also *Everyday Preventive Actions Can Help Fight Germs, Like Flu*, CTRS. FOR DISEASE CONTROL & PREVENTION (Sept. 2020), <https://www.cdc.gov/flu/pdf/freere-sources/updated/everyday-preventive-actions-8.5x11.pdf> [<https://perma.cc/R9RQ-6TT5>].

⁴⁰ See *Coronavirus Disease 2019*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/coronavirus/2019-ncov/index.html> [<https://perma.cc/KL62-6ZQW>] (last visited Aug. 3, 2021) (recommending testing, wearing a mask, and if sick, staying home).

Since 2004, the HHS Secretary has determined that several well-known outbreaks were public health emergencies warranting authorization of unapproved medical devices. These outbreaks included the H1N1 (swine flu) pandemic in 2009 and the material threats of Ebola and Zika viruses in 2014.⁴¹ During these outbreaks, EUAs were issued only for diagnostic tests and for personal protective equipment, specifically N95 respirators.⁴² These devices are essential to protecting those who are healthy and identifying those who are ill as a means to contain the illness and prevent its spread.⁴³

Similarly, during the COVID-19 pandemic, the first medical devices the FDA authorized were IVD (COVID-19 diagnostic) tests and PPE. By June 1, 2020, the FDA granted eighty-five EUAs for IVD tests and fifteen EUAs for PPE, four of which addressed filtering respirators or face shields.⁴⁴ The consistency with which the FDA issues EUAs for diagnostic tests and protective equipment suggests that these devices are frequently essential to public health and will almost certainly be the subject of future EUAs. Consequently, Class II medical devices, which include diagnostic testing and protective equipment, are the target of the regulatory improvements this Note recommends.⁴⁵

Therapeutic medical products, a second step of the CDC protection plan, take more time to develop when a new infectious disease emerges.⁴⁶ As a result, the few

⁴¹ *Id.*

⁴² See *Historical Information About Device Emergency Use Authorizations*, *supra* note 33.

⁴³ See, e.g., Stephen M. Parodi & Vincent X. Liu, *From Containment to Mitigation of COVID-19 in the US*, 323 JAMA 1441, 1441–42 (Apr. 21, 2020) (discussing “precaution equipment like N95 masks,” tests “to establish the extent of community spread,” and isolation of infected patients as mitigation measures).

⁴⁴ See *Emergency Use Authorization: Coronavirus*, *supra* note 34.

⁴⁵ Other types of medical devices are less suitable for EUAs. Class I devices “present minimal potential for harm to the user” and are generally exempt from the regulatory process. Class III devices are a smaller class of life-sustaining or implanted devices which need greater regulation to ensure safety. See *Learn If a Medical Device Has Been Cleared by FDA for Marketing*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/consumer-s-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing> [<https://perma.cc/374J-ZBYH>] (last updated Dec. 29, 2017).

⁴⁶ After the health emergency was announced on January 31, 2020, the first COVID-19 IVD test received an EUA four days later. In contrast, the first EUA for a COVID-19 treatment came four months later on April 30, 2020. Compare HHS Press Office, *supra* note 1 (announcing the emergency on January 31, 2020), and *FDA Combating COVID-19 with Medical Devices*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/media/136702/download> [<https://perma.cc/R6PP-V889>] (last updated Nov. 24, 2020) (identifying the CDC’s 2019-nCoV Real-Time RT-PCR Diagnostic Panel as an authorized in vitro diagnostic on February 4, 2020), with *FDA Combating COVID-19 with Therapeutics*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/media/136832/download> [<https://perma.cc/TRQ3-Z4JN>] (last updated Dec. 2, 2020) (identifying Fresenius Medical Care’s continuous renal replacement therapy as the first authorized therapeutic), and Letter from U.S. Food & Drug Admin. to Denise Oppermann, Fresenius Medical Care (Apr. 30, 2020), [hereinafter “Letter to Denise Oppermann”] <https://www.fda.gov/media/137520/download> [<https://perma.cc/LFS2-S4ZS>].

instances where the FDA issued EUAs for drugs during previous outbreaks were limited to unproven uses for drugs that had already received FDA approval.⁴⁷ In the case of COVID-19, the intense national focus on the pandemic increased attention on treatments, leading to off-label use even without an EUA.⁴⁸ In response, the FDA implemented a Coronavirus Treatment Acceleration Program (CTAP) specifically to address the need for rapid development of safe and effective treatments for COVID-19.⁴⁹ However, according to the FDA website, the overwhelming majority of EUAs granted through August 2021 were for medical devices, providing ample evidence that medical devices are far more likely to receive EUAs than therapeutic treatments.⁵⁰

The third action of the CDC protection plan, vaccination, also takes significant time to develop when a new virus emerges.⁵¹ Because a vaccine is a biological product, the FDA can authorize an emergency use, and, in fact, the FDA granted its

⁴⁷ The FDA authorized only three drug treatments for H1N1 and issued no EUAs for Ebola or Zika treatments. See *Emergency Use Authorization--Archived Information*, *supra* note 36 (showing the three archived drug EUAs for H1N1); *Emergency Use Authorization: Coronavirus*, *supra* note 34 (showing no EUAs for treatments of Zika or Ebola). One H1N1 treatment, peramivir, that was authorized by an EUA had mixed results. See Debra Birnkrant & Edward Cox, *The Emergency Use Authorization of Peramivir for Treatment of 2009 H1N1 Influenza*, 361 *NEW ENG. J. MED.* 2204 (2009) (noting that the success of the treatment was difficult to ascertain).

⁴⁸ See Doriane Lambelet Coleman & Philip M. Rosoff, *The Enhanced Danger of Physicians' Off-label Prescribing During a Public Health Emergency*, 7 *J.L. & BIOSCIENCES* 1, 2–3, 14–16 (June 28, 2020) (discussing the negative consequences of prescribing drugs for unapproved uses and proposing regulation of experimental use even during a public health crisis).

⁴⁹ *Coronavirus Treatment Acceleration Program (CTAP)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap> [<https://perma.cc/F7QZ-JES5>] (last updated July 16, 2021). Multiple types of treatments have been studied, including antivirals, cell and gene therapies, immunomodulators, and neutralizing antibodies, and ten COVID-19 treatments received EUAs. *Id.* One treatment is now FDA-approved. See *FDA Approves First Treatment for COVID-19*, U.S. FOOD & DRUG ADMIN. (Oct. 22, 2020), <https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19> [<https://perma.cc/P59P-4JHT>].

⁵⁰ See *Emergency Use Authorization: Coronavirus*, *supra* note 34 (showing the vast majority of current EUAs are for IVD tests and other medical devices, rather than therapeutics); see also *Medical Devices*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices> [<https://perma.cc/P59P-4JHT>] (last visited Aug. 4, 2020) (highlighting numerous medical devices related to COVID-19 and linking to “Emergency Use Authorizations (EUAs) for COVID-19”).

⁵¹ See C. PHYSICIANS PHILA., *Vaccine Development, Testing, and Regulation*, C. PHYSICIANS PHILA., <https://www.historyofvaccines.org/content/articles/vaccine-development-testing-and-regulation> [<https://perma.cc/HK4M-U6NM>] (last visited Aug. 4, 2021) (“Vaccine development is a long, complex process, often lasting 10-15 years . . .”).

inaugural EUA for an anthrax vaccine in 2005.⁵² However, between 2005 and the COVID-19 pandemic in 2020, the FDA did not authorize any vaccines using the EUA process. Instead, the FDA used its full regulatory process to *approve* an Ebola vaccine in 2019 without need for an EUA.⁵³ The urgency of the COVID-19 pandemic caused the FDA to issue guidance for EUAs for vaccines to protect against coronavirus.⁵⁴ Further, the U.S. government created an initiative, Operation Warp Speed, to focus executive actions on the rapid development of COVID-19 vaccines.⁵⁵

Consequently, COVID-19 vaccines were developed and authorized for distribution prior to receiving FDA approval.⁵⁶ Even in this clear emergency, however, an EUA for a COVID-19 vaccine is only granted as a temporary measure to allow the vaccine to be given to the public while its manufacturer pursues FDA approval. The full approval process continues to be preferred by the FDA and by

⁵² *Emergency Use Authorization--Archived Information*, *supra* note 36 (showing issuance on Jan. 14, 2005 and termination on Feb. 1, 2006). The Anthrax Vaccine Adsorbed (AVA) was the subject of multiple court actions to establish whether the military could administer the unapproved AVA to service members without their consent. After the D.C. District Court issued an order halting the vaccination program ““unless and until FDA classifies AVA as a safe and effective drug for its intended use,”” the Court examined whether the 2004 Project BioShield Act created another option for administering the vaccine. *Doe v. Rumsfeld*, No. 03-707, 2005 U.S. Dist. LEXIS 5573, at *1 (D. D.C. Apr. 6, 2021). The Court modified the injunction to allow defendants to administer AVA ““on a voluntary basis, pursuant to the terms of a lawful emergency use authorization (‘EUA’)”” *Id.* at *2–3 (citation omitted). However, the Court explained its rationale as an interpretation of congressional intent with the BioShield Act and expressly made ““no finding as to the lawfulness of any specific EUA that has been or may be approved by the Department of Health and Human Services.”” *Id.* at *3 (citation omitted).

⁵³ See *Ebola Preparedness and Response Updates from FDA*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/ebola-preparedness-and-response-updates-fda> [<https://perma.cc/WA9G-LV3>] (last updated Jan. 13, 2021). Similarly, an Ebola treatment was approved by the FDA on Oct 14, 2020, without having needed an EUA. *Id.*

⁵⁴ U.S. DEP’T. OF HEALTH & HUM. SERVS., EMERGENCY USE AUTHORIZATION FOR VACCINES TO PREVENT COVID-19 (May 25, 2021), <https://www.fda.gov/media/142749/download> [<https://perma.cc/BZC6-DE6J>].

⁵⁵ Stephen M. Hahn, Patrizia Cavazzoni & Peter Marks, *An Update and Behind the Scenes: FDA’s Coronavirus Treatment Acceleration Program*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/news-events/fda-voices/update-and-behind-scenes-fdas-coronavirus-treatment-acceleration-program> [<https://perma.cc/BCS2-WK63>] (last updated July 14, 2020).

⁵⁶ See *Emergency Use Authorization: Coronavirus*, *supra* note 34 (listing current EUAs specifically for vaccines); *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum*, U.S. FOOD & DRUG ADMIN. (Nov. 20, 2020), <https://www.fda.gov/media/144416/download> [<https://perma.cc/9ZGB-Q4UK>] (detailing the first vaccine EUA granted in 2020 to Pfizer).

vaccine developers under most circumstances.⁵⁷ In short, the majority of products granted EUAs have been and are likely to remain Class II medical devices.

B. The Evolution of the EUA Statute

1. The BioShield Act in Practice

The BioShield Act of 2004 was a response to the terrorist attacks on September 11, 2001, and to a bioterrorism attack using anthrax spores sent through U.S. mail that followed a week later.⁵⁸ Congress used the BioShield Act to create Emergency Use Authorizations in anticipation of another military or terrorist attack involving chemical, biological, radioactive, or nuclear (CBRN) weapons.⁵⁹ Congress envisioned the EUA of medical countermeasures as a tool to assist with a military response.⁶⁰ Hence, the purpose of the Act was “to provide protections and countermeasures against chemical, radiological, or nuclear agents that may be used in a terrorist attack against the United States.”⁶¹ Under the Act, a government or industry sponsor could request an EUA in response to an emergency, provide sufficient evidence to permit substantive review, and, if authorized by the FDA, immediately make its product available to the public.⁶² However, the vast majority of applications for EUAs have been for biological threats to public health, rather than the anticipated military or terrorist attack.⁶³

In authorizing the “introduction into interstate commerce . . . of a drug, device, or biological product intended for use in an actual or potential emergency,” the BioShield Act contained some restrictions.⁶⁴ First, it required a declaration of emergency by the HHS Secretary, based on a domestic, military, or public health

⁵⁷ See, e.g., Berkeley Lovelace Jr., *From Employer Mandates to TV Ads: What Full FDA Approval Could Mean for Covid Vaccines*, CNBC (May 18, 2021, 10:12AM), <https://www.cnbc.com/2021/05/18/covid-vaccines-what-full-fda-approval-means-for-you.html> [<https://perma.cc/BW87-YVXU>] (explaining advantages to companies of receiving full FDA approval).

⁵⁸ John A. Casciotti, *Fundamentals of Military Health Law: Governance at the Crossroads of Health Care and Military Functions*, 75 A.F. L. REV. 201, 206–07 (2016).

⁵⁹ Project BioShield Act of 2004, Pub. L. No. 108–276, 118 Stat. 835, 853.

⁶⁰ See *id.*

⁶¹ *Id.*

⁶² See U.S. DEP’T OF HEALTH & HUM. SERVS., EMERGENCY USE AUTHORIZATION OF MEDICAL PRODUCTS AND RELATED AUTHORITIES: GUIDANCE FOR INDUSTRY AND OTHER STAKEHOLDERS, 0910-0595 (Jan. 2017).

⁶³ *Emergency Use Authorization: Other Current EUAs*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#othercurrenteuas> [<https://perma.cc/YK5L-XUAP>] (last visited Jan. 27, 2022) (showing most EUAs are related to naturally occurring biological threats, while just three are not: an anthrax EUA, a nerve agent EUA and a freeze-dried plasma EUA).

⁶⁴ Project BioShield Act of 2004, Pub. L. No. 108–276, 118 Stat. 835, 853–59.

emergency or a “heightened risk of attack.”⁶⁵ Second, the Act provided automatic termination of the EUA within one year, unless specific steps were taken for renewal.⁶⁶ Over time, a series of amendments modified and relaxed these restrictions, with the last major amendment occurring in 2013.⁶⁷

The Medical Products EUA statute currently requires a “declaration that the circumstances exist justifying the authorization,” rather than requiring a declared emergency.⁶⁸ The justifying circumstances may be a “significant potential” for a domestic, military, or public health emergency, the emergency itself, or a “material threat” sufficient to affect national security.⁶⁹ In other words, the Secretary could decide that a significant potential for a yet-unrealized emergency provides the circumstances to justify an EUA absent any actual emergency. Second, rather than an automatic expiration, the termination of the EUA now occurs when the Secretary determines “that the circumstances [justifying the authorization] have ceased to exist” or when the product approval status changes.⁷⁰

2. Key Provisions of the Medical Products EUA Statute

(a) Criteria for Issuance of Authorization

Criteria within the Medical Products EUA statute define which medical products may be authorized for emergency use. When the HHS Secretary determines that a CBRN agent can cause “a serious or life-threatening disease or condition,” three elements must exist for the product to be authorized for emergency use:

1. Reasonable belief “that the product may be effective in diagnosing, treating or preventing” the disease or condition caused by the agent,
2. “The known and potential benefits of the product . . . outweigh the known and potential risks of the product” in treating the disease or condition, and
3. “No adequate, approved, and available alternative to the product” exists.⁷¹

If the determination of emergency or potential emergency is based on a CBRN agent “that may cause . . . an imminently life-threatening and specific risk to United States military forces” then the Secretary of Defense must request the emergency

⁶⁵ *Id.* at 854.

⁶⁶ *Id.* at 854–55.

⁶⁷ John D. Blum & Jordan Paradise, *Public Health Preparedness & Response: An Exercise in Administrative Law*, 20 DEPAUL J. HEALTH CARE L. 1, 13–16 (2018). Amendments included the PREP Act of 2006, the PAHPA of 2006, and the Pandemic and All-Hazards Preparedness Reauthorization Act (“PAHPRA”) of 2013. *Id.*

⁶⁸ 21 U.S.C. § 360bbb-3(b)(1) (2017).

⁶⁹ *Id.* § 360bbb-3(b)(1).

⁷⁰ *Id.* § 360bbb-3(b)(2).

⁷¹ *Id.* § 360bbb-3(c). *See also* Blum & Paradise, *supra* note 67, at 15.

use.⁷² This special requirement when military forces are involved highlights the envisioned use of EUAs for both public health and military emergencies in response to a threat to either population.⁷³ A final provision specifies “that other criteria as the [HHS] Secretary may by regulation prescribe are satisfied,” allowing for regulatory additions.⁷⁴

(b) Scope of Authorization

The authorization for emergency use requires a statement of scope.⁷⁵ The statement must list “each disease or condition that the product may be used to diagnose, prevent, or treat,” as well as the HHS Secretary’s conclusions that the benefits outweigh the risks.⁷⁶ Additionally, the Secretary must provide “conclusions . . . concerning the safety and potential effectiveness of the product” and include “to the extent practicable . . . an assessment of the available scientific evidence.”⁷⁷ While this appears to require an assessment and justification tailored to the product being authorized, in practice, the conclusions appear to use boilerplate language to comply with this requirement.⁷⁸ Generally, the EUA is issued as an authorization letter from the FDA, which includes the scope and other required elements.⁷⁹

(c) Conditions of Authorization

The Medical Products EUA statute provides that “to the extent practicable” the Secretary “shall . . . establish such [required] conditions on an authorization . . . as

⁷² 21 U.S.C. § 360bbb-3(c)(4) (2017).

⁷³ *Id.* §§ 360bbb-3(b)(1)(B), 360bbb-3(b)(6), 360bbb-3(c)(4).

⁷⁴ *Id.* § 360bbb-3(c)(5).

⁷⁵ *Id.* § 360bbb-3(d).

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Compare* Letter from U.S. Food & Drug Admin. to Jill Taylor, Director, Wadsworth Ctr. N.Y. State Dep’t Health (Mar. 10, 2020), <https://www.fda.gov/media/135661/download> [<https://perma.cc/5BVR-AMLY>], *with* Letter from U.S. Food & Drug Admin. to Chris Andry, Professor & Chair, Dep’t Pathology & Lab’y Med., B.U. Sch. Med. (July 10, 2020), <https://www.fda.gov/media/140024/download> [<https://perma.cc/49DL-E5TW>], *and* Letter from U.S. Food & Drug Admin. to Jonathan Flint, Ctr. Neurobehavioral Genetics, UCLA (Oct. 6, 2020), [hereinafter “Letter to Jonathan Flint”] <https://www.fda.gov/media/142802/download> [<https://perma.cc/74TL-ZRWH>] (using identical language regardless of whether the recipient is a government agency, a medical center, or a university).

⁷⁹ *See, e.g.*, Letter from U.S. Food & Drug Admin. to Lauren Bricks, COO, Ipsum Diagnostics LLC (Apr. 1, 2020) <https://www.fda.gov/media/136618/download> [<https://perma.cc/3DZT-UTJT>]; Letter from U.S. Food & Drug Admin. to Robert J. Rae, CEO, Pro-Lab Diagnostics (Aug. 23, 2020), <https://www.fda.gov/media/141146/download> [<https://perma.cc/DYL3-JCVM>]; Letter from U.S. Food & Drug Admin. to Michelle Ortiz, COO, Synergy Diagnostic Laboratory, Inc. (Apr. 16, 2021), <https://www.fda.gov/media/147685/download> [<https://perma.cc/3FQH-ZXFF>].

the Secretary finds necessary or appropriate”⁸⁰ Again, the required conditions intended “to protect public health” are established at the discretion of the Secretary, who decides whether a possible condition is practicable, necessary or appropriate.⁸¹ Moreover, the possible “appropriate conditions” listed in the subsection deal solely with providing information about the medical product, reporting, and record keeping.⁸² Even if the Secretary finds it appropriate to require them, none of these conditions verifies the safety and efficacy of the product itself.⁸³

In addition, the Medical Products EUA statute retains the original wording of the BioShield Act related to manufacturing. The Secretary “may waive or limit, to the extent appropriate” based on the circumstances, “requirements regarding current good manufacturing practice” that would otherwise apply.⁸⁴ While the FDA may impose manufacturing-related conditions for biological products or drugs,⁸⁵ a full waiver has repeatedly been granted for EUAs issued for medical devices related to COVID-19, including PPE (respirators),⁸⁶ IVTs (diagnostic tests),⁸⁷ and therapeutic treatment systems.⁸⁸

3. *Discretion to Provide Flexibility*

What should be clear from this review of the current statute and its modifications since 2004 is that many requirements for granting EUAs are discretionary and can be easily satisfied. For example, reasonable belief that a potential benefit outweighs potential harm does not require the production of scientific evidence. HHS is authorized to declare the need for an EUA, determine the appropriate conditions for authorizing a particular product, waive relevant good manufacturing practices for it, and continue to allow the product to be marketed under the EUA indefinitely with very little guidance or regulation.⁸⁹

The lack of regulatory rigor in the EUA process is intentional: Congress built agency discretion into the statutes and subsequently expanded such discretion in an

⁸⁰ 21 U.S.C. § 360bbb-3(e)(1)(a) (2017).

⁸¹ *Id.*

⁸² *Id.* § 360bbb-3(e).

⁸³ *Id.*

⁸⁴ *Id.* § 360bbb-3(e)(3).

⁸⁵ *See, e.g.*, Letter from U.S. Food & Drug Admin. to Eli Lilly and Company (Feb. 21, 2021) <https://www.fda.gov/media/145801/download> [<https://perma.cc/ELL6-XYR2>] (requiring good manufacturing practices and imposing six other manufacturing-related conditions, including independent third-party review for therapeutic drugs).

⁸⁶ *See, e.g.*, Letter from U.S. Food & Drug Admin. to Rochelle P. Walensky, Director, Ctrs. for Disease Control & Prevention. (Mar. 28, 2020), <https://www.fda.gov/media/135763/download> [<https://perma.cc/ULP6-MCW9>].

⁸⁷ *See, e.g.*, Letter to Jonathan Flint, *supra* note 78.

⁸⁸ *See, e.g.*, Letter to Denise Oppermann, *supra* note 46.

⁸⁹ 21 U.S.C. § 360bbb-3 (2017).

effort to decrease time to market.⁹⁰ While the HHS Secretary “may by regulation prescribe” criteria and “may . . . establish such conditions on an authorization . . . as the Secretary finds necessary or appropriate to protect the public health,” there is no statutory obligation for the Secretary to do so.⁹¹ Similarly, “the Secretary may waive or limit, to the extent appropriate given the applicable circumstances” good manufacturing processes that help assure quality.⁹² These flexible measures may serve well when an emergency, such as an active terrorist attack, requires immediate action, and additional quality assurance steps would cause delays that would cost lives. However, when an emergency has a longer duration,⁹³ continued flexible measures could do more harm than good, allowing inadequately tested medical devices to enter the market without delivering a corresponding benefit.

In recent decisions, the FDA has used its discretion under the Medical Products EUA statute to allow companies to validate their COVID-19 tests and begin marketing or using the tests with simple notification to the FDA.⁹⁴ Although the FDA expected companies would then file EUA applications within a reasonable time, its policy allowed medical devices onto the market without any initial oversight. The relaxed requirements for EUAs are a departure from the established FDA processes used in overseeing foods, prescription drugs, and other medical products, and are designed as a kind of short-cut. However, weaker regulations also open the door for diminished safety and effectiveness when products are introduced to the market with minimal quality assurance.⁹⁵

⁹⁰ Compare National Defense Authorization Act of Fiscal Year 2004, Pub. L. No. 108-136, 117 Stat. 1392, 1684 (allowing the declaration of “an emergency justifying the authorization” based only upon determination of “military emergency . . .”), with Project Bioshield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835, 854 (adding the HHS Secretary’s determination that “a public health emergency” exists as a basis for authorization), and Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, Pub. L. No. 113-5, 127 Stat. 161, 180-81 (adding “the identification of a material threat” as a basis and expanding the Secretary’s power to waive or limit requirements) (each Act codified at 21 U.S.C. § 360bbb-3).

⁹¹ 21 U.S.C. § 360bbb-3 (2017).

⁹² *Id.*

⁹³ The Zika emergency, for example, continues to be active years after its initial February 26, 2014 declaration. See *Emergency Use Authorizations for Medical Devices*, *supra* note 26.

⁹⁴ POLICY FOR CORONAVIRUS DISEASE-2019 TESTS DURING THE PUBLIC HEALTH EMERGENCY (REVISED), U.S. DEPT. HEALTH & HUM. SERV. (May 11, 2020), <https://www.fda.gov/media/135659/download> [<https://perma.cc/K7RA-NY3K>] (indicating commercial manufacturers could distribute and laboratories could use diagnostic tests prior to EUA submission).

⁹⁵ Perhaps recognizing that testing medical devices for quality assurance is desirable, the PAHPRA of 2013 included a new subsection (m) for “categorization of laboratory tests associated with devices subject to authorization.” 21 U.S.C. § 360bbb-3(m) (2017). This section allows the Secretary to categorize a laboratory examination related to the device if the categorization “would be beneficial to protecting the public health.” *Id.* Yet, the FDA did

C. Regulatory Gap Between FDA Approval and EUAs

In contrast with the EUA process, the FDA requires “compliance with good manufacturing practices” for *approval* of medical devices, such as IVD products⁹⁶ and drugs for human consumption.⁹⁷ “The essential purpose” of such compliance “is to maintain the safety and quality” of medical products “during the manufacturing stage, rather than to address problems only after they have caused harm to consumers.”⁹⁸ Manufacturing practices required for FDA approval include testing and quality system requirements to help guarantee that the products will be safe and effective when introduced to commerce.⁹⁹ The FDA regulations may also require manufacturers to track medical devices and perform postmarket surveillance.¹⁰⁰

While EUAs have successfully reduced the regulatory burden and shortened time to market, they have also removed the quality controls and performance standards that are part of the FDA approval process. The language of the Medical Products EUA statute mandates conditions for unapproved products to ensure information sharing and reporting of adverse events, but it does not address other quality concerns.¹⁰¹ Under such relaxed standards, devices in which the failure mode is not easily detected may not be reported, even as the devices cause harm to their users or to public health in general.

Such a result occurred during the COVID-19 pandemic when rapid diagnostic tests proved to have high rates of false negatives¹⁰² and when authorized N95 respirators did not adequately filter particles.¹⁰³ Although previous biological threats or emergencies were addressed more reliably than the COVID-19 pandemic,¹⁰⁴ the lack of statutory language to help ensure safety and effectiveness when a device is introduced in the market left the regulatory scheme prone to failure. Particularly if successes in the past were due to institutional knowledge and optional employment

not incorporate this discretionary element in its policies or EUAs for medical devices during the COVID-19 pandemic.

⁹⁶ 21 C.F.R. § 809.20 (2020).

⁹⁷ *Id.* §§ 210–211.208.

⁹⁸ *U.S. v. Various Articles of Drug*, No. H-95-912, 1996 U.S. Dist. LEXIS 22867, at *10 (D. Md. June 6, 1996).

⁹⁹ *See* Quality System Regulation, 21 C.F.R. §§ 820–820.250 (2020).

¹⁰⁰ *Id.* §§ 821–822.38.

¹⁰¹ *See* 21 U.S.C. § 360bbb-3 (2017).

¹⁰² *See* Abbott ID NOW Point-of-Care Test, *supra* note 6.

¹⁰³ *See* Certain Filtering Facepiece Respirators from China May Not Provide Adequate Respiratory Protection – Letter to Health Care Providers, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/letters-health-care-providers/certain-filtering-facepiece-respirators-china-may-not-provide-adequate-respiratory-protection-letter> [<https://perma.cc/Z3ZF-8JF2>] (last updated Oct. 15, 2020).

¹⁰⁴ *See, e.g.*, Blum & Paradise, *supra* note 67, at 17–21 (discussing the effective use of EUAs in response to the ZIKA virus).

of unmandated safeguards,¹⁰⁵ the reliance on personnel rather than protocol cannot guarantee consistent future results and leaves public health vulnerable.

Furthermore, the FDA standard for approval of medical devices and drugs is proof of safety and effectiveness.¹⁰⁶ In comparison, the EUA mechanism requires only a conclusion that the medical product has *potential* to be effective, without requiring proof.¹⁰⁷ The risk of harm from an authorized product is lessened by the fact that most EUAs are issued for Class II medical devices, which typically have fewer serious risks than Class III devices, and for FDA-approved drugs to be used in an unapproved manner.¹⁰⁸ But the EUA mechanism does not mitigate the risk of harm from ineffective drugs or medical devices, and it may underestimate unanticipated harmful effects when those products are used for a particular illness.

The problem is not, however, simply that the EUA process lacks the rigorous standards that the FDA uses for approving medical products. The regulatory gap between the mechanisms for approval and authorization does not, by itself, explain why EUAs have been used successfully in the past,¹⁰⁹ while the response to COVID-19 has been called “disastrous,”¹¹⁰ a failure whose magnitude is “astonishing.”¹¹¹ The problem, as explored below, is a regulatory gap combined with inconsistent application of available regulatory measures.

D. The Impact on National Health: COVID-19 Case Study

During the COVID-19 pandemic, the regulatory gap between the FDA approval standards and the requirements for EUAs resulted in predictable problems. Even while following the Medical Product EUA statute, the decisions and actions taken by the agency caused delays without eliminating burdensome requirements or preventing fraudulent activities. These issues threatened national public health precisely at a time when America needed to rely upon the FDA for effective protection.

First, the discretionary nature of the statute governing EUAs left opportunity for vacillation between over- and under-regulation. When laboratories initially

¹⁰⁵ Although this is a supposition, it is based on the wide discretion granted to FDA personnel in determining appropriate protocols for EUAs.

¹⁰⁶ See Casciotti, *supra* note 58, at 207.

¹⁰⁷ 21 U.S.C. § 360bbb-3(c)(2)(B) (2017) (allowing authorization if the FDA believes “the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product”).

¹⁰⁸ See *Emergency Use Authorization: Coronavirus*, *supra* note 34.

¹⁰⁹ See Blum & Paradise, *supra* note 67, at 19 (attributing “an international decline in the incidence of Zika” to “the availability of detection assays through issuance of emergency use authorizations”).

¹¹⁰ Martha Kinsella, *COVID-19 Shows the Disastrous Results of What Happens When Science Is Sacrificed for Politics*, BRENNAN CTR. FOR JUST. (May 11, 2020) <https://www.brennancenter.org/our-work/analysis-opinion/covid-19-shows-disastrous-results-what-happens-when-science-sacrificed> [https://perma.cc/6DAC-XGGN].

¹¹¹ Editors, *Dying in a Leadership Vacuum*, 385 NEW ENG. J. MED. 1479, 1479 (2020).

began developing COVID-19 tests, the FDA believed its emergency powers included “the power to regulate clinical laboratory services.”¹¹² The FDA has clear authority to “regulate test kits,” including requiring EUAs for unapproved IVD test kits and sample collection kits to be marketed.¹¹³ However, Congress has not given the FDA clear authority for laboratory developed tests (LDTs), which are “intended for clinical use and designed, manufactured, and used within a single laboratory.”¹¹⁴ Thus, when those tests are shared outside the laboratory, they enter a regulatory grey area, and the FDA issued four guidance documents from February to May 2020, with “evolving versions of the FDA’s policy on EUAs for COVID-19 diagnostic tests.”¹¹⁵

In the uncertainty regarding its emergency powers, the FDA instructed laboratories to stop any use of LDTs without authorization.¹¹⁶ In one case, the FDA allowed testing of new samples but prohibited the lab from performing retrospective testing on samples it had previously collected.¹¹⁷ In reaction to the negative outcomes from this over-restriction, the FDA reversed course for the regulation of antibody (serological) tests.¹¹⁸ The agency called attention to its new policy “explaining that FDA does not intend to object when developers of serological tests market or use their tests without prior FDA review” where certain conditions were

¹¹² 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, 80–82 (2020) (discussing FDA regulation of in-house laboratory testing under its emergency powers early in the pandemic).

¹¹³ *Id.* at 86.

¹¹⁴ *Id.* at 87.

¹¹⁵ *Id.* at 82–83.

¹¹⁶ *Id.* at 85–85.

¹¹⁷ Megan Doerr & Jennifer K. Wagner, *Research Ethics in a Pandemic: Considerations for the Use of Research Infrastructure and Resources for Public Health Activities*, 7 J.L. & BIOSCIENCES 1, 2–3 (2020). The Seattle Flu Study (SFS) collected nasal swabs for annual flu research and petitioned the FDA “for permission to use [its] existing samples bank to track COVID-19 spread.” *Id.* The SFS team then “decided to test the samples without the explicit approval of public health authorities.” *Id.* After a positive result was confirmed by an independent Washington laboratory, “FDA regulators ordered SFS to stop retrospective testing of their existing samples.” *Id.* Later, the FDA determined that SFS could test new samples, while still prohibiting retrospective testing. *Id.*

¹¹⁸ Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: Serological Test Validation and Education Efforts, <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-test-validation-and-education-efforts> [<https://perma.cc/J5KU-ZPMK>] (last updated Apr. 18, 2020) (“Recognizing that more flexibility was needed during a pandemic of this scale and speed, and incorporating feedback from the medical community, states and test developers, we have also provided regulatory flexibility for serological tests in an effort to provide laboratories and health care providers with early access to these tests with the understanding that the FDA had not reviewed or authorized (or ‘approved’) them . . .”).

met.¹¹⁹ Changing policies and guidance documents discouraged development for early tests and later enabled market introduction of unreliable and unreviewed tests.¹²⁰

Second, FDA policies created delays in the availability of key protective measures identified by the CDC to help stop the spread of a pandemic. The FDA authorized the first IVD test for COVID-19 use, a test developed by the CDC and intended to be the primary test used in the United States, on February 4, 2020.¹²¹ The next non-CDC test, the cobas SARS-CoV-2, was authorized on March 12, 2020, more than five weeks later.¹²² The impact of this five-week delay would have been smaller if the CDC test had proved reliable.¹²³ However, the initial CDC test had cross-contamination issues that compliance with good manufacturing practices could have helped avoid.¹²⁴ Further, while the CDC validated its test in the laboratory, the final manufactured test was not tested using the quality systems required for non-emergency FDA approval.¹²⁵

The FDA requires reporting of adverse events once an approved or authorized medical product is in the field as an after-the-fact safety measure to detect unknown or unanticipated problems.¹²⁶ Reporting from public health labs using the CDC test raised the alarm about quality problems, but the CDC took a month to correct the problem, “exacerbating nationwide delays in testing.”¹²⁷ The lack of a reliable test

¹¹⁹ *Id.*

¹²⁰ See Walter G. Johnson & Gary E. Marchant, *Legislating in the Time of a Pandemic: Window of Opportunity or Invitation for Recklessness?*, 7 J.L. & BIOSCIENCES 1, 1 (2020).

¹²¹ Letter from U.S. Food & Drug Admin. to Robert R. Redfield, Director, Ctrs. for Disease Control & Prevention (Dec. 1, 2020), <https://www.fda.gov/media/134919/download> [<https://perma.cc/N6YV-ML7K>] (“On February 4, 2020, based on [a] request [by the Centers for Disease Control and Prevention (CDC)], the Food and Drug Administration (FDA) issued a letter authorizing emergency use of the CDC 2019–Novel Coronavirus (2019–nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel . . .”).

¹²² Letter from U.S. Food & Drug Admin. to Rita Hoady, Senior Manager, Roche Molecular Systems (Apr. 12, 2020), <https://www.fda.gov/media/136046/download> [<https://perma.cc/7K42-58UM>] (“On March 12, 2020, based on your request the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the cobas SARS-CoV-2 for use on the cobas 6800/8800 Systems for the qualitative detection of nucleic acid from SARS-CoV-2.”).

¹²³ See David Willman, *Contamination at CDC Lab Delayed Rollout of Coronavirus Tests*, WASH. POST (Apr. 18, 2020), https://www.washingtonpost.com/investigations/contamination-at-cdc-lab-delayed-rollout-of-coronavirus-tests/2020/04/18/fd7d3824-7139-11ea-aa80-c2470c6b2034_story.html [<https://perma.cc/D36J-FSS6>] (indicating that weeks were lost while the CDC worked to address a false positive accuracy problem in its original test).

¹²⁴ *Id.*; see also *Facts About the Current Good Manufacturing Practices (CGMPs)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmps> [<https://perma.cc/4YAF-XFL7>] (last updated June 1, 2021).

¹²⁵ Willman, *supra* note 123; see also Quality System Regulation, 21 C.F.R. §§ 820–820.250 (2020).

¹²⁶ 21 U.S.C. § 360bbb-3(e)(1)(A)(iii) (2017); 21 C.F.R. § 821.1 (2020).

¹²⁷ Willman, *supra* note 123.

“kept the public health labs from performing disease surveillance intended to predict and minimize harm before the virus became widely established in the United States.”¹²⁸ The “nation’s inability to rapidly expand the availability of testing” magnified the impact, resulting in greater spread of the disease.¹²⁹

Third, when the FDA relaxed the EUA process, allowing companies to introduce their medical products into the market before submitting an EUA application or without providing test data, the result was an increase in fraudulent and non-performing devices.¹³⁰ Where the agency was initially too restrictive in regulating EUAs for IVD tests, its regulation of antibody tests was too lax, forcing a subsequent policy modification.¹³¹ The FDA discovered that flexible guidelines were used by some manufacturers to make false claims and that “a concerning number of commercial serology tests are . . . performing poorly based on an independent evaluation by the [National Institute of Health].”¹³²

Fourth, even when authorizing a medical product for emergency use, the FDA’s processes were initially antiquated and burdensome to applicants.¹³³ Some labs opted to forgo deployment of their diagnostic tests “because the EUA application was too difficult,” waiting instead for “a more lenient regulatory framework.”¹³⁴ Fortunately, the FDA has modified its requirements and processes during the course of the pandemic to make them simpler and speedier.¹³⁵ Additionally, numerous scholars have proposed solutions specifically to facilitate scientific developments and support collaborative research on public health issues during a future emergency.¹³⁶

¹²⁸ *Id.*

¹²⁹ *Id.*

¹³⁰ See, e.g., *Insight into FDA’s Revised Policy on Antibody Tests: Prioritizing Access and Accuracy*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy> [<https://perma.cc/VB6G-UNE3>] (last updated May 4, 2020) (“We unfortunately see unscrupulous actors marketing fraudulent test kits and using the pandemic as an opportunity to take advantage of Americans’ anxiety.”).

¹³¹ *Id.*

¹³² *Id.*

¹³³ Chaarushena Deb, Osman Moneer & W. Nicholson Price II, *COVID-19, Single-Sourced Diagnostic Tests, and Innovation Policy*, 7 J.L. & BIOSCIENCES 1, 5 (2020). For example, applicants were initially required to file “documents physically on CDs or thumb drives” by mailing them to the FDA, resulting in nonproductive transfer delays. *Id.*

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ Those solutions include pooling research results globally to accelerate scientific discovery, providing intellectual property rights for later licensing to enable early sharing, broadening patent infringement exemptions for lifesaving technologies and development, and simplifying the EUA application process for non-manufacturing developers of medical devices. See Muhammad Zaheer Abbas, *Treatment of the Novel COVID-19: Why Costa Rica’s Proposal for the Creation of a Global Pooling Mechanism Deserves Serious Consideration*, 7 J.L. & BIOSCIENCES 1, 9 (2020) (discussing Costa Rica’s proposal for a

In summary, the gap between the tightly regulated FDA approval process and the loosely regulated EUA process has allowed the FDA to swing between the two extremes.¹³⁷ On one end, the FDA employs restrictive policies that may make safe and effective medical products unavailable when needed during a public health emergency. On the other end, the FDA takes a hands-off approach that provides the market with medical products that may not work as intended and may not be safe. Either extreme fails to meet the requirement for reliable and readily available medical products to help protect the public from deadly infectious disease.

E. A Proposed Solution: Post-manufacturing Independent Testing

1. One Small Step for Regulation

The FDA's primary mission is to "protect public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, [and] medical devices" ¹³⁸ The FDA also supports the Nation's counterterrorism capability by "fostering development of medical products to respond to deliberate and naturally emerging public health threats," enabled by the Medical Products EUA statute.¹³⁹ These dual roles can be in conflict when the FDA is pressured to quickly authorize emergency use in response to a health threat at the expense of its standards for safety and efficacy. The question is how to reconcile these competing objectives to provide better assurance of efficacy during a public health emergency.

The answer is to leave the EUA process intact, retaining its key features of flexibility with discretionary action to respond quickly to a domestic, military, or public health emergency, but to add a small, vital step to ensure safety and efficacy for the public. That step is *post-manufacturing independent testing of critical performance parameters*.

The first element of this proposal is to require *post-manufacturing testing*, performed after the device is manufactured but before it is released to the market.

global intellectual property pooling mechanism); Adrian Thorogood, *Policy-aware Data Lakes: A Flexible Approach to Achieve Legal Interoperability for Global Research Collaborations*, 7 J.L. & BIOSCIENCES 1 (2020) (proposing a "policy-aware data lake" as a new model allowing countries to share scientific data globally during public health emergencies); Jorge L. Contreras, *Research and Repair: Expanding Exceptions to Patent Infringement in Response to a Pandemic*, 7 J.L. & BIOSCIENCES 1, 2 (2020) (recommending expansion of two "long-standing but narrow exemptions from patent infringement" to facilitate research development during a public health crisis); Deb et al., *supra* note 133.

¹³⁷ Note that political pressures have also played a role unique to the COVID-19 pandemic. An examination of political factors is beyond the scope of this paper, however, the recommendations included in section III.E could reduce the likelihood of agency discretion being used for political purposes.

¹³⁸ U.S. FOOD & DRUG ADMIN., MISSION POSSIBLE: HOW FDA CAN MOVE AT THE SPEED OF SCIENCE, (2015), <https://www.fda.gov/media/93524/download> [<https://perma.cc/W6DQ-4832>].

¹³⁹ *Id.*

Unlike FDA-approved devices, devices that receive EUAs are not required by statute to be tested after manufacturing.¹⁴⁰ As a result, a device may perform as expected during its development phase, and the *design* of the device may be sound, but an error that is introduced in the *manufacturing* process may go undetected. The time-critical early phases of an emergency may further encourage a manufacturer to rely on its design and rush a defectively manufactured device to market. This was precisely the case with the original IVD test kits developed by the CDC to detect COVID-19 in patient samples.¹⁴¹ The devices were cross-contaminated so that the test kits produced false positive results, detecting COVID-19 even when the virus was not present in the samples.¹⁴² If post-manufacturing testing had been required as a condition of the EUA, the error would likely have been detected and corrected *before* the defective devices were sent to laboratories for use.

The second element of this proposal is to require *independent testing of critical performance parameters* to verify that the device performs as intended and within established criteria. In the example of the CDC's IVD test kits, the kits were intended to reliably detect COVID-19 in samples that contained the virus. Consequently, when a kit showed a positive reading for a sample that was known to be free of the COVID-19 virus and should have produced a negative result, a laboratory could quickly identify that the kit was defective.¹⁴³

A greater danger may be the case where the untested device is not discovered to have defects. For example, in the case of PPE, the FDA issued an umbrella EUA for specific filtering respirators made in China that were intended to filter 95% of the airborne particles.¹⁴⁴ Unfortunately, subsequent testing revealed that dozens of the Chinese respirators failed to provide adequate filtration.¹⁴⁵ By the time the FDA revised its EUA for these devices and warned health care providers with its letter on May 7, 2020, the substandard respirators had been legally authorized for import into the United States for more than one month.¹⁴⁶ A regulatory requirement that a device perform according to its stated parameters—in this case, 95% filtration—would likely have prevented the distribution and use of a faulty product.

¹⁴⁰ *Supra*, Section III.B.2(c).

¹⁴¹ *See* Willman, *supra* note 123.

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ Matthew Perrone, *US Pulls Permission for Chinese Masks Found Defective*, U.S. NEWS (May 8, 2020), <https://www.usnews.com/news/health-news/articles/2020-05-08/us-pulls-permission-for-chinese-masks-found-defective> [<https://perma.cc/967Z-BTDN>]; *see also* Letter from U.S. Food & Drug Admin. to Manufacturers of Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China; Health Care Personnel; Hospital Purchasing Departments and Distributors; Importers and Commercial Wholesalers; and Any Other Applicable Stakeholders (May 7, 2020), [hereinafter “Letter to Manufacturers of Imported Respirators”] <https://www.nj.gov/health/workplacehealthand-safety/documents/peosh/EUA-FFRs-Manufactured-China-letter.pdf> [<https://perma.cc/38F6-VTEF>].

¹⁴⁵ Perrone, *supra* note 144.

¹⁴⁶ Letter to Manufacturers of Imported Respirators, *supra* note 144.

The third element of this proposal is *independent testing*, requiring the testing of the device to be conducted by an independent laboratory or agency. In the example of the Chinese respirators, the FDA had established performance criteria, and the respirators were eligible for an EUA if the *manufacturer's* test reports demonstrated adequate filtration.¹⁴⁷ The FDA granted the EUA based on data provided by the manufacturer showing that respirators met the criteria. Subsequent testing by NIOSH and other independent labs,¹⁴⁸ however, showed much lower filtration rates for some respirators than the manufacturers claimed for their devices.¹⁴⁹ Independent laboratories or testing agencies can use specialized equipment to reliably measure the performance of devices¹⁵⁰ and lack an incentive to make fraudulent claims about the devices.¹⁵¹ If independent testing had been required for the devices, any respirators that failed to perform properly would have been denied an EUA and would not have been permitted to enter the U.S. market.¹⁵²

Thus, the three key elements of this proposal are that 1) the testing occurs after manufacturing, when the device is ready for public use; 2) the testing verifies that the device performs as expected according to established criteria; and 3) an independent agency, rather than the manufacturer, conducts the testing.

While this proposal introduces a new verification step, such a solution does not add a large regulatory burden to the applicant. In fact, it removes a step that normally falls to the applicant under good manufacturing practices: verifying that the medical product conforms to specifications and performs correctly.¹⁵³ The burden of

¹⁴⁷ *Id.*

¹⁴⁸ Although not FDA-approved, MIT labs independently performed filtration testing, having identified the potential for fraud with masks that were not certified by a U.S. agency; see Kylie Foy, *Tests Verify If Uncertified N95 Masks Are Effective*, MIT (May 7, 2020), <https://www.ll.mit.edu/news/tests-verify-if-uncertified-n95-masks-are-effective> [<https://perma.cc/LJR7-278M>].

¹⁴⁹ *Id.*; Perrone, *supra* note 144.

¹⁵⁰ See e.g., Foy, *supra* note 148 (describing the setup and protocol used by MIT to test filtration efficiency).

¹⁵¹ For example, NIOSH is federal agency that “has the mandate to assure ‘every man and woman in the Nation safe and healthful working conditions and to preserve our human resources.’” *About NIOSH*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/niosh/about/default.html> [<https://perma.cc/QZX2-42VY>].

¹⁵² Good manufacturing practices, for example, require establishing “procedures for finished device acceptance to ensure that the production run [of the devices] meets acceptance criteria.” 21 C.F.R. § 820.80(d) (2020). Finished devices are then “held in quarantine or otherwise adequately controlled” until authorized to be released for distribution. *Id.* In addition, sampling plans can be developed using statistical techniques to ensure the tested products are representative of the production run. See *id.* § 820.250.

¹⁵³ “The essential purpose of [the FDA’s Current Good Manufacturing Practice] requirements is to maintain the safety and quality of drugs during the manufacturing stage, rather than to address problems only after they have caused harm to consumers.” *U.S. v. Various Articles of Drug*, No. H-95-912, 1996 U.S. Dist. LEXIS 22867, at *10 (D. Md. June 6, 1996) (citation omitted). To be clear, a manufacturer may wish to continue to perform its

verification would be transferred instead to an independent agency that is qualified and prepared to test performance parameters. Fortunately, during circumstances in which an EUA may be issued, the FDA has additional resources at its disposal to respond to the emergency and to work in cooperation with other agencies.¹⁵⁴ Further, the speed with which independent labs have found performance shortcomings during the coronavirus pandemic indicates a post-manufacturing verification measure would be unlikely to appreciably delay market introduction dates.

In short, the proposed requirement for independent testing prior to shipment is designed to be a targeted, workable solution specifically to fill the regulatory gap and ensure that medical devices authorized under the Medical Product EUA statute are safe and effective.

2. *One (Modest) Leap for Pandemic Preparedness*

The post-manufacturing testing solution proposed in this Note focuses squarely on ensuring the safety and effectiveness of the medical product, however, it offers additional advantages for pandemic preparedness in general.

First, a required testing procedure for Class II medical devices removes an element of uncertainty for the FDA when an emergency first arises. Hesitation and inconsistent steps, caused by the identified regulatory gap and illustrated by the COVID-19 examples, have interfered with the FDA's ability to fulfill its objective of ensuring swift availability of safe products. Thus, in the early phases of a pandemic, when the CDC, research laboratories, manufacturers, and the FDA are moving quickly to address the emergent concern, the standard procedure would be a certain step, an essential means to avoid non-performing or faulty medical devices. Additionally, the testing proposed here could be the "stitch in time" that saves weeks that would otherwise be required for detection and correction. It could help prevent the stop and go, revise and retract, confusion of messages that characterized the early days of the COVID-19 pandemic. It is possible that, even though the proposed testing adds a new step to the EUA process, all parties would ultimately welcome the clarity and benefits it produces.

Second, independent testing labs can collect objective data for use in comparisons between medical devices that perform the same function. On September 15, 2020, months after the start of the pandemic, the FDA requested performance data for certain authorized COVID-19 molecular diagnostic tests.¹⁵⁵

own post-manufacturing quality assurance, but the proposed EUA testing requirement will, by definition, fall externally to an independent lab or agency and does not add a burden to the supplier.

¹⁵⁴ Under the Project BioShield Act of 2004, "the Secretary is authorized . . . to enter into interagency agreements and other collaborative undertakings with other agencies of the United States Government." Pub. L. No. 108-276, 118 Stat. 835, 851.

¹⁵⁵ News Release, U.S. Food & Drug Admin., *Coronavirus (COVID-19) Update: FDA Publishes Comparative Performance Data for COVID-19 Molecular Diagnostic Tests* (Sept. 15, 2020), <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19->

However, many suppliers opted not to return test results or provided data that could not be used.¹⁵⁶ When the FDA compared the usable supplier data, sensitivity testing for the authorized SARS-CoV-2 molecular diagnostic tests showed great variation, with levels of detection ranging from 180 to 540,000 NDU/mL.¹⁵⁷ In other words, some IVD tests were much more effective in detecting a small amount of viral material and identifying a positive COVID-19 result than others, yet comparisons between the tests were not available in the first six months that COVID-19 testing was performed.

If all EAUs required mandatory testing, sets of incomplete performance data would not be an issue. Instead, the FDA would collect valid data using consistent measurement standards for each authorized medical device, and based on the data, could improve plans for making effective devices widely available. For example, if comparative information were available when IVD tests were first developed, the FDA could avoid large discrepancies in test performance by identifying and selectively authorizing only the most effective tests. Manufacturers could then develop supply strategies and concentrate production efforts on those tests, leading to better availability of reliable tests. Finally, such standardization might enable faster diagnostic test results, solving another problem that arose during the COVID-19 pandemic.¹⁵⁸ Because delayed test results can leave people uncertain whether to self-quarantine while awaiting their results or continue interacting in the community, potentially spreading contagion,¹⁵⁹ any improvement in rapid, accurate diagnostic results would likely translate to improved public health outcomes.

Third, the proposed testing encourages suppliers to employ manufacturing practices that consistently produce quality devices. During the COVID-19 pandemic, the FDA reminded manufacturers that medical devices are subject to ongoing surveillance and that respirators may, for example, be “subject to random sampling and NIOSH testing upon importation into the United States.”¹⁶⁰ This

update-fda-publishes-comparative-performance-data-covid-19-molecular-diagnostic [https://perma.cc/7HA2-3VPQ].

¹⁵⁶ See SARS-CoV-2 Reference Panel Comparative Data, *Table I*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-reference-panel-comparative-data> [https://perma.cc/Q7KG-WP8V] (last visited July 7, 2021).

¹⁵⁷ *Id.* at *Table 2*. The unit of measure, NDU/mL, refers to Nucleic Acid Amplification Test (NAAT) Detectable Units (NDU) per milliliter. *Id.* The table data show that the least sensitive test required 3000 times the amount of detectable viral material to detect the virus as the most sensitive test.

¹⁵⁸ Jamie Ducharme, *Patients Are Waiting Weeks for COVID-19 Test Results. Here's Why That's a Huge Problem*, TIME (Jul. 22, 2020, 11:07 AM), <https://time.com/5869130/covid-19-test-delays/> [https://perma.cc/MZ5P-RPHE]. Although standardization, by itself, does not result in faster test results, the FDA could selectively approve tests that have a faster turnaround time, and testing centers could develop streamlined procedures to reduce processing time for those authorized tests. *See id.* (offering additional time-saving testing ideas).

¹⁵⁹ *Id.*

¹⁶⁰ Letter to Manufacturers of Imported Respirators, *supra* note 144, at 5.

reminder was likely intended to prompt those suppliers to make in-house improvements to be certain their products would pass any subsequent test conducted by NIOSH. A system of independent verification creates an incentive for suppliers to focus on quality and to detect and fix problems upstream in the manufacturing process. Consequently, a regulatory change that requires post-manufacturing independent testing of critical performance parameters benefits public health by nudging suppliers toward making higher quality medical products.

A final benefit is that, if needed, the proposal could be limited to just two types of medical devices and still achieve outsized results. The medical devices almost certain to be subjects of EUAs are diagnostic tests and respirators. These devices perform a critical role in identifying patients who are sick and preventing the spread of disease to people who are healthy. If these devices are unreliable, they can pose a danger to public health, giving people a false sense of security as they unwittingly spread disease. The FDA validates this concern, warning in its policy guide that “false results can negatively impact not only the individual patient but also can have broad public health impact.”¹⁶¹

Happily, implementing mandatory post-manufacturing testing for just diagnostic tests and respirators would cover 90% of the EUAs issued. During the COVID-19 pandemic, the FDA compared performance of only selected molecular IVD tests, but it tracked other categories of EUAs it granted.¹⁶² By October 2020, more than 84% of EUAs were for IVD tests, and another 7% were for PPE, confirming that the overwhelming majority of EUAs are issued for these two Class II medical devices.¹⁶³ The performance metrics for IVD tests and respirators are established and relatively straightforward.¹⁶⁴ In fact, NIOSH is already performing respirator testing for industry,¹⁶⁵ and the FDA could identify independent labs or create an agency to provide similar services for IVD tests.

In summary, the FDA could concentrate its efforts on the proposed post-manufacturing testing of IVD tests and respirators and achieve disproportionate benefits. Not only would the FDA ensure the safety and effectiveness of almost all

¹⁶¹ POLICY FOR CORONAVIRUS DISEASE-2019 TESTS, *supra* note 94, at 8.

¹⁶² *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> [<https://perma.cc/CL87-SXB5>] (last visited July 7, 2021).

¹⁶³ *See id.* The percentages were calculated by tallying the number of EUAs listed for each type of device and dividing by the total number of issued EUAs. In comparison, drugs and biologic products, for which testing procedures would likely be significantly more complicated, only received 1% of the EUAs during this period. *Id.*

¹⁶⁴ *See, e.g.*, 42 C.F.R. § 84 (respirators); *Recognized Consensus Standards*, U.S. FOOD & DRUG ADMIN. (June 7, 2021), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/Results.cfm?start_search=1&ProductCode=&Category=&Type=&Title=&Organization=&ReferenceNumber=C24-A&RegulationNumber=&PAGENUM=10 [<https://perma.cc/8M3M-EJHL>] (identifying the Statistical Quality Control for Quantitative Measurement Procedures standard for InVitro Diagnostics).

¹⁶⁵ It should be noted that this testing is performed for a fee, as outlined in 42 C.F.R. §§ 84.20–84.24. A similar fee structure could be developed for IVD tests to help defray the costs of this testing proposal.

medical products it authorizes during an emergency, but it could also address the shortcomings identified previously in Section III.D and improve its general pandemic preparedness and response.

3. *The Means to Implement: Legislative Action*

Currently, only the Medical Products EUA statute, Section 360bbb-3 of the U.S. Code, governs the issuance of EUAs.¹⁶⁶ Under subsection (i), “actions under the authority of this section . . . are committed to agency discretion,”¹⁶⁷ allowing the “principal agency for protecting the health of all Americans,” HHS, to take actions it judges to be appropriate.¹⁶⁸ Congress also generally prohibits states from imposing additional or more stringent requirements for medical devices.¹⁶⁹ Consequently, the HHS Secretary has few constraints and broad decision-making power for issuing EUAs. But despite this authority, the Secretary has not opted to add quality-focused conditions or to require proof of performance of the ready-for-market product in numerous EUAs during the COVID-19 pandemic.¹⁷⁰

Given the apparent reluctance of HHS (or more narrowly, the FDA) to use its authority to verify the quality of medical devices that are anticipated to be essential during infectious disease emergencies, the responsibility likely falls to Congress. Congressional action to amend 21 U.S.C. § 360bbb-3 and mandate testing by an independent FDA-approved lab would fill the identified regulatory gap.¹⁷¹ Alternatively, the FDA itself could be required to test randomly selected samples of manufactured product to guarantee the safety and efficacy of the product entering the market. In either case, the statutory amendment could leverage current CFR regulatory language that requires verification for FDA-approved products.

For example, the additional regulation should require that “acceptance criteria”¹⁷² or “quality system requirements”¹⁷³ be identified for the product. It appears that such criteria are generally determined by the manufacturer, but the FDA could establish minimum performance criteria instead of or in addition to manufacturers’ criteria.¹⁷⁴ Further regulatory language should state that “product

¹⁶⁶ 21 U.S.C. § 360bbb-3 (2017).

¹⁶⁷ *Id.*

¹⁶⁸ *Introduction: About HHS*, U.S. DEP’T HEALTH & HUM. SERVS., <https://www.hhs.gov/about/strategic-plan/introduction/index.html> [<https://perma.cc/DZQ3-GJYF>] (last visited July 7, 2021).

¹⁶⁹ 21 U.S.C. § 360k.

¹⁷⁰ *Emergency Use Authorization*, *supra* note 162.

¹⁷¹ 21 U.S.C. § 360bbb-3(m) provides for “categorization of laboratory tests associated with devices subject to authorization” if the categorization “would be beneficial to protecting the public health.” A laboratory test that verifies the safety and efficacy of a medical device would also be beneficial to protecting public health, and the new language could be added within this section.

¹⁷² *See* 21 C.F.R. § 820.86 (2020).

¹⁷³ *See id.* §§ 820.20–820.25.

¹⁷⁴ *Id.* § 820.80.

shall be tested, or otherwise verified” by an independent laboratory or government agency prior to the issuance of the EUA. Finally, the statutory addition should state that test results must show “conformance of product with acceptance criteria” for the device to receive an EUA.¹⁷⁵ Procedures should be developed to obtain a sample of finished product and expedite the testing to provide an answer with minimal delay. A device that does not meet acceptance criteria based on test results should not be given an EUA.¹⁷⁶

4. *Beyond Devices*

Drugs and biologics not only represent a much smaller percentage of products authorized for use in an emergency, they also have more stringent provisions for establishing that they can be safely used by humans.¹⁷⁷ When the FDA issues an EUA for a drug, and the safety of that drug has been previously demonstrated, it remains a question whether the drug will work as intended in treating the new illness.¹⁷⁸ This question cannot be answered as easily as a test can demonstrate the performance of a device, especially because the FDA is cautious about authorizing use of an unproven drug unless patients are very sick and have exhausted other options.¹⁷⁹ And, even where potential therapeutics are FDA-approved drugs whose safety and efficacy have been proven for other uses, the promotion for off-label use can have negative consequences.¹⁸⁰ Given these complications for drugs and biologics, the proposal recommended in this Note may be best limited to medical devices.¹⁸¹

Additionally, this proposal envisions a typical usage in the future when a new disease surfaces on a global scale and threatens public health. However, its measures would, in principle, be equally effective for protective equipment used in the event of a chemical, bioterror, radiation, or nuclear threat.¹⁸² Protective equipment that

¹⁷⁵ *Id.* §§ 820.20, 820.86.

¹⁷⁶ *See id.* § 820.80(d). “Finished devices shall not be released for distribution until: (1) The activities required in the DMR are completed; (2) the associated data and documentation is reviewed; (3) the release is authorized by the signature of a designated individual(s); and (4) the authorization is dated.” *Id.*

¹⁷⁷ *See, e.g.*, 42 C.F.R. § 11.60 (2020).

¹⁷⁸ *See* Birnkrant & Cox, *supra* note 47.

¹⁷⁹ *See, e.g.*, 21 C.F.R. § 312.305 (2021) (outlining criteria for expanded access to investigational drugs based on life-threatening conditions).

¹⁸⁰ *See generally* Coleman & Rosoff, *supra* note 48 (discussing the negative consequences of prescribing drugs for unapproved uses and proposing regulation of experimental use even during a public health crisis).

¹⁸¹ This is not to suggest that drugs and biologics should escape testing. It is simply to acknowledge that the testing recommended here may be inadequate or duplicative of other measures that are already in place for those products.

¹⁸² For a detailed discussion of biological attacks, see Barry Kellman & Zachary D. Clopton, *A Global Architecture for Medical Counter-Measure Preparedness Against Bioviolence*, 6 U. ST. THOMAS L.J. 550 (2009). *See also* Brooke Courtney, Susan Sherman

demonstrates effective performance, such as masks or other shielding personal gear, can then be authorized for distribution in the market. Fortunately, testing to verify the quality and performance of equipment can and should be completed on an ongoing basis, prior to an emergency.¹⁸³ Such measures ensure that stockpiled equipment meets standards and will provide the expected protection against threats. The FDA can utilize those same quality measures to verify performance and authorize use of unapproved equipment to reduce risk and achieve efficacy goals.¹⁸⁴

IV. CONCLUSION

The repeated struggles by regulators to identify the correct level of oversight needed to protect public health during the COVID-19 pandemic illustrates the need for clear guidelines. Although the FDA is permitted to require more stringent testing or verification prior to authorization of use, during this public health emergency, it has erred on the side of issuing the EUA or even allowing medical devices to enter the market prior to the issuance of an EUA. This may be due to the FDA's dual role as a slow and careful regulator for full FDA approval and as a rapid response facilitator for emergency use without FDA approval, making prioritization of conflicting objectives difficult.

New legislation requiring verification that a medical device works as claimed *prior* to introduction to the market, rather than afterwards, could significantly reduce EUA revisions or product recalls due to quality concerns. This is especially true when the testing protocols are relatively simple to implement for the medical devices most likely to require EUAs. Given that the need to recall or discontinue use of defective medical devices may cause delays in developing or sourcing effective alternatives,¹⁸⁵ the new testing requirement would help the FDA meet its objectives without sacrificing speed. Moreover, the rapid availability of effective medical devices would support CDC public health objectives of identifying disease and preventing spread during a new outbreak. Finally, this proposal would help restore public confidence in the FDA by reducing the need for recalls and warnings and by strengthening the FDA's ability to respond quickly and efficiently in protecting Americans during a time of pandemic.

& Matthew Penn, *Federal Legal Preparedness Tools for Facilitating Medical Countermeasure Use During Public Health Emergencies*, 41 J.L. MED. & ETHICS (SPECIAL SUPPLEMENT) 22 (Supp. 2013).

¹⁸³ Courtney et al., *supra* note 182, at 23–24.

¹⁸⁴ To be clear, not all CBRN threats can be addressed with the proposed legislation. The scope of this paper is limited to naturally occurring biological threats which have historically caused the greatest number of EUA applications. *See Emergency Use Authorization--Archived Information*, *supra* note 36.

¹⁸⁵ *See Willman*, *supra* note 123.