The Food, Drug, and Cosmetic Act's Emergency Use Authorization: A Pandemic Vaccine Godsend with Devils in the Details

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ABSTRACT

The COVID-19 pandemic presented a decisive test of the Emergency Use Authorization (EUA) mechanism, which Congress created in 2003, to utilize the best available medical countermeasure in a public health emergency when there is no FDA-approved product. For nine months, three COVID-19 vaccines under FDA-issued EUAs were the nation's primary weapon to fight the historic pandemic. The results demonstrated two things: first, the EUA mechanism worked remarkably well in reducing morbidity and mortality; and second, in an effort to improve preparedness for a future potential pandemic, there are significant lessons to be learned from FDA actions on implementation details.

I. INTRODUCTION

Coronavirus Disease 2019 (COVID-19) was, according to the Centers for Disease Control and Prevention (CDC), the worst pandemic to hit Americans in over 100 years.[1] The way out of it, according to the CDC, was vaccination with new vaccines that were not approved by the Food and Drug Administration (FDA) but were available under EUAs. This would be, by far, the most significant test to date of the EUA mechanism that Congress added to the Federal Food, Drug, and Cosmetic Act (FDCA) in the post-9/11 scramble to improve bioterrorism response and public health emergency preparedness. How well the EUA mechanism and FDA's implementation of it worked in the COVID-19 EUA vaccination program is the subject of this Article.

This Article in Section II briefly covers the background of the reasons Congress established the EUA mechanism. Section III describes the three COVID-19 vaccine EUAs issued by FDA, including how FDA addressed a number of implementation details for which the statute delegated administrative discretion to the agency. Section IV walks through a chronology of the approximately nine-month period when the EUA vaccination program was the public health system's way out of the pandemic. Section

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[1] *See infra* note 43.

V provides an analysis of several key issues that emerged during implementation that appeared to have a significant impact on the effectiveness of the vaccination program, particularly in relation to communications with potential vaccine recipients, in meeting the objective of minimizing morbidity and mortality. Finally, Section VI provides conclusions on how well the EUA mechanism and FDA's implementation worked and recommendations on lessons learned that may strengthen preparedness for the next potential pandemic.

II. BACKGROUND: THE REASONS CONGRESS ESTABLISHED THE EMERGENCY USE AUTHORIZATION MECHANISM

Prior to the amendment of the FDCA to add the ability of FDA to grant an EUA, both the Department of Defense (DoD) and the Department of Health and Human Services (HHS) stumbled in trying to utilize effectively medical countermeasures to emerging health threats. For DoD, the context was the first Persian Gulf War in 1990–91. Concerned that the Iraqi armed forces could use nerve agents or biological weapons against U.S. forces, DoD sought to use certain medical countermeasures, including one unapproved vaccine and one drug approved for some purposes but not this intended purpose. Under the FDCA, the only authority for these uses was under Investigational New Drug (IND) regulations, essentially designed for the regulation of clinical research trials, which generally include a requirement for informed consent of the recipient, unless it is "not feasible."[2] At DoD's request, FDA adopted a new interim final rule to permit a waiver of the informed consent requirement as not feasible in certain military combat situations. FDA then issued waivers because of military combat exigencies for the use of two investigational drugs, a nerve gas pretreatment pill and a botulism poisoning preventative vaccine. This new FDA informed consent exception regulation was challenged in court but upheld by the U.S. Court of Appeals for the District of Columbia Circuit as a permissible regulatory action by FDA.[3] The court summarized the premise for the new regulation as follows:

> DOD concluded that obtaining informed consent in the heat of imminent or ongoing combat would not be practicable. In battlefield situations, the DOD maintained, "if a soldier's life will be endangered by nerve gas . . . it is not acceptable from a military standpoint to defer to whatever might be the soldier's personal preference" for treatment. The safety of other personnel in a soldier's unit and the accomplishment of the combat mission, the DOD urged, warranted mandatory use of investigational drugs.[4]

The court concluded that the interim final rule was a permissible application of the statutory authority to waive informed consent when it is not feasible.

But controversy continued to swirl, fueled by suspicions among some Gulf War veterans that use of these investigational drugs may have contributed to unexplained

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[2] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(i)(4) (2021).

[3] Doe v. Sullivan, 938 F.2d 1370 (D.C. Cir. 1991).

[4] *Id.* at 1373 (citations omitted).

"Gulf War illnesses."[5] One result of this controversy was the enactment by Congress in 1997 of 10 U.S.C. § 1107, which maintained the special authority for a waiver of informed consent for products subject to IND regulations when those products are for military use, but required presidential approval to use it.[6] Separately, a report by the RAND Corporation, commissioned by DoD, reviewed the cumbersome effort to administer a broad scope disease prevention program under IND regulations. The report suggested consideration of a potential legislative change for a new "limited purpose" FDA drug approval category for countermeasures needed by the military, as well as civilian public health or emergency response authorities for bioterrorism threats.[7]

This suggestion of a new FDA authority to allow for the use of unapproved but promising medical countermeasures received no immediate legislative traction. But the terrorist attacks of September 11, 2001, and the anthrax postal attack several weeks later, jarred the nation and both military and civilian public health communities, triggering an urgent re-examination of emergency preparedness. In 2002, a senior DoD official at a National Defense and Human Research Protections Conference suggested: "When the particular use of a drug is not approved by FDA for general commercial marketing, perhaps experts could agree on a limited approval for special emergency use, such as a bioterrorism event."[8] In 2003, President George W. Bush proposed Project BioShield legislation "to quickly make available effective vaccines and treatments against agents like anthrax, botulinum toxin, Ebola, and plague."[9] Approving this legislation, the House Committee on Energy and Commerce put it this way:

> During times of nation[al], military, or public health emergency, the American people may be placed at risk of exposure to biological, chemical, radiological, or nuclear agents, and the diseases caused by such agents. Unfortunately, there may not be approved or available countermeasures to treat diseases or conditions caused by such agents. Currently, companies have little incentive to research, develop, or produce vaccines or other drugs simply for a possible one-time purchase by the Federal government for the Strategic National Stockpile. Most current private sector research and development dollars go for drugs or devices that will have continuous commercial application . . . .

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[5] *See generally*, INST. OF MED., GULF WAR AND HEALTH: VOLUME 1: DEPLETED URANIUM, SARIN, PYRIDOSTIGMINE BROMIDE, AND VACCINES (2000), https://www.nap.edu/catalog/9953/gulf-war-and-health-volume-1-depleted-uranium-sarin-pyridostigmine (last visited Sept. 18, 2021) [https://perma.cc/RC3R-4QYS].

[6] *See* 144 CONG. REC. S7149 (June 25, 1998), 143 CONG. REC. S7253 (July 11, 1997) (both reference remarks of Senator Byrd); *see also* 21 C.F.R. § 50.23(d) (2021).

[7] Richard A. Rettig, *Military Use of Drugs Not Yet Approved by the FDA for CW/BW Defense: Lessons from the Gulf War*, RAND NAT'L DEF. RSCH. INST., 78–79 (1998), https://www.rand.org/pubs/monograph_reports/MR1018z9.html (last visited Sept. 18, 2021) [https://perma.cc/7JQZ-Z4ED].

[8] Ellen Embrey, *Protecting the Nation's Military May Include the Use of Investigational New Drugs*, 10 ACCOUNTABILITY IN RSCH. 85, 89 (2003).

[9] *State of the Union Address*, Jan. 28, 2003, 1 Pub. Papers of Pres. George W. Bush 82, 86 (2003).

> Even if a product has been developed to treat such diseases or conditions, if the product has not yet been approved by the Food and Drug Administration (FDA), access to the therapy is greatly limited . . . .
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> Under present law, if a product is not approved by the FDA, then it is unlawful to provide that product to an individual, unless the product has been authorized for distribution under an investigational new drug (IND) application (for a drug and biologic) or an investigational device exemption (IDE). When a drug or device is available under such procedures, a number of conditions apply that make the use of an IND or IDE infeasible in times of national emergency, where drugs and devices may need to be deployed at rapid rates. Even if a drug, biologic, or device is highly promising in treating a disease or condition associated with biological chemical radiological or nuclear agents, and even if it is the only therapy available, current FDA law does not allow for rapid deployment of the product.[10]

The reference to IND conditions that are infeasible in a national emergency likely contemplated FDA's informed consent regulatory requirements for INDs—requirements designed to regulate clinical research trials. Under these rules, "no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject . . . . An investigator shall seek such consent only under circumstances . . . that minimize the possibility of coercion or undue influence."[11] Further, FDA rules include a required statement to the subject "that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;" and that "participation is voluntary [and] refusal to participate will involve no penalty or loss of benefits to which the [research] subject is otherwise entitled."[12]

The congressional committee's summary of the need for new legislation reflected the unsuccessful efforts of the CDC in response to the 2001 anthrax mail attack to protect postal workers with a post-exposure anthrax vaccine under an investigational new drug protocol and its required research-based informed consent form. In that case, according to a thorough after action study, a CDC effort to vaccinate potentially exposed postal workers resulted in very low uptake—a result attributable to factors including that the IND informed consent form was construed by many as representing a liability waiver as part of a medical experiment where postal workers would be

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[10] H.R. REP. NO. 108-147, pt. 1, at 2 (2003); *see generally* Jonathan L. Iwry, *This Teachable Moment: How COVID-19 Provides Lessons from FDA's Past and Present that Will Benefit its Future Preparedness: FDA Emergency Use Authorization from 9/11 to COVID-19: Historical Lessons and Ethical Challenges*, 76 FOOD & DRUG L. J. 337 (2021).

[11] 21 C.F.R. § 50.20 (2021).

[12] 21 C.F.R. § 50.25 (2021).

human "guinea pigs."[13] Experience shows that IND rules are very good for regulating clinical trials but very poor for tackling a public health emergency.[14]

Building on lessons learned in both military and civilian public health emergency contexts, Congress created the EUA mechanism. Under an unusual legislative process, the legislation was considered under a dual track and enacted first as part of the National Defense Authorization Act for Fiscal Year 2004,[15] and then enacted again as part of the Project BioShield Act of 2004, which superseded the first enactment.[16] Both enactments added section 564 to the FDCA[17] to create the "Emergency Use Authorization" as a new category of permission to introduce into interstate commerce a drug, vaccine, or medical device for use during the period of the emergency. The new category is something less than outright approval based on the FDCA standard of **"**full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use,"[18] but decidedly more than the statutory IND standard of permitted if "intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs."[19] Based on finding a homeland security, public health, or military emergency, an EUA may be granted to counter "a serious or life-threatening disease or condition" when "there is no adequate, approved, and available alternative" and "based on the totality of scientific evidence available . . . , including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that" "the product may be effective" and that "the known and potential benefits . . . outweigh the known and potential risks of the product, taking into consideration the material threat" being countered.[20]

Based on clearing this lower bar of safety and effectiveness, an EUA may be granted subject to a number of special conditions that do not accompany full product approvals. These conditions "shall, for a person who carries out any activity for which the authorization is issued," include "to the extent practicable given the applicable circumstances" of the emergency, conditions

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[13] Sandra Quinn, *The Anthrax Vaccine and Research: Reactions from Postal Workers and Public Health Professionals*, 6 BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRAC. & SCI. 321, 326 (2008).

[14] *See* John Casciotti, Cynthia Ryan, Dean Gerald Sienko & Robert C. Williams, *Law at the Intersection of Civilian and Military Public Health Practice*, 35 J.L, MED. & ETHICS 83, 85–86 (2007) ("A big problem with chemical, biological, radiological, or nuclear threats is that the drug industry does not have a whole lot of interest in this area because it does not give them blockbuster marketing possibilities. As a result, there are not a lot of medical countermeasures licensed or approved by the FDA to be used against these threats. Before the Project BioShield Act of 2004 was passed, the only real tool available to use such measures that were not FDA approved but were promising, was to use investigational new drug protocols. This really does not work. It's a square peg in a round hole to try to use those processes which are designed for the regulation of clinical research trials to try to carry out a critical public health emergency program. The military's success in trying this has been poor, and CDC's success in the context of the 2001 response to the anthrax postal attacks was not very effective either. The solution to this problem is the EUA.").

[15] Pub. L. No. 108–136, § 1603(a), 117 Stat. 1381 (2003).

[16] Pub. L. 108–276, 118 Stat. 835 (2004).

[17] 21 U.S.C. § 360bbb-3 (2021).

[18] Federal Food, Drug, and Cosmetic Act, § 505(b)(1)(A)(i), 21 U.S.C. § 355(b)(1)(A)(i) (2021).

[19] Federal Food, Drug, and Cosmetic Act, § 505(i)(1), 21 U.S.C. § 355(i)(1) (2021); *see also* § 520(g)(2)(A), 21 U.S.C. § 360j(g)(2)(A) (comparable provision for investigational devices).

[20] Federal Food, Drug, and Cosmetic Act, § 564(c), 21 U.S.C. § 360bbb-3(c) (2021).

> the Secretary [of HHS] finds necessary or appropriate to protect the public health, including . . . [a]ppropriate conditions designed to ensure that individuals to whom the product is administered are informed—that the Secretary has authorized the emergency use of the product; of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and . . . of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.[21]

These conditions are far less than the strict requirements noted above for IND products but, depending on discretionary judgments about what is "practicable," "necessary," or "appropriate," they are potentially more than conditions applicable to approved products.[22] Prior to the COVID-19 public health emergency, the EUA

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[21] Federal Food, Drug, and Cosmetic Act, § 564(e)(1)(A), 21 U.S.C. § 360bbb-3(e)(1)(A) (2021), which provides the following (emphasis added):

(e) Conditions of authorization.

(1) Unapproved product.

(A) Required conditions. With respect to the emergency use of an unapproved product, the Secretary, *to the extent practicable* given the applicable circumstances described in subsection (b)(1), shall, for a person who carries out any activity for which the authorization is issued, *establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following*:

(i) Appropriate conditions designed to ensure that health care professionals administering the product are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and

(III) of the alternatives to the product that are available, and of their benefits and risks.

(ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and

(III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

(iii) Appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the product.

(iv) For manufacturers of the product, appropriate conditions concerning recordkeeping and reporting, including records access by the Secretary, with respect to the emergency use of the product.

[22] A pre-pandemic FDA issuance that remained in effect throughout the period of the EUA vaccination program. U.S. FOOD & DRUG ADMIN., EMERGENCY USE AUTHORIZATION OF MEDICAL PRODUCTS AND RELATED AUTHORITIES: GUIDANCE FOR INDUSTRY AND OTHER STAKEHOLDERS 24 (Jan. 2017), https://www.fda.gov/media/97321/download [https://perma.cc/FWP8-QFSW] [hereinafter FDA, EUA MEDICAL PRODUCTS GUIDANCE]. ("[T]he statute requires that FDA ensure that recipients are informed to the extent practicable given the applicable circumstances . . . [t]hat they have the option to accept or refuse the EUA product and of any consequences of refusing administration of the product." This is an inaccurate description of the statute in that it omits the important statutory qualification that conditions on use of the EUA product are to be those "the Secretary finds necessary or appropriate to protect the public health." Similarly, the Appendix of that document incorrectly stated that "discretionary" conditions—

mechanism had been used on a number of occasions.[23] In 2017, at DoD's urging, Congress amended the EUA statute to allow FDA to issue EUAs for medical countermeasures to battlefield trauma injuries in addition to the previous scope relating to chemical, biological, radiological, and nuclear hazards.[24]

This then is the EUA regulatory framework applicable to use of unapproved but promising medical countermeasures to deal with emergency threats when there are no adequate FDA-approved products available. There are two key attributes of this EUA framework. First, from the standpoint of minimizing morbidity and mortality, it is far superior to attempting to execute large scale public health programs under research-based IND rules.[25] This is especially true when the medical countermeasure involves not treatment of sick patients anxious to recover but vaccinating healthy people who may not understand or be paying much attention to the extent of their vulnerability to a deadly and highly communicable new disease or the net benefit of vaccination. The second key attribute of the EUA framework is that there are many details concerning matters such as information provided to potential recipients regarding risks and benefits, consent, and consequences of refusing treatment that are unspecified in the statute and subject to discretionary judgments in the particular emergency involved. Experience with the COVID-19 EUA vaccination program highlighted, for better or for worse, both of these attributes.

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described as those "deemed necessary to protect the public health"—do not include the "required" condition of a fact sheet for recipients that advises them of their "option to accept or refuse product."). *Id.* at 45. These inaccurate statements may have been intended to signal an agency preference on discretionary statutory implementation. *See also* Casciotti et al., *supra* note 14 ("There is one issue that has not been fleshed out yet by the FDA and it is an 'option to refuse' an EUA product. In general, I think FDA's feeling is that there should be the option to refuse. You might say it is a second cousin to [IND] informed consent, though it really should be considered differently. Indeed, there may be circumstances, such as for first responders or to deal with a highly communicable disease, in which it may be appropriate not to have an option to refuse for selected groups of people, but instead have a mandatory program. I think it would be wise to keep all options on the table.").

[23] *See generally*, U.S. FOOD & DRUG ADMIN., EMERGENCY USE AUTHORIZATION–ARCHIVED INFORMATION, https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information (last visited Aug. 18, 2021) [https://perma.cc/ATU9-RKBK]. The first EUA, issued to allow the Department of Defense to use licensed anthrax vaccine to protect military members in the 2004 Iraq War from the threat of inhalation anthrax as a biological weapon, resulted from a federal court decision, *Doe v. Rumsfield*, 341 F.Supp.2d. 1 (D.C.D.C. 2004), that overruled FDA's view that the vaccine license was not limited to cutaneous exposure but also covered inhalation exposure. *See* 70 Fed. Reg. 5,452, 5,454 (Feb. 2, 2005) ("But for the Court's order, FDA would not consider the use of [anthrax vaccine] for inhalation anthrax to be an unapproved use.").

[24] Pub. L. 115-92, § 1(a), 131 Stat. 2023 (2017).

[25] HENRY FORD HEALTH SYSTEM, INFORMED CONSENT FORM AND HIPAA AUTHORIZATION, A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE 3 STUDY TO ASSESS THE EFFICACY AND SAFETY OF AD26.COV2.S FOR THE PREVENTION OF SARS-COV-2-MEDIATED COVID-19 IN ADULTS AGED 18 YEARS AND OLDER 2, 10, 11, 28 (Sept. 24, 2020), https://www.henryford.com/-/media/files/henry-ford/hcp/covid19/j-and-j-covid19-study/informed-consent-form--irb-jj-trial.pdf [https://perma.cc/65XD-6CB6]. As an example of the application of the IND regulations and the impact on communications to prospective vaccine recipients, the informed consent form at the Henry Ford Health System in Detroit, one of the sites of the HHS-funded clinical trial of the Jenssen COVID-19 vaccine, was twenty-nine pages long and included statements such as: "We do not know if getting the study vaccine will benefit you in any way." The vaccine "is 'investigational,' which means" "it can only be used in a research study such as this one." The vaccine "has been studied in the test tube and in animals with no vaccine related adverse effects observed." "I freely agree to participate in this research study." *Id.*

III. THE COVID-19 VACCINE EUAS

This section describes the three EUAs granted by FDA for COVID-19 vaccines under the framework summarized in Section II. On December 11, 2020, FDA granted the first EUA for a COVID-19 vaccine, this one for the Pfizer vaccine. The letter of authorization to Pfizer stated FDA's conclusions that the vaccine met the statutory criteria for an EUA and did so using the same phrasing as the statute.[26] The authorization specified that a fact sheet for vaccination providers and a fact sheet for recipients, both referred to as "authorized labeling," were required to be made available to those groups.[27] Among the "conditions of authorization" was that "all descriptive printed matter, advertising, and promotional material . . . shall be consistent with the authorized labeling" and comply with the prohibition in section 502(a) of the FDCA on labeling that is "false or misleading in any particular."[28] Another condition was that all such materials "clearly and conspicuously shall state that" the vaccine "has not been approved or licensed by FDA, but has been authorized for emergency use."[29] Additionally, the emergency use of the vaccine "must be consistent with, and may not exceed, the terms of the Authorization, including the . . . Conditions of Authorization."[30] The authorization letter also required the manufacturer to report adverse events to the Vaccine Adverse Event Reporting System (VAERS) to continue activities under the IND application, including safety and other reports, and to conduct post-authorization observational studies regarding the full EUA-eligible population.[31]

The required fact sheet for recipients provided "information to help you understand the risks and benefits" of this "unapproved vaccine that may prevent COVID-19."[32] The fact sheet said that in "an ongoing clinical trial," the vaccine "has been shown to prevent COVID-19 following 2 doses," but it "has not undergone the same type of review as an FDA-approved" vaccine.[33] The fact sheet listed nineteen "side effects that have been reported with" the vaccine, including severe and non-severe allergic reactions, injection site pain, fever, and feeling unwell, and added that "these may not be all the possible side effects," noting that the vaccine "is still being studied in clinical trials."[34] The fact sheet explained that the EUA "is based on the totality of scientific evidence available showing that the product may be effective" "and that the known

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[26] *See* Letter of Authorization from Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin., to Elisa Harkins, Pfizer, Inc. at 4 (Dec. 11, 2020), reprinted at 86 Fed. Reg. 5,200, 5,202 (Jan. 19, 2021) [hereinafter Initial Pfizer EUA Letter].

[27] *Id.*

[28] *Id.* at 4, 8.

[29] *Id.* at 8.

[30] *Id.* at 5.

[31] *Id.* at 6–7.

[32] *See* U.S. FOOD & DRUG ADMIN., FACT SHEET FOR RECIPIENTS AND CAREGIVERS: EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 12 YEARS OF AGE AND OLDER 1 (Revised Dec. 2020), archived copy available at: http://www.gtbindians.org/downloads/covidinfo.pdf [https://perma.cc/LY8U-9L8Y] [hereinafter FDA, FACT SHEET FOR RECIPIENTS AND CAREGIVERS]; *see also infra* note 83.

[33] *Id.* at 3, 7.

[34] *Id.* at 3–4.

and potential benefits of the product outweigh the known and potential risks."[35] With respect to the statutory provision regarding appropriate information on an option to accept or refuse, and the consequences, if any, of refusing, the fact sheet said: "It is your choice to receive or not receive . . . the [v]accine[, and s]hould you decide not to receive it, it will not change your standard medical care."[36]

One week after granting the Pfizer EUA, FDA issued an EUA for the Moderna vaccine; the letter of authorization was very similar to that for the Pfizer product and included all the same conditions.[37] Similarly, the fact sheet for recipients very closely resembled the Pfizer vaccine fact sheet.[38] A little more than two months after the Moderna EUA, FDA issued the third COVID-19 vaccine EUA, this one for the one-dose product sponsored by Janssen Biotech, a company affiliated with Johnson & Johnson.[39] Again, all the same conditions were established for the Janssen product as the other two and the fact sheet for recipients was quite similar to the others.[40] A number of amendments and revisions were made to the three EUAs during the course of the EUA vaccination program. The amendments expanded the age range authorized to receive the vaccines, added information about unusual additional side effects observed, authorized an additional dose for immunocompromised individuals, and made other adjustments.[41]

For all three vaccines, FDA regulatory determinations stated in the Letters of Authorization tracked closely with the minimum statutory criteria for issuing an EUA. And for all three products, the mandatory terms of messaging to potential vaccine recipients reflected language of disclaimer, including that although it was authorized for emergency use, it had not been approved by FDA, had not had the same type of FDA review as approved products, and was still being studied in clinical trials.[42]

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[35] *Id.* at 7.

[36] *Id.* at 4.

[37] Letter of Authorization from Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin. to Carlota Vinals, ModernaTX, Inc. (Dec. 18, 2020), reprinted at 86 Fed. Reg. 5,200, 5,211 (Jan. 19, 2021).

[38] *See* U.S. FOOD & DRUG ADMIN., FACT SHEET FOR RECIPIENTS AND CAREGIVERS, EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER (Revised Aug. 27, 2021), https://www.fda.gov/media/144638/download (last visited Sept. 19, 2021) [https://perma.cc/PF3D-TXYW].

[39] *See* Letter from Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin. to Ruta Walawalker, Janssen Biotech, Inc. (Feb. 27, 2021), reprinted at 86 Fed. Reg. 28,608, 28,619 (May 27, 2021).

[40] *See* U.S. FOOD & DRUG ADMIN., FACT SHEET FOR RECIPIENTS AND CAREGIVERS: EMERGENCY USE AUTHORIZATION (EUA) OF THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER (Revised July 8, 2021), https://www.fda.gov/media/146305/download [https://perma.cc/Z27B-29QW].

[41] *See, e.g.*, Letter of Authorization from Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin., to Elisa Harkins, Pfizer, Inc. (Reissued Aug. 23, 2021), https://www.fda.gov/media/150386/download [https://perma.cc/P9Y7-9WS2] [hereinafter Pfizer EUA Letter Aug. 23]

[42] *See supra* notes 32, 38, and 40.

IV. CHRONOLOGY OF THE COVID-19 EUA VACCINATION PROGRAM

Section IV summarizes consequential events and circumstances during the course of the EUA vaccination program over the approximately nine-month period before the COVID-19 vaccination program began the transition to reliance on FDA-licensed vaccines. Significant aspects of the program that related directly to the EUA conditions established by FDA evolved in dramatic ways over the course of this nine-month period. Most significantly, the evolution related to vaccine endorsements and mandates intended to overcome vaccine hesitancy among a substantial portion of the population.

1. Months One Through Three: Initial Ramp-Up of the EUA Vaccination Program

With the issuance of the Pfizer vaccine EUA on December 11, 2020, the federal government began the COVID-19 EUA vaccination program. In the first month of that program, statistics dramatized the extraordinary degree of difficulty. At the end of December, the CDC reported: "As 2020 draws to a close, COVID-19 cases and deaths continue to rise across the United States. This is the worst pandemic to hit Americans in over 100 years."[43] In the seven days ending on January 13, 2021, there was an average of 3,644 deaths per day in the United States, the highest total for any week during the pandemic.[44] In the second month of the program, the President gave an address marking the grim milestone of more than 500,000 American deaths from COVID-19 and calling on Americans to "stay socially distanced, to mask up, [and] get vaccinated when it's your turn."[45] The reference to "your turn" reflected that in the first three months of the program, there was a very limited supply of vaccine and the CDC was allocating vaccine to give priority to certain groups based on occupation, age, or health status.[46] In the third month of the vaccine program, the President said in another speech: "The more people get vaccinated, the faster we will beat this pandemic." He added: "To address this challenge, we're going to launch a massive campaign to educate people about the vaccines—that they are safe and effective, and that they can go and get those shots and be good."[47]

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[43] Press Release, Ctrs. for Disease Control & Prevention, CDC 2020 in Review (Dec. 29, 2020), https://www.cdc.gov/media/releases/2020/p1229-cdc-2020-review.html [https://perma.cc/JQ54-EGZV].

[44] *COVID Data Tracker: Trends in Number of COVID-19 Cases and Deaths in the US Reported to CDC, by State/Territory*, CTRS. FOR DISEASE CONTROL & PREVENTION (last visited Sept. 17, 2021), https://covid.cdc.gov/covid-data-tracker/#trends_dailydeaths [https://perma.cc/R8PA-GCFA] [hereinafter *COVID Data Tracker–Deaths*].

[45] *Remarks by President Biden on the More Than 500,000 American Lives Lost to COVID-19*, THE WHITE HOUSE (Feb. 22, 2021), https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/02/22/remarks-by-president-biden-on-the-more-than-500000-american-lives-lost-to-covid-19/ [https://perma.cc/LC5J-NUJ5].

[46] *See, e.g.*, Initial Pfizer EUA Letter, *supra* note 26 ("Pfizer Inc. will supply . . . COVID-19 [v]accine . . . to emergency response stakeholders as directed by the U.S. government, including the Centers for Disease Control and Prevention (CDC) . . . for use consistent with the terms and conditions of this EUA.").

[47] *Remarks by President Biden at a FEMA COVID-19 Vaccination Facility*, THE WHITE HOUSE (Feb. 26, 2021), https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/02/26/remarks-by-president-biden-at-a-fema-covid-19-vaccination-facility/ [https://perma.cc/KXY5-PTH2].

2. Months Four and Five: Vaccine Supply Catches Up with Demand; Vaccine Hesitancy Becomes a Concern

Relevant to the President's promise of a massive education campaign, in the fourth month of the EUA vaccination program, a Kaiser Family Foundation (KFF) survey indicated 17% of adults wanted to "wait and see" how others fared with the vaccines before deciding whether to get vaccinated.[48] In the fourth and fifth months of the program, vaccine supply caught up with and passed vaccine demand.[49] At the beginning of the fifth month, the seven-day average number of doses administered per day was nearly 3.5 million, the most of any seven-day period.[50] Presidential remarks touted the 150 millionth shot given and achieving sufficient supply to make all adults eligible to be vaccinated within a matter of days, adding: "What we do now is going to determine how many people we'll . . . save or lose in the months of April and May and June before we get to July 4th."[51] FDA and CDC hit a speed bump with a ten day pause in use of the Janssen vaccine to assess reports of a rare and severe type of blood clot,[52] and then hit a much bigger speed bump in the rate of vaccinations administered. At the end of the fifth month, the seven-day average was about 2 million per day, down from 3.5 million one month earlier.[53] Aligning with this decline, the Director of the National Institute of Allergy and Infectious Diseases (NIAID) (who also served as the White House's chief COVID-19 medical advisor) signaled a shift away from seeking a "mystical level of herd immunity" to simply vaccinating as many people as possible.[54]

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[48] *KFF COVID-19 Vaccine Monitor: July 2021*, KAISER FAM. FOUND. (Aug. 4, 2021), https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-july-2021/ [https://perma.cc/5XCH-9ZKN].

[49] *See Supply vs Demand: Which States are Reaching their COVID-19 Vaccine Tipping Points?*, KAISER FAM. FOUND. (May 4, 2021), https://www.kff.org/policy-watch/supply-vs-demand-which-states-are-reaching-their-covid-19-vaccine-tipping-points/ [https://perma.cc/CW8C-RHFR].

[50] *COVID Data Tracker – Daily Count of Total Doses Administered and Reported to CDC by Date Administered, United States*, CTRS. FOR DISEASE CONTROL & PREVENTION (data point for Apr. 11, 2021), https://covid.cdc.gov/covid-data-tracker/#vaccination-trends [https://perma.cc/9ZT5-93DT] (last visited Sept. 17, 2021) [hereinafter *COVID Data Tracker – Doses*].

[51] *Remarks by President Biden Marking the 150 millionth COVID-19 Vaccine Shot*, THE WHITE HOUSE (Apr. 6, 2021), https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/04/06/remarks-by-president-biden-marking-the-150-millionth-covid-19-vaccine-shot/ [https://perma.cc/HM5P-ZAPQ].

[52] Press Release, Ctrs. for Disease Control & Prevention, Joint CDC and FDA Statement on Johnson & Johnson COVID-19 Vaccine (Apr. 13, 2021), https://www.cdc.gov/media/releases/2021/s0413-JJ-vaccine.html [https://perma.cc/AL28-XCUU]; Press Release, Ctrs. for Disease Control & Prevention, FDA and CDC Lift Recommended Pause on Johnson & Johnson (Janssen) COVID-19 Vaccine Use Following Thorough Safety Review (Apr. 23, 2021), https://www.cdc.gov/media/releases/2021/fda-cdc-lift-vaccine-use.html [https://perma.cc/T3JX-7XZA].

[53] *COVID Data Tracker – Doses*, *supra* note 50 (referring to data points for May 10, 2021 and April 11, 2021).

[54] Apoorva Mandavilli, *Reaching 'Herd Immunity' Is Unlikely in the U.S., Experts Now Believe*, N.Y. TIMES (May 3, 2021), https://www.nytimes.com/2021/05/03/health/covid-herd-immunity-vaccine.html [https://perma.cc/GGD7-MRE6].

3. Months Six and Seven: Stronger Endorsements of Vaccines; Pleas to the Unvaccinated

In the sixth month of the EUA COVID-19 vaccination program, CDC continued to sharpen its messaging, completely abandoning cautious wording or disclaimer language and fully endorsing vaccinations with the EUA products. Examples of this revised CDC messaging: "The science shows #COVID19 vaccines ARE safe and effective for those 12 and older."[55] "COVID vaccines are safe and effective."[56] "Vaccination is our way out of this pandemic."[57] Nonetheless, at the end of the sixth month, the vaccination rate continued to decline: the seven-day moving average was 1.1 million per day, down from 2 million one month earlier.[58]

In the seventh month of the program, the President expressed the alarm of the public health community: "Right now, as I speak to you, millions of Americans are still unvaccinated and unprotected. And because of that, their communities are at risk. Their friends are at risk. The people they care about are at risk. This is an even bigger concern because of the Delta variant."[59] Media reports at that time highlighted what was called "a race between the highly contagious delta variant and the rollout of vaccines."[60] The impact of that rollout was called "extraordinary" by a Yale School of Public Health study that estimated that it "saved some 279,000 lives and prevented 1.25 million hospitalizations . . . ."[61] But vaccine hesitancy persisted. KFF survey data indicated the "wait and see" group still accounted for 10% of the adult population (down from 17% three months earlier), while those who would be vaccinated "only if required" or would "definitely not" be vaccinated remained at 20% (the same as three months earlier).[62] KFF also reported that 20% of unvaccinated adults say the main reason they have not gotten the vaccine is the newness of the vaccines, followed by 11% each who say the main reason is that they are worried about side effects, they

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[55] Rochelle Walensky, MD, MPH (@CDCDirector), TWITTER (May 28, 2021), https://t.co/hQN16usTvH/ Twitter [https://perma.cc/65YQ-TE3J].

[56] *Your COVID-19 Vaccination*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 24, 2021), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/your-vaccination.html [https://perma.cc/8DZK-74FG].

[57] Press Release, Ctrs. for Disease Control & Prevention, Statement from CDC Director Rochelle P. Walensky, MD, MPH (June 4, 2021), https://www.cdc.gov/media/releases/2021/s0604-director-statement.html [https://perma.cc/ME29-8BXL].

[58] *COVID Data Tracker – Doses*, *supra* note 50 (referring to data points for June 10, 2021 and May 10, 2021).

[59] *Remarks by President Biden on the COVID-19 Response and the Vaccination Program*, THE WHITE HOUSE (July 6, 2021), https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/07/06/remarks-by-president-biden-on-the-covid-19-response-and-the-vaccination-program-6/ [https://perma.cc/3SNV-FRQU].

[60] Erin Cunningham & Paul Schemm, *Spread of Delta Variant Raises Stakes for Vaccination*, WASH. POST (July 7, 2021), https://www.washingtonpost.com/world/2021/07/07/coronavirus-latest-updates/ [https://perma.cc/J2DJ-4UKS].

[61] Press Release, Michael Greenwood, Yale, U.S. Vaccination Campaign Prevented Up To 279,000 COVID-19 Deaths (July 8, 2021), https://news.yale.edu/2021/07/08/us-vaccination-campaign-prevented-279000-covid-19-deaths [https://perma.cc/YNE2-3MXR]; *see also* Alison Galvani, *Deaths and Hospitalizations Averted by Rapid U.S. Vaccination Rollout*, THE COMMONWEALTH FUND (July 7, 2021), https://www.commonwealthfund.org/publications/issue-briefs/2021/jul/deaths-and-hospitalizations-averted-rapid-us-vaccination-rollout [https://perma.cc/D3YS-WGEQ].

[62] *KFF COVID-19 Vaccine Monitor: July 2021*, *supra* note 48.

don't trust the government, they don't think they need the vaccine, and they just don't want to get the vaccine.[63] At the end of the seventh month, the seven day moving average of vaccines administered per day was approximately 450,000, down from 1.1 million one month earlier.[64]

4. Month Eight: More Aggressive Messaging; Pivot to Vaccine Mandates for the Unvaccinated

Reversing the dramatic decline in the number of vaccinations administered per day became the priority issue in the eighth month of the COVID-19 EUA vaccination program. The CDC Director said: "There is a clear message that is coming through: This is becoming a pandemic of the unvaccinated."[65] She added: "With vaccines available across the country, the suffering and [death from COVID-19] are nearly entirely avoidable."[66] The Surgeon General issued an advisory on health misinformation in which he said: "During the COVID-19 pandemic, health misinformation has sowed confusion, reduced trust in public health measures, and hindered efforts to get Americans vaccinated . . . . [W]e know enough to be sure that misinformation is an urgent threat."[67] The President pressed the point much harder by criticizing social media platforms he said were not doing enough to block vaccine misinformation which he said was "killing people."[68]

On the issue of vaccine hesitancy, when asked whether full approval of the vaccines would make a difference, the Director of FDA's Center for Biologics Evaluation and Research (CBER)—FDA vaccine chief—said "there are any number of people who are saying that they are really uncomfortable with" what they perceive to be "an experimental vaccine." "This EUA thing sounds really weird to them. They want an FDA-approved product."[69] As part of an effort to counter such misgivings, the NIAID

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[63] *KFF COVID-19 Vaccine Monitor: June 2021*, KAISER FAM. FOUND. (June 30, 2021), https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-june-2021/ [https://perma.cc/5SK8-798F].

[64] *COVID Data Tracker – Doses*, *supra* note 50 (referring to data points for July 10, 2021 and June 10, 2021).

[65] *Press Briefing by White House COVID-19 Response Team and Public Health Officials*, THE WHITE HOUSE (July 16, 2021), https://www.whitehouse.gov/briefing-room/press-briefings/2021/07/16/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-45/ [https://perma.cc/KSH6-YFXC] [hereinafter *Press Briefing by White House, July 16*].

[66] *The Path Forward: A Federal Perspective on the COVID-19 Response: Hearing Before the S. Comm. on Health, Educ., Lab. & Pensions*, 117th Cong. (2021) (testimony of Rochelle P. Walensky, M.D., M.P.H., Director, Ctrs. for Disease Control and Prevention, Dep't of Health and Hum. Servs.), https://www.help.senate.gov/imo/media/doc/Walensky%20Testimony1.pdf [https://perma.cc/V3HE-PT93].

[67] VIVEK H. MURTHY, CONFRONTING HEALTH MISINFORMATION: THE U.S. SURGEON GENERAL'S ADVISORY ON BUILDING A HEALTHY INFORMATION ENVIRONMENT (2021), https://www.hhs.gov/sites/default/files/surgeon-general-misinformation-advisory.pdf [https://perma.cc/S6LF-DEDZ].

[68] Matt Viser, Rachel Lerman & Tyler Pager, *'They're Killing People': Biden Aims Blistering Attack at Tech Companies Over Vaccine Falsehoods*, WASH. POST (July 17, 2021), https://www.washingtonpost.com/politics/biden-vaccine-social-media/2021/07/16/fbc434bc-e666-11eb-8aa5-5662858b696e_story.html [https://perma.cc/83B9-RK5U].

[69] Laurie McGinley, *Q&A: When Might the Coronavirus Vaccines Get Full Approval?*, WASH. POST (Aug. 2, 2021) (interview of Peter Marks, Director of the Center for Biologics Evaluation and Research), https://www.washingtonpost.com/health/2021/08/02/coronavirus-vaccines-fda-full-approval-timeline/ [https://perma.cc/22UB-AYT5].

Director said that "is really a false narrative," adding "you should consider this as good as fully approved and get vaccinated."[70] Additionally, an updated CDC "Science Brief" said the vaccines are "highly effective" against COVID-19 hospitalization and death, including from variant strains.[71] Such endorsements were a further stark contrast to FDA's disclaimer messaging.

In addition to extensive efforts to try to persuade the unvaccinated to get the shots, the White House apparently concluded that vaccine mandates would be necessary and pivoted sharply to that objective. The Justice Department's Office of Legal Counsel (OLC) posted a recently completed, important legal opinion[72] provided to the White House on the actual impact of the "option to refuse" in the EUA statute, which FDA made a required condition under all three COVID-19 vaccine EUAs. Under the OLC opinion, which represented that FDA agreed, the requirement does not go beyond the vaccination provider advising the recipient that the recipient may decline. The vaccine provider giving the recipient that information in no way restricts the ability of any employer to require vaccination as a condition of employment, or a university to mandate vaccination as a condition of enrollment, even if the vaccine provider works for that employer or university in its occupational health clinic or student clinic.[73] Deflecting any concern about mislabeling or exceeding the terms of the EUA, both of which were specifically prohibited by the letters of authorization, the opinion further represented FDA's view that a vaccine provider controlled by the entity (such as an employer or college) requiring vaccination with an EUA product could supplement the required FDA fact sheet (which includes notice of the option to refuse) "with factually accurate information about the possible nonmedical consequences of the person choosing not to use the product."[74] The OLC conclusion that the "option to refuse" is less than it might appear was not self-evident. The opinion noted, for example, that a CDC official told the CDC's Advisory Committee on Immunization Practices in August 2020 that EUA vaccines were not allowed to be mandatory.[75]

Also, on the subject of vaccine mandates, to help counter the situation in which "[p]eople are dying and will die who don't have to die," the President ordered federal government personnel to either get vaccinated or submit to frequent COVID-19 diagnostic testing, and praised the state and local governments and private employers

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[70] Bill Chappell, *Fauci Says Teachers Should Be Required to Be Vaccinated*, NPR (Aug. 10, 2021) (quoting an MSNBC interview statement), https://www.npr.org/sections/coronavirus-live-updates/2021/08/10/1026384528/fauci-teachers-vaccination-mandates-schools-students-covid [https://perma.cc/8PCE-BNU3].

[71] *Science Brief: COVID-19 Vaccines and Vaccination*, CTRS. FOR DISEASE CONTROL & PREVENTION (July 27, 2021), https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html [https://perma.cc/YM6Y-LJFE].

[72] Whether Section 564 of the Food, Drug, and Cosmetic Act Prohibits Entities from Requiring the Use of a Vaccine Subject to Emergency Use Authorization, 45 Op. O.L.C. 1, 7–9 (2021) (Memorandum Opinion for the Deputy Counsel to the President, from Dawn Johnsen, Acting Assistant Attorney General), https://www.justice.gov/olc/file/1415446/download [https://perma.cc/L9AP-HZ42].

[73] *Id.*

[74] *Id.* at 13; *supra* note 14; *but see* Ariz. Op. Att'y Gen. No. I21-007 (R21-006), 2021 ARIZ. AG LEXIS 7.

[75] Whether Section 564 of the Food, Drug, and Cosmetic Act Prohibits Entities from Requiring the Use of a Vaccine Subject to Emergency Use Authorization, 45 Op. O.L.C. at 7 n. 8.

that were taking similar steps.[76] As a preview of a planned harder push on mandatory vaccinations when the vaccines begin to be licensed within a few weeks, the President indicated unvaccinated military members would be ordered to be vaccinated.[77] The NIAID Director predicted that following vaccine licensure "we will see a lot more local mandates for vaccination as a requirement," and added, apparently alluding to the EUA's "option to refuse" and the perception among some that it meant more than what the OLC opinion concluded, that corporations and colleges will no longer be "a little bit hesitant to" establish mandates "because they didn't have the cover, as it were, of a full [FDA] approval."[78]

At the end of the eighth month of the EUA vaccination program, there was a modest uptick in vaccine uptake, perhaps caused by a combination of frightening new data on delta variant infections, the stepped-up persuasion efforts, and increased traction for vaccine mandates: the seven-day moving average was approximately 692,000 shots per day, up from 450,000 the previous month, but still far below the 1.1 million per day the month before that.[79] But in the so-called race between the delta variant and the vaccination rate, delta was winning: the seven-day moving averages of the number of new COVID-19 cases per day reported was approximately 120,000, up from 21,000 one month before,[80] and the number of hospitalized patients per day was approximately 62,000, up from 14,000 one month before.[81]

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[76] *Remarks by President Biden on Fighting the COVID-19 Pandemic*, THE WHITE HOUSE (Aug. 3, 2021), https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/08/03/remarks-by-president-biden-on-fighting-the-covid-19-pandemic/ [https://perma.cc/BV4R-W4MR]. In several cases, litigation challenges to mandatory vaccination requirements on the grounds of the option to refuse under the vaccine EUAs were unsuccessful. *See, e.g.*, Klaassen v. Trs. of Ind. Univ., No. 1:21-CV-238 DRL, 2021 U.S. Dist. LEXIS 133300, at *117 (N.D. Ind. July 18, 2021) (Motion for preliminary injunction denied; the students' option to refuse was not violated by the university's vaccine requirement as a condition of enrollment: "Though the students may have to forego a semester of school or transfer somewhere else—certainly a difficult and inconvenient choice, and not one lightly tossed aside—they have options."); Bridges v. Hous. Methodist Hosp., 543 F. Supp. 3d 525, 527, 528 (S.D. Tex. 2021) (the option to refuse "neither expands nor restricts the responsibilities of private employers; in fact, it does not apply at all to private employers like the hospital in this case." The employee "can freely choose to accept or refuse a COVID-19 vaccine; however, if she refuses, she will simply need to work somewhere else."); Valdez v. Grisham, No. 21-cv-783 MV/JHR, 2021 U.S. Dist. LEXIS 173680, at *14–15 (D.N.M. Sept. 13, 2021) ("[T]o to the extent that the vaccines at issue here remain subject to the EUA provisions of the FDCA," the state's order that "hospital workers and individuals who seek entry into the State Fair" be vaccinated "does not run afoul of those provisions.").

[77] Press Release, The White House, Statement by President Joe Biden on COVID-19 Vaccines for Service Members (Aug. 9, 2021), https://www.whitehouse.gov/briefing-room/statements-releases/2021/08/09/statement-by-president-joe-biden-on-covid-19-vaccines-for-service-members/ [https://perma.cc/4EAN-TYGB].

[78] *Transcript: The Rachel Maddow Show, 8/9/21*, MSNBC (Aug. 9, 2021), https://www.msnbc.com/transcripts/transcript-rachel-maddow-show-8-9-21-n1276402 [https://perma.cc/6KWL-HGWV].

[79] *COVID Data Tracker – Doses*, *supra* note 50 (referring to data points for August 10, 2021, July 10, 2021, and June 10, 2021).

[80] *COVID Data Tracker – Trends in Number of COVID-19 Cases and Deaths in the US Reported to CDC, by State/Territory*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://covid.cdc.gov/covid-data-tracker/#trends_dailycases [https://perma.cc/F2LV-T8SN] (last visited Sept. 17, 2021) (data points for August 10, 2021 and July 10, 2021) [hereinafter *COVID Data Tracker – Cases*].

[81] *COVID Data Tracker – Prevalent Hospitalizations of Patients with Confirmed COVID-19, United States*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://covid.cdc.gov/covid-data-tracker/#

5. Month Nine and Beyond: Much Stronger Push for Mandates; Begin Transition to Licensed Vaccines

In response to the delta variant surge, at the beginning of the ninth month of the EUA vaccination program, the White House amplified its shift in emphasis to mandatory vaccinations. The White House Coronavirus Response Coordinator said "vaccination requirements are gaining momentum across the country and are already covering tens of millions of workers, educators, college and university students, and healthcare providers" and "[t]hrough vaccination requirements, employers have the power to help end the pandemic."[82] Also, about that time, FDA issued the fifth revision to the Pfizer vaccine EUA and the third revision to the Moderna vaccine EUA allowing a third dose for immunocompromised individuals, but the original EUA conditions and disclaimers remained unchanged.[83] Soon after that, an unusual "joint statement" attributable to the heads of the CDC, FDA, NIAID, the Surgeon General, and other chiefs of HHS health components announced plans to soon offer a booster dose of the Pfizer and Moderna vaccines and indicated a similar action for the Janssen vaccine would likely follow.[84]

The ninth month of the vaccination program also began a transition from an EUA program to a hybrid program with FDA approval of the Biological License Application for the Pfizer vaccine for the prevention of COVID-19 in individuals sixteen years of age and older.[85] At the same time, FDA reissued the Pfizer vaccine EUA, explaining that although the vaccine was approved, the EUA would continue to cover use of EUA-labeled product in circulation, use in individuals ages twelve through fifteen, and use to provide an additional dose to certain immunocompromised individuals.[86] The revised information fact sheet for recipients advised that: "The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under Emergency Use Authorization (EUA) have the

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hospitalizations [https://perma.cc/CZ29-DY5T] (last visited Sept. 17, 2021) (data points for Aug. 10, 2021 and July 10, 2021) [hereinafter *COVID Data Tracker–Hospitalizations*].

[82] *Press Briefing by White House COVID-19 Response Team and Public Health Officials*, THE WHITE HOUSE (Aug. 12, 2021) (remarks of Jeffrey Zients), https://www.whitehouse.gov/briefing-room/press-briefings/2021/08/12/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-49/ [https://perma.cc/ED25-BQ25].

[83] Pfizer EUA Letter Aug. 23, *supra* note 41, at 2 n.7; Letter of Authorization from Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin., to Carlota Vinals, ModernaTX, Inc. (Aug. 12, 2021), https://www.fda.gov/media/144636/download [https://perma.cc/F7M8-TP2Z].

[84] Press Release, Ctrs. for Disease Control & Prevention, Joint Statement from HHS Public Health and Medical Experts on COVID-19 Booster Shots (Aug. 18, 2021), https://www.cdc.gov/media/releases/2021/s0818-covid-19-booster-shots.html [https://perma.cc/7GM5-GPXU] [hereinafter CDC Press Release, Booster Shots].

[85] Letter of BLA Approval from Mary A. Malarkey, Dir., Off. of Compliance & Biologics Quality, Ctr. for Biologics Evaluation & Rsch., U.S. Food & Drug Admin., and Marion F. Gruber, Dir., Off. of Vaccines Rsch. & Rev., Ctr. for Biologics Evaluation & Rsch., U.S. Food & Drug Admin., to Amit Patel, BioNTech Mfg. GmbH (Aug. 23, 2021), https://www.fda.gov/media/151710/download [https://perma.cc/7YDJ-8R8J].

[86] Pfizer EUA Letter Aug. 23, *supra* note 41, at 2 ("FDA is reissuing the August 12, 2021 letter of authorization in its entirety with revisions incorporated to clarify that the EUA will remain in place for the Pfizer-BioNTech COVID-19 vaccine for the previously-authorized indication and uses, and to authorize use of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved BLA.").

same formulation and can be used interchangeably to provide the COVID-19 vaccination series."[87] Although interchangeable, EUA uses were still covered by the previous EUA disclaimers and conditions, including clear and conspicuous notice that the "product has not been approved or licensed by the FDA,"[88] and notice to recipients that the two products "are legally distinct" and "[u]nder the EUA, it is your choice to receive or not receive the vaccine."[89]

At the end of the ninth month of the vaccination program, the President said:

> Many of us are frustrated with the nearly 80 million Americans who are still not vaccinated, even though the vaccine is safe, effective, and free . . . . This is a pandemic of the unvaccinated. And it's caused by the fact that despite America having an unprecedented and successful vaccination program, despite the fact that for almost five months free vaccines have been available in 80,000 different locations, we still have nearly 80 million Americans who have failed to get the shot.[90]

To remedy this, he announced a whole new set of vaccination requirements, including an emergency rule from the Occupational Safety and Health Administration mandating that all employers of 100 or more employees require them to be vaccinated or document weekly negative COVID-19 tests, as well as vaccination orders for federal employees, employees of federal contractors, health care workers in facilities receiving Medicare or Medicaid funding, and teachers in federally operated schools and federally funded pre-school programs—adding up to, according to the President, two-thirds of all American workers.[91]

Reflecting the President's frustration, a data snapshot at the end of the ninth month showed trends moving in the wrong direction. These were the approximate seven-day moving averages: 619,000 shots administered per day, down from 692,000 the previous month;[92] 137,000 new COVID-19 cases per day, up from 120,000 one month

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[87] U.S. FOOD & DRUG ADMIN., VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT COMIRNATY (COVID-19 VACCINE, MRNA) AND PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) (2021) https://www.fda.gov/media/144414/download [https://perma.cc/C2XX-59FM] [hereinafter FDA VACCINE INFORMATION FACT SHEET.

[88] Pfizer EUA Letter Aug. 23, *supra* note 41, at 11–12.

[89] FDA VACCINE INFORMATION FACT SHEET, *supra* note 87, at 1 n.1, 6.

[90] *Remarks by President Biden on Fighting the COVID-19 Pandemic at the White House Briefing Room*, THE WHITE HOUSE (Sept. 9, 2021), https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/ [https://perma.cc/8U6N-UF2Q].

[91] *Id.*; THE WHITE HOUSE, PATH OUT OF THE PANDEMIC: PRESIDENT BIDEN'S COVID-19 ACTION PLAN (Sept. 9, 2021), https://davidscott.house.gov/uploadedfiles/white_house_covid_action_plan.pdf.

[92] *COVID Data Tracker–Doses*, *supra* note 50 (referring to data points for September 10, 2021 and August 10, 2021).

before;[93] more than 92,000 hospitalized patients per day, up from 62,000 one month before;[94] and 1,264 deaths per day, up from 737 one month earlier.[95]

The vaccination program would continue as a hybrid program for months more, with some licensed vaccine and some vaccine continuing to be used under EUAs, especially for the challenging task of vaccinating mid-teen and younger children. These would be the medical countermeasures relied upon in what the President called both a successful vaccination program and a frustrating ongoing battle against the pandemic of the unvaccinated.

V. ANALYSIS OF KEY ISSUES IMPACTING THE EFFECTIVENESS OF THE EUA VACCINATION PROGRAM

Based on the legal and factual matters summarized above, several key issues emerge and require additional analysis, particularly in relation to regulatory actions affecting communications with potential vaccine recipients. This section will explore those issues, including 1) the conflicting messages of disclaimer versus endorsement, 2) informed consent and the option to refuse, 3) information provided to prospective vaccine recipients, and 4) notice regarding the consequences of refusing the vaccine.

1. The Conflicting Messaging Problem of Disclaimer Versus Endorsement

It might be said that the hallmark of all hard decisions is that there are competing compelling interests and very imperfect information on which to base a decision. That can be said of the decision on whether and how strongly to endorse an EUA vaccine. One of the compelling interests is to protect the credibility of the public health institutions in the event there later emerges a popular perception that the vaccine was unsafe or ineffective. That hard lesson was a product of the experience with the 1976 swine flu vaccination program—in the press commonly referred to as the swine flu "fiasco."[96] In that case, the CDC and the era's preeminent public health experts recommended a massive vaccination program to fend off a feared pandemic of a novel flu strain.[97] The President was photographed being vaccinated and led the call for the public to follow his lead.[98] After approximately 40 million people were vaccinated, there was discovered a higher-than-expected incidence of Guillain-Barre Syndrome, a serious neurological disorder, with an estimated small increased risk.[99] Although a rare

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[93] *COVID Data Tracker–Cases*, *supra* note 80 (referring to data points for September 10, 2021 and August 10, 2021).

[94] *COVID Data Tracker–Hospitalizations*, *supra* note 81 (referring to data points for September 10, 2021 and August 10, 2021).

[95] *COVID Data Tracker–Deaths*, *supra* note 44 (referring to data points for September 10, 2021 and August 10, 2021).

[96] *See* David J. Sencer & J. Donald Millar, *Reflections on the 1976 Swine Flu Vaccination Program*, EMERGING INFECTIOUS DISEASES 29, 32 (2006), https://doi.org/10.3201/eid1201.051007.

[97] *Id.* at 30.

[98] *Id.* at 32.

[99] *Id.*

adverse event, because the feared pandemic never materialized, the widely perceived lesson learned was that the judgment of the public health experts was way off base and their credibility should not be so readily trusted.[100] FDA's mandated disclaimer messaging on the COVID-19 vaccines—insisting that recipients be told clearly and conspicuously that the vaccines were not FDA-approved, had not undergone the same type of review as an FDA-approved vaccine, and were still being studied—was consistent with that lesson learned.

On the flip side of that coin, if the deadly pandemic is real and the vaccine benefits clearly outweigh the risks, anything less than an unequivocal endorsement risks a heartbreaking failure to prevent some amount of preventable death and suffering. As the President put it in the eighth month of the EUA vaccination program: "People are dying and will die who don't have to die."[101] The President's, NIAID's, and CDC's endorsement messaging on COVID-19 vaccines was consistent with this compelling interest. What is especially notable is the clear conflict between the messaging of the three leading agencies within HHS. FDA insisted, for example, that all promotional material must "clearly and conspicuously" state that the vaccine "has not been approved or licensed by FDA."[102] The CDC and NIAID disregarded that requirement, CDC calling the vaccines "safe and effective," and NIAID saying they should be considered "as good as fully approved."[103] Further, by issuing written materials using the "safe and effective" language associated with licensed vaccines, CDC, which was directing the introduction into interstate commerce of the vaccine by the manufacturers,[104] was arguably violating FDA's prohibition on labeling that is "misleading in any particular."[105] The CDC and NIAID seemingly decided that notwithstanding the apparent violations of FDA conditions and disclaimers, it was more important to try to overcome the unrelenting vaccine hesitancy that unnecessarily added to morbidity and mortality—death and suffering the CDC Director said were "nearly entirely avoidable" in this "pandemic of the unvaccinated."[106]

Whichever of the two compelling interests hindsight might value or devalue, the scenario of conflicting messaging from the three agencies of HHS most depended upon to mitigate the crisis is quite problematic. The stalemate of conflicting messages from HHS provided a weakened defense to the ubiquitous social media misinformation the President condemned as "killing people."[107] Without minimizing the hard decision of disclaimer versus endorsement, a lesson learned for the next similar crisis is that conflicting messages are highly unsatisfactory. Rather, the Secretary of HHS should make every effort to ensure that FDA, CDC, NIAID, and other leading HHS components executing the Secretary's statutory authorities have a single coherent message on the vaccines authorized to counter the pandemic threat. The "joint

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[100] *Id.* ("[T]he perception prevailed that the program was motivated by politics rather than science.").

[101] *Remarks by President Biden on Fighting the COVID-19 Pandemic*, *supra* note 76.

[102] FDA, FACT SHEET FOR RECIPIENTS AND CAREGIVERS, *supra* note 32.

[103] Bill Chappell, *supra* note 70; Walensky, *supra* note 55.

[104] *See* Initial Pfizer EUA Letter, *supra* note 26.

[105] Federal Food, Drug, and Cosmetic Act, § 502(a)(1), 21 U.S.C. § 352(a)(1) (2021).

[106] *See Press Briefing by White House, July 16*, *supra* note 65; *The Path Forward: A Federal Perspective on the COVID-19 Response*, *supra* note 66.

[107] *See* Viser et al., *supra* note 68.

statement" on booster shots in the ninth month of the EUA vaccination program[108] is an example of such a single coherent message.

2. Informed Consent and the Option to Refuse

The summary in Section II above of the EUA legal framework highlighted the issue of informed consent under the three noted regulatory categories of approved, IND, and EUA. A bit more elaboration is needed. As a baseline, with a very limited number of specialized exceptions, all medical care is under common law standards subject to the informed consent of competent patients. There are two parts to this. The "consent" part reflects the liberty interest in a general right of a person with capacity to refuse medical treatment, even lifesaving treatment.[109] This autonomy interest, however, has some limitations, such as in connection with contagious diseases, where courts have upheld the authority of the government to require vaccinations in order to protect the public.[110] All or almost all states generally require vaccinations for school attendance for diphtheria, tetanus, pertussis, polio, measles, mumps, rubella, and chickenpox.[111] Additionally, many states have enacted a version of the Model State Emergency Health Powers Act, which, during a public health emergency, allows the public health authority to require vaccination against a contagious disease as a condition for avoiding isolation or quarantine.[112]

To a substantial extent, the "consent" part of informed consent is the same across all three regulatory categories of medical products—approved, EUA, or IND—a person with capacity can accept or reject after being informed of the medical benefits, risks, and alternatives. For licensed vaccines against communicable diseases, acceptance may be a condition for attending school or for some employment. But for IND vaccines, consent must minimize coercion or undue influence and thus may not be a condition for employment or school enrollment.[113] EUA products do not necessarily require anything additional to baseline consent requirements applicable to approved products, but might under the statute, depending on what the Secretary of HHS decides is "practicable" in the emergency and "necessary or appropriate to protect the public health."[114] As highlighted above, FDA imposed the condition of advising recipients of the option to refuse the EUA vaccines and maintained that

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[108] *See* CDC Press Release, Booster Shots, *supra* note 84.

[109] *See, e.g.*, Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261, 277 (1990) ("[T]he common-law doctrine of informed consent is viewed as generally encompassing the right of a competent individual to refuse medical treatment.").

[110] *See, e.g.*, Jacobson v. Massachusetts, 197 U.S. 11 (1905).

[111] *See State-by-State: Vaccinations Required for Public School Kindergarten*, PROCON/ENCYCLOPEDIA BRITANNICA, INC., https://vaccines.procon.org/state-by-state-vaccinations-required-for-public-school-kindergarten/ [https://perma.cc/5W8B-RVF4] (last accessed Oct. 4, 2021).

[112] LAWRENCE O. GOSTIN, THE MODEL STATE EMERGENCY HEALTH POWERS ACT: AS OF DECEMBER 21, 2001 § 603(a) (Dec. 21, 2001), https://stacks.cdc.gov/view/cdc/6562 [https://perma.cc/2TF7-CHBG] ("During a state of public health emergency . . . [t]o prevent the spread of contagious or possibly contagious disease the public health authority may isolate or quarantine . . . persons who . . . are unable or unwilling for reasons of health, religion, or conscience to undergo vaccination pursuant to this Section.").

[113] 21 C.F.R. § 50.20 (2021).

[114] *See* 21 U.S.C. § 360bbb-3(e)(1)(A) (2021); FDA, EUA MEDICAL PRODUCTS GUIDANCE, *supra* note 22, at 24–25.

requirement for the Pfizer EUA vaccine even after FDA licensed the Pfizer vaccine and said the two products were "interchangeable."[115]

The question of whether to have such a condition should take into account that requiring the EUA vaccine provider to advise the recipient of an option to refuse the vaccine has essentially no practical significance. This is because, as recognized by the OLC opinion (in which FDA reportedly concurred) referenced above,[116] the prospective recipient's employer or the school the recipient attends has the same authority to require an EUA vaccine as a condition of employment or enrollment as that employer or school would have were the vaccine fully licensed. Further, under that opinion, this is no less true if the employer or school is a public entity or if the entity controls the vaccine provider.[117] Thus, establishing the EUA condition of an option to refuse a vaccine adds nothing tangible to the normal consent requirement that would apply to any licensed vaccine. There likely are, however, intangible effects, whether intended or not, of another "clear and conspicuous" reminder that the EUA vaccine is unapproved and making employers and colleges, as the NIAID Director put it, "a little bit hesitant" to establish the vaccine mandates the White House would embrace as necessary to protect the public health.[118]

3. The Requirements for Information to the Recipients

This is the "informed" part of informed consent. Under the common law standard, a health care provider has a duty to ensure that the patient receives sufficient information to make an informed decision, including the nature and purpose of the treatment, the risks and consequences involved, and the alternative courses of treatment and non-treatment.[119] A good example of the operation of such an information standard in the context of FDA-licensed vaccines is provided by the CDC's Vaccine Information Statements (VISs).[120] For instance, the flu vaccine VIS explains that influenza is a contagious disease that kills thousands of people in the United States each year and causes many more hospitalizations; that the vaccine prevents millions of illnesses and is recommended by the CDC annually for everyone

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[115] *See supra* notes 87–89 and accompanying text.

[116] *See supra* note 72.

[117] One exception to this, where there is a practical significance of the option to refuse, is for military personnel. This is due to a separate statute, 10 U.S.C. § 1107a, which provides that if FDA establishes an option to refuse under section 564 of the FDCA, then the entire military chain of command below the President is precluded from requiring military members to receive an EUA vaccination. 10 U.S.C. § 1107a(a)(1). This is ironic in that as a general rule, in the balancing of individual interests versus society interests, the military is at an extreme end of the spectrum, where the individual military member's interests are uniquely subordinated to society's interests, as represented by accomplishing the military mission that society's leaders have ordered, even beyond the point of terrifying personal hazard. *See generally*, John A. Casciotti, *Fundamentals of Military Health Law: Governance at the Crossroads of Health Care and Military Functions*, 75 A.F. L. REV. 201, 203 (2016); *see also* Orloff v. Willoughby, 345 U.S. 83, 92, 94 (1953) ("The military constitutes a specialized community governed by a separate discipline from that of the civilian," and "the very essence of [military] service is the subordination of the desires and interests of the individual to the needs of the service.").

[118] *See Transcript: The Rachel Maddow Show, 8/9/21*, *supra* note 78.

[119] *See generally*, CAITLIN O. BRADLEY, HEALTH CARE LAW: A PRACTICAL GUIDE § 19.02(2) (Matthew Bender 2d ed. 2021).

[120] *About VISs*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vaccines/hcp/vis/about/index.html [https://perma.cc/YW2C-LP4A] (last visited Sept. 20, 2021).

six months of age or older; that even if the vaccine does not match the prevailing strains that season, "it may still provide some protection;" and that there "may be a very small increased risk of Guillain-Barré Syndrome."[121] The measles, mumps, and rubella (MMR); tetanus and diphtheria (TD); varicella (chickenpox); and polio VISs describe these diseases and several medical contraindications and warn of minor adverse reactions.[122] The MMR VIS advises that "more serious reactions happen rarely," and the Varicella VIS states they happen "very rarely."[123] The polio VIS advises that although polio has been eliminated in the United States, it still occurs in other parts of the world where it may cause paralysis that can lead to permanent disability or death, and vaccination is the best way to protect the U.S. population.[124] All of these VISs note "a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death," and describe the VAERS system for reporting adverse events and the National Vaccine Injury Compensation Program.[125]

To a substantial extent, the "informed" part of informed consent is the same across all three regulatory categories of medical products—approved, EUA, or IND—a person must be informed of the medical benefits and risks and of alternative options. But for IND products, as noted above, "informed" must generally also include notice that the product involves "research," including any "experimental" attributes, and that refusal entails no penalty or loss of benefits.[126] These additional requirements do not apply to EUA products. EUA products do not necessarily require anything additional to baseline information requirements applicable to approved products, but might involve additional conditions, depending on what the Secretary of HHS decides is "practicable" in the emergency and "necessary or appropriate to protect the public health."[127] Assuming that baseline information standards would already cover the risks and benefits in the same way VISs do, what might be addressed by additional conditions could be notice that the product is not approved by FDA but only authorized for emergency use.

On this score, as noted above, FDA on one hand and CDC and NIAID on the other took decidedly conflicting positions. FDA required disclaimers and maintained them

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[121] CTRS. FOR DISEASE CONTROL & PREVENTION, INFLUENZA (FLU) VACCINE (INACTIVATED OR RECOMBINANT): WHAT YOU NEED TO KNOW (Aug. 6, 2021), https://www.cdc.gov/vaccines/hcp/vis/vis-statements/flu.pdf [https://perma.cc/Y29W-FG8H] [hereinafter FLU VIS].

[122] CTRS. FOR DISEASE CONTROL & PREVENTION, MMR VACCINE (MEASLES, MUMPS, AND RUBELLA): WHAT YOU NEED TO KNOW (Aug. 6, 2021), https://www.cdc.gov/vaccines/hcp/vis/vis-statements/mmr.pdf [https://perma.cc/8656-CYJV] [hereinafter MMR VIS]; CTRS. FOR DISEASE CONTROL & PREVENTION, TD (TETANUS, DIPHTHERIA) VACCINE: WHAT YOU NEED TO KNOW (Aug. 6, 2021), https://www.cdc.gov/vaccines/hcp/vis/vis-statements/td.pdf [https://perma.cc/9T3V-5K8D] [hereinafter TD VIS]; CTRS. FOR DISEASE CONTROL & PREVENTION, VARICELLA (CHICKENPOX) VACCINE: WHAT YOU NEED TO KNOW (Aug. 6, 2021), https://www.cdc.gov/vaccines/hcp/vis/vis-statements/varicella.pdf [https://perma.cc/EPW6-VUP6] [hereinafter VARICELLA VIS]; CTRS. FOR DISEASE CONTROL & PREVENTION, POLIO VACCINE: WHAT YOU NEED TO KNOW (Aug. 6, 2021), https://www.cdc.gov/vaccines/hcp/vis/vis-statements/ipv.pdf [https://perma.cc/HU7C-X3N9] [hereinafter POLIO VIS].

[123] MMR VIS, *supra* note 122, at 2; VARICELLA VIS, *supra* note 122, at 2.

[124] POLIO VIS, *supra* note 122, at 1.

[125] FLU VIS, *supra* note 121, at 2; MMR VIS, *supra* note 122, at 2; TD VIS, *supra* note 122, at 2; VARICELLA VIS, *supra* note 122, at 2; POLIO VIS, *supra* note 122, at 2.

[126] 21 C.F.R. § 50.25 (2021).

[127] 21 U.S.C. § 360bbb-3(e)(1)(A) (2021).

for the Pfizer EUA vaccine even after licensing the Pfizer vaccine and calling the two products "interchangeable."[128] In contrast, the CDC and NIAID ignored the disclaimers and strongly endorsed the COVID-19 vaccines with information constructs comparable to VISs for licensed vaccines. If there is a public health campaign analogy to the emphasis of political election campaigns on "swing voters," there may be "swing vaxxers" who could go either way on vaccination, depending on what messages get through and ring true to them. This notion is supported by the survey data described above identifying a "wait and see" group on intentions to receive a COVID-19 vaccine.[129] In assessing what information, if any, additional to that associated with the common law standard, such as in VISs, is practicable in the emergency and necessary or appropriate to protect the public health, consideration should be given to how "swing vaxxers" will receive and react to it. For example, FDA's mandated disclaimer messaging likely contributed to the misperception of—to use the description of FDA vaccine chief noted above—"any number of people" that without "an FDA-approved product," the vaccines are "experimental" under what they see as "this really weird" "EUA thing."[130]

4. Notice Regarding the Consequences of Refusing

One other matter regarding potential information to be provided to recipients under section 564 of the FDCA is on the "consequences, if any" of refusing the EUA vaccine. For the COVID-19 vaccines, FDA included in the required fact sheet for recipients the statement that: "Should you decide not to receive it, it will not change your standard medical care."[131] Although FDA provided no other explanation, an inference to be drawn is that FDA considered its role to be limited to medical consequences, excluding non-medical consequences, such as those addressed in the OLC opinion discussed above.

Beyond that, the required statement does not provide an inference as to the foundation on which it is based. FDA's regulatory jurisdiction over the distribution, labeling, and administration of an EUA vaccine may have no intersection at all with the health care system that would provide medical care to the individual. In simple terms, in the case of a COVID-19 patient who had no contact with the vaccine or any vaccine provider who later shows up at a hospital emergency room, the hospital has not done anything in connection with the vaccine or that patient that is within the cognizance of the FDCA. IND regulations require, as noted above, notice to a research subject that "refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled,"[132] but in the case of INDs, unlike EUAs, the institution responsible for the IND protocol is more likely to have exclusive access to the product and some relationship with the prospective recipients. Further, in any event, that notice requirement does not apply to EUAs. In practical terms, the

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[128] *See* FDA VACCINE INFORMATION FACT SHEET, *supra* note 87.

[129] *See KFF COVID-19 Vaccine Monitor: July 2021*, *supra* note 48.

[130] *See* McGinley, *supra* note 69; *see also The Path Forward: A Federal Perspective on the COVID-19 Response*, *supra* note 66, at 10 (Testimony of Rochelle P. Walensky: "Strong confidence in vaccines within communities leads to more people getting vaccinated, and to fewer COVID-19 illnesses, hospitalizations, and deaths."); Dorit R. Reiss & Arthur Caplan, *Experimental? It Doesn't Mean What You Think It Means*, 98 DENV. L. REV. FORUM (Oct. 7, 2021).

[131] *See* FDA, FACT SHEET FOR RECIPIENTS AND CAREGIVERS, *supra* note 32, at 3.

[132] 21 C.F.R. § 50.25(a)(8) (2021).

statement in the fact sheet is probably true as a function of common law: doctors have no lesser duty to provide competent care to their patients who could have and should have done a better job protecting their own health, whether that involves obesity, smoking, motorcycle helmets, flu shots, or anything else. However, there is no such additional statement regarding impact on future medical treatment included in the VISs noted above, which are an example of the information that should be part of informed consent for any vaccine. Therefore, assuming that the basis for the fact sheet statement is nothing more than the common law standard and assuming the common law standard does not include such a statement in the "informed" part of informed consent, the fact sheet statement may have been included merely because it seemed right to say something. In other words, it seems to be essentially nothing more than an IND echo, detached from any real EUA regulatory jurisdiction.

VI. CONCLUSIONS AND RECOMMENDATIONS

The discussion above supports two conclusions. First, the creation by Congress of the EUA mechanism in the FDCA was a godsend. During the nine-month EUA vaccination program, nearly 180 million Americans were fully vaccinated[133] and the program was credited with savings hundreds of thousands of lives.[134] There is no reliable way to estimate how this would have been different if there were no EUA mechanism and the public health system of the country had to do the best it could with vaccines under IND regulations and protocols centered on the conduct of clinical research. But prior experiences in both the military and civilian public health systems suggest results would have fallen short to a horrifying extent. The second conclusion is that there are devils in the details regarding EUA conditions established by FDA, particularly in relation to communications with potential vaccine recipients, and that these details may make a significant difference in how well an EUA vaccination program achieves its objective of minimizing pandemic morbidity and mortality. In the interest of preparedness for the next possible pandemic, the following recommendations address those details.

1. The Secretary of HHS Should Prevent Conflicting Messaging

As a matter of statutory authority, the responsibility for the actions of FDA, CDC, NIAID, and other components of HHS rests with the Secretary of HHS.[135] The delegations of pertinent statutory authorities can be handled in multiple ways. Doing so in a way that allows for contradictory policy and messaging is counterproductive and unsatisfactory. Recognizing that there will always be competing compelling interests and imperfect information, whether formally or informally, the best expertise of the Department on matters of vaccine regulation, public health, and scientific

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[133] *COVID-19 Vaccinations in the United States, Cumulative Count of Fully Vaccinated People Reported to CDC by Date Administered, United States*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://covid.cdc.gov/covid-data-tracker/#vaccination-trends_vacctrends-fully-cum [https://perma.cc/VC8F-FSKS] (last visited Sept. 17, 2021).

[134] *See Remarks by President Biden on the COVID-19 Response and the Vaccination Program*, *supra* note 59.

[135] *See, e.g.*, 21 U.S.C. § 393(d) (2021) ("The Secretary [of HHS], through the Commissioner [of Food and Drugs] shall be responsible for executing this [Act]."); *see also* U.S. FOOD & DRUG ADMIN., FDA STAFF MANUAL GUIDE 1410.10, DELEGATIONS OF AUTHORITY TO THE COMMISSIONER OF FOOD AND DRUGS 1 (2016), https://www.fda.gov/media/81983/download [https://perma.cc/ECB5-6EWR].

evaluation should be brought to bear (without political interference) on the pandemic emergency to produce a coherent, unified policy and message on medical countermeasures.

2. Recognize that EUA Conditions are Discretionary

Section 564 of the FDCA was conceptualized as a mechanism in between IND regulations and regulations governing product approvals. This may create an impulse to set EUA conditions around some conceptual midpoint between INDs and approved products. But that is not what the statute actually says. It says, "the Secretary, to the extent practicable given the applicable circumstances" of the emergency "shall . . . establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health."[136] No FDA regulation alters the statutory standard, which reflects the need to deal effectively with the circumstances of the particular public health emergency at hand. Notwithstanding FDA's sometimes tangled description,[137] the conditions are discretionary based on the Secretary's judgments about what is practicable in the particular emergency at hand and necessary or appropriate to protect the public health. In the context of communications to potential vaccine recipients, recognizing the discretionary nature of EUA conditions is the first step to ensuring that the conditions established most effectively reflect what is practicable in the emergency and what will best protect the public health.

3. Establish EUA Conditions by Addition, Not Subtraction

Because the EUA authority was designed as a necessary alternative to IND regulations as the mechanism to provide medical countermeasures to respond to a public health emergency, there may be a temptation to start with a proxy IND construct and then dial it halfway back to something that seems suitable for an EUA. Indeed, some of the conditions on the COVID-19 vaccine EUAs hint of that formulation. But recognizing the discretionary character of EUA conditions, in establishing requirements affecting communications to potential vaccine recipients, the better methodological approach is to start with a proxy regulatory construct applicable to a licensed vaccine, such as that represented by VISs, then, because it is not licensed, decide what other conditions, if any, should be added based on what is practicable in the circumstances of the particular emergency at hand and necessary or appropriate to protect the public health.

4. In Considering Adding an "Option to Refuse" Condition, Assess the Real Value Added

Because fully licensed vaccines almost certainly already include an option to refuse, even though refusing may entail adverse employment, education, or other consequences, section 564 issue should first recognize that there is virtually no practical effect to requiring notice of an option to accept or refuse the EUA vaccine. This is because, as noted above, in almost all circumstances, imposing this condition does not add to or subtract from the right of an individual to decline any vaccine, including any licensed vaccine. Recognizing the absence of any practical effect, the

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[136] 21 U.S.C. § 360bbb-3(e)(1)(A) (2021).

[137] *See supra* note 22 and accompanying text.

deliberation on whether to add as an EUA condition notice to individuals of an option to accept or refuse the vaccine should consider whether there is any actual net positive value in protecting the public health. If there is no such value added, following the template of VISs may be what best advances the public health.

5. In Considering Adding Notice of Consequences of Refusing, Assess FDA's Administrative Jurisdiction

Similarly, as with the non-health-related consequences of refusing a vaccine just discussed, the health-related consequences of accepting or refusing a vaccine in terms of future treatment of disease are also not affected by the regulatory status of the vaccine as licensed or EUA. Therefore, there is no compelling need to provide a different notice for an EUA vaccine than for a licensed vaccine. And because both the health-related (i.e., future treatment by health care providers) and non-health-related (i.e., employment or school enrollment) consequences are independent of the types of transactions over which FDA has regulatory jurisdiction, it is unclear what would stand behind any representation as to such consequences. Thus, again, the best option may be to follow the template of VISs, which will already inform potential vaccine recipients of the consequences of refusing in the context of the health risks and benefits of and the alternatives to vaccination.

6. Carefully Monitor Ongoing Developments with an Eye Toward Updating Conditions and Messaging

As evidenced by the several amendments to the COVID-19 vaccine EUA letters of authorization and fact sheets which reacted to new, updated information regarding effectiveness, contraindications, adverse events, or other matters, EUA details are not set in stone and can be modified as circumstances change. The same is true of EUA conditions. Therefore, as circumstances evolve, judgments on what conditions are practicable in the emergency and necessary or appropriate to protect the public health should take into account those changed circumstances and make appropriate adjustments. For example, monitoring of adverse event data after millions of vaccine doses have been given, as well as comparisons of morbidity and mortality data on vaccinated versus unvaccinated individuals over a period of time, may affect the weighing of risks and benefits, disclaimers, and endorsements.

7. In Considering Adding Disclaimer Language, Assess the Impact on "Swing Vaxxers"

The COVID-19 EUA vaccination program must be seen as a great public health success. Nonetheless, a big part of the story was vaccine hesitancy, which persisted in spite of very strong endorsements from the CDC, NIAID, and the President, and was likely exacerbated not only by social media misinformation but also by disclaimers from the agency in charge of regulating vaccines that appeared to corroborate the view that the vaccines were too new to be trusted. Although under one point of view disclaimers might be thought practicable in the emergency and necessary or appropriate to protect the public health, the effect they will likely have on that percentage of the public who are "swing-vaxxers" should be very carefully considered as part of a single, coherent message from HHS.

8. COVID-19 Pandemic Reviews Should Thoroughly Assess the Use and Results of the EUA Authority for Vaccines

There are many issues regarding the responses of the United States and the world to the COVID-19 pandemic. There will be multiple after-action assessments. This pandemic was the first major test of the EUA mechanism established by Congress to assure that the best available medical countermeasures can be used in a public health emergency. How that authority was used and the lessons learned for future emergency preparedness should be a priority subject for after-action assessments.