

Drug and Vaccine Development and Access

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SUMMARY. This Chapter explains how drugs and vaccines for COVID-19 can reach the market in the United States. As is always true, drug and vaccine manufacturers may seek U.S. Food and Drug Administration (FDA) approval of their products via traditional approval mechanisms and drug manufacturers may offer pre-approval access under the expanded access or right to try pathways. In a public health emergency like COVID-19, an additional mechanism is also available: the Emergency Use Authorization (EUA) pathway. This Chapter (1) assesses how FDA has used its EUA authorities for COVID-19 drugs thus far, (2) considers how FDA has balanced the need for robust evidence of safety and effectiveness for COVID-19 pharmaceuticals against the urgent need to speed patients' access amid the clinical and political realities of the pandemic, and (3) highlights considerations specific to vaccines should FDA be faced with a request to issue an EUA for a COVID-19 vaccine. The Chapter concludes with recommendations for policymakers and regulators at the federal and state levels. The recommendations aim to improve public understanding of the regulatory process for COVID-19 drugs and vaccines, protect scientific decision making from undue political pressure, and ensure that manufacturers develop robust evidence of safety and effectiveness—and ultimately safe and effective COVID-19 countermeasures.

Introduction

This Section briefly explains the typical regulatory processes for U.S. Food and Drug Administration (FDA) approval of drugs and vaccines and for pre-approval access for seriously ill patients, absent a public health emergency. It then explains the additional “emergency use authorization” (EUA) mechanism that is available during public health emergencies, such as the COVID-19 pandemic. Although these authorities make FDA the primary gatekeeper for drugs and vaccines in the United States, this Section highlights the gatekeeping role that states also can play through their authority to regulate medical practice.

FDA Approval and Pre-Approval Access

Before a new drug or vaccine may be distributed in interstate commerce in the United States, FDA must approve the product as safe and effective for its specific intended use. Although different statutory provisions govern drug (21 U.S.C. § 355(d)) and vaccine approvals (42 U.S.C. § 262(a)), FDA generally interprets the approval standards for both products to be the same, including requiring that there be “substantial evidence” of effectiveness. To make the necessary showing of safety and effectiveness, drug and vaccine manufacturers typically generate a significant amount of information about their products, starting with pre-clinical testing

in laboratories and animals, and then—if scientifically valuable and ethically permissible—proceeding to three phases of clinical trials in humans, studying the product for the specific use for which approval is sought.

This process serves FDA’s mission to protect and promote the public health in various ways, including helping to protect patients and consumers from unsafe and ineffective products. It also helps to ensure that necessary information about the effects of drugs and vaccines is generated and encourages beneficial innovation by incentivizing the development of products that actually work (Eisenberg, 2007). But this process takes significant time, and some argue that it delays patient access (though it is only in hindsight that we can know access was delayed to a safe and effective product).

There are ways that patients can access products for uses that FDA has not approved, or products that are not FDA-approved for any use. If necessary to ensure that a drug or vaccine’s benefits outweigh its risks, FDA can require a risk mitigation program—known as a Risk Mitigation and Evaluation Strategy (REMS)—which can limit the ways the approved product is used in medical practice (21 U.S.C. § 355-1). Even so, once FDA has approved a product for one use, health care professionals are generally free to prescribe

and dispense it for any use, including unapproved uses (known as “off-label” uses) unless restricted by law or regulation. Within this regulatory gap, state tort law and medical board oversight serve as mechanisms that afford legal and disciplinary recourse should a health care professional fail to exercise reasonable medical judgment in prescribing a product for an off-label use. Additionally, recognizing that patients who face serious illnesses without good treatment options are sometimes willing to accept significant risk or uncertainty, Congress and FDA have created various pathways for manufacturers to provide patients wholly unapproved, experimental products outside of clinical trials for treatment purposes. One long-standing form of such pre-approval access is “expanded access,” which requires authorization by FDA, a statement explaining why the patient needs access, and the manufacturer’s willingness to provide the product, among other things. In May 2018, Congress enacted the federal Right to Try Act, creating a separate pathway for pre-approval access for certain patients and drugs that does not require FDA authorization (Fernandez Lynch et al., 2018).

FDA’s Power to Issue Emergency Use Authorizations During Public Health Emergencies

All of the above-described processes for developing and accessing drugs and vaccines remain available during public health emergencies. Manufacturers may seek FDA approval for drugs or vaccines for COVID-19 with clinical trial data showing substantial evidence of effectiveness (and if necessary to ensure that benefits outweigh risks, FDA could require REMS for COVID-19 drugs or vaccines). Likewise, manufacturers may provide COVID-19 patients pre-approval access to experimental products through expanded access, as Gilead Sciences did with remdesivir early in studying the drug for COVID-19, or through the right to try pathway. After permitting expanded access for remdesivir, Gilead obtained an EUA for the drug and is now winding down its expanded access program (Gilead, 2020). Health care professionals also generally may prescribe and dispense already-approved products for COVID-19. For example, based on reports of new research suggesting dexamethasone, a long-approved corticosteroid, can reduce mortality in certain severely-ill COVID-19 patients, health care professionals increased off-label use of the drug.

In addition to these mechanisms, in 2004 Congress created the EUA pathway for FDA to authorize pre-approval use of medical products during public health emergencies. Specifically, Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) allows FDA to issue EUAs authorizing the distribution of unapproved medical products, including drugs, devices, and vaccines, when the secretary of the Department of Health and Human Services (HHS) determines there is a “public health emergency, or a significant potential for a public health emergency” (21 U.S.C. § 360bbb-3). Secretary Alex Azar issued such an emergency declaration for COVID-19 on February 4, 2020. FDA can also issue EUAs for unapproved uses of already-approved products. Even though health care professionals can prescribe and dispense products for off-label uses without such an authorization, in the absence of an EUA the federal government could not stockpile and distribute products for off-label uses through the Strategic National

Stockpile, and liability protections for manufacturers and health care professionals under the Public Readiness and Emergency Preparedness Act may not be available.

For FDA to issue an EUA, whether for an unapproved product or an off-label use of an approved product, various criteria must be met. These include that the manufacturer shows that “it is reasonable to believe” “the product may be effective” for the relevant condition—a bar that is decidedly lower than the “substantial evidence” of effectiveness required for FDA approval. FDA may impose restrictions on products through EUAs, including requiring information collection through patient registries or restricting who may administer the product and to what categories of patients. EUAs are time-limited—they only remain in effect during the public health emergency. Additionally, the FDCA requires FDA to “periodically” review the EUAs that it has issued and authorizes FDA to revoke or revise EUAs at any time if appropriate to protect public health or safety. FDA, thus, has broad power to shape how drugs and vaccines distributed under EUAs are used, and can change conditions or revoke permission to distribute more easily than it can for approved drugs and vaccines.

For each pathway to distribute drugs and vaccines, FDA typically decides whether a product meets relevant standards and determines any conditions on authorization. Given the political nature of responses to public health emergencies, however, it is important to understand that FDA is an agency within HHS and federal law expressly authorizes the HHS secretary, a member of the president’s cabinet—and not FDA—to make these decisions. The secretary delegates that decision-making authority to FDA and rarely has overridden an FDA decision about product approval. But it has happened at least once. In 2011, then-Secretary Kathleen Sebelius directed FDA to decline to approve levonorgestrel (Plan B One Step) as an over-the-counter emergency contraceptive for all ages, notwithstanding FDA’s determination that the scientific evidence supported approval (Heinzerling, 2014).

The States’ Role

Although FDA (or HHS) plays the primary role in determining which drugs and vaccines may be distributed and used in the United States, states also can play a role in determining COVID-19 patients’ access to these products. State boards of medicine and pharmacy may use their authority to regulate medical practice in ways that restrict off-label uses of already-approved products. For example, in March 2020, there were concerns about shortages of chloroquine and hydroxychloroquine—drugs approved for malaria, lupus, and rheumatoid arthritis but touted as having potential for COVID-19—in part because of reports that health care professionals were hoarding the drugs. In response, some states (and the District of Columbia) limited off-label prescribing or dispensing of the drugs for COVID-19 and took steps to communicate the lack of reliable evidence demonstrating their effectiveness for COVID-19 (AMA, 2020).

Although it has not yet happened for COVID-19 drugs or vaccines, states might also try to use their authority to regulate medical practice to completely prohibit use of an FDA-authorized COVID-19

product (e.g., by prohibiting prescribing or dispensing of a particular drug because in the state's view it is not effective) or permit access to a product that lacks any FDA authorization at all (e.g., because in the state's view FDA set the bar for effectiveness too high). Such efforts may be less likely than limits on product use, however, because state prohibitions on FDA-authorized products may be preempted and state laws or regulations more permissive than federal ones may be without practical effect, as states cannot exempt drug and vaccine manufacturers from applicable federal requirements (Zettler, 2017).

Assessing the Regulatory Approach During the COVID-19 Pandemic

In a global public health emergency, like the COVID-19 pandemic, FDA is faced with an undeniably difficult task. On one hand, developing rigorous evidence of products' safety and effectiveness is no less important—rather it is equally, if not more, important (London & Kimmelman, 2020). Generating this evidence will take time. Pre-approval access, including via EUAs, has the potential to interfere with this necessary evidence generation by making it difficult to enroll participants in clinical trials. On the other hand, there is an urgent need to move as quickly as possible. The addition of the EUA mechanism to the FDCA arguably reflects a societal decision that FDA ought to have flexibility to lower standards of safety and effectiveness during public health emergencies to speed access to promising, but unproven, products. FDA is likely to face tremendous political pressure—whether from the White House, HHS, Congress, industry, patients, or other stakeholders—to use that flexibility, and may lose public trust if the agency is viewed as unresponsive to patients' concerns. This Section examines how FDA has balanced these sometimes-competing societal interests and operated amid these political realities during the COVID-19 pandemic thus far.

Balancing Evidence and Access

The federal government, including FDA, has taken some beneficial steps to exercise flexibility and proactively speed the development of promising COVID-19 drugs and vaccines. For example, the federal government created "Operation Warp Speed," a public-private partnership of industry and government representatives working together on medical product development, currently prioritizing vaccines. FDA also has issued dozens of guidance documents explaining the agency's thinking on various issues relating to drugs and biological products for COVID-19. Such guidance documents can help clarify what is needed to bring a drug or vaccine to market. As a final example, FDA has made use of the flexibility that the EUA mechanism offers by issuing, and revoking, EUAs. As of the time of writing, the agency has issued three EUAs for drugs to treat COVID-19—for hydroxychloroquine (on March 28, 2020), chloroquine (on March 28, 2020), and remdesivir (on May 1, 2020)—and revoked two of the EUAs, for hydroxychloroquine and chloroquine, on June 15, 2020. The EUA still in effect for remdesivir is based in part on the results of a randomized, double-blind, controlled clinical trial in 1,063 hospitalized subjects with severe COVID-19, showing a statistically significant reduction in recovery time for those receiving remdesivir (Beigel et al., 2020).

At the same time, there is room for improvement, particularly with respect to public understanding of EUAs, implementation of FDA's EUA authorities, and providing equitable access to COVID-19 countermeasures. For example, although FDA generally distinguishes between EUAs and approvals in its communications, some media reports continue to equate EUAs with FDA approval, including by reporting that FDA "approved" the drugs for which it issued EUAs. It is critical that policymakers, health care professionals, and the public understand that EUAs are a form of pre-approval access, and that products issued EUAs are not necessarily safe or effective countermeasures for COVID-19. Misunderstandings about what an EUA signifies could drive inappropriate policy decisions or undermine public trust in FDA decisions when products issued EUAs prove ineffective or unsafe.

Another major concern is that FDA, perhaps driven by political pressure, may too freely issue EUAs for COVID-19 countermeasures, even judged against the relatively low statutory standard for issuing EUAs. The now-revoked EUAs for hydroxychloroquine and chloroquine provide apt examples. That the EUAs were ultimately revoked is not in and of itself troubling. Because the EUA mechanism is designed to permit FDA to authorize products with less evidence than is required for approvals, we should expect that FDA will authorize products that, once placed on the market, no longer meet the criteria for an EUA (or ultimately prove unsafe or ineffective), and FDA should revoke EUAs when evidence warrants such action. A revocation reflects the uncertainty surrounding safety and effectiveness of countermeasures that receive an EUA, along with the iterative nature of EUA issuance and oversight. In the case of hydroxychloroquine and chloroquine, however, FDA's original decision to issue the authorizations rested on a particularly shaky foundation: limited data of effectiveness from one randomized pilot study of 30 subjects that found little to no effect of the drugs in COVID-19, and an open-label, non-randomized study in 26 subjects that was later discredited (Hirji et al., 2020). FDA also issued the EUAs notwithstanding several known risks of the drugs—which were already approved for other uses—including risks of serious heart arrhythmias. Moreover, FDA issued the EUAs only nine days after the president publicly touted the drugs as COVID-19 countermeasures and, according to a whistleblower complaint from the former director of the Biomedical Advanced Research and Development Authority, at the secretary of HHS's direction—raising significant concerns about political interference in public health decision making (Wamsley, 2020). Similarly, although FDA has not yet faced the question of whether to issue an EUA for a COVID-19 vaccine, concerns about political interference in such a decision have been raised, particularly if an EUA application is under review shortly before the November 2020 election (Joffe & Fernandez Lynch, 2020).

To be sure, concerns about tainted decision making are not limited to the EUA context. For example, the appointed "chief advisor" for Operation Warp Speed stepped down as a board member for Moderna, a company with one of the leading COVID-19 vaccine candidates, to take the position. He, however, reportedly kept his stock in Moderna—valued at over \$10 million—until a senator publicly called for him to divest it, raising questions about financial

conflicts of interest within Operation Warp Speed. Conflicts of interest are particularly troubling in health and public health decision making, especially during a raging and unpredictable pandemic where few countermeasures exist (Sagonowsky, 2020).

Yet another major concern is how to provide fair and equitable access to COVID-19 countermeasures once they are available under an EUA or an approval (Gostin et al., 2020). For example, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices has been considering whether and how to prioritize COVID-19 vaccine access for essential workers and high-risk sub-populations that have been disproportionately affected by COVID-19 and an ad hoc committee of the National Academies of Sciences, Engineering, and Medicine and the National Academy of Medicine is developing a framework for equitable vaccine distribution to aid policymakers (National Academies, 2020; Twohey, 2020). Many aspects of product access, such as ensuring the affordability of countermeasures and developing logistical arrangements for fair distribution, generally fall outside FDA's purview and likely require intragovernmental and cross-sector coordination. But there are steps that FDA might take to use the authorities that it does have to further the goal of equitable access. For instance, Sarpatwari and colleagues argued that by revising the EUA for remdesivir to require a registry that collects information on patient demographics (among other things), FDA could use its existing authority to enable better tracking of access disparities for that drug (Sarpatwari et al., 2020).

Special Considerations for Vaccines

An EUA for a COVID-19 vaccine would pose many of the same issues as those posed by drug EUAs, as well as additional issues specific to vaccines (Joffe & Fernandez Lynch, 2020; Lurie et al., 2020). A drug that is issued an EUA is typically administered to a sick person with no other treatment options, whereas a vaccine is administered to a healthy person. This difference in health status alters the ethical and clinical risk-benefit calculus. A COVID-19 vaccine also may be used widely across the population in individuals of varying ages and co-morbidities. Moreover, any COVID-19 vaccine will be introduced against the background of existing vaccine-hesitancy, and creating and maintaining public trust in FDA's decision making will be more difficult, if not impossible, in the absence of robust data (Parasidis, 2016).

Vaccine research and development takes time. The quickest vaccine to come to market was the mumps vaccine, which took four years from the time virus samples were collected to FDA approval. Most vaccines take a decade or longer to develop, due to the intricacies in honing the vaccine formula to assess safety and effectiveness, and to ensure that the vaccine provides sufficient antibodies to protect against the virus over time. Death or serious side effects from a COVID-19 vaccine would likely cause mass panic amongst the public and drive people away from vaccination—particularly if the COVID-19 vaccine were not supported by robust evidence demonstrating its safety and effectiveness. Although not perfectly analogous for various reasons, one worthwhile example to consider is the 1976 swine flu vaccination program. The swine flu vaccine was rushed to market to address a public health

emergency. Although an outbreak of swine flu did not materialize, the vaccine itself caused dozens of deaths and thousands of vaccine-induced injuries, including paralysis (Parasidis, 2017).

For all of these reasons, developing rigorous evidence of safety and effectiveness, and developing such evidence across all sub-populations for which a vaccine is intended, will be particularly critical before distributing a COVID-19 vaccine. Consistent with this idea, in June 2020 FDA issued a guidance document on COVID-19 vaccines that, while not foreclosing the possibility of EUAs, emphasized the importance of “completion of large randomized clinical efficacy trials” (FDA, 2020).

Insofar as individuals may fall into a high-risk category of death or serious injury from COVID-19, they may be willing to voluntarily accept inoculation with a vaccine for which there is only minimal data on safety and efficacy (Lurie et al., 2020). The normative basis for this predicament assumes that no effective treatment for COVID-19 is available. But even if FDA were to issue an EUA to facilitate voluntary access to an unapproved vaccine, use of such vaccine must be entirely voluntary. We concur with the policy proposals set forth by Mello and colleagues, who argue that the fact that a COVID-19 vaccine has been authorized for use—via an EUA or otherwise—is an insufficient basis for mandatory vaccination; as a matter of public health ethics, mandates should be viewed as a last resort and used only if several other measures are first exhausted and appropriate risk mitigation procedures have been implemented (Mello et al., 2020). 🦠

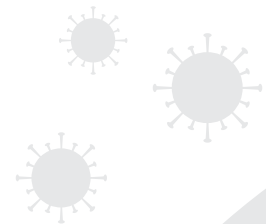
Recommendations for Action

Federal government:

- FDA (and others in the federal government) should clearly communicate and reiterate that EUAs are not “approvals” and that the standard for issuing an EUA does not include a determination that the product has been shown to be safe or effective for its intended purpose.
- For all decisions that FDA makes about COVID-19 countermeasures, the agency should be as proactively transparent as the law permits it to be. Such transparency will help the public understand the agency’s reasoning and what is known about the safety and effectiveness of COVID-19 countermeasures, as well as encourage public trust in agency decision-making. Subsequent recommendations provide specific examples of the kinds of information that the agency should proactively disclose.
- FDA should make decisions about which products to authorize or approve for COVID-19 based on the best available public health and scientific evidence, to help ensure better decisions and public trust in those decisions. Although regulatory decisions about drugs and vaccines should always be made in this manner, political pressure on FDA, whether from Congress, the White House, HHS, industry, patients, or others, may be particularly acute during pandemics. For this reason, Congress and FDA should consider creating specific processes to protect decision making during pandemics, such as requiring FDA to proactively release detailed information about the basis for its EUA decisions immediately after they are made. Ultimately, Congress should consider making FDA a stand-alone agency, outside of HHS (Califf et al., 2019).
- FDA should issue EUAs judiciously. The FDCA permits, but does not require, FDA to issue an EUA when the specified criteria are met. The agency retains flexibility to determine that an EUA is not appropriate for the public health even when all statutory criteria are met.
- FDA should consider routinely requiring patient registries for products that are issued EUAs to help gather information both about patient outcomes and about any disparities in access to such products (Sarpawari et al., 2020).
- Consistent with its obligations under Section 564 of the FDCA, FDA should actively and carefully review EUAs, revoking or revising them when needed. The results of FDA’s reviews, coupled with a summary analysis of data, should be made public as soon as they are completed. In some circumstances, such as COVID-19, a post-market review may be appropriate as frequently as weekly. In other instances, more time between reviews may be appropriate. The rationale underlying the timing of the post-market reviews should be data-driven and publicly disclosed.
- FDA should decline to authorize EUAs for COVID-19 vaccines. Insofar as FDA considers issuing an EUA for a COVID-19 vaccine, it should be limited to use, on a voluntary basis, to individuals with a documented higher than baseline risk of death or serious injury from COVID-19. Issuance of an EUA for a vaccine that can be used across the entire population may create unnecessary risks to healthy individuals, and may delay or prevent completion of clinical trials on vaccine safety and efficacy.
- Congress should reconsider whether EUAs for vaccines intended for widespread use in healthy people are ever appropriate and consider appropriate revisions to Section 564 of the FDCA (21 U.S.C. § 360bbb-3).

State governments:

- State officials and agencies, including boards of medicine and pharmacy and public health departments, should clearly communicate to health care institutions, health care professionals, and the public that EUAs are not FDA approvals, the difference between approvals and EUAs, and what is known, and not known, regarding the safety and effectiveness of products available under EUAs.
- State boards of medicine and pharmacy should discourage off-label use of existing products unless strong evidence supports use for COVID-19.



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