What FDA Has Done So Far In Response To COVID-19

By **Joanne Hawana, Aaron Josephson and Ben Zegarelli**

Joanne Hawana

Aaron Josephson

Ben Zegarelli

State and local governments are taking sweeping actions to protect the public from the continued spread of COVID-19, as are private businesses.

Although the federal response to the recently declared pandemic started slowly, we are now seeing frequent and promising announcements from various agencies within the U.S. Department of Health and Human Services with responsibilities related to the public health emergency. (HHS Secretary Alex Azar issued the current federal public health emergency declaration on Feb. 4.)

One agency within HHS, the U.S. Food and Drug Administration, is responsible for assuring the safety and effectiveness of medical products. It therefore has oversight over clinical trials for promising coronavirus treatments (i.e., drugs, vaccines, devices), as well as authority to authorize the emergency marketing of such products. There has been an uptick in this kind of activity in recent weeks as the agency has allowed multiple commercial and clinical laboratory tests to diagnose the novel coronavirus — named SARS-CoV-2 — to be used in the field.

But the FDA's role in responding to a public health emergency is broader than that. The FDA also is policing the marketplace for fraudulent products claiming to treat or prevent COVID-19, working to ensure the safety of the food supply, and performing other critical functions.

What is the FDA’s ongoing and evolving response to the pandemic? It is important to highlight the breadth and diversity of the agency’s mandate and the substantial role it plays in protecting Americans from harm.

Exercising Flexibility to Expand COVID-19 Testing

The FDA typically oversees the development and approval of diagnostic tests. Due to the widespread shift lately to our collective consciousness, many may now understand that the FDA can also issue emergency use authorizations, or EUAs, that allow a test or other medical product — including therapeutics and vaccines — to be marketed in an emergency without all the typical steps involved in premarket review and approval.

The FDA granted its first EUA on Feb. 4 for a SARS-CoV-2 test kit developed by the U.S. Centers for Disease Control and Prevention; as has been widely reported, however, this test was later demonstrated to have problems detecting the virus.

On Feb. 29, to speed development of additional tests, the FDA released an important enforcement policy for COVID-19 molecular diagnostics tests developed and used in laboratories certified to perform high-complexity testing under the Clinical Laboratory Improvement Amendments.

The agency’s policy was effective immediately and enabled laboratories to use any COVID-19 tests they developed prior to issuance of an emergency authorization, with the goal of

achieving more rapid and broader testing capacity in the United States. The policy document described the circumstances under which the FDA would not object to the use of newly developed diagnostics for clinical testing while the developing laboratories pursue EUAs.

The agency issued an EUA on the same day it authorized the emergency use of the New York State Wadsworth Center's diagnostic test. (This EUA was amended and reissued on March 15). On March 12, the FDA took a step further, announcing that it would allow the New York State Department of Health to authorize New York clinical laboratories to use validated COVID-19 diagnostic tests on patients without first obtaining an EUA.

Also on March 12, the FDA granted a third EUA for a diagnostic test — representing the first commercially distributed COVID-19 diagnostic test to receive an EUA — noting in its announcement that "FDA did not object to [the developer] pre-positioning its test so that labs could be ready to initiate testing immediately upon authorization of the EUA. Because of that pre-positioning, laboratories can immediately run tests on [this] high-volume platform, which will greatly increase national testing capacity."

Since that time, and as of March 22, the FDA has granted 11 additional EUAs for COVID-19 diagnostic test kits from commercial entities, which includes the first point-of-care diagnostic (announced on March 21).

Additionally, on March 16, the agency expanded the policy for clinical laboratories in order to allow both clinical labs and commercial diagnostic developers to develop and deploy SARS-CoV-2 tests without an EUA as long as certain criteria are met. The updated guidance also provides recommendations for test developers that may wish to develop serological tests for use during this coronavirus outbreak (which are less effective for diagnosis than molecular tests but can still be an important tool in increasing the number of people tested).

The FDA's updated policy requires:

- The test to go through a state regulatory approval process (which does not have to be identical to the system already used by the New York State Department of Health);

- If the test developer is a clinical laboratory then no EUA submission is required, although the FDA requests that states notify the agency of their actions to approve such tests;

- If the test developer is a commercial manufacturer, the FDA will not object to the distribution and use of such tests on clinical specimens after the manufacturer validates the test so long as instructions for use and data about performance characteristics are made available and an EUA is submitted to the FDA within 15 days of completing validation;

- For serological tests in particular, the same criteria apply, but this subset of tests is subject to an additional requirement to be labeled with appropriate warnings, including information about the test's effectiveness and that it was not reviewed by the FDA.

Much mainstream press in the past few weeks has been devoted to lack of test availability and issues with the early CDC-developed test. The issuance of more EUAs (generally approved by the FDA within 24 hours of receipt), along with the FDA's flexibility with state regulators that oversee their local clinical labs, should dramatically increase the number of tests conducted within the United States.

Monitoring the Supply Chain and Developing Unique Policies in Response to Critical Needs

In addition to ensuring the safety and availability of diagnostics and medical treatments, the agency oversees the drug supply chain and monitors drug and device shortages, and on Feb. 27 it announced the first coronavirus-related drug shortage.

Federal law requires drug manufacturers to notify the FDA when they become aware of a circumstance that could lead to a shortage and the FDA maintains a list on its website of drugs in shortage. The FDA has a few tools to mitigate drug shortages, including extending expiration dates and expediting review of alternative therapies, although many stakeholders consider the agency's role to be too minimal and in need of additional attention from Congress.

Unlike drugs, however, there is no statutory requirement for device manufacturers to notify the FDA of potential or actual shortages. This makes it difficult for the FDA to have a clear and up-to-date picture of device shortages and therefore difficult for the agency to take steps to mitigate such shortages. Congress is looking to fix that problem.

The Mitigating Emergency Drug Shortages Act, which is being considered for inclusion in one of the numerous coronavirus-related legislative vehicles under discussion, would require the FDA to maintain a public list of devices (including diagnostic tests) in shortage and the estimated duration of the shortage, among other information.

In the meantime, the FDA is exercising its existing authorities in creative ways to address potential supply chain disruptions and shortages. For example, the FDA and CDC announced on March 2 that certain respirators — including N95 respirators — can be used in health care settings in an effort to maximize the number of respirators available. (A respirator may be regulated by the CDC, but not by the FDA if the manufacturer does not make claims about health care uses.) And on March 22, the agency released a policy aimed at increasing the availability of ventilators and other respiratory devices.

Further, on March 14, the FDA issued an immediately-in-effect policy that provided guidelines to pharmacists who wished to compound alcohol-based hand sanitizers, which are regulated as nonprescription drug products and have been in short supply since the start of the COVID-19 outbreak. The agency stated it would not take enforcement action against pharmacists that comply with the criteria set forth in the policy, including that they conduct such compounding within state-licensed pharmacies, federal facilities or FDA-registered outsourcing facilities.

Quickly afterward — on March 20 — the agency expanded its hand sanitizer enforcement

policy to allow other, nonpharmacy facilities to manufacture specific alcohol-based products subject to very narrow conditions. Facilities not already registered with the FDA as drug manufacturers must let the agency know they will be producing and distributing hand sanitizer products. This new policy is particularly unusual and reflects the unprecedented scope of the public health emergency we are currently facing.

The agency is also taking steps to connect directly with health care providers to help mitigate shortages of certain critical health care products needed during the COVID-19 crisis.

Specifically, on March 11, the FDA issued a letter to providers recommending strategies for conserving personal protective equipment, or PPE, such as surgical masks, gowns and suits in light of potential supply shortages or disruptions. It also developed a webpage with answers to common questions about PPE shortages. The FDA issued another letter to health care providers on March 20 with conservation strategies for mitigating potential glove shortages, and one on March 22 about facilitating access to ventilators.

Treatments and Vaccines for COVID-19

Although the FDA will not publicly announce or make available information about investigational new drug applications, compassionate use requests, or what emergency clinical use of unapproved drugs, biologics or medical devices it has granted, in recent days several private entities have made their own announcements regarding the FDA's authorization of emergency use applications.

Hopefully, one or more of these experimental treatments demonstrates some effectiveness against the SARS-CoV-2 virus, and the agency can move swiftly to authorize a larger clinical trial and ultimately marketing approval for COVID-19 therapeutic products.

Protecting American Consumers

The FDA has also stepped up its regulatory and enforcement activities in many other areas related to consumer-directed products. Considering the FDA was created in large part to prevent the marketing of fraudulent (i.e., misbranded and adulterated) food and medical products, the agency has several clear and effective authorities to protect patients and consumers, including — if needed — seizing fraudulent products and imposing fines on offending manufacturers and distributors.

Most notably, on March 9, the FDA and the Federal Trade Commission jointly issued warning letters to seven companies for fraudulent product claims relating to COVID-19. The agency also reported that it was engaged in ongoing activities to protect consumers from this type of unscrupulous behavior. The FDA has established a cross-agency task force to monitor the market for fraudulent products related to COVID-19, to coordinate monitoring activities with private businesses, and to work with retailers and online marketplaces to quickly remove such products from the market. Indeed, the FDA's March 9 announcement also noted that over three dozen listings of fraudulent COVID-19 products had already been removed by online retailers.

In addition, on March 20, the FDA issued a consumer alert emphasizing that it has not yet authorized any at-home, direct-to-consumer tests for COVID-19. This announcement appears to be creating some confusion about the applicability of the various FDA enforcement policies in place for COVID-19 diagnostic tests, as summarized above, and the agency is expected to clarify the policy expeditiously.

Lastly, although the FDA has suspended most domestic and foreign inspections, the agency is stressing that it will use additional measures to ensure the safety of imported foods and medical products, highlighting its clear authority to "refuse admission of products that fail sample testing or may violate other applicable legal requirements."

The FDA also has the authority to rely on review of records in lieu of an in-person inspection of a drug facility, but such authority does not extend to establishments where other FDA-regulated commodities are manufactured or stored. This may be another area of interest for Congress as it seeks to ensure the FDA has the tools it needs to be flexible while still maintaining appropriate oversight during an emergency.

With its federal partners, the FDA has and will continue to be at the forefront of the response to the COVID-19 pandemic. We expect the agency to continue to take groundbreaking steps to protect the public health during the ongoing emergency.

Joanne Hawana is a member, Aaron Josephson is a senior director and Ben Zegarelli is an associate at Mintz Levin Cohn Ferris Glovsky and Popeo PC.