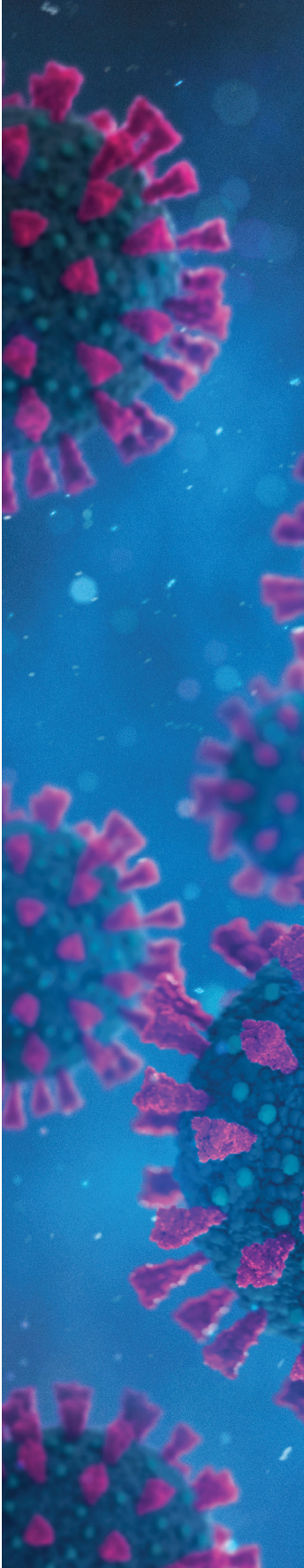


FDA'S WORK TO COMBAT THE COVID-19 PANDEMIC



FDA’s Work to Combat the COVID-19 Pandemic

July 2022¹

Introduction

On March 11, 2020, the World Health Organization declared COVID-19 a global pandemic. The pandemic has caused unimaginable harms, with over 1,000,000 American lives lost to the disease. These two years have also seen unprecedented progress in pandemic preparedness across the U.S. government, particularly at the U.S. Food and Drug Administration. The FDA continues to build on the foundation of scientific rigor, thoughtfulness, and adaptability in rising to this challenge. The agency is deeply appreciative of Congress’ support to ensure the American public’s access to medical products they need to diagnose, treat, and prevent COVID-19.

The FDA is responsible for monitoring the continued performance, safety, availability, and effectiveness of the COVID-19-related products on the market now, as well as in the years to come. To accomplish this long-range mission, the FDA is hiring and training new talent, building large data infrastructure and analytic capacity, modifying processes, and developing new partnerships. These efforts improve the resiliency of the agency and the health of Americans, responding to the COVID-19 pandemic and preparing for future crises such as public health emergencies, supply chain disruptions, geopolitical changes, and natural disasters.

This document outlines much of the broad range of work the FDA is undertaking to combat the COVID-19 pandemic and prepare for future emergencies.

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¹ Unless otherwise specified, all data presented is current as of April, 2022



Vaccines

Vaccines save lives by preventing disease, hospitalizations, and deaths. Given the COVID-19 public health emergency (PHE), development timelines for COVID-19 vaccines were shortened without compromising safety and effectiveness standards. The FDA's Center for Biologics Evaluation and Research (CBER), in close partnership with industry and governmental partners, facilitated the needed scientific studies and manufacturing process validations to support this timeline. CBER issued an Emergency Use Authorization (EUA) for the first COVID-19 vaccine within eight months of the declaration of a PHE and licensed the first COVID-19 vaccine within two years, less than 100 days from the Biologics License Application submission. Typical vaccine development and approval can take 10 years or longer.

Over [570 million doses](#) of vaccines have been administered in the U.S., and [82.2% of the American public over age five](#) has received at least one dose of a vaccine per CDC data.

After authorization, CBER tracks the safety and performance of these vaccines in the real world. Even very large clinical trials are sometimes too small to detect extremely rare side effects and may not be designed to learn about the efficacy of a vaccine in certain groups, like patients with cancer. Real World Evidence (RWE) is the analysis of anonymous health information for millions of people collected through multiple sources such as

electronic health records, insurance claims, reports, and public health databases.

The FDA uses RWE and multiple other tools to detect potential safety issues early and mitigate them, as well as to answer critical questions around vaccine effectiveness, duration of protection, impacts of variants and mutations, and more.

CBER conducted 24 research studies in FY 2020 and 2021 which have produced more than 58 publications,³ with wide-ranging implications for evaluating antibody and vaccine effectiveness, relevant for COVID-19 and for future vaccine development and regulation.

The FDA has:

- Issued EUAs for three vaccines, two of which are authorized for the population age 6 months and up.²
- Approved two vaccines.
- Reviewed over 1,300 EUA amendments to authorized COVID-19 vaccines.²
- Held nine advisory committee meetings regarding COVID-19 vaccines.
- Issued five draft, updated, or final guidances, related to COVID-19 vaccines.
- Continually reviewed and updated EUAs to include authorizations for boosters, immunocompromised people, and other special circumstances.

- **The Vaccine Adverse Events Reporting System (VAERS)** relies on healthcare providers, vaccine recipients, and parents of vaccine recipients to send in reports of their experiences. CBER received 812,147 VAERS reports in FY 2021 relating to the COVID-19 vaccines, a 1,488% increase over the FY 2020 reports.
- **The Biologics Effectiveness and Safety System (BEST)** and the Centers for Medicare & Medicaid Services data systems are tracking 16 potential rare adverse reactions in data representing 120 million people. The FDA detected four such potential reactions (pulmonary embolism, acute myocardial infarction, immune thrombocytopenia, and disseminated intravascular coagulation) and issued a protocol and [public communication](#).

² Current as of June 23, 2022

³ Current as of June 28, 2022



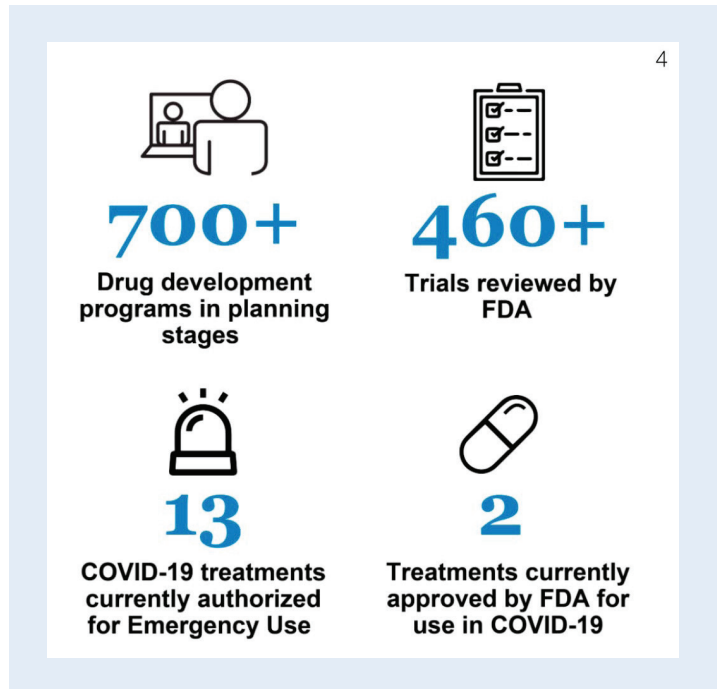
Pharmaceuticals

Treatments are crucial for saving lives from COVID-19 infection.

Congress established a process called [Emergency Use Authorization \(EUA\)](#) to make appropriate treatments available to patients as quickly as possible during PHEs when [certain criteria are met](#). The FDA's [Coronavirus Treatment Acceleration Program \(CTAP\)](#) uses multiple methods to expedite development of treatments including targeted guidance, communications, and interdisciplinary teams to assist drug sponsors with trial design and data submissions.

The FDA has been closely monitoring data from multiple sources to rapidly identify emerging potential safety issues associated with drugs and biologics used to treat or prevent COVID-19. These include safety issues that may not have been captured in a clinical trial, or those that arise from the misuse or off-label use of these products. The FDA can use this information to revise EUAs including updating the authorized Fact Sheets; communicate with the public, health care professionals, and other stakeholders; or act against fraudulent products. To accomplish this, the FDA uses two main systems:

- **The [FDA Adverse Event Reporting System \(FAERS\)](#)**, enables healthcare professionals, consumers, and manufacturers to submit adverse event reports, medication error reports and product quality complaints. In 2021, the FDA launched a new [COVID-19 EUA FAERS Public Dashboard](#) to provide the public with easy access to COVID-19 EUA products adverse event data.
- **The [FDA Sentinel System](#) and other Real World Data (RWD) systems**, which assess potential safety signals in health records, insurance claims, and other RWD. The FDA enhanced these systems in response to the COVID-19 pandemic to include new electronic health records data and to increase the speed of signal detection. This supports the FDA's efforts to characterize the natural history of COVID-19 and to better understand the use and performance of drugs and biologics used to treat or prevent COVID-19. As of June 1, 2022, Sentinel completed 62 COVID-19 related analyses in the Sentinel Distributed Databases and associated electronic health record sources.



Antivirals: [> 23 million courses](#) of two types of antiviral pills have been purchased by the federal government for 2022. Millions of doses of an IV antiviral medication have been administered.

Antibodies: [7.1 million courses](#) of antibody treatments have been distributed by the federal government.

- **Treatment:** [65-90 % reduction](#) in hospitalization or death depending on the product.
- **Prevention:** [77% reduction](#) in infection in those who cannot respond to vaccinations.

4 As of May 31, 2022, the [FDA has authorized 13 treatments, approved 2 treatments, and reviewed more than 460 trials. In addition, more than 700 drug development programs are in planning stages.](#)



Devices, including Tests and Personal Protective Equipment

Medical diagnostics and other devices are necessary in combatting the pandemic:

- Tests allow people to seek early care, get the appropriate medications, quarantine to prevent infecting others, and return to travel and work more safely.
- Personal Protective Equipment (PPE) like masks, respirators, and gloves protect against infection.
- Other devices, like ventilators and syringes, are needed to treat sick patients.

Many of these were in short supply at the beginning of pandemic, so the FDA leveraged the EUA regulatory pathway to make tests and other devices available to patients as quickly as possible while assuring that they are appropriately safe and effective.

Many of the manufacturers of these products are new and unfamiliar with the FDA's policies and procedures, which required the FDA Center for Devices and Radiological Health (CDRH) to organize significant outreach to prepare them for regulation. CDRH has hired new reviewers, conducted town hall meetings, created new validation templates and guidances, assembled a software SWAT team, partnered with sister agencies (such as the National Institutes of Health (NIH) and Biomedical Advanced Research and Development Authority) to support development and FDA authorization of devices with novel technologies, and created new review mechanisms.



The FDA has:

- Reviewed > 8,000 EUA device submissions (> 5,000 for tests), which is 100 times more than in any prior public health emergency.
- Issued EUAs for >800 devices, 450 of which are for tests, including 19 OTC tests.
- Approved/cleared 706 PPE devices, 109 ventilators, and 635 other devices such as infusion pumps and syringes through non-EUA pathways.

CDRH managed >400,000 inquiries and interactions related to COVID products, and held 105 town hall webinars for >53,000 participants.

The FDA and firms have taken postmarket actions, including EUA revocation and recall for many devices⁵.

COVID-19 DEVICE POSTMARKET METRICS



45 WARNING LETTERS ISSUED (2021)

64 DEVICES RECALLED (2021)

263 EUAS REVOKED (COVID-19 PHE TOTAL)

315 TESTS REMOVED FROM NOTIFICATION LISTS (COVID-19 PHE TOTAL)

⁵ As of December, 2021

Tracking real-world performance of tests is important for the FDA to be able to continue to make sure that the available tests are working correctly. To accomplish this, test results need to be captured consistently; results for most over-the-counter (OTC) rapid tests and tests performed at a hospital or laboratory are not always structured in the same ways, and do not always align with the systems that store health information from electronic medical records and insurance claims. To solve these issues, the FDA is leading efforts, such as the *Systematic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD)*, to capture and integrate test data, laboratory data, and patient health data. The FDA is also collaborating with NIH's Variant Task Force (VTF) program to identify and prioritize tests that can detect circulating variants, assess how current tests perform with new variants, and model the anticipated effect of new mutations on multiple different kinds of tests.

Over 630,000 CDRH staff hours have been spent on COVID-19 work in 2020-2021.

OTC Tests: Hundreds of millions of COVID-19 tests have already been performed in the U.S., and over [one billion tests](#) are being contracted by the Biden Administration. The FDA focused particularly on the authorizations of 18 home-use tests as they are relatively inexpensive, allow people to stay in quarantine during testing, and provide faster results. A rollout of home-based testing at this scale is unprecedented, and the FDA's experience regulating novel technologies during this pandemic will facilitate a fast and robust response to a future crisis and to emerging variants.





Resilient Supply Chains

COVID-19 highlighted vulnerabilities in the medical supply chain. Supply chain disruptions for products like ventilators, pharmaceuticals, active ingredients, and PPE were already beginning to occur before COVID-19 cases were identified in the U.S. As demand increased, stockpiling occurred globally, and manufacturing was disrupted. Although the agency has intervened where possible to mitigate medical product shortages, responding to the massive shortages complicated by the pandemic has required establishing new or much more comprehensive programs, focused on three areas:

- Monitoring and visualization of supply, demand, and the availability of supplies by integrating data from a wide variety of sources, such as active ingredient manufacturers, product manufacturers, distributors, suppliers, and end-users like hospitals and pharmacies.
- Prediction of products at risk of shortage using statistical methods and artificial intelligence.
- Prevention or mitigation of shortages with evidence-based strategies such as enforcement discretion; expedited review of manufacturing supplements, generic drug applications, or premarket devices; and requesting that manufacturers identify alternative suppliers, redistribute stock, or increase manufacturing.
- The programs developed are expected to be beneficial for preventing future shortages including in other emergencies like natural disasters (hurricanes and winter storms), labor disputes, and shipping disruptions.

PHARMACEUTICALS

- CDER's Drug Supply Chain Surveillance System is being developed to provide enhanced insight into the drug supply chain—from active ingredient suppliers to clinical settings such as hospitals and pharmacies. This system will utilize existing as well as new data sources to identify early signals that may indicate shortages so they can be prevented and mitigated.
 - CDER was able to work with manufacturers to prevent 482 potential shortages in 2020-2021. Consequently, there was no increase in the number of shortages: 46 in 2019, 43 in 2020 and 38 in 2021.
 - CDER accomplished this in part by expediting review and approval of > 1,300 manufacturing supplements and > 100 generic drugs.

For example, starting in April 2020, there were shortages of Cisatracurium, a necessary medication for some patients on ventilators with dangerously low oxygen levels. The FDA identified this shortage and expedited the review of a generic version of the drug to increase supply. CDER also issued temporary guidances on compounding to allow for a wider array of compounding formulations to address certain supply disruptions.

VACCINES AND BIOLOGICS

- CBER's shortages program was able to work with manufacturers to prevent 34 potential shortages in calendar years 2020 and 2021. CBER accomplished this, in part, by expediting review and approval of 17 biologics license application supplements and 15 lot release submissions for CBER-regulated products.

ANIMAL DRUGS

- The FDA Center for Veterinary Medicine (CVM) Animal Drug and Manufacturing System is launching in 2022 and will generate reports with necessary data for the analysis of potential animal drug shortages, which have more than tripled during pandemic.

DEVICES

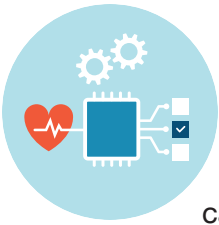
- CDRH's new Resilient Supply Chain Program (RSCP) program aims to develop and apply state-of-the-art supply chain intelligence to predict and prevent supply chain shortages. CDRH has implemented the reporting authority that requires manufacturers to report the shortage of certain medical devices utilizing a newly created webform, and actively maintains a medical device shortage list. In addition, CDRH has integrated internal and external data sources for supply chain analysis and modeling to inform shortage mitigations.
 - The RSCP has performed outreach to >1000 manufacturers in 12 countries to perform impact assessments and inform mitigation strategies.
 - CDRH has performed hundreds of shortage assessments on PPE, COVID-19 testing supplies and equipment, ventilators, and other related device shortages, and has provided evidence-based data to support both regulatory and non-regulatory mitigations.



For example, CDRH, in partnership with the Biomedical Advanced Research and Development Authority and the U.S. Department of Defense, helped to coordinate a series of military airlifts of millions of testing swabs during a severe shortage.

IMPORT IMPROVEMENTS

- The FDA Office of Regulatory Affairs is investing in import modernization with our partner government agencies. For example, FDA continues to work with U.S. Customs and Border Protection to refine existing data interfaces and with the U.S. Postal Service to develop a data exchange to better track and target international mail. These efforts should enable more effective and efficient legitimate trade, while intercepting potentially harmful products before they enter the U.S.



Advanced Manufacturing and Innovation

The COVID-19 pandemic has revealed that most existing manufacturing systems, which depend on a limited number of facilities fed by long and complex global supply chains, can be disrupted by delays, shortages of raw materials, contamination events, or other disturbances. In some cases, this can lead to shortages of much-needed medical products.



Advanced manufacturing is a set of manufacturing technologies and principles that can allow for products to be manufactured in a new or innovative way, such as novel technological approaches that permit production through a distributed network of smaller plants capable of responding in an agile and adaptable way to supply chain threats. Advanced manufacturing techniques can help protect against emerging threats, public health emergencies, natural disasters, and economic supply chain shifts by:

- **Matching supply to meet demand** by creating agile and high-throughput production systems that can scale to respond to new threats and changes in demand.
- **Improving supply chain resilience** by integrating independent operations end to end so that a single plant can depend on fewer input sources and is thus less susceptible to shortages.
- **Creating cost-effective small-footprint plants** that may make the manufacture of medications, including those for rare diseases, more financially viable and may lead to cost savings for consumers.
- **Increasing product quality, manufacturing, consistency, and output** through improving process design and process controls that can detect non-conforming materials in real time.

There are multiple production techniques that could be considered “advanced,” and there is explosive growth in the development of new techniques. Evaluating and regulating advanced manufacturing is complex: the array of different manufacturing techniques is vast, many technologies are designed to be adapted to changing circumstances, and the amounts of data collected can be staggering. Yet, the potential of these technologies is extraordinary, and the FDA has a critical role in facilitating this innovation with respect to medical product manufacturing.

- For **pharmaceutical manufacturing**, the chemical reactions and purification steps to make active ingredients typically occur in different rooms, different plants, different companies, or even different countries. The blending, weighing, compressing, and coating of a pill may occur somewhere else

altogether. There are many advanced manufacturing techniques in development to integrate these steps, incorporate real-time quality controls, and transform physical plant infrastructure. During the

pandemic, CDER and CBER partnered to launch the Center for the Advancement of Manufacturing Pharmaceuticals and Biopharmaceuticals. The FDA has conducted COVID-related research projects exploring active pharmaceutical ingredient manufacturing processes, smart data analytics for product quality, techniques to make monoclonal antibodies, and more. In addition, the FDA has increased its support of targeted research, testing, and training in advanced manufacturing technologies.

- For **vaccine manufacturing**, messenger RNA (mRNA) vaccines have emerged as a powerful platform technology. These vaccines have several advantages: the vaccine antigen can be redesigned relatively easily to target new diseases or new variants and can be simpler to manufacture. Still, they present several new unique manufacturing challenges, such as the need for suitable delivery vehicles (for example lipid nanoparticles), very cold storage, and reliance on specialized materials (reagents). Production of these, and other vaccines, may benefit from several advanced manufacturing techniques. For example, distributed manufacturing in decentralized or mobile units could allow vaccines to be produced near the site of distribution, reducing the cost and risks of transportation. CBER is working to launch a demonstration project for mRNA vaccine manufacturing which will focus on best practices in integrated and continuous vaccine manufacturing. This work is relevant for multiple vaccines, including influenza, COVID-19 variants, and other pathogens.
- For **medical device manufacturing**, new robotics, additive manufacturing (also known as 3D printing), and digital design tools can allow changes in a manufacturing process in response to a new need. Robotics and design tools can also be used to reconfigure a device to be able to use a new part without any loss of effectiveness. CDRH has invested in the *Medical Device Information Analysis and Sharing Initiative* to integrate data from patients, providers, payers, device manufacturers and regulators to understand “blind spots” in product safety and manufacturing quality that can be improved with advanced manufacturing techniques. CDRH also initiated two programs to work directly with manufacturers on “proof-of-concept” manufacturing technologies, called the *Advanced Manufacturing Technology Clearinghouse* and the *Voluntary Improvement Program*.

The FDA is a global leader in advanced manufacturing regulation, supporting the development of two International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use guidelines on continuous manufacturing and manufacturing using cell lines.⁶

CDER held > 150 meetings with drug manufacturers and approved 15 applications and supplements, which use new technologies (e.g., continuous manufacturing and 3D printing) to manufacture products used in the treatment of cystic fibrosis, HIV/AIDS, breast cancer, leukemia, asthma, and two critical drugs needed during COVID-19.

One CDRH and industry collaboration reduced technology implementation time from 18 to eight months, resulting in a reduction in non-conformances of 45% and projected savings of \$30 million.

The Ventilator Digital Twin Project. A digital twin is a model of all the objects, people, designs, processes, and systems involved in the creation of a complex device. This allows one to virtually “try out” a new technique. The Ventilator Digital Twin can model the impact of disruptions like social distancing or parts shortages on ventilator production and come up with solutions.

⁶ ICH Q13 Continuous Manufacturing of Drug Substances and Drug Products and Q5A Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin



Inspections, Investigations, Imports, and Fraud

Inspections and examinations of firms, manufacturing facilities, and imported products, are a critical component of the FDA's strategy to protect the public from harmful or fraudulent products.

The need for these field activities, which are led by ORA in partnership with the relevant centers, only continues to grow. As one example, the number of imported medical product lines increased by 42% in FY 2015-2021, including a 9% increase during pandemic (FY 2020-2021). The pandemic brought about additional unique challenges:

- Inspections were initially significantly limited due to travel bans and risk to personnel, though mission critical inspections were continued throughout.
- Accelerated growth in the vaccine industry necessitated new inspection programs.
- Online marketplace revenue grew from \$360 billion in 2019 to \$768 billion in 2021, including ~\$56 billion in health products, increasing the potential for fraudulent online activities.

To **facilitate inspection activities**, the FDA is initiating a new inspection planning system that will be more efficient, transparent, and adaptable to changing needs. This will help prioritize high-impact inspections such as those for facilities manufacturing COVID-19 vaccines or ingredients used in multiple critical products, as well as the inspections needed for clinical trials of COVID-19 drugs. The FDA is also developing new approaches to inspect firms utilizing novel advanced manufacturing techniques.

To **identify fraudulent products**, ORA has begun a proof of concept using handheld, field-deployable, fraud detection tools including Raman Spectrometers (Progeny) and counterfeit detection devices (CD5). Additionally, ORA is standing up 2-person satellite laboratories at selected international mail facilities. These hand-held devices and satellite laboratories can be used to analyze the chemical composition of a

The FDA launched a data system to track and flag online sales of potentially fraudulent COVID-19 related products.

product to verify authenticity and detect potential contamination directly on site. The ORA's Forensic Chemistry Center experts can then review this field-generated data in real time. If successful, one

or more of these pilots could allow field staff to decide about admitting an imported product much faster than if they need to send samples to a fixed laboratory and wait

The FDA has:

- Identified > 1,706 fraudulent and/or unapproved medical products related to COVID-19.
- Issued > 219 [warning letters](#) to companies and individuals selling unproven products and >70% of recipients took voluntary action in response.
- Identified 340 contaminated hand sanitizers (see Box 4).
- Continued mission-critical inspections throughout.
- Reinvigorated a system to conduct > 1,400 domestic and > 500 foreign remote assessments.
- Conducted domestic inspections at standard operational levels since October 2021.
- Resumed foreign facility surveillance inspections in March 2022.

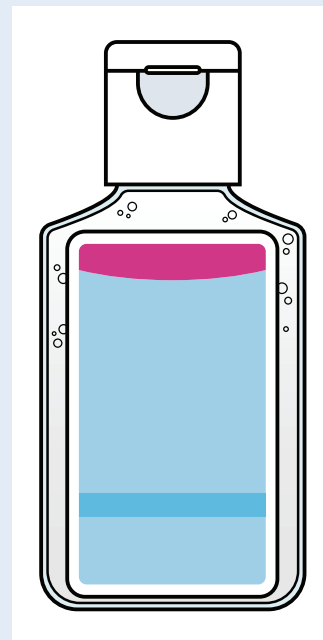
Combatting False Marketing:

The Genesis II Church of Florida falsely marketed a chlorine dioxide formulation, a bleach-like disinfectant, as a treatment for a range of conditions including COVID-19. The FDA sent a joint warning letter with the Federal Trade Commission, which the manufacturer defied. The FDA then successfully pursued in court a temporary restraining order, a preliminary injunction, and, ultimately, a permanent injunction, which enjoins the manufacturer from labeling, holding, or distributing the product.

hours or days for a result. This could reduce the time it takes for the FDA to intercept fraudulent products, expedite legitimate trade, and potentially promote mitigation of supply chain issues.

To **prevent harm to consumers and animals from violative or fraudulent products**, the FDA takes multiple different actions. Illustrative examples include issuing consumer warnings about unapproved and unauthorized products distributed with fraudulent claims to treat or prevent COVID-19 in humans and animals; alerting healthcare providers on how to identify fraudulent PPE; and pursuing regulatory actions to stop the production, importation, distribution, and use of potentially harmful products like contaminated hand sanitizers.

Combatting Fatal Contamination: The FDA noted 2,660 cases of poisonings reported to the National Poison Data System⁷, including 18 confirmed deaths, from ingestion of contaminated hand sanitizers. The FDA saw a sharp increase in [hand sanitizer products](#) from Mexico that were labeled to contain ethanol (also known as ethyl alcohol) but, among other concerns, tested positive for methanol contamination; 84% of the samples of alcohol-based hand sanitizers imported from Mexico analyzed by the agency from April 2020 through December 2020 were not in compliance with the FDA's regulations, and more than half of the samples were found to contain toxic ingredients, including methanol and/or 1-propanol, at dangerous levels. The FDA worked with companies and retailers to recall dozens of violative products. In January 2021, due to safety concerns about alcohol-based hand sanitizers manufactured in Mexico, the agency placed all such products on an import alert, which was the first time the FDA had issued a countrywide import alert for any category of drug product. In addition, as part of the agency's efforts to protect consumers from potentially dangerous or violative hand sanitizers, the agency published on its [website](#) a list of over 250 hand sanitizers that consumers should not use, released a [guidance](#), developed [safety toolkits](#) in multiple languages, and issued [warning letters](#).



⁷ Between Jan 1, 2020 and March 20, 2022



Crosscutting Activities

Crosscutting Research

Regulatory science is the science of developing evidence-based tools, standards, and approaches to assess safety, efficacy, quality, and performance of all FDA-regulated products. Much research conducted at the FDA is relevant to multiple different products and may involve more than one FDA center or office. The studies below have resulted in more than 60 publications:

- **Laboratory standards and techniques** such as the development of reagents, reference panels, and artificial intelligence (AI) to identify targets for new drug development.
- **Immunology research including** neutralizing antibody studies, cytokine studies, and a model of the interactions between the virus, immune system, and body tissues.
- **Advanced manufacturing research** including an analysis of the current advanced manufacturing landscape, 3D printing pilots, and IT and physical infrastructure plans.
- **The RWD Research Lab** including pilot projects to establish rapid-cycle analytic approaches and foster collaboration on topics such as understanding vaccine effectiveness.
- **Transmission research** including studies on SARS-CoV-2 transmission in food or on surfaces, and algorithms to link maternal and infant data to understand perinatal transmission.

The FDA has created translations of FDA health [communications in numerous languages](#), including EUA fact sheets in multiple languages.

Health Equity

Many diseases, including COVID-19, disproportionately impact racial and ethnic minority communities. The FDA Office of Minority Health and Health Equity (OMHHE) launched The [Enhance EQUITY Initiative](#) to advance diversity in clinical trials, increase equitable data efforts, and increase understanding of diverse stakeholder perspectives. OMHHE launched [The COVID-19 and Health Equity Innovation Award](#) which has funded five studies on topics such as understanding COVID-19 outcomes by different demographic variables, including ethnicity, race, age, and geography among others; racial and ethnic minority participation in COVID-19 clinical trials; and understanding diverse patient perspectives, preferences, and unmet needs. OMHHE also supported four additional COVID-19 research projects.

Identifying Variants in Wastewater

Testing for SARS-CoV-2 in wastewater can indicate a surge one to two weeks before a rise in cases. Wastewater also gives a snapshot of a whole population served by a wastewater system, not just those who get tested. Most of the wastewater surveillance for SARS-CoV-2 tests only small fragments of the virus, which can indicate the quantity of the virus present but unfortunately does not give any indication about the proportion of variants within a sample. The FDA Center for Food Safety and Applied Nutrition's (CFSAN) existing GenomeTrakr program uses whole genome sequencing to evaluate the genomes of pathogens in the food supply. CFSAN deployed a similar technology to sequence SARS-CoV-2 in > 50 sites in the U.S. geographic regions with high percentages of agricultural and food facility workers, whose health is critical for stability of the U.S. food supply chain. These data can be used to monitor circulating variants and their impact on vaccines, therapeutics, and diagnostics. Furthermore, the analysis software CFSAN developed has been adopted by other partners, including the U.S. Centers for Disease Control and Prevention (CDC).

Understanding COVID-19 Spread from Animals

Approximately 75% of recently emerging infectious diseases affecting humans are of animal origin, including HIV, Ebola, and influenza. Mink, deer, and other animals are known to be reservoirs for SARS-CoV-2. Humans have transmitted SARS-CoV-2 back to animals, including some domestic dogs and cats. Researchers are currently exploring how environmental factors, including ground and wastewater, play a role in viral transmission. Recognizing that the health of people, animals, and the environment is intertwined, CVM is partnering with other government agencies, such as the U.S. Department of Agriculture and CDC, to solidify a [One Health](#) approach to the FDA's human and animal public health work, and the FDA is standing up a One Health Center of Excellence. An example of CVM's One Health approach is the work being done with other veterinary diagnostic laboratories to identify COVID-19 variants in animal populations and compare them to those in humans. This type of approach is vital to understanding not just COVID-19, but many other emerging threats, such as antimicrobial resistance.



