



**STATEMENT**

**OF**

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**OFFICE OF REGULATORY AFFAIRS**

**FOOD AND DRUG ADMINISTRATION**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**BEFORE THE SUBCOMMITTEE ON MANUFACTURING, TRADE, AND**

**CONSUMER PROTECTION**

**COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION**

**UNITED STATES SENATE**

**“Protecting Americans from COVID-19 Scams”**

**JULY 21, 2020**

## Introduction

Good morning, Chairman Moran, Ranking Member Blumenthal, and Members of the Subcommittee. I am Catherine Hermsen, and I serve as Assistant Commissioner of the Office of Criminal Investigations (OCI) within the Office of Regulatory Affairs (ORA) at the Food and Drug Administration (FDA or the Agency), which is part of the U.S. Department of Health and Human Services (HHS). Thank you for the opportunity to submit written testimony to discuss FDA's efforts to monitor and take action against firms that sell products with fraudulent claims of effectiveness against COVID-19.

I am pleased to submit testimony along with Mr. Andrew Smith, Director of the Bureau of Consumer Protection at the U.S. Federal Trade Commission (FTC), and the Attorney General of the State of Kansas, Mr. Derek Schmidt. FDA works collaboratively with FTC and our federal and state law enforcement partners, as well as other federal and state agencies, on a day-in and day-out basis across the Agency's programs, to ensure coordination across the federal government and between the federal government and the states.

FDA has a long history of investigating those who sell fraudulent products, which led to some of the Agency's, and its predecessors', founding legislation, such as the Pure Food and Drugs Act of 1906 and the Federal Food, Drug, and Cosmetic Act of 1938.<sup>1</sup> Our experience with previous outbreaks such as swine flu and avian influenza has shown that fraudulent cures or elixirs will emerge during any public health crisis, sold by unscrupulous actors capitalizing on the fears of vulnerable consumers. In 2003, FDA and FTC discovered several websites offering bogus Severe Acute Respiratory Syndrome (SARS) products, such as unapproved drugs offered for sale with claims to treat or cure the respiratory illness, as well as websites promising that consumers

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<sup>1</sup> When the U.S. Department of Agriculture was created in 1862, the Patent Office's Agricultural Division was transferred to the new Department, becoming the Division of Chemistry in 1890 and the Bureau of Chemistry in 1901. In 1927, the Bureau of Chemistry became the United States Food, Drug and Insecticide Administration, and in 1930 the name was shortened to the U.S. Food and Drug Administration. Ten years later, in 1940, FDA was transferred from the U.S. Department of Agriculture to the newly created Federal Security Agency, which was renamed the Department of Health Education and Welfare in 1953, and again renamed the Department of Health and Human Services in 1979.

would be protected from SARS if they purchased and used items such as personal air purifiers, hand sanitizers, respirator masks, latex gloves, colloidal silver and oregano oil, and SARS “prevention kits” that packaged various items together, such as gloves and masks. Later, during the 2009 H1N1 influenza virus, FDA discovered online sales of counterfeit versions of the antiviral drug Tamiflu® (oseltamivir phosphate) shortly after FDA issued an Emergency Use Authorization during that public health emergency.

In the past months, we have seen an unprecedented proliferation of fraudulent products related to the COVID-19 pandemic, and more than ever before, the Internet is being used as the primary vehicle for marketing these unproven products. FDA considers the sale and promotion of these products to be a threat to the public health. Fraudulent COVID-19 products come in many forms, including medical devices like personal protective equipment (PPE) and diagnostic tests, purported vaccines, and even purported dietary supplements and other foods. Products like these that claim to diagnose, cure, mitigate, treat, or prevent COVID-19 and haven’t been authorized, cleared, or approved for that use, not only defraud consumers of money – they also can place consumers at risk for serious and life-threatening harm. Using these products may lead to delays in getting proper diagnosis and treatment of COVID-19 and other potentially serious diseases and conditions; indeed, they may sometimes even cause serious illness or death themselves.

Fraudulent products have not been submitted to FDA for review, and may pose a serious safety risk to consumers. Beyond having no proven therapeutic value, these illegal products may contain dangerous substances or be adulterated with contamination and filth due to poor manufacturing standards. FDA oversight helps ensure U.S. consumers have access to safe and effective medical products. When fraudulent products attempt to bypass FDA and its scientific review, the results can be deadly.

### **FDA’s Long-Standing Collaboration with FTC**

FDA and FTC have a long history of collaboration in protecting the health and wellbeing of the U.S. public, dating back to the 1920’s. Between December 2002 and July 2003 alone, during the first SARS pandemic, the two agencies issued a combined total of more than 200 warning letters

and other advisories to various companies selling unproven and fraudulent health products over the Internet and by other means. These requests for compliance were directed at several waves of fraudulent products offered for sale during that time period preying on consumers' fears about biological, chemical, and nuclear terrorism threats and the SARS epidemic. And in 2018, FDA and FTC issued joint warning letters to the sellers of unapproved opioid cessation products with false and misleading claims about their ability to help in the treatment of opioid addiction and withdrawal.

Most recently, in March 2020, FDA and FTC sent the first warning letters to seven firms that offered for sale unproven products – including teas, essential oils, and colloidal silver – with false and misleading claims to treat or prevent coronavirus, in violation of the Federal Food, Drug, and Cosmetic Act and the Federal Trade Commission Act.

### **FDA's COVID-19 Fraud Task Force**

To address the rapid proliferation of fraudulent COVID-related products, earlier this year FDA quickly assembled a cross-agency task force. This task force combines FDA's scientific and regulatory knowledge of human and animal drugs, biologics, medical devices, and dietary supplements and other foods, with our investigators and special agents who specialize in health fraud, compliance and enforcement, cybercrime, and import operations, to issue warning letters and to employ the full complement of FDA's enforcement tools, including civil injunctions, debarments and criminal investigations.

At the outset, it became clear that the Internet was the primary mechanism for the sale of fraudulent COVID-19-related consumer products – creating an immediate problem: the speed at which sellers can post, change, move or remove listings for these products online. In fact, ORA investigators identified approximately 64,000 domain names registered from January-March 2020 that contained COVID-19-targeted terms – names like “covid19cure.com,” “coronavirus-home-kits.com” and “cureforcoronavirus.com.” Questionable social media and online marketplace postings were also widespread, and once the virus reached the U.S., FDA began

receiving Internet-related complaints about, for example, fake COVID-19 cures, illegitimate test kits, and substandard or counterfeit respirators and face masks.

To proactively identify and neutralize these threats to consumers and the public health, in March 2020 FDA launched “Operation Quack Hack.” Operation Quack Hack leverages Agency expertise and advanced analytics to protect consumers from fraudulent products during the COVID-19 pandemic. Building upon our previous experience with illegal online pharmacies, a team of consumer safety officers, special agents and intelligence analysts triages incoming complaints about fraudulent and unproven medical products. Where appropriate, complaints are then sent to other agencies or to FDA Centers for additional review, or referred for a warning letter, civil action or criminal investigation. In some cases, following a preliminary investigation, the team sends an abuse complaint to the domain name registrars or online marketplaces. These abuse complaints are intended to notify companies that may not have been aware that their platforms were being used to sell an unapproved, unauthorized, or uncleared medical product during the COVID-19 pandemic.

Our task force has reported hundreds of online postings for fraudulent and unproven COVID-19 products, and has already contacted numerous parts of the online ecosystem to request that they be vigilant in removing unapproved, unauthorized, and uncleared products with false and misleading COVID-19 claims from their Internet sites. Nearly all of these listings were thereafter removed by the companies. In addition, the task force continues to monitor the Internet for new products, and to ensure that listings for fraudulent products that were previously removed by the online marketplaces, social media platforms, or domain name registrars do not return on new sites with the same or new fraudulent claims. The task force has identified several common products offered for sale with false and misleading claims to treat and prevent COVID-19, including colloidal silver, mineral solutions, and essential oils. And, for unapproved, unauthorized, and uncleared products coming from abroad, FDA screens imports to protect U.S. consumers. In addition, FDA has trained imports staff to screen products entering the U.S. using portable devices that improve detection of illicit products, increasing FDA's ability to prevent such products from being sold in the U.S.

We continue to monitor the online ecosystem for fraudulent products peddled by bad actors seeking to profit from this global pandemic, and will work with online marketplaces, domain name registrars, payment processors, and social media websites so that they can investigate and remove from their platforms products that fraudulently claim to diagnose, cure, mitigate, treat or prevent COVID-19, and keep those products from reappearing under different names.

Of course, FDA also partners with other federal regulatory and law enforcement agencies, including the FTC, and through the efforts of the U.S. Department of Justice (DOJ), to coordinate our investigations and enforcement activities and to efficiently collect and disseminate information related to surveillance findings, referrals, and consumer complaints about fraudulent and unproven products sold with claims to diagnose, cure, mitigate, treat, or prevent COVID-19 or coronavirus generally.

### **Recent COVID-Related Enforcement Efforts**

As of July 1, FDA has reviewed thousands of websites, social media posts, and online marketplace listings, and we have identified more than 780 fraudulent or unproven products related to COVID-19 being offered for sale. These actions have resulted in issuing more than 80 warning letters to sellers of products like homeopathic drug products, nasal sprays, colloidal silver products, purported herbal products, chlorine dioxide products, antibody tests, and others to U.S. consumers. In addition, listings for more than 195 unapproved, uncleared, or unauthorized products that claimed to diagnose, cure, mitigate, treat, or prevent COVID-19 have been removed by online marketplaces, and the Agency has issued more than 260 abuse complaints to domain name registrars, resulting in those registrars taking 189 websites offline.

As noted above, FDA has a long-standing history of collaboration with the FTC, and we often coordinate activities related to companies marketing fraudulent COVID-related products. For example, in April 2020, FDA and FTC jointly issued a warning letter to a seller of fraudulent chlorine dioxide products, equivalent to industrial bleach, frequently referred to as “Miracle Mineral Solution” or “MMS,” as a treatment for COVID-19. FDA had received reports of

people experiencing serious adverse events, including severe vomiting, severe diarrhea, life-threatening low blood pressure, and acute liver failure after drinking certain chlorine dioxide products. FDA had not approved the seller's product for any use, despite the defendants' claims that these products can be used to cure, mitigate, treat or prevent diseases such as COVID-19, Alzheimer's, autism, brain cancer, multiple sclerosis and HIV/AIDS. Claims made on the seller's websites, which provided a link to purchase MMS, included, "The Coronavirus is curable, you believe that? . . . MMS will kill it."<sup>2</sup>

In response to the April 2020 joint FDA/FTC warning letter, the defendants indicated that they would continue to sell MMS in violation of the law; shortly thereafter, a federal court issued a preliminary injunction requiring the seller to immediately stop distributing its unapproved and potentially dangerous product.<sup>3</sup> On July 9, 2020, the Court issued an order of permanent injunction against the entity defendant and two of the named individual defendants.<sup>4</sup> In a separate criminal proceeding, on July 8, the U.S. Attorney's Office for the Southern District of Florida announced criminal charges against four defendants, resulting from a criminal investigation conducted by FDA's Office of Criminal Investigations. The defendants were charged with conspiracy to defraud the United States, conspiracy to violate the Federal Food, Drug and Cosmetic Act, and criminal contempt.<sup>5</sup>

FDA also works with both U.S. and international law enforcement agencies to keep unproven products out of our country. For example, several months ago, we intercepted and investigated a case of misdeclared COVID-19 "treatment kits" offered for import. As a result, OCI special agents, with the help of domestic and international law enforcement counterparts in the United

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<sup>2</sup> See: <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/genesis-2-church-606459-04082020>

<sup>3</sup> See: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-federal-judge-enters-temporary-injunction-against-genesis-ii-church>

<sup>4</sup> See: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-july-9-2020>

<sup>5</sup> See: <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/father-and-sons-charged-miami-federal-court-selling-toxic-bleach-fake-miracle-cure-covid-19-and>

Kingdom, led the DOJ to bring a criminal complaint against a British man who sought to profit from this pandemic and jeopardize the public health.<sup>6</sup>

More recently, FDA has warned consumers and health care professionals about hand sanitizer products containing methanol, or wood alcohol — a substance often used to create fuel and antifreeze that is not an acceptable active ingredient for hand sanitizer products, and that can be toxic when absorbed through the skin, as well as life-threatening when ingested.<sup>7</sup> We have seen an increase in hand sanitizer products that are labeled to contain ethanol but that have tested positive for methanol contamination. State officials have reported recent adverse events in both adults and children ingesting hand sanitizer products contaminated with methanol – including blindness, hospitalizations, and death. In addition to warning the public about these dangerous hand sanitizer products, we are communicating with manufacturers and distributors about recalling them. We continue to test hand sanitizers offered for sale to U.S. consumers, including those being offered for import into the country, and are maintaining and continually updating a list on our website of hand sanitizer products that FDA has recommended be recalled because they were tested and found to contain methanol or are purportedly made at the same facility as methanol-contaminated products.

COVID-related testing products have also been the subject of recent FDA action. Last month, FDA issued warning letters to six companies for marketing adulterated and misbranded COVID-19 antibody tests.<sup>8</sup> Violations outlined in the warning letters included: offering test kits for sale in the United States directly to consumers for at-home use without marketing approval, clearance, or authorization from FDA; misbranding products with labeling that falsely claims the products are “FDA approved”; and labeling that bears the FDA logo, which is not for use on private sector materials. At the present time, there are no diagnostic or antibody COVID-19 test kits that are authorized, cleared or approved to be used completely at home. Testing in the home can present unique and potentially serious public health risks, including whether a lay user can

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<sup>6</sup> See: <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/uk-national-charged-shipping-mislabeled-and-unapproved-treatments-patients-suffering-covid-19>

<sup>7</sup> See: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-methanol#products>

<sup>8</sup> See: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-warning-letters-companies-inappropriately-marketing-antibody>



collect their specimen, run the test, and interpret their results accurately. While FDA has authorized several diagnostic COVID-19 tests for use with at-home collection of samples that can be sent to a lab for processing and test reporting, FDA has not authorized any serology tests for use with at-home sample collection. We have requested that the companies take immediate steps to correct the violations cited in the warning letters, including ceasing the sale of the products and preventing future sales.

## **Conclusion**

FDA will continue to collaborate with the FTC and our other federal and state partners to protect consumers from fraudulent products peddled by bad actors seeking to profit from this global pandemic, and we strongly encourage anyone aware of suspected fraudulent medical products related to the COVID-19 public health emergency to report them to us. We are committed to protecting Americans from unsafe products, and will continue our efforts to find and stop those selling unproven products that fraudulently claim to diagnose, cure, mitigate, treat, or prevent COVID-19. Unscrupulous actors must not be permitted to take advantage of a pandemic to increase their profits while jeopardizing the public health.

FDA appreciates the support and interest of Congress, and this Subcommittee, in our work related to COVID-19. Thank you for the invitation to provide a written statement for the hearing.