

# United States Senate

WASHINGTON, DC 20510

March 2, 2020

Dr. Stephen M. Hahn  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20093

Dear Dr. Hahn:

We write today to request information on the steps the U.S. Food and Drug Administration (FDA) is taking to prevent scammers from peddling ineffective and potentially dangerous coronavirus cures to the public. As the impact of the virus grows, it is imperative that we work to ensure that consumers, especially seniors, are not misled into purchasing such products.

In December, Chinese officials began reporting a novel virus originating in Wuhan, China. Researchers soon identified the virus as a new coronavirus strain (which causes COVID-19).<sup>1</sup> To date, the virus has infected nearly 90,000 people and killed over 3,000.<sup>2</sup> On January 30<sup>th</sup>, the World Health Organization declared the novel coronavirus a global health emergency,<sup>3</sup> and on January 31<sup>st</sup>, HHS Secretary Azar declared it a U.S. public health emergency.<sup>4</sup>

Though the Administration is working with both federal researchers<sup>5</sup> and private sector companies to develop a vaccine and therapeutics, there is currently no cure for COVID-19.<sup>6</sup> However, as public concern over the new coronavirus has grown, scammers have begun marketing fraudulent coronavirus “cures” to a nervous public—placing vulnerable Americans at risk. Some online scammers are urging Americans to try drinking chlorine dioxide to “wipe []

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<sup>1</sup> New York Times, “Coronavirus Map: Tracking the Spread of the Outbreak,” K.K. Rebecca Lai, Jin Wu, Allison McCann, Derek Watkins, Jugal K. Patel, and Richard Harris, February 18, 2020, <https://www.nytimes.com/interactive/2020/world/asia/china-wuhan-coronavirus-maps.html>.

<sup>2</sup> Johns Hopkins, “Coronavirus COVID-19 Global Cases by Johns Hopkins CSSE,” <https://gisanddata.maps.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6>.

<sup>3</sup> NPR, “WHO Declares Coronavirus Outbreak a Global Health Emergency,” January 30, 2020, <https://www.npr.org/sections/goatsandsoda/2020/01/30/798894428/who-declares-coronavirus-outbreak-a-global-health-emergency>.

<sup>4</sup> U.S. Department of Health and Human Services, “Secretary Azar Declares Public Health Emergency for United States for 2019 Novel Coronavirus,” January 31, 2020, <https://www.hhs.gov/about/news/2020/01/31/secretary-azar-declares-public-health-emergency-us-2019-novel-coronavirus.html>.

<sup>5</sup> National Institute of Allergy and Infectious Diseases, “Developing Therapeutics and Vaccines for Coronaviruses,” January 31, 2020, <https://www.niaid.nih.gov/diseases-conditions/coronaviruses-therapeutics-vaccines>.

<sup>6</sup> The Hill, “U.S. partnering with drugmakers coronavirus vaccine,” Nathaniel Weixel, February 18, 2020, <https://thehill.com/policy/healthcare/483509-us-to-partner-with-sanofi-on-coronavirus-vaccine>.



out” coronavirus, while others are pushing the falsehood that “boiled garlic can cure the virus.”<sup>7</sup> And some television programs are promoting fraudulent miracle cures, such as a “Silver Solution” that can “eliminate [coronavirus] within 12 hours” and “boost[] [the] immune system.”<sup>8</sup>

Health fraud products—like fake coronavirus cures—are “articles of unproven effectiveness that are promoted to cure disease or improve health or well being” that can, at best, “deny, delay, or interfere with” a patient’s access to effective treatment, and, at worst, “cause death, injury or [another] serious adverse effect.”<sup>9</sup> The FDA considers the removal of fraudulent products from the market to be “one of the Agency’s top priorities.”<sup>10</sup> The FDA shares oversight of fraudulent health products with the Federal Trade Commission (FTC).<sup>11</sup> The FTC “enforces...truth-in-advertising laws,” which require ads—including those making health or fitness claims—to be “truthful, not misleading, and when, appropriate, backed by scientific evidence.”<sup>12</sup> The FDA, meanwhile, “regulates safety, manufacturing, and product labeling” for foods, drugs, and devices, and can take action when individuals or manufacturers misbrand or promote unproven claims about their products.<sup>13</sup> The FTC and FDA work in close collaboration when combatting health fraud.

The FDA has several tools to combat fraud, including sending scammers warning letters; seizing fraudulent products from the market; and referring individuals for criminal prosecution.<sup>14</sup> In response to the coronavirus outbreak, the FDA additionally “established a cross-agency task force dedicated to closely monitoring for fraudulent products and false product claims” related to COVID-19 and has “reached out to major retailers to ask for their help in monitoring their online marketplaces for fraudulent products.”<sup>15</sup> The agency has already worked with retailers to remove “more than a dozen of these types of product listings online” and is committed to “taking action” to further combat these unlawful products.<sup>16</sup>

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<sup>7</sup> USA Today, “Those coronavirus ‘cures’ you’re hearing about? They’re fake. Don’t drink chlorine dioxide.” Sarnac Hale Spencer, February 14, 2020, <https://www.usatoday.com/story/news/health/2020/02/14/there-cure-coronavirus-no-do-not-drink-chlorine-dioxide/4751565002/>.

<sup>8</sup> Newsweek, “Televangelist Sells \$125 ‘Silver Solution’ As Cure for Coronavirus,” Hunter Moyler, February 12, 2020, <https://www.newsweek.com/televangelist-show-guest-promotes-silver-solution-cure-coronavirus-1487069>.

<sup>9</sup> U.S. Food and Drug Administration, Compliance Program Guidance Manual, “Chapter 63—Health Fraud: Human Drugs,” <https://www.fda.gov/media/75221/download>, p. 2.

<sup>10</sup> U.S. Food and Drug Administration, “Medication Health Fraud,” December 18, 2019, <https://www.fda.gov/drugs/buying-using-medicine-safely/medication-health-fraud>.

<sup>11</sup> Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration (May 1971), <https://www.ftc.gov/policy/cooperation-agreements/memorandum-understanding-between-federal-trade-commission-food-drug>.

<sup>12</sup> With the exception of prescription drug and restricted medical device advertising, which are regulated by the FDA. Federal Trade Commission, “Truth In Advertising,” <https://www.ftc.gov/news-events/media-resources/truth-advertising>.

<sup>13</sup> U.S. Food and Drug Administration, “How to Spot Health Fraud,” Paula Kurzweil, March 8, 2018, <https://www.fda.gov/drugs/bioterrorism-and-drug-preparedness/how-spot-health-fraud>; 21 USC § 378.

<sup>14</sup> U.S. Food and Drug Administration, Compliance Program Guidance Manual, “Chapter 63—Health Fraud: Human Drugs,” <https://www.fda.gov/media/75221/download>, p. 5.

<sup>15</sup> Commissioner Stephen M. Hahn, M.D., “FDA’s Actions in Response to 2019 Novel Coronavirus at Home and Abroad,” February 14, 2020, <https://www.fda.gov/news-events/press-announcements/fdas-actions-response-2019-novel-coronavirus-home-and-abroad>.

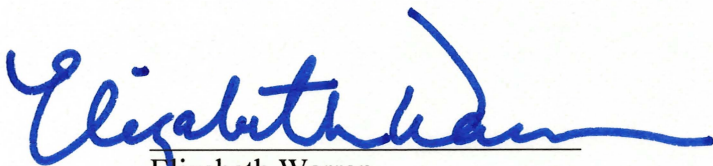
<sup>16</sup> *Id.*




These are positive steps taken by the agency in order to help protect public health. To help us better understand the steps that the FDA is taking to combat coronavirus scams and the ways that Congress could better support the agency in this effort, we request answers to the following questions no later than March 16, 2020:

1. Which offices within the FDA has the agency included in its “cross-agency task force” dedicated to monitoring and combatting fraudulent coronavirus products? What are the responsibilities of each office on the task force?
2. What steps is the FDA taking to actively monitor television, Internet, and other sources for fraudulent coronavirus claims? Has the agency noticed patterns in the intended targets (for example, targeting specific ages or geographic areas) of the fraudulent claims?
3. How many warning or untitled letters, if any, has the FDA sent to individuals or companies marketing fraudulent products marketed as a treatment or cure for coronavirus?
4. Has the FDA seized or requested a recall of any products from the market claiming to cure, treat, or prevent coronavirus? If so, what are those products?
5. Has the FDA referred any individuals or companies for criminal prosecution as a result of claims related to coronavirus cures?
6. Does the agency have adequate budgetary resources and authority to address the marketing and distribution of fraudulent coronavirus products? If not, what additional resources or authorities are necessary?

Sincerely,



Elizabeth Warren  
United States Senator



Robert P. Casey, Jr.  
United States Senator