

# United States Senate

WASHINGTON, DC 20510

August 27, 2020

The Honorable Stephen Hahn  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993

Dear Commissioner Hahn:

Nursing homes continue to be at the epicenter of the spread of the novel coronavirus (COVID-19) in the United States. To date, over 70,000 residents and workers in nursing homes and other long term care settings have lost their lives to COVID-19, and more than 378,000 have been infected.<sup>1</sup> Recent reports from state inspection officials have revealed that in more than one such facility, residents were treated with hydroxychloroquine without their consent or without approval from state officials. As the agency charged with protecting the public health by ensuring the “safety, efficacy and security” of pharmaceutical products, we request information on what the Food and Drug Administration (FDA) is doing to track adverse events associated with the use of hydroxychloroquine in this population.<sup>2</sup>

Early in the pandemic, and without significant study or consensus among the scientific community, the Trump Administration inappropriately looked to hydroxychloroquine as a potential treatment for COVID-19.<sup>3</sup> On March 19, President Trump announced that hydroxychloroquine, a drug approved to treat several other conditions, was one of several drugs that was being reviewed by the FDA to treat COVID-19.<sup>4</sup> Soon after, President Trump even went so far as to tout the drug’s benefits, noting that use of the drug could be “one of the biggest game changers in the history of medicine.”<sup>5</sup> On March 28, the FDA issued an Emergency Use Authorization (EUA) allowing the hydroxychloroquine sulfate and chloroquine phosphate

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<sup>1</sup> The COVID Tracking Project, “The Long-Term Care COVID Tracker,” <https://covidtracking.com/data/longtermcare> (last visited August 26, 2020)

<sup>2</sup> U.S. Food & Drug Administration, “What We Do,” <https://www.fda.gov/about-fda/what-we-do> (updated Mar. 28, 2018).

<sup>3</sup> Katie Thomas and Denise Grady, “Trump’s Embrace of Unproven Drugs to Treat Coronavirus Defies Science,” New York Times, March 20, 2020, <https://www.nytimes.com/2020/03/20/health/coronavirus-chloroquine-trump.html>; Marisa Taylor and Aram Roston, “Pressed by Trump, U.S. pushed unproven coronavirus treatment guidance,” Reuters, April 4, 2020, <https://www.reuters.com/article/us-health-coronavirus-usa-guidance-exclu/exclusive-pressed-by-trump-u-s-pushed-unproven-coronavirus-treatment-guidance-idUSKBN21M0R2>; Jared Hopkins, “States Try Reducing Malaria-Drug Hoarding Amid Unproven Coronavirus Benefit,” Wall Street Journal, April 6, 2020, <https://www.wsj.com/articles/states-try-reducing-malaria-drug-hoarding-amid-unproven-coronavirus-benefit-11586095200>.

<sup>4</sup> White House, Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force in Press Briefing, March 19, 2020, <https://www.whitehouse.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-6/>.

<sup>5</sup> <https://abcnews.go.com/Health/timeline-tracking-trump-alongside-scientific-developments-hydroxychloroquine/story?id=72170553>

products donated to the Strategic National Stockpile (SNS) to be distributed and used for certain hospitalized patients.<sup>6</sup>

Between the middle of February and the end of April, the use of hydroxychloroquine increased significantly and patients who regularly used hydroxychloroquine to treat other conditions like lupus experienced shortages.<sup>7</sup> Despite the increasing use of hydroxychloroquine, scientific studies soon indicated that the use of hydroxychloroquine to treat individuals with COVID-19 could lead to serious complications.<sup>8</sup> On April 24, the FDA issued a warning that hydroxychloroquine should not be used outside a hospital or clinical trial due to the possibility that it could lead to heart arrhythmias, which could be fatal.<sup>9</sup> On June 15, the FDA revoked the previously issued EUO for hydroxychloroquine, and on July 1, the FDA published safety issues associated with hydroxychloroquine as a treatment for COVID-19, including “reports of serious heart rhythm problems and other safety issues, including blood and lymph system disorders, kidney injuries, and liver problems and failure.”<sup>10</sup>

Although the FDA and the scientific community have now concluded that hydroxychloroquine is not an effective treatment for COVID-19, and that it can have serious side effects for some individuals, the Trump Administration continues to issue misleading statements regarding the efficacy and safety of this drug as a treatment for COVID-19.<sup>11</sup> This mixed messaging from the Trump Administration coupled with an absence of clear guidance, has led to the drug’s

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<sup>6</sup> U.S. Food & Drug Administration, Coronavirus (COVID-19) Update: Daily Roundup March 30, 2020, March 30, 2020, <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-march-30-2020>.

<sup>7</sup> Muthiah Vaduganathan, et al., “Prescription Fill Patterns for Commonly Used Drugs During the COVID-19 Pandemic in the United States,” *Journal of the American Medical Association*, May 28, 2020, <https://jamanetwork.com/journals/jama/fullarticle/2766773>; Christopher Rowland, “As Trump touts an unproven coronavirus treatment, supplies evaporate for patients who need those drugs,” *Washington Post*, March 23, 2020, <https://www.washingtonpost.com/business/2020/03/20/hospitals-doctors-are-wiping-out-supplies-an-unproven-coronavirus-treatment/>.

<sup>8</sup> Laurie McGinley, et al., “FDA warns about hydroxychloroquine dangers, citing serious heart issues, including death,” *Washington Post*, April 24, 2020, <https://www.washingtonpost.com/health/2020/04/24/fda-warns-about-hydroxychloroquine-dangers-citing-serious-heart-issues-including-death/>.

<sup>9</sup> U.S. Food & Drug Administration, “FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems,” April 24, 2020, <https://www.fda.gov/drugs/fda-drug-safety-podcasts/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or>.

<sup>10</sup> U.S. Food & Drug Administration, Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine, June 15, 2020, <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chloroquine-and>; U.S. Food & Drug Administration, “FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems,” April 24, 2020, <https://www.fda.gov/drugs/fda-drug-safety-podcasts/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or>; Libby Cathey, “Timeline: Tracking Trump alongside scientific developments on hydroxychloroquine,” *ABC News*, August 8, 2020, <https://abcnews.go.com/Health/timeline-tracking-trump-alongside-scientific-developments-hydroxychloroquine/story?id=72170553>.

<sup>11</sup> Quint Forgy and Caitlin Oprysko, “‘I happen to think it works’: Trump doubles down on hydroxychloroquine,” *Politico*, July 28, 2020, <https://www.politico.com/news/2020/07/28/fauci-trump-ineffective-coronavirus-treatment-383809>; Anne Gearan, et al., “Trump says he is taking hydroxychloroquine to protect against coronavirus, dismissing safety concerns,” *Washington Post*, May 18, 2020, [https://www.washingtonpost.com/politics/trump-says-he-is-taking-hydroxychloroquine-to-protect-against-coronavirus-dismissing-safety-concerns/2020/05/18/7b8c928a-9946-11ea-ac72-3841fcc9b35f\\_story.html](https://www.washingtonpost.com/politics/trump-says-he-is-taking-hydroxychloroquine-to-protect-against-coronavirus-dismissing-safety-concerns/2020/05/18/7b8c928a-9946-11ea-ac72-3841fcc9b35f_story.html).

continued use, even after the FDA issued warnings about its safety.<sup>12</sup> In fact, over the past six months there have been numerous reports of nursing homes using hydroxychloroquine to treat residents with COVID-19.<sup>13</sup> In one particularly troubling instance, a nursing home reportedly used hydroxychloroquine as an ingredient in their “Covid Cocktail” and administered it to residents as a preventative measure.<sup>14</sup> According to family and residents, consent was not given for the use of this treatment, violating standards of medical ethics.<sup>15</sup>

Recently, state inspection reports revealed that residents in nursing homes were treated with hydroxychloroquine in Pennsylvania and Texas without authorization and without the consent of the residents or their family members or guardians. In Pennsylvania, one nursing home treated 205 of 435 residents without first receiving authorization to use this experimental treatment by the Department of Health.<sup>16</sup> According to the health inspection of the facility, it also “failed to report medication errors and adverse events occurring during hydroxychloroquine sulfate treatment.”<sup>17</sup> In Texas, a nursing home reportedly treated patients for COVID-19 using hydroxychloroquine.<sup>18</sup> State inspection reports reveal that that same nursing home was cited for treating patients with cognitive impairment for COVID-19 without getting consent from their guardians or legal representatives.<sup>19</sup>

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<sup>12</sup> David Knowles, “Hydroxychloroquine still being used to treat coronavirus,” Yahoo News, May 1, 2020, <https://news.yahoo.com/hydroxychloroquine-still-being-used-to-treat-coronavirus-213655822.html>; Faith Abubey, “VA still using controversial drug on Georgia veterans with COVID-19 despite FDA warning,” 11 Alive, April 29, 2020, <https://www.11alive.com/article/news/investigations/va-still-using-hydroxychloroquine-despite-fda-warning/85-aec06401-4979-4273-888c-ce0a85ff21c8>.

<sup>13</sup> Nick Powell, “Even after deaths and positive tests, Texas City doctor declares victory with Trump-touted drug,” Houston Chronicle, May 14, 2020, <https://www.houstonchronicle.com/news/houston-texas/houston/article/texas-city-nursing-home-doc-unproven-trump-drug-15270476.php>; Vinny Vella, “Pennsylvania nursing homes are treating coronavirus patients with the unproven malaria drug Trump touted — sometimes without consent,” The Philadelphia Inquirer, May 11, 2020, <https://www.inquirer.com/news/coronavirus-nursing-homes-pennsylvania-hydroxychloroquine-pennsylvania-broomall-southeastern-veterans-center-20200511.html>.

<sup>14</sup> Debbie Cenziper and Shawn Mulcahy, “The ‘Covid Cocktail’: Inside a Pa. nursing home that gave some veterans hydroxychloroquine even without covid-19 testing,” Washington Post, July 7, 2020, <https://www.washingtonpost.com/business/2020/07/07/covid-cocktail-inside-pa-nursing-home-that-gave-some-veterans-hydroxychloroquine-even-without-covid-19-testing/>.

<sup>15</sup> Debbie Cenziper and Shawn Mulcahy, “The ‘Covid Cocktail’: Inside a Pa. nursing home that gave some veterans hydroxychloroquine even without covid-19 testing,” Washington Post, July 7, 2020, <https://www.washingtonpost.com/business/2020/07/07/covid-cocktail-inside-pa-nursing-home-that-gave-some-veterans-hydroxychloroquine-even-without-covid-19-testing/>.

<sup>16</sup> Pennsylvania Department of Health, Brighton Rehabilitation and Wellness Center Patient Care Inspection Results, June 18, 2020, <https://sais.health.pa.gov/commonpoc/Content/PublicWeb/ltc-survey.asp?Facid=020802&PAGE=1&NAME=BRIGHTON+REHABILITATION+AND+WELLNESS+CENTER&SurveyType=H&COUNTY=BEAVER>.

<sup>17</sup> Pennsylvania Department of Health, Brighton Rehabilitation and Wellness Center Patient Care Inspection Results, June 18, 2020, <https://sais.health.pa.gov/commonpoc/Content/PublicWeb/ltc-survey.asp?Facid=020802&PAGE=1&NAME=BRIGHTON+REHABILITATION+AND+WELLNESS+CENTER&SurveyType=H&COUNTY=BEAVER>.

<sup>18</sup> Nick Powell, “Even after deaths and positive tests, Texas City doctor declares victory with Trump-touted drug,” Houston Chronicle, May 14, 2020, <https://www.houstonchronicle.com/news/houston-texas/houston/article/texas-city-nursing-home-doc-unproven-trump-drug-15270476.php>.

<sup>19</sup> The Resort at Texas City, Health Inspection Survey on May 13, 2020 Report, <https://www.cms.gov/files/zip/nursing-home-infection-control-surveys.zip>.

To provide additional clarity regarding the FDA's actions to ensure that this drug is being used safely and properly, we request the following information:

- 1) Has FDA imposed additional post market surveillance requirements on the manufacturers of hydroxychloroquine? If so, please describe these requirements.
- 2) What steps has the FDA taken to monitor the use of hydroxychloroquine both before and since the revocation of the EUA? Please describe the steps that have been taken, including whether such steps include monitoring use outside of hospital or clinical trial settings.
- 3) Has FDA taken steps to track the use of hydroxychloroquine among seniors (adults age 65 or older) for treatment or prevention of COVID-19? If so, please describe the steps that have been taken.
- 4) How many adverse event reports has FDA received regarding hydroxychloroquine since (a) President Trump's March 19 announcement, (b) FDA's issuance of the EUA, and (c) FDA's revocation of the EUA? How many of those reports are associated with seniors?
- 5) Is FDA conducting additional analysis of the adverse event reports linked to hydroxychloroquine? If so, please describe the analyses being conducted.
- 6) Has FDA received any complaints regarding the use of hydroxychloroquine in nursing homes or other congregate care facilities? If so, please provide those complaints.
- 7) Has FDA issued any warning letters to nursing homes or other congregate care facilities regarding the use of hydroxychloroquine? If so, please provide those letters.

Given the urgency of this matter we request this information as soon as possible, but in no event later than September 10, 2020. We look forward to your prompt attention to this matter.

Sincerely,

/s/

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Robert P. Casey, Jr.  
United States Senator

/s/

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Ron Wyden  
United States Senator

/s/

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Elizabeth Warren  
United States Senator