

United States Senate

WASHINGTON, DC 20510

August 27, 2020

The Honorable Christi Grimm
Inspector General
Office of Inspector General
Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

Dear Ms. Grimm:

Recent reports from state inspection officials have revealed that residents in multiple nursing homes were treated for COVID-19 with hydroxychloroquine without their informed consent or without approval from state officials. Such actions may be in violation of Centers for Medicare and Medicaid Services (CMS) rules that provide residents the right “to be informed of, and participate in, his or her treatment.”¹ We write to request the Office of Inspector General (HHS OIG) investigate whether CMS is appropriately monitoring the use of hydroxychloroquine in nursing homes, and taking steps necessary to ensure that resident rights are protected.

A growing body of scientific evidence is demonstrating that hydroxychloroquine is not an effective treatment for COVID-19, and that it can even have serious side effects for some individuals. However, the Trump Administration continues to issue misleading statements regarding the efficacy and safety of this drug as a treatment for COVID-19,² doubling down on statements and actions it took to promote the drug early in the pandemic.³ For a limited time this drug, which is commonly used to treat several other conditions, was given an Emergency Use Authorization (EUA) for the experimental treatment of COVID-19 in supervised hospital

¹ 42 CFR §483.10(c).

² 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.

³ 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>

settings.⁴ This authorization was later revoked by the FDA on June 15, 2020.⁵ In revoking the EUA, the FDA concluded the following:

Specifically, FDA has determined that CQ [chloroquine] and HCQ [hydroxychloroquine] are unlikely to be effective in treating COVID-19 for the authorized uses in the EUA. Additionally, in light of ongoing serious cardiac events and other serious side effects, the known and potential benefits of CQ and HCQ no longer outweigh the known and potential risks for the authorized use. This warrants revocation of the EUA for HCQ and CQ for the treatment of COVID-19.⁶

These safety concerns are particularly acute for seniors, who are more susceptible to severe COVID-19 illness and death, and have a greater incidence of co-morbid conditions that may be affected by these drugs' side effects.⁷ Medical experts have also raised concern that seniors are more likely to be taking prescription medication that affects their heart rhythm, which could be compounded by hydroxychloroquine.⁸ Nursing homes are already at the epicenter of COVID-19 epidemic. More than 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.⁹ Adding the inappropriate use of hydroxychloroquine to the mix, particularly without the informed consent of patients or their family members or guardians, could well worsen the toll.

Recent state inspection reports of nursing homes in Pennsylvania and Texas reveal that residents were treated with hydroxychloroquine without state authorization and without the informed consent of the residents or their family members or guardians. Nationwide, nursing homes are required to ensure that residents or their guardians "are fully informed and understand their health status, care and treatments," and in some states, the use of experimental or off-label treatments, like hydroxychloroquine, may only take place with the consent and consultation of the state's health department.¹⁰

⁴ 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>.

⁵ 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>.

⁶ U.S. Food & Drug Administration, Emergency Use Authorization: Drug Products, <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs>.

⁷ Alicia Lasek, "Malaria drugs approved for COVID-19 use: Geriatrician warns of side effects in elderly," McKnights Long-Term Care News, March 30, 2020, <https://www.mcknights.com/news/clinical-news/malaria-drugs-approved-for-covid-19-use-geriatrician-warns-of-side-effects-in-elderly/>.

⁸ Kelly Servick, "Antimalarials widely used against COVID-19 heighten risk of cardiac arrest. How can doctors minimize the danger?," Science Magazine, April 21, 2020, <https://www.sciencemag.org/news/2020/04/antimalarials-widely-used-against-covid-19-heighten-risk-cardiac-arrest-how-can-doctors>.

⁹ The COVID Tracking Project, "The Long-Term Care COVID Tracker," <https://covidtracking.com/data/longtermcare> (last visited August 26, 2020).

¹⁰ Centers for Medicare and Medicaid Services, State Operations Manual Appendix PP – Guidance to Surveyors for Long Term Care Facilities, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf; 28 Pa. Code § 201.29(o).

In Pennsylvania, where consultation with the state health department is required, one nursing home treated 205 of their 435 residents using hydroxychloroquine without proper approval from state officials.¹¹ According to a state inspection report issued on June 18, not only was this treatment undertaken without consultation with the state, it was still taking place five days after the FDA issued warnings against its use in non-hospital settings.¹² Additionally, according to the report, the nursing home failed to “report medication errors and adverse events occurring during Hydroxychloroquine [*sic*] sulfate treatment,” as required by the EUA.¹³ In Texas, state inspection reports reveal that a nursing home was cited for treating cognitively impaired patients for COVID-19 without getting consent from their family or guardians first.¹⁴ Because inspection records are redacted to preserve patient privacy, it is not clear what drugs they were given; however, media reports indicate that this same facility was using hydroxychloroquine to treat patients with COVID-19.¹⁵

The above cases, in Pennsylvania and Texas, represent just two examples where nursing home residents were improperly treated with this controversial drug. While these were captured by the limited infection control and complaint inspections that have been taking place in nursing homes since the start of the pandemic, with regular inspections suspended and visitation by families and ombudsman limited, it is possible that other instances like these have gone un-checked. For months, media reports have indicated that nursing homes across the United States used hydroxychloroquine to treat residents.¹⁶ In one case, a nursing home for veterans in Pennsylvania

¹¹ 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>.

¹² 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>; 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>.

¹³ 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>.

¹⁴ 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>.

¹⁵ 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>

¹⁶ 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>; “NCDHHS receives 1.5 million hydroxychloroquine tablets for long term care facilities, hospitals,” WSOCTV, April 24, 2020, <https://www.wsocvtv.com/news/local/fda-warns-about-antimalarial-drug-being-tested-covid-19-patients/OJZ7L4L3SBCAVIKNNXAPKVRED4/>; Andrew Selsky, “Oregon OKs malaria drug for COVID-19 patients in care facilities, prisons,” KVAL, April 2, 2020, <https://kval.com/news/local/oregon-oks-malaria-drug-for-covid-19-patients-in-care-facilities-prisons>; Nolan Clay, “Coronavirus in Oklahoma: More Norman nursing home

reportedly referred to hydroxychloroquine as an ingredient in their “Covid Cocktail” and administered it to residents as a preventive measure.¹⁷ According to family and residents, consent was not given for the use of this treatment.¹⁸

The use of this experimental treatment on patients without proper approval and without their consent is a violation of patient rights. As such, we request that HHS OIG open an investigation to determine:

- 1) Whether nursing homes violated the rights of residents by treating them with hydroxychloroquine without their informed consent, or the informed consent of their guardians; and
- 2) Whether nursing homes properly tracked and reported adverse events associated with the use of hydroxychloroquine; and
- 3) Whether CMS took actions to ensure that nursing homes have followed all requirements for participation in Medicare and Medicaid regarding the approval and use of hydroxychloroquine; and
- 4) Whether CMS has properly used its authority to hold providers accountable for known misuse of this treatment, and whether appropriate guidance was given to providers about the use of hydroxychloroquine.

Sincerely,

/s/

Robert P. Casey, Jr.
United States Senator

/s/

Ron Wyden
United States Senator

/s/

Elizabeth Warren
United States Senator

residents test positive,” The Oklahoman, April 1, 2020, <https://oklahoman.com/article/5659094/coronavirus-in-oklahoma-more-norman-nursing-home-residents-test-positive>.

¹⁷ 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/>.

¹⁸ 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/>.