TAMMY BALDWIN
WISCONSIN

United States Senate
WASHINGTON, DC 20510

COMMITTEES:
APPROPRIATIONS
COMMERCE
HEALTH, EDUCATION, LABOR, AND PENSIONS

April 28, 2020

Christi Grimm
Principal Deputy Inspector General
HHS Office of Inspector General
330 Independence Avenue, SW
Washington, DC 20201

Dear Principal Deputy Inspector General Grimm,

I write to request that the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) investigate the Trump Administration's promotion of hydroxychloroquine as a treatment for the novel coronavirus, or COVID-19. Hydroxychloroquine is approved by the Food and Drug Administration (FDA) for the prevention and treatment of malaria, as well as certain autoimmune conditions such as lupus and rheumatoid arthritis.[1] It is not, however, approved for the treatment of COVID-19. At the time of this writing, no FDA-approved treatment for COVID-19 exists.

However, on March 19, 2020, President Trump began advertising and promoting hydroxychloroquine as a potential treatment for COVID-19 to the American public.[2] In a tweet from March 21, the President described the combination of hydroxychloroquine and azithromycin, a common antibiotic, as "one of the biggest game changers in the history of medicine,"[3] and on March 23, he noted in a White House press briefing that the federal government was working to obtain large quantities of the drug at his direction.[4] On April 4, the President expressed his support for usage of the drug, adding that individuals had "nothing to lose,"[5] and on April 11, he suggested that he might take it himself.[6] This list constitutes only a summary of the President's statements promoting hydroxychloroquine over the past six weeks.

Federal agencies also appear to have lent credibility to this campaign. On March 28, the FDA issued an Emergency Use Authorization (EUA) allowing hydroxychloroquine and chloroquine phosphate products donated to the Strategic National Stockpile (SNS) to be distributed and used for certain hospitalized patients with COVID-19.[7] In mid-April, a spokesperson for the Federal Emergency Management Agency (FEMA) confirmed that the agency had distributed almost 20 million tablets of hydroxychloroquine to cities around

[1] https://medlineplus.gov/druginfo/meds/a601240.html
[2] https://www.whitehouse.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-6/
[3] https://twitter.com/realDonaldTrump/status/1241367239900778501?s=20
[4] https://www.whitehouse.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-9/
[5] https://www.whitehouse.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-19/
[6] https://www.cnn.com/2020/04/05/health/trump-lupus-hydroxychloroquine-coronavirus-protection/index.html
[7] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidtherapeutics

the country, including to Milwaukee, Wisconsin.[8] After my staff requested more information on this shipment, FEMA confirmed that Milwaukee received two rounds of shipments from the SNS on April 6 and April 8, containing over 335,800 tabs of hydroxychloroquine. The agency also noted that Milwaukee had been included in a "hot zone list" on April 8 for the distribution of hydroxychloroquine. It remains unclear as to how FEMA deemed Milwaukee a "hot zone" or if the agency has any information regarding the entities in Milwaukee that requested this shipment. Further, the agency has failed to provide any clarity regarding distribution or final delivery locations in Milwaukee, or justification for its prioritization of a shipment of an unproven therapeutic over other requested supplies, including swabs for use in COVID-19 testing and ventilators.

Finally, last week, Dr. Rick Bright was removed from his position as the director of HHS' Biomedical Advanced Research and Development Authority (BARDA) and Deputy Assistant Secretary for Preparedness and Response, and was then demoted to a role at the National Institutes of Health. This change came after reportedly expressing the need for a more in-depth assessment of the use of hydroxychloroquine for COVID-19.[9] In a statement following his dismissal, Dr. Bright said the following:

> "I believe this transfer was in response to my insistence that the government invest the billions of dollars allocated by Congress to address the COVID-19 pandemic into safe and scientifically vetted solutions, and not in drugs, vaccines and other technologies that lack scientific merit."

Time and again, this administration has demonstrated a lack of competence in managing our response to this pandemic. I am extremely concerned that the promotion of hydroxychloroquine exemplifies another effort to prioritize the misguided whims of the White House over science and public health. While the President has touted the benefits of hydroxychloroquine as a treatment for COVID-19, the evidence remains inconclusive. A recent study from the Department of Veterans Affairs (VA) found that patients with severe cases of COVID-19 treated with hydroxychloroquine alone showed a significantly higher risk of all-cause mortality over either supportive care or a combination of hydroxychloroquine and azithromycin.[10] And, a study in Brazil was ended over concerns regarding patient safety after COVID-19 patients taking a higher dose of hydroxychloroquine developed irregular heart rates that increased their risk of a potentially fatal heart arrhythmia.[11]

I strongly support efforts to develop a treatment for COVID-19 that is safe, effective, and approved by the FDA, however, I am incredibly concerned that the actions of the administration have distracted us from this effort and jeopardized the health of thousands of Americans in the process. Therefore, I request that HHS OIG examine the following questions:

1. Please describe the body of scientific evidence used to inform the President's public statements starting on March 19, 2020 which promoted the use of hydroxychloroquine and the extent to which such statements were supported by public health officials within the administration.

2. Please describe the scientific evidence used to inform the FDA's decision to issue an EUA on March 28, 2020, the officials involved in approving this decision, and the impact of this decision on use of hydroxychloroquine as an experimental treatment for COVID-19.

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[8] https://www.politico.com/news/2020/04/14/fema-ships-out-hydroxychloroquine-tablets-186102
[9] https://www.nytimes.com/2020/04/22/us/politics/rick-bright-trump-hydroxychloroquine-coronavirus.html
[10] https://www.fiercepharma.com/pharma/hydroxychloroquine-takes-another-hit-failed-small-scale-covid-19-study
[11] https://www.nytimes.com/2020/04/12/health/chloroquine-coronavirus-trump.html

3. How did FEMA determine which cities would receive shipments of hydroxychloroquine from the SNS? Were shipments made in response to formal requests from states, localities, or health systems? And, were shipments intended to bolster the availability of hydroxychloroquine for individuals with chronic conditions for which the drug is an approved treatment or was this an effort to promote the drug as a possible treatment for COVID-19?

4. To the extent possible, please provide a comprehensive and detailed list of all entities in the state of Wisconsin that requested a shipment of hydroxychloroquine from the SNS.

5. To the extent possible, please provide a comprehensive and detailed list of all entities in the state of Wisconsin that received a shipment of hydroxychloroquine from the SNS.

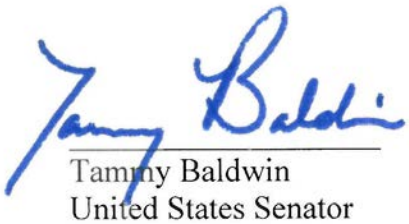
6. How did FEMA prioritize shipments of hydroxychloroquine to "hot zones" over other requested supplies, such as personal protective equipment, ventilators, and testing supplies?

7. On April 24, 2020, the FDA issued a drug safety communication cautioning against the use of hydroxychloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems.[12] Please describe the body of scientific evidence used to inform this communication and the officials involved.

8. Please examine the extent to which administration officials may have benefitted financially or otherwise from increased distribution and use of hydroxychloroquine.

The COVID-19 pandemic threatens the overall health and safety of families across the country, in every single state. In the words of Dr. Bright, "to combat this deadly virus, science — not politics or cronyism — has to lead the way." Thank you for your prompt attention to this urgent matter, and I look forward to the findings of this report.

Sincerely,



Tammy Baldwin
United States Senator

[12] https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or