TAMMY BALDWIN
WISCONSIN

United States Senate
WASHINGTON, DC 20510

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

May 14, 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 recognize your commitment to facts and the truth, which you have demonstrated through your work as an independent, federal watchdog of waste, fraud and abuse. Most notably, your Department of Health and Human Services (HHS) Office of the Inspector General (OIG) report released in April found, in part, "widespread shortages" of personal protective equipment that frontline health care workers need to stay safe, and "severe shortages" of testing kits. This report, which was wrongly criticized by President Trump,[1] correctly exposed the gaps in the White House's response and affirmed the experiences of our frontline health care workers. I thank you for your efforts to ensure that we have the facts needed to respond to the COVID-19 pandemic.

On April 28, 2020, I requested an HHS OIG investigation into the Trump Administration's promotion of hydroxychloroquine as a treatment for COVID-19. Hydroxychloroquine is not a Food and Drug Administration (FDA) approved treatment for COVID-19, and as of this writing, no FDA-approved treatment exists. I also had a number of questions concerning a shipment of hydroxychloroquine by the federal government to Milwaukee. I have requested any information regarding the entities in Milwaukee that received this shipment, and clarity regarding distribution or final delivery locations of the 335,800 tablets of hydroxychloroquine that were shipped to Milwaukee.

Just three days after I called for this HHS OIG investigation, I was disappointed that President Trump announced he was planning to replace you with the nomination of Jason C. Weida, of Massachusetts, to be Inspector General of HHS.[2] Since my April 28 correspondence to you, new evidence has emerged in regards to the administration's promotion of hydroxychloroquine. Consequently, I request that the OIG seek to investigate the additional questions outlined below.

As I noted previously, hydroxychloroquine is approved by the FDA for the prevention and treatment of malaria, as well as certain autoimmune conditions such as lupus and rheumatoid

[1] https://thehill.com/homenews/administration/491561-trump-decries-ig-report-on-hospital-shortages-as-another-fake-dossier
[2] https://www.whitehouse.gov/presidential-actions/president-donald-j-trump-announces-intent-nominate-appoint-individuals-key-administration-posts-37/

arthritis.[3] It is not, however, approved for the treatment of COVID-19. Despite a lack of robust scientific evidence, the President spent over a month promoting hydroxychloroquine,[4] going so far as to suggest that he might even take it himself.[5]

New reporting indicates that this effort was informed not by experts or scientific evidence, but instead by political advocates with special access to the White House, such as Fox News host Laura Ingraham, a television commentator with no medical experience.[6] A series of unproven cable news segments on hydroxychloroquine seemingly influenced President Trump, and thus Administration policy, including policies guiding the distribution of this drug to states. While governors submitted requests for critical resources such as personal protective equipment and testing supplies, the administration focused its efforts on pressuring states into accepting large quantities of hydroxychloroquine. On May 2, the Washington Post reported that President Trump asked Keith Frankel, "a vitamins executive who occasionally socializes with Trump at his Mar-a-Lago Club in Palm Beach, Fla.," to call California Governor Gavin Newsom and urge him to purchase millions of tablets of hydroxychloroquine from an Indian manufacturer.[7] When Gov. Newsom did not agree, Mr. Frankel apparently spoke to hospital officials in New Jersey and the state health commissioner in New York about obtaining large quantities of hydroxychloroquine.

The President's promotional campaign appears to have been further supported by political appointees within our Federal agencies, including officials within the Federal Emergency Management Administration (FEMA) and the FDA. 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.[8] Five days prior, Bloomberg News reported that the FDA had lifted import restrictions on an Indian company that supplies tablets and raw materials for making hydroxychloroquine.[9] The company's factories had been under an import alert since 2015, after inspectors discovered multiple violations of FDA manufacturing guidelines, including "systemic data manipulation" in tests meant to ensure efficacy and safety.

Any objections from public health experts appear to have been cast aside in favor of prioritizing the misguided impulses of the President and White House over science and public health. New evidence from a recent whistleblower complaint filed by Dr. Rick Bright, who was removed from his position as the director of HHS' Biomedical Advanced Research and Development

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[3] https://medlineplus.gov/druginfo/meds/a601240.html
[4] https://www.washingtonpost.com/politics/2020/04/24/rise-fall-trumps-obsession-with-hydroxychloroquine/
[5] https://www.cnn.com/2020/04/05/health/trump-lupus-hydroxychloroquine-coronavirus-protection/index.html
[6] https://www.latimes.com/politics/story/2020-04-14/trump-touts-unproven-drugs-for-the-coronavirus
[7] https://www.washingtonpost.com/politics/34-days-of-pandemic-inside-trumps-desperate-attempts-to-reopen-america/2020/05/02/e99911f4-8b54-11ea-9dfd-990f9dcc71fc_story.html
[8] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidtherapeutics
[9] https://www.bloomberg.com/news/articles/2020-03-23/fda-lifts-import-curbs-on-maker-of-unproven-virus-drug-in-india

Authority (BARDA) and Deputy Assistant Secretary for Preparedness and Response, points to a pattern of Administration officials placing political interests above the needs of patients.[10]

According to Dr. Bright's whistleblower complaint, HHS leadership pursued widespread distribution of hydroxychloroquine in an effort to score a "BIG immediate win" and align themselves with the President's misguided promotional campaign. Officials including Secretary Alex Azar, General Counsel Bob Charrow, and Assistant Secretary for Health Admiral Brett Giroir reportedly went to extreme lengths to promote the drug to the detriment of patient safety, going above and beyond the very FDA guidance that they reportedly sought to influence. At one point, when cautioned that the agency's EUA limited the use of hydroxychloroquine and chloroquine to the treatment of hospitalized patients, Admiral Giroir responded with the following:

> "The EUA matters not…the drug is approved [and] therefore can be prescribed as per doctor's orders. That is a FINAL ANSWER."

Public health expertise should matter. Science should matter. When fact-based evidence is disregarded as inconvenient for the President's fact-free publicity campaign, patients and families pay the price.

On May 11, a study published in the Journal of the American Medical Association found that there was no benefit to treating hospitalized COVID-19 patients with hydroxychloroquine.[11] Another recent study published in the New England Journal of Medicine found that hydroxychloroquine did not lower the risk of death among coronavirus patients, with the authors noting that these results "do not support the use of hydroxychloroquine at present."[12] And, a 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.[13]

The administration could have utilized science and evidence to inform their decisions during a pandemic, which as of this writing, has taken over 80,000 American lives. But instead, they have continued to offer falsehoods to suffering patients and their families. The promotion of hydroxychloroquine demonstrates yet another effort by this White House to accommodate and empower the mistaken whims of the President over science and public health.

As I noted in my previous correspondence, 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 by the administration's seemingly preferred approach, which prioritizes politics over science and jeopardizes the health of thousands of Americans and Wisconsinites. Therefore, I

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[10] https://www.cnn.com/2020/05/05/politics/rick-bright-full-complaint/index.html
[11] https://jamanetwork.com/journals/jama/fullarticle/2766117
[12] https://www.nejm.org/doi/full/10.1056/NEJMoa2012410
[13] https://apnews.com/a5077c7227b8eb8b0dc23423c0bbe2b2

request that HHS OIG examine the following questions, in addition to those submitted in my April 28 correspondence:

1. Please describe the body of scientific evidence used to inform the actions of Administration officials, including Secretary Azar, Dr. Kadlec, and Admiral Giroir, in promoting hydroxychloroquine for treatment of COVID-19 in non-clinical settings and without physician supervision.

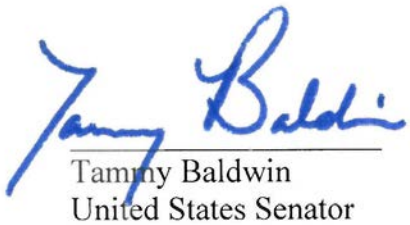
2. Please describe in detail the steps taken by Administration officials, including Secretary Azar, Dr. Kadlec, and Admiral Giroir, to promote hydroxychloroquine for treatment of COVID-19 in non-clinical settings and without physician supervision, including any direct contact with state or local government officials.

3. Please describe the legal authorities that allowed Admiral Giroir to order that the nation's supply chain be mobilized to "flood" states with hydroxychloroquine, including through direct distributions to pharmacies.

4. Please describe the scientific evidence used to inform FDA's decision to lift import restrictions on Ipca Laboratories Ltd., which stated in a March 21 securities filing that FDA had "made exception to the import alert" for three facilities that supply tablets and raw materials used to make hydroxychloroquine.

Americans everywhere are hopeful that we will soon discover a treatment for COVID-19, but peddling false hope and unproven science to the public gets us nowhere. Thank you for your prompt attention to this urgent matter, and I look forward to reviewing the findings of this report.

Sincerely,



Tammy Baldwin
United States Senator