TAMMY BALDWIN
WISCONSIN

United States Senate
WASHINGTON, DC 20510

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

June 8, 2020

The Honorable Peter T. Gaynor
Administrator
Federal Emergency Management Agency
500 C Street S.W.
Washington, D.C. 20472

The Honorable Robert Kadlec, M.D.
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Administrator Gaynor and Assistant Secretary Kadlec:

I write to request more information from the Federal Emergency Management Agency (FEMA) and the Assistant Secretary for Preparedness and Response (ASPR) regarding the oversight and distribution of hydroxychloroquine, including the distributions made to states and cities from the Strategic National Stockpile (SNS).

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. For months President Trump has sought to promote this drug as a potential treatment for COVID-19 to the American public, despite mounting scientific evidence that hydroxychloroquine may cause serious side effects in patients with COVID-19, and in some cases, increase their risk of death.[2]

On March 28, 2020, the FDA issued an Emergency Use Authorization (EUA) to allow hydroxychloroquine sulfate and chloroquine phosphate products donated to the Strategic National Stockpile (SNS) to be distributed and used for certain patients with COVID-19.[3] In issuing this EUA, the FDA specifically noted that the drug should only be used to "treat adult and adolescent patients who weigh 50 kg or more hospitalized with COVID-19 for whom a clinical trial is not available, or participation is not feasible." The next day, the Department of Health and Human Services (HHS) announced that it would be accepting a donation of thirty

[1] https://medlineplus.gov/druginfo/meds/a601240.html
[2] https://apnews.com/a5077c7227b8eb8b0dc23423c0bbe2b2
[3] https://www.fda.gov/media/136534/download

million doses of hydroxychloroquine and one million doses of medical grade chloroquine phosphate to the Strategic National Stockpile (SNS).[4]

On April 14, 2020, a spokesperson for FEMA confirmed that the SNS had sent out 19.1 million tablets of hydroxychloroquine in two shipments to cities around the country.[5] Following a request for additional information, FEMA officials informed my staff that this included over 335,800 tablets of hydroxychloroquine sent to Wisconsin hospitals, pharmacies, and care sites.

Recently released documents indicate that the FDA used extremely limited scientific evidence to inform its issuance of an EUA.[6] Furthermore, a whistleblower complaint filed by Dr. Rick Bright, who 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, describes a number of Administration officials taking questionable action to promote hydroxychloroquine beyond and in of violation of the FDA's EUA. According to an email exchange from April 4, 2020, HHS Assistant Secretary for Health Adm. Brett Giroir instructed both of you, as well as Vice Director for Logistics of the Joint Chiefs of Staff Rear Adm. John Polowczyk, to "flood NY and NJ with treatment courses [of hydroxychloroquine]."[7] The complaint also alleges that Mr. Gaynor received instructions from FDA Commissioner Dr. Stephen Hahn to distribute hydroxychloroquine to pharmacies nationwide, despite the boundaries outlined in the EUA. FEMA's responses to inquiries from my staff thus far indicate that the drug was in fact distributed to pharmacies, despite a clear authorization for use only in hospital settings.

I am alarmed by this pattern of efforts to cast aside scientific evidence and appropriate agency oversight in order to appease the whims of the White House. Furthermore, I am concerned by a lack of accountability from both ASPR and FEMA, which have claimed to have little insight into the distribution of hydroxychloroquine. This, despite the fact that the supply was obtained and stored in the SNS managed by ASPR, and distributed to states and cities by FEMA as part of the Administration's response to the COVID-19 pandemic. Willful ignorance is either an intentional effort to evade oversight, or demonstrative of widespread incompetence. Both are unacceptable as our country continues to face a public health crisis.

On April 28, I wrote to the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) to request an investigation into the Administration's promotion of hydroxychloroquine as a treatment for COVID-19.[8] The Department of Homeland Security (DHS) OIG has also been notified of this request. As I await a response, I request that you provide a written response to the following:

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[4] https://www.hhs.gov/about/news/2020/03/29/hhs-accepts-donations-of-medicine-to-strategic-national-stockpile-as-possible-treatments-for-covid-19-patients.html
[5] https://www.politico.com/news/2020/04/14/fema-ships-out-hydroxychloroquine-tablets-186102
[6] https://www.documentcloud.org/documents/6935092-LEOPOLD-FDA-FOIA-Hydroxychloroquine-Study.html#document/p7
[7] https://www.cnn.com/2020/05/05/politics/rick-bright-full-complaint/index.html
[8] https://www.baldwin.senate.gov/imo/media/doc/Baldwin%20HHS%20OIG%20Request-%20Hydroxychloroquine.4.28.20.pdf

1. How many tablets of hydroxychloroquine and chloroquine phosphate remain in the Strategic National Stockpile (SNS)? Does ASPR intend to replenish these supplies? If so, will ASPR and other federal agencies again attempt to secure donations from private companies?

2. What evidence-based analysis has ASPR conducted to determine if a supply of hydroxychloroquine and chloroquine phosphate for hospitalized patients with COVID-19 is needed in the SNS? If ASPR has determined that a supply of hydroxychloroquine and chloroquine phosphate is needed, how did it determine what amounts are appropriate to include in the SNS?

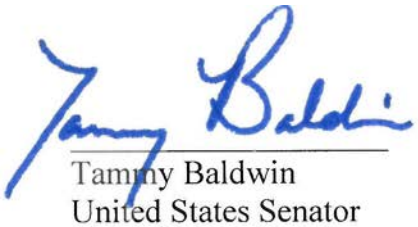
3. How did FEMA determine which cities and states would receive shipments of hydroxychloroquine? Was it based on an analysis of COVID-19 hotspots or was this in response to requests from states, localities, health systems or individuals?

4. Did FEMA prioritize shipments of hydroxychloroquine over other supplies requested by states, including requests for personal protective equipment (PPE) and ventilators?

5. FEMA has indicated that pharmacies and care sites also received shipments of hydroxychloroquine, despite the fact that the FDA's EUA is limited to patients hospitalized with COVID-19. How is FEMA working to ensure that shipments of hydroxychloroquine are used for purposes outlined in the FDA's EUA or for conditions for which the drug is an approved treatment?

ASPR and FEMA both play an important role in responding to disasters and emergencies, including the COVID-19 pandemic. I appreciate your attention to this important issue, and expect that you will be able to provide more information regarding distributions of hydroxychloroquine.

Sincerely,



Tammy Baldwin
United States Senator