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United States Senate
WASHINGTON, DC 20510

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

June 4, 2020

Dr. Stephen Hahn
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hahn:

I write to request more information on the Food and Drug Administration's (FDA) regulation and oversight of hydroxychloroquine, including the FDA's Emergency Use Authorization (EUA) issued on March 28, 2020.

Hydroxychloroquine is approved by the 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 however, President Trump has sought to promote this drug as a potential treatment for COVID-19 to the American public. This is 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]

As the Commissioner of the FDA, you play a critical role in ensuring that Americans can trust the safety and efficacy of treatments and medical products, especially during times of extreme uncertainty. The COVID-19 pandemic has presented this nation with a unique set of challenges, and I appreciate your efforts to confront this virus. However, I am concerned that you have put science and public health aside in the Trump Administration's efforts to promote hydroxychloroquine. According to a whistleblower complaint filed by Dr. Rick Bright, you issued instructions to distribute hydroxychloroquine to pharmacies nationwide, despite the fact that the EUA did not provide for outpatient use.[3] The FDA also opted to lift import restrictions on Ipca Laboratories, Ltd., an Indian company that supplies tablets and raw materials for making chloroquine, despite the fact that drugs manufactured in the company's factories had been under an import alert since 2015 for multiple violations of FDA manufacturing guidelines.[4] In

[1] https://medlineplus.gov/druginfo/meds/a601240.html
[2] https://apnews.com/a5077c7227b8eb8b0dc23423c0bbe2b2
[3] https://www.cnn.com/2020/05/05/politics/rick-bright-full-complaint/index.html
[4] https://www.bloomberg.com/news/articles/2020-03-23/fda-lifts-import-curbs-on-maker-of-unproven-virus-drug-in-india

documents obtained following a Freedom of Information Act (FOIA) request, the FDA notes in its own administrative record that tablets were "manufactured by never previously inspected IPCA facilities in India" and that "IPCA has a low reputation for quality."[5] This same document indicates that the FDA used extremely limited clinical data to inform its actions. Further, recent reporting describes your efforts to personally intervene in establishing a clinical trial for hydroxychloroquine for a physician who had similarly begun promoting the drug beyond the limitations envisioned by the EUA.[6]

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.[7] As I await a response from the OIG, I request that you provide a written response to the following:

1. 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.

2. The EUA requires that prescribing health care providers submit patient outcome reports, adverse events, and medication errors associated with the use of hydroxychloroquine and chloroquine. What actions has FDA taken to ensure compliance with this requirement? What data and information has FDA received from prescribing health care providers, and when will FDA make this data and information public?

3. In March, FDA lifted import restrictions on Ipca Laboratories Ltd., which makes tablets and raw materials for hydroxychloroquine. Ipca factories have been under an import alert from the FDA since 2015, after inspectors discovered multiple violations of manufacturing guidelines, including "systemic data manipulation" in tests to ensure the efficacy and safety of certain drugs. Has FDA conducted additional inspections of Ipca Laboratories' factories to confirm that these supplies could be safely imported? Please provide all documentation of the inspections and any other information that informed the decision to lift these import restrictions.

4. 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.[8] Please describe the scientific evidence used to inform this communication and the officials involved in its release.

5. Please provide more information regarding the process by which FDA would reconsider or revise the entirety or aspects of its existing EUA for hydroxychloroquine, including

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[5] https://www.documentcloud.org/documents/6935092-LEOPOLD-FDA-FOIA-Hydroxychloroquine-Study.html#document/p7

[6] https://www.vanityfair.com/news/2020/05/documents-expose-fda-commissioners-interventions-on-behalf-of-trump

[7] https://www.baldwin.senate.gov/imo/media/doc/Baldwin%20HHS%20OIG%20Request-%20Hydroxychloroquine.4.28.20.pdf

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

whether the President's promotion and reported personal use of the drug have factored into FDA's decision to not revoke or revise the EUA to date.

When your nomination for FDA Commissioner was considered by the Senate Health, Education, Labor and Pensions Committee, on which I serve, you testified that you "believe strongly in the importance of science, data, and the law that have guided and should continue to guide the decision-making at the FDA." It was my understanding that this belief would guide your work as Commissioner, no matter the circumstances. Now, more than ever, we need science, data, and the law to guide the decisions at the FDA. Thank you for your prompt attention to this urgent matter, and I look forward to your written response.

Sincerely,

Tammy Baldwin
United States Senator