Congress of the United States
Washington, DC 20515

April 16, 2020

The Honorable Stephen Hahn, MD
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Hahn:

We write in regard to the Food and Drug Administration's (FDA) March 28, 2020 Emergency Use Authorization (EUA) to allow hydroxychloroquine sulfate (HCQ) and chloroquine phosphate (CQ) to be used as unapproved, potential therapeutics for coronavirus 2019 (COVID-19) patients. As you know, these oral prescription drugs have long been used for treatment of malaria, Lupus, rheumatoid arthritis, and other anti-inflammatory conditions. We have heard directly from our constituents and have seen a number of reports that the EUA and coordinated efforts by the Administration to procure the medication for the Strategic National Stockpile (SNS) have created nationwide shortages for patients that are currently prescribed HCQ to maintain a healthy quality of life. In addition, we remain concerned about the promotion of HCQ as a potential therapy for COVID-19 without robust clinical evidence or consensus that it is effective and despite the greater medical community's concerns about its safety.

FDA plays an essential role in protecting public health by assuring the safety, effectiveness, and security of human and animal drugs, vaccines and other biological products for human use, and medical devices. It has been FDA's longstanding position that products that claim to cure, mitigate, treat, diagnose or prevent disease, but are not proven safe and effective for those purposes, can place consumers at risk for serious harm. There are currently no FDA approved therapeutics for COVID-19.

We are grateful for the FDA's efforts to swiftly authorize testing, equipment modifications, and other therapies to help address the COVID-19 outbreak. Although there are investigational COVID-19 vaccines and treatments under development, these investigational products are in the early stages of product development and have not yet been fully tested for safety or effectiveness, including HCQ. As Ambassador Debbie Birx stated during the White House Coronavirus Taskforce Briefing on March 31, "There's no magic bullet. There's no magic vaccine or therapy." Until we can complete the requisite clinical trials and ensure these therapies are effective, we urge the Administration to be more measured in its promotion of certain drugs and treatments, and to remain committed to safe scientific medical review processes. We also ask that as FDA considers drugs through its expedited processes, including investigational antivirals, immunotherapeutic, and host-directed therapies, that the agency maintains its strong standard of review, including the requirement that all medical products be safe and effective.

With respect to the HCQ Emergency Use Authorization, we ask that you provide Congress a written response to this letter within seven days that includes answers to the following questions:

- The EUA issued for HCQ and CQ was granted to the Biomedical Advanced Research and Development Authority (BARDA) on March 28, 2020. Please provide further information regarding the agency's interactions with BARDA on this EUA, including the timeline of when the EUA was submitted by BARDA, and the scope of the EUA for purposes of inclusion in the SNS for COVID-19 patients.
- What steps did FDA take to expedite authorization of HCQ for emergency use? How did the actions taken by FDA related to this authorization compare to authorizations given to other products needed in response to COVID-19?
- Specifically, what scientific evidence, research, and studies were utilized to make the decision to allow HCQ and CQ therapeutics to be made available in the SNS for purposes of COVID-19 treatment?
- Which drug manufacturers, academic researchers, partners in the public and private sectors are working with the agency to rapidly collect and analyze information in areas such as illness patterns and treatment outcomes? Please provide a list of all entities that have reached out to FDA or the Coronavirus Treatment Acceleration Program (CTAP).
- We applaud the launch of the CTAP, however it is unclear how decisions are being made by the CTAP. Please provide further information related to CTAP, including what tools the program will use to expedite the development and review of COVID-19 treatments, and what offices or divisions within FDA will be participating in this program.
- What role, if any, did the White House or political appointees play in the decision process for the EUA for HCQ and CQ?
- Since attention has been brought to HCQ and CQ, both drugs are now listed on FDA's drug shortage list. How is FDA working with manufacturers to ensure continued access of HCQ for Lupus, rheumatoid arthritis, and malaria patients?

We applaud FDA's efforts to enhance and expand its work across the federal government and innovators in academia and industry to accelerate COVID-19 treatments and other medical countermeasures. We understand the gravity and urgency of providing authorizations and guidance during this public health emergency, but at the same time, it is critical that our decisions to help do not result in harm, the spread of misinformation, and unintended consequences. We encourage the development of COVID-19 therapies that meet the agency's world-respected gold standard and approval process, which relies on data from adequate and well-controlled trials. We also urge you to protect and preserve the supply chain for Lupus, malaria, and rheumatoid arthritis patients who need HCQ to maintain a baseline quality of life.

Thank you for your dedicated work and efforts during this unprecedented time.

Sincerely,

Alma S. Adams, Ph.D.
Member of Congress

Anna G. Eshoo
Member of Congress

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Eddie Bernice Johnson
Member of Congress

[X] _____
Bonnie Watson Coleman
Member of Congress

[X] _____
John Garamendi
Member of Congress

[X] _____
Gilbert R. Cisneros, Jr.
Member of Congress

[X] _____
Nanette Diaz Barragán
Member of Congress

[X] _____
David N. Cicilline
Member of Congress

[X] _____
Jared Huffman
Member of Congress

[X] _____
Frederica Wilson
Member of Congress

[X] _____
Barbara Lee
Member of Congress

[X] _____
Deb Haaland
Member of Congress

[X] _____
Gwen Moore
Member of Congress

[X] _____
Debbie Dingell
Member of Congress

[X] _____
Ayanna Pressley
Member of Congress

[X] _____
Chellie Pingree
Member of Congress

[X] _____
André Carson
Member of Congress

[X] _____
Grace F. Napolitano
Member of Congress

[X] _____
Suzan DelBene
Member of Congress

[X] _____
Mike Thompson
Member of Congress

[X] _____
Lisa Blunt Rochester
Member of Congress

[X] _____
James P. McGovern
Member of Congress

[X] _____
Jackie Speier
Member of Congress

[X] _____
Joyce Beatty
Member of Congress

[X]
Rosa L. DeLauro
Member of Congress

[X]
Nydia M. Velázquez
Member of Congress

[X]
Joseph P. Kennedy, III
Member of Congress

[X]
Donald S. Beyer Jr.
Member of Congress

[X]
Jan Schakowsky
Member of Congress

[X]
Jerry McNerney
Member of Congress

[X]
Bobby L. Rush
Member of Congress

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Lois Frankel
Member of Congress

[X]
Marcia L. Fudge
Member of Congress

[X]
Peter Welch
Member of Congress

[X]
Eleanor Holmes Norton
Member of Congress

[X]
Jimmy Panetta
Member of Congress

[X]
Mark Pocan
Member of Congress

[X]
Jahana Hayes
Member of Congress

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David Trone
Member of Congress

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Doris Matsui
Member of Congress

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Judy Chu
Member of Congress

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Darren Soto
Member of Congress

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Tony Cárdenas
Member of Congress

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Susan A. Davis
Member of Congress

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Gerald E. Connolly
Member of Congress

[X]
Mark Takano
Member of Congress

[X] _____
Salud O. Carbajal
Member of Congress

[X] _____
Bradley S. Schneider
Member of Congress

[X] _____
Raúl Grijalva
Member of Congress

[X] _____
Kathleen Rice
Member of Congress

[X] _____
Val Demings
Member of Congress

[X] _____
Sharice L. Davids
Member of Congress

[X] _____
David Scott
Member of Congress

[X] _____
Terri A. Sewell
Member of Congress

[X] _____
J. Luis Correa
Member of Congress