RIK MEHTA
FOR US SENATE

Monday, April 13, 2020

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

Dear Commissioner Hahn,

We would like to commend your work as Commissioner of the U.S. Food and Drug Administration during this pandemic. We understand, as former public health officials, that the most difficult part of your job is not making decisions based in good science or bad science but making decisions in the absence of science.

This pandemic is undoubtedly one of the greatest tests our nation and our people have collectively faced in over a century, and we have a moral duty and obligation to protect our country through evidence-based decisions. However, all too often, the FDA Commissioner is required to act on judgment in the absence of robust data when facing a public health emergency. Anticipating this, the Food, Drug and Cosmetic Act was written to allow you, at the pleasure of the President, the discretion and authority to act broadly. The issuance of your enforcement discretion policies and the appropriate use of your Emergency Use Authorizations have shown to us your fearless leadership to tackle COVID-19 and to take calculated risks for the sake of all Americans.

Currently, not enough data exists to support the full FDA approval of hydroxychloroquine and chloroquine as effective treatments for patients infected with COVID-19. However, the time to collect the data to support a full FDA approval is not feasible during an exigent threat to public health. This is why the Emergency Use Authorization provisions have been written to give broad discretion to the Commissioner to allow for the use of products that would otherwise be considered unapproved under restricted circumstances when facing a chemical, biological, radiological and nuclear (CBRN) emergency declared by the HHS Secretary.

The standard to allow for medical product use under EUA is clear.[1] Medical products that may be considered for an EUA are those that "may be effective" to prevent, diagnose, or treat serious or life-threatening diseases or conditions that can be caused by a CBRN agent. There is no question that COVID-19 is a CBRN threat. But most importantly, the terms “may be effective” was intentionally written to allow for a lower standard of evidence under a public health emergency because robust data may not be readily available. The determination on whether a product may be effective is conducted on a case-by-case basis using a risk-benefit analysis and taking the totality

[1] Emergency Use Authorization of Medical Products and Related Authorities, Guidance for Industry and Other Stakeholders, 2017 at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

of the scientific evidence available under consideration. If such evidence allows you, as the FDA Commissioner, to reasonably believe that the product may be effective for the specified use then it may be approved for use under an EUA.

We understand that there are a few, smaller scale studies that have shown hydroxychloroquine and chloroquine suppress symptoms of COVID-19 and some that show it does not. We also understand that hydroxychloroquine and in combination with azithromycin can prolong QT intervals resulting in torsade de pointes along with an increase in the risk of other arrhythmias. However, given the exigent threat COVID-19 has posed and the small body of evidence for decision-making available, we fully support your decision to approve the use of hydroxychloroquine and chloroquine under an EUA. It is this specific circumstance that the law was written to allow for decision-making in absence of robust science. As COVID-19 incident rates continue to climb, especially here in New Jersey, the mortality rates are also increasing and therefore, patients must have a right to try a drug to treat their life-threatening condition as determined by their doctor. With nearly 17,000 deaths in the United States, and growing, we cannot prevent or usurp the clinical judgment of our frontline doctors and their ability to treat patients as they see fit. In the absence of science, we must trust the clinical judgment of doctors who are collecting such anecdotal evidence on the frontlines.

The letter issued by Sen. Bob Menendez and Rep. Bill Pascrell asking you to reverse course on the issuance of an EUA will create a chilling effect within the medical community and we urge you to ignore it.[2] It's partisan fearmongering that could literally endanger lives. Moreover, the removal of these products from EUA could potentially spur a rise in fraudulent, counterfeit, and black-market access of these drugs which could lead to other unintended dangerous outcomes documented by your administration.[3]

A patient's constitutional right to try a drug should not be weighted on its availability and should not be reserved for only FDA-approved indications such as patients with autoimmune diseases like rheumatoid arthritis and lupus. The focus for your FDA should not be on which disease state gets the drug, but how to build an ample and robust supply for all Americans by bringing our drug manufacturing back to America and quickly. The shortage of these drugs is nothing more than failed policies by the previous President that have recklessly allowed for an over-reliance of our supply chain on foreign governments.

We write to you today to encourage you now to make three policy changes. First, we encourage you to allow for certain exemptions to the Drug Master File to allow for new API sources in order to increase the availability of these drugs in the United States. Patients should not have to pick between one disease state or the other because of shortages. Second, we implore you to form a rapid response task force with the Office of Regulatory Affairs to expedite facility inspections for any new API or finished drug manufacturer in the U.S. and to allow for any COVID-related product to be in a highly-secured supply chain with expedited import/export entry, when needed. And lastly, we encourage you consolidate all FDA regulated COVID products (drug, biologic, device and diagnostic etc.) into a single FDA taskforce. We applaud the early steps of your Agency by creating a special emergency program to expedite drug development (Coronavirus Treatment Acceleration Program) to move new treatments to patients as quickly as possible, while at the same

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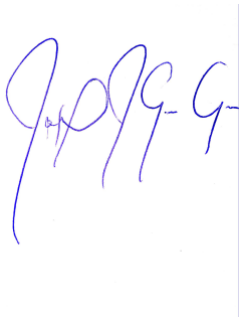
[2] Pascrell, Menendez Demand FDA Heed Science Over Politics at https://pascrell.house.gov/uploadedfiles/fda_covid-19_drugs_letter_final_final.pdf

[3] https://www.fda.gov/drugs/coronavirus-covid-19-drugs/fraudulent-activity-and-unlawful-sales-unapproved-and-misbranded-drug-products-covid-19

time finding out whether they are helpful or harmful. We encourage you to take the next step by streamlining all development programs along with inspectional programs into an Agency-wide rapid response task force with one FDA lead.

In the absence of science, we must act on our judgement. That judgement may come in the form of clinical and medical experience; and sometimes it is based on our principles and faith. We understand that you are facing one of the most precarious public health emergencies we have seen in over a century and we applaud your concerted efforts to advance evidence-based rapid treatment options. But, most importantly, we applaud your willingness to act decisively in the absence of robust science.

Sincerely,



Rik Mehta, PharmD, JD, LLM
Candidate for U.S. Senate

Ret. Adm. Joxel Garcia, MD
14th Assistant Secretary of Health