

United States Senate  
WASHINGTON, DC 20510

May 6, 2020

The Honorable Stephen M. Hahn  
Commissioner of Food and Drugs  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Dear Commissioner Hahn:

In response to the coronavirus disease 2019 (COVID-19) pandemic, the Food and Drug Administration (FDA) has acted to increase the availability of possible COVID-19 treatments, diagnostic tests, and other medical products. We write to request information about how the agency is tracking the usage, safety, and effectiveness of these products in order to protect and ensure the health and safety of all Americans during the COVID-19 pandemic.

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), the FDA Commissioner may issue Emergency Use Authorizations (EUAs), which “allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases... when there are no adequate, approved, and available alternatives.”<sup>1</sup>

Since February 4, 2020, the FDA has issued 112 EUAs for COVID-19-related medical products, including tests, personal protective equipment, and ventilators.<sup>2</sup> This is an unprecedented expansion of EUAs—only 77 EUAs were issued between 2005 and 2018.<sup>3</sup> The seriousness of the COVID-19 pandemic indeed warrants extraordinary measures, but it also places on the FDA the burden to track the usage of these newly-authorized products.

As the FDA rapidly expands access to COVID-19-related medical products, it must also track these newly authorized products and uses to ensure that any benefits are not outweighed by negative consequences and to inform the agency’s future decisions. Federal law mandates that the FDA require the monitoring and reporting of adverse events in certain products approved through EUAs.<sup>4</sup> For example, FDA required such monitoring and reporting in a March 28, 2020

---

<sup>1</sup> U.S. Food & Drug Administration, “Emergency Use Authorization,” <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>; 21 U.S.C. 360bbb-3; Congressional Research Service, “Emergency Use Authorization and FDA’s Related Authorities,” Agata Dabrowska, August 13, 2018, <https://crsreports.congress.gov/product/pdf/IF/IF10745>.

<sup>2</sup> U.S. Food & Drug Administration, “Coronavirus Disease 2019 (COVID-19) EUA Information,” accessed May 6, 2020, <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas>.

<sup>3</sup> Science, “FDA – EUAs – current and past.xlsx,” <https://www.sciencemag.org/file/fda-euas-current-and-pastxlsx>.

<sup>4</sup> Congressional Research Service, “Emergency Use Authorization and FDA’s Related Authorities,” Agata Dabrowska, August 13, 2018, <https://crsreports.congress.gov/product/pdf/IF/IF10745>.

EUA for chloroquine phosphate and hydroxychloroquine sulfate (“hydroxychloroquine”).<sup>5</sup> It is critical that the FDA is able to track and analyze this data as efficiently and comprehensively as possible to appropriately evaluate the safety and efficacy of products that are authorized under a lower evidentiary standard than what would be imposed when evaluating the products under the clearance or approval standards.

Concerns raised about the safety, efficacy, and quality of hydroxychloroquine for the treatment of COVID-19 highlight how important it is for the FDA to track the health and safety outcomes of products authorized via EUA. The FDA issued an EUA for hydroxychloroquine on March 28, 2020,<sup>6</sup> not long after President Trump reportedly “contacted Dr. Stephen Hahn, the FDA administrator, and other top health officials, questioning whether they were moving rapidly enough to make the drugs more widely available.”<sup>7</sup> We are concerned that the EUA may have been issued despite known issues relating to safety, efficacy, and quality.<sup>8</sup> There is limited evidence of hydroxychloroquine’s effectiveness in treating COVID-19, but well-known lethal cardiac side effects.<sup>9</sup> There are also reports that the FDA lowered its quality-control standards so that the Administration could accept Bayer Pharmaceutical’s donation of millions of hydroxychloroquine tablets for distribution under the EUA,<sup>10</sup> and could import hydroxychloroquine from Ipca Laboratories, which had previously been cited by the FDA for manufacturing lapses.<sup>11</sup> Finally, a study of patients hospitalized with COVID-19 at U.S. Veterans Health Administration hospitals found that there was no benefit to patients who took hydroxychloroquine to treat COVID-19,<sup>12</sup> and the FDA has now cautioned against its widespread use.<sup>13</sup> This information underscores the critical importance of tracking and reporting the post-EUA safety, efficacy, and quality of products authorized to fight COVID-19.

---

<sup>5</sup> Letter from RADM Denise M. Hinton to Dr. Rick Bright, March 28, 2020, <https://www.fda.gov/media/136534/download>.

<sup>6</sup> *Id.*

<sup>7</sup> Reuters, “Exclusive: Pressed by Trump, U.S. pushed unproven coronavirus treatment guidance,” Marisa Taylor and Aram Roston, April 4, 2020, <https://www.reuters.com/article/us-health-coronavirus-usa-guidance-exclusiveUSKBN21M0R2>.

<sup>8</sup> Science, “Former FDA leaders decry emergency authorization of malaria drugs for coronavirus,” Charles Piller, April 7, 2020, <https://www.sciencemag.org/news/2020/04/former-fda-leaders-decry-emergency-authorization-malaria-drugs-coronavirus>.

<sup>9</sup> *Id.*

<sup>10</sup> Reuters, “Exclusive: FDA may have dropped standards too far in hunt for chloroquine to fight coronavirus – sources,” Katherine Eban, April 16, 2020, <https://www.reuters.com/article/us-health-coronavirus-bayer-chloroquine/exclusive-fda-may-have-dropped-standards-too-far-in-hunt-for-chloroquine-to-fight-coronavirus-sources-idUSKBN21Y2LO>.

<sup>11</sup> Science, “Former FDA leaders decry emergency authorization of malaria drugs for coronavirus,” Charles Piller, April 7, 2020, <https://www.sciencemag.org/news/2020/04/former-fda-leaders-decry-emergency-authorization-malaria-drugs-coronavirus>.

<sup>12</sup> CNN Health, “Study finds no benefit, higher death rate in patients taking hydroxychloroquine for Covid-19,” Elizabeth Cohen and Dr. Minali Nigam, April 21, 2020, <https://www.cnn.com/2020/04/21/health/hydroxychloroquine-veterans-study/index.html>.

<sup>13</sup> U.S. Food and Drug Administration, “FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems,” April 24, 2020, <https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or>.

Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, said on April 29, 2020, that data from a trial testing the antiviral drug remdesivir was promising, and said that it “will be the standard of care.”<sup>14</sup> On May 1, 2020, the FDA issued an EUA for remdesivir to be used for the treatment of patients hospitalized with COVID-19.<sup>15</sup> The EUA requires that Gilead Sciences, the maker of remdesivir, as well as healthcare facilities and providers receiving remdesivir, track serious adverse events and report them to the FDA.<sup>16</sup> Healthcare facilities are also required to maintain records regarding the use of remdesivir that must be made available to FDA for inspection upon request. Given that demand for remdesivir will likely be extremely high, it is imperative that the FDA track and analyze all available data and information associated with the administration of remdesivir under the EUA, including reported adverse events, to ensure that remdesivir’s benefits outweigh its risks. Furthermore, the FDA must ensure that Gilead Sciences, and healthcare facilities and providers, report adverse events and maintain records as required by the EUA.

In the face of this pandemic, the FDA has an important role enabling the rapid emergency use of various drugs, biological products, and devices, including diagnostics, using data-driven, science-based decision-making processes. We urge the FDA to track and analyze adverse events, outcomes data, and product quality issues for products authorized under EUAs to ensure their benefits outweigh their risks. We also request that you provide answers to the following questions by May 20, 2020.

1. Please describe the systems and procedures that the FDA has in place for tracking adverse events related to the wide array of COVID-19-related products that have been authorized by EUAs.
  - a. Are the same systems and procedures in place for blanket EUAs? If not, how are they different?
2. Please describe the systems and procedures that the FDA has in place for tracking postmarket outcomes data and information on COVID-19-related medical products.
  - a. The EUA for hydroxychloroquine includes that “If and when HHS establishes a process for collecting outcomes data [associated with the use of the authorized chloroquine phosphate or hydroxychloroquine sulfate], HHS will inform public health authorities about such process.”<sup>17</sup> Has HHS established such a process and/or informed the FDA of such process? Please share any communications or documents regarding such a process.
3. Please describe the systems and procedures that the FDA has in place for tracking product quality data and information related to COVID-19-related products that have been authorized by EUAs.
4. Please provide a document describing, for each active COVID-19-related EUA, any arrangement the FDA has with companies, healthcare facilities, providers, or other

---

<sup>14</sup> CNBC, “Dr. Anthony Fauci says Gilead’s remdesivir will set a new ‘standard of care’ for coronavirus treatment,” Berkeley Lovelace, Jr. April 29, 2020, <https://www.cnbc.com/2020/04/29/dr-anthony-fauci-says-data-from-remdesivir-coronavirus-drug-trial-shows-quite-good-news.html>.

<sup>15</sup> Letter from RADM Denise M. Hinton to Ashley Rhoades, May 1, 2020, <https://www.fda.gov/media/137564/download>.

<sup>16</sup> *Id.*, pp. 4–5.

<sup>17</sup> Letter from RADM Denise M. Hinton to Dr. Rick Bright, March 28, 2020, <https://www.fda.gov/media/136534/download>.

entities, to collect, monitor, and report adverse events, outcomes, and product quality data and information, and whether any such arrangement is a condition of said EUA.

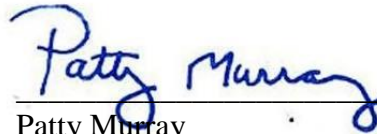
5. Please provide any documents or policies regarding how the FDA uses adverse events, outcomes, and product quality data and information to inform future EUAs for COVID-19-related medical products. What plans or processes has the FDA established for revoking or amending EUAs, if necessary, based on this data?
6. What is FDA doing to ensure that companies, healthcare facilities, and providers are appropriately collecting, monitoring, and reporting adverse events, outcomes, and product quality data and information? What actions, if any, is FDA prepared to take if these entities are not collecting, monitoring, or reporting this data and information?
7. Has the COVID-19 pandemic exposed shortcomings in the FDA's authorities and abilities to obtain and use postmarket data and information that should be addressed by legislative action? Does FDA have sufficient authority to revoke EUAs and recall medical products subject to those EUAs if necessary?

Sincerely,



---

Elizabeth Warren  
United States Senator



---

Patty Murray  
United States Senator