

August 26, 2020

The Honorable Dr. Stephen Hahn
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Hahn:

I write to inquire about the Food and Drug Administration (FDA)'s process for communicating changes in Emergency Use Authorizations (EUAs) to medical providers in the field. New information about these medical products' safety and effectiveness continues to emerge as the coronavirus pandemic continues, which may require revisions and revocations of the authorizations. The FDA is required by law to establish conditions upon the use of medical products authorized under an EUA that are necessary or appropriate to protect public health, including conditions that ensure health care professionals and patients are informed of the "significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown."¹ It is essential that the FDA ensure changes to EUAs related to these significant benefits and risks are promptly and clearly communicated to healthcare professionals and patients.

The coronavirus pandemic has led to unprecedented use of the EUA process. The FDA authorized only 77 products for emergency use between 2005 and 2018,² but has authorized at least 270 during the coronavirus pandemic, including 20 types of Personal Protective Equipment (PPE) and related devices.³ As supply chain disruptions and shortages of essential medical products such as PPE continue to affect our health system,⁴ health care providers have sought out medical products that the FDA has authorized under EUAs and have relied on those products to protect their and their patients' health. The emergency authorizations for these products are typically based on limited evidence of safety and efficacy that may not otherwise satisfy the

¹ 21 U.S.C. 360bbb-3(e).

² Science, "FDA – EUAs – current and past.xlsx." <https://www.sciencemag.org/file/fda-euas-current-and-pastxlsx>.

³ U.S. Food & Drug Administration, "Coronavirus Disease 2019 (COVID-19) EUA Information," accessed August 24, 2020, <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas>.

⁴ Boston Globe, "'It's like pulling teeth': There's still a PPE shortage -- and a second wave could send medical workers into crisis mode," Naomi Martin, June 21, 2020, <https://www.bostonglobe.com/2020/06/21/nation/dangerous-shortages-protective-gear-persist-mass-hospitals-clinicians-say/>.

FDA's non-emergency pre-market review standards.⁵ The FDA is required to periodically review the circumstances and appropriateness of the emergency authorizations, and it may revise or revoke an EUA when criteria for authorization are no longer met, including when, based on the totality of scientific evidence available to FDA, it is no longer reasonable to believe that the known and potential benefits outweigh the known and potential risks.⁶ Any revisions to the authorization based on a change in the significant known or potential risks or benefits must be appropriately communicated to health care practitioners, including (but not limited to) publishing terminations or revocations of EUAs in the Federal Register with an explanation of the reason for the decision.⁷ These notifications are important for protecting the public health. Insufficient notification regarding changes related to the safety and efficacy of these products has the potential to create dangerous confusion about products that have been widely used during this pandemic.

To date, several EUAs have been modified or revoked because of new information after authorization. The FDA revoked the EUA for the use of hydroxychloroquine sulfate (HCQ) to treat COVID-19 patients because, among other things, "data from a large randomized controlled trial showed no evidence of benefit for mortality or other outcomes such as hospital length of stay or need for mechanical ventilation of HCQ treatment in hospitalized patients with COVID-19."⁸ In April, FDA amended the EUA for Abbott Diagnostics' ID NOW COVID-19 test to change the instructions for use to remove certain types of swabs used for transport, due to concerns that dilution in transport could decrease detection of positive samples that are near the limit of detection.⁹ In addition, reported issues with the ID NOW COVID-19 test led FDA to issue a news release about the test in May, alerting the public that early data suggest that the test may return false negative results.¹⁰

In the case of filtering facepiece respirators (FFRs), in May and June, the FDA revised and reissued the EUA for imported, non-National Institute for Occupational Safety and Health (NIOSH)-approved disposable FFRs to remove certain respirators that failed to meet eligibility criteria.¹¹ In addition, in June, FDA reissued EUAs to designate which respirators are appropriate

⁵ Food and Drug Administration, "Emergency Use Authorization of Medical Products and Related Authorities," January 2017, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities#euas>.

⁶ 21 U.S.C. 360bbb-3(g) and (c)(2)(B).

⁷ Food and Drug Administration, "Guidance Document: Emergency Use Authorization of Medical Products and Related Authorities," January 2017, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities#footnote59>.

⁸ Letter from Denise M. Hilton, Chief Scientist, Food and Drug Administration, to Gary L. Disbrow, Ph.D., Director, Medical Countermeasure Programs, Biomedical Advanced Research and Development Authority, June 15, 2020, <https://www.fda.gov/media/138945/download>.

⁹ Letter from FDA to Abbott Diagnostics Scarborough, Inc., April 21, 2020, <https://www.fda.gov/media/137181/download>.

¹⁰ Food and Drug Administration, "Coronavirus (COVID-19) Update: FDA Informs Public About Possible Accuracy Concerns with Abbott ID NOW Point-of-Case Test," press release, May 14, 2020, <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-informs-public-about-possible-accuracy-concerns-abbott-id-now-point>.

¹¹ Food and Drug Administration, "Certain Filtering Facepiece Respirators from China May Not Provide Adequate Respiratory Protection – Letter to Health Care Providers," June 7, 2020, <https://www.fda.gov/medical-devices/letters-health-care-providers/certain-filtering-facepiece-respirators-china-may-not-provide-adequate-respiratory-protection-letter#1>; <https://www.fda.gov/media/136664/download>.

for decontamination. For example, FDA revised the EUA for imported, non-NIOSH-approved disposable FFRs to remove decontaminated respirators from the scope of the EUA. As a result, imported, non-NIOSH approved disposable FFRs cannot be safely decontaminated and reused unless they are listed in an EUA for an individual decontamination system.¹² These changes have had implications for health care workers, including Massachusetts providers. My office has heard from some Massachusetts providers who are still using respirator masks designed for single use for up to five shifts at a time;¹³ under these circumstances, it is essential that health care organizations have clear information about which types of masks are safe for reuse. Yet some Massachusetts providers have expressed concern about the safety of decontaminating and reusing certain respirator masks and other forms of PPE.

Transparency about the known and potential risks and benefits of drugs, devices, and biological products authorized under EUAs is critical to protecting public health. However, notification about such risks and benefits are of little use if they are not clearly communicated to health care practitioners and other first responders. With supply chains continuing to experience instability and first responders continuing to face shortages of PPE, Massachusetts health care workers are relying on the FDA to safeguard their health.

To better understand how the FDA communicates changes to health care practitioners and the public, I request answers to the following questions by September 9, 2020. I also request answers to the letter Senator Patty Murray and I sent to the FDA on May 6, 2020, regarding how the FDA tracks and analyzes adverse events, outcomes data, and product quality issues for products authorized under EUAs to ensure that benefits outweigh their risks.¹⁴

1. Please describe steps the FDA takes to inform any entity that is using a product authorized under an EUA of any modifications or revocations of the EUA, either directly or by imposing conditions on the product manufacturers and importers.
2. Please describe steps the FDA takes to inform any entity that is using a product authorized under an EUA of preliminary data that suggests a change in the known and potential benefits and risks associated with the use of the product that has not yet resulted in modification or revocation of the EUA.

¹² Food and Drug Administration, “Coronavirus (COVID-19) Update: FDA Reissues Emergency Use Authorizations Revising Which Types of Respirators Can be Decontaminated for Reuse,” press release, June 7, 2020, <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-reissues-emergency-use-authorizations-revising-which-types>; <https://www.fda.gov/media/136664/download>; [Decontamination Systems for Personal Protective Equipment EUAs, https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/decontamination-systems-personal-protective-equipment-euas](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/decontamination-systems-personal-protective-equipment-euas).

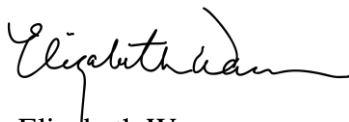
¹³ Boston Globe, “It’s like pulling teeth’: There’s still a PPE shortage, and a second wave could send medical workers into crisis mode,” Naomi Martin, June 21, 2020, <https://www.bostonglobe.com/2020/06/21/nation/dangerous-shortages-protective-gear-persist-mass-hospitals-clinicians-say/>.

¹⁴ Letter from U.S. Senators Elizabeth Warren and Patty Murray to Commissioner of Food and Drugs Stephen M. Hahn, May 6, 2020, <https://www.warren.senate.gov/imo/media/doc/2020.05.06%20Letter%20to%20FDA%20re%20data%20tracking.pdf>.

3. Please describe how the FDA enforces compliance with modifications or revocations of an EUA, including any consequences for continued distribution or use after a product is no longer authorized.
4. Please describe the role of health care workers and patient advocates in collecting and evaluating information about the safety and effectiveness of products authorized under an EUA, and how their perspectives are considered in decisions about whether to modify or revoke an EUA.

Thank you for your consideration of this urgent matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Elizabeth Warren", with a stylized flourish at the end.

Elizabeth Warren
United States Senator