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Congress of the United States
House of Representatives
Washington, DC 20515

May 26, 2020

Stephen Hahn
Administrator
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Administrator Hahn:

I write to you today alarmed by reports regarding the efficacy of the Battelle Critical Care Decontamination System (CCDS) in sterilizing personal protective equipment (PPE). The Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for the system on March 28, 2020, enabling hospitals, health systems, and states to use the system to decontaminate and reuse PPE.[1] Unfortunately, this system may not work as advertised, and recent reporting calls into question whether the FDA succumbed to political pressure in extending the EUA. Millions of taxpayer dollars and the lives of an untold number of frontline healthcare workers are potentially at risk if the CCDS does not perform as expected.

The CCDS is manufactured by Battelle Memorial Institute based in Columbus, Ohio. The company claims their system "can decontaminate thousands of N95 respirators using concentrated, vapor phase hydrogen peroxide."[2] The system can allegedly "decontaminate the same respirator multiple times without degrading N95 respirator performance."[3] The company submitted a request for an EUA to the FDA, with strong and public support from Ohio Governor Mike DeWine, President Donald Trump, and multiple members of the Ohio Congressional Delegation. In the wake of severe shortages of PPE, Governor DeWine and President Trump made a concerted effort to push for the approval of the EUA. In a White House press briefing, President Trump said, "We worked on that as soon as I heard from Mike today, I got involved and the FDA is now involved and we're trying to get a fast approval for the sterilization of masks."[4] On March 29, the President tweeted, "Hope the FDA can approve Mask Sterilization equipment ASAP."[5] Later that day, the FDA issued an EUA for the system, allowing its limited use for sterilization of desperately needed N95s for health care workers.

The authorization granted by FDA was narrower than what Battelle requested. According to the company, the CCDS can sterilize up to 160,000 N95 masks per day for reuse. The EUA instead allowed for up to 10,000 masks per day and limited the deployment of Battelle's technology nationally. Governor DeWine

[1] Emergency Use Authorization (EUA) for the emergency use of the Battelle CCDS Critical Care Decontamination System™ at the Battelle Memorial Institute, FDA, Retrieved at: https://www.fda.gov/media/136529/download
[2] Battelle CCDS, Battelle, Retrieved at: https://www.battelle.org/inb/battelle-critical-care-decontamination-system-for-covid19
[3] Battelle, as cited.
[4] President Donald Trump, White House Press Briefing, Retrieved at: https://www.youtube.com/watch?v=hsxU4MwZ_nw
[5] realDonaldTrump, Twitter, Retrieved at: https://twitter.com/realDonaldTrump/status/1244296475254968320?ref_src=twsrc%5Etfw%7Ctwcamp%5Etweetembed%7Ctwterm%5E1244296475254968320&ref_url=https%3A%2F%2Fwww.10tv.com%2Farticle%2Fpresident-trump-calls-quick-fda-approval-battelle-technology-sterilize-masks-2020-mar

sharply criticized the FDA for limitations in the EUA.[6] Additionally, Ohio Representatives Steve Stivers and Troy Balderson asked that the waiver be expanded for nationwide deployment of the technology.[7] Less than 48 hours later, the FDA reissued the EUA, increasing to the maximum capacity that Battelle had requested initially.[8] Governor DeWine said after conversations with the FDA, "I anticipate a positive announcement soon."[9]

Today, hospitals throughout the state of California are using this technology, including several in and around Orange County.[10] According to research published by the National Institutes of Health (NIH) in mid-April, an N95 respirator can be sterilized only 2 to 3 times using vaporized hydrogen peroxide before the fit and integrity of the masks begin to be compromised.[11] The EUA allows the CCDS to be used to sterilize masks up to 20 times.[12] While the NIH study proves the effectiveness of vaporized hydrogen peroxide systems like the CCDS, it also raises questions about the number of cycles before respirators become unsafe. Frontline health care workers have noted that the masks do not fit as well after a few cycles, indicating that they are less effective after a certain number of uses.[13] Frontline healthcare workers, hospitals, and the American public deserve to know the possible risks of the CCDS.

I am concerned that the FDA allowed external pressure from the President and Members of Congress to influence its decision making in issuing this EUA. I ask that you respond to the following questions by June 2, 2020:

1. Why did the FDA change its original EUA to allow for nationwide deployment of the Battelle system outside of operations by the Battelle Memorial Institute?
2. Why did the FDA change its original EUA to allow it to be used on more masks each day?
3. Did the FDA receive additional information about the system's performance from scientists that impacted its decision in expanding the use of the CCDS?
4. Did the FDA review the NIH study after its release and consider limiting the EUA based on the findings?

Additionally, I request the following documents:

1. All correspondence between the FDA and the White House regarding the CCDS contract;
2. All correspondence between the FDA and the Defense Logistics Agency regarding the CCDS contract;
3. All internal FDA correspondence regarding the CCDS contract;

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[6] Governor DeWine, Lt. Governor Husted Express Disappointment in FDA's Decision to Limit Use of Battelle Technology, Office of the Governor, State of Ohio, Retrieved at: https://governor.ohio.gov/wps/portal/gov/governor/media/news-and-media/dewine-husted-on-fda-decision-to-limit-use-of-battelle-technology

[7] Stivers, Balderson: FDA Should Allow Battelle to Decontaminate Masks at Full Capacity, Congressman Steve Stivers, Retreived at: https://stivers.house.gov/news/documentsingle.aspx?DocumentID=402961

[8] FDA Issues and Expands EUA for for Respirator Decontamination System, RAPS, Retrieved at: https://www.raps.org/news-and-articles/news-articles/2020/3/fda-issues-and-expands-eua-for-respirator-decontam

[9] FDA lifts restrictions on Ohio-based Battelle's mask-sterilizing technology amid coronavirus shortages, USA Today, Retrieved at: https://www.usatoday.com/story/news/nation/2020/03/29/coronavirus-fda-eases-restrictions-mask-sterilization-technology/2936670001/

[10] Battelle Hospital List, CDPH, Retrieved at: https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/Battelle-Hospital-List.aspx

[11] NIH study validates decontamination methods for re-use of N95 respirators, NIH, Retrieved at: https://www.nih.gov/news-events/news-releases/nih-study-validates-decontamination-methods-re-use-n95-respirators

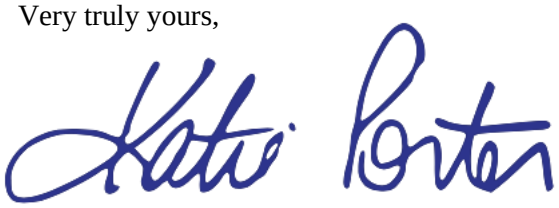
[12] Emergency Use Authorization (EUA) for the emergency use of the Battelle CCDS Critical Care Decontamination System™ at the Battelle Memorial Institute, FDA, Retrieved at: https://www.fda.gov/media/136529/download

[13] Trump Administration Paying Huge Premium for Mask-Cleaning Machines. Which Don't Do the Job. NBC, Retrieved at: https://www.nbcnews.com/politics/white-house/trump-administration-paying-huge-premium-mask-cleaning-machines-which-don-n1210896

4. All correspondence between the FDA and Battelle Memorial Institute regarding the CCDS contract;
5. Any analysis of the efficacy of the CCDS in the FDA's possession; and
6. Any correspondence between the FDA and healthcare providers regarding the CCDS.

Thank you for your attention to this important issue, and I look forward to hearing from you.

Very truly yours,



KATIE PORTER
Member of Congress