

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

WASHINGTON OFFICE:
1221 LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-3515
PHONE: (202) 225-5355
WORTHINGTON OFFICE:
250 EAST WILSON BRIDGE ROAD
SUITE 100
WORTHINGTON, OH 43085
PHONE: (614) 523-2555

March 18, 2020

The Honorable Dr. Stephen Hahn
Director
U.S. Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Avenue
Building 32, Room 2346
Silver Springs, MD 20993

Dear Director Hahn,

We write to seek your immediate review and approval of Battelle Memorial Institute's process to decontaminate and reuse personal protective equipment (PPE).

Battelle conducted research for the U.S. Food and Drug Administration (FDA) Office of Counterterrorism and Emerging Threats in 2016 to evaluate the effectiveness and impact of decontamination on N95 filtering facepiece respirators (FFR) in the event of a pandemic (*e.g.*, influenza or SARS-CoV-2) requiring large numbers of filtering facepiece respirators (FFRs), a common form of PPE used by healthcare workers for protection on the frontline. Research has demonstrated that respirators can be repeatedly decontaminated during a crisis for up to 20 cycles without affecting fit or degrading the respirator. The approach to decontaminate and reuse FFRs in an emergency scenario employs Vapor Phase Hydrogen Peroxide (VPHP) decontamination which is an effective standard decontaminant used in research, pharmaceutical, and medical facilities.

Battelle, the largest independent research and development nonprofit in the world, and OhioHealth, the largest healthcare system in central Ohio, have established a process to collect used N-95 masks at OhioHealth, decontaminate them at Battelle, and return them to OhioHealth. The decontamination process uses high concentration VPHP to kill all SARS-CoV-2. The decontamination process takes 6-8 hours per cycle, is conducted in Battelle's facilities, and is potentially deployable to other locations in the coming months. This process is effective on N-95 PPE masks, face shields, goggles and other common PPE.

In order for decontaminated N-95 PPE masks to be placed back into the clinical setting, **hospitals such as OhioHealth need FDA approval as soon as possible.** It is our understanding the FDA SARS-CoV-2 Incident Management Group is currently reviewing the request. We urge your immediate review so Battelle and OhioHealth can put these decontaminated N-95 PPE masks back into use for our frontline health care professionals.

Rapid action by the FDA to enable the reuse of this critical PPE is in the best interest of our constituents and would serve as a model for the rest of the country during this national emergency. Thank you for considering this request. Please do not hesitate to reach out to Brittany Madni in Congressman Balderson's office at madni@mail.house.gov should you have any questions.

Sincerely,

A handwritten signature in blue ink that reads "Troy Balderson". The signature is stylized with a large, looping "T" and "B".

Troy Balderson
Member of Congress

A handwritten signature in blue ink that reads "Joyce Beatty". The signature is written in a cursive, flowing style.

Joyce Beatty
Member of Congress

A handwritten signature in blue ink that reads "Steve Stivers". The signature is written in a cursive, flowing style.

Steve Stivers
Member of Congress