3D Printing of Face Masks and Face Shields to Address the Coronavirus Public Health Crisis in New Mexico

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ABSTRACT

Shortages of personal protective equipment (PPE) in the State of New Mexico (NM), particularly in regions with limited access to healthcare facilities, led to exploration of 3D printing options for PPE production. Open-source Version 2 Wiles COVID Pandemic Masks, a 3-part design (mask, filter box, and filter), are printed with thermoplastic polyurethane (TPU), a pliable filament material. Printing with TPU makes our masks contourable to the face and provides a tight seal during use. Filter boxes for the masks and 3DVerkstan 3D printed face shield headbands are printed using polylactic acid polymer filament. Filters consist of two layers of hospital grade, high efficiency particulate air filters that we tested and found to be 95% efficient at capturing particles 270 nm (0.27 mm) and larger. To date we have distributed 3,679 face masks and 2,395 face shields. We effectively created a system for fabrication and distribution of 3D PPE for NM.

Keywords: COVID-19, 3D Printing, Personal Protective Equipment, Corona Virus, Additive Manufacturing

INTRODUCTION

New Mexico (NM) has seen disproportionate effects of Coronavirus Disease 19 (COVID-19) in the northwest region of the state, particularly the eastern part of the Navajo Nation (NN) and the surrounding cities providing healthcare to that territory. As of May 18, 2020, the NN has the highest infection rate per capita in the United States (US) according to John Hopkins University.[1] As of May 26, 2020, the county most affected by COVID-19 in NM is McKinley County, with 3,064 cases per 100,000 people. For perspective, Cook County, Illinois has the highest number of COVID-19 infections in the US with 1,411 cases per 100,000 people. The three counties that service the eastern part of NN are remote locales with only 52 intensive care beds and limited access to running water and electrical power.

There have been local personal protective equipment (PPE) shortages, particularly in regions of NM with limited access to healthcare facilities. Subsequently, multiple groups at The University of New Mexico (UNM) began exploring 3D printing options to readily mass-produce PPE for community and healthcare providers. Logistically, it is very difficult to provide disposable PPE and continuous replenishment of these supplies to the remote regions of our state in a timely manner. We aimed to provide reusable, sterilizable face masks and face shields to healthcare providers, first responders, and residents of remote NM communities disproportionately affected by COVID-19. The Dean of the School of Engineering at UNM appointed the senior author to lead the institution's efforts toward this aim. Using US Food and Drug Administration (FDA) guidance, particularly the "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency" issued on March 25, 2020,[2] we began fabricating 3D printed face masks and shields.

Figure 1. The Version 2 Wiles COVID-19 Pandemic 3D printed face masks with filter boxes, including a modification to use thermoplastic polyurethane filament to provide flexibility, comfort, and a tight seal for wearers. We print them in four sizes to allow for wide community, first responder, and healthcare provider use – small narrow (purple), small wide (green), large narrow (orange), and large wide (red).

This article describes the materials and methods used to fabricate PPE, testing completed on PPE, distribution strategies of PPE, and the lessons learned for future response of subsequent pandemics. All face masks and face shields were fabricated at the UNM School of Engineering COSMIAC (Configurable Space Microsystems Innovations and Applications Center) research facility.

FACE MASK AND SHIELD DESIGN SELECTION INCLUDING FDA CONSIDERATIONS

We explored multiple mask designs on the National Institutes of Health (NIH) open source 3D print exchange website under the COVID-19 Supply Chain Response link.[3] After consideration of nearly ten mask designs, we decided to use the Version 2 Wiles COVID Pandemic Mask designed by Dr. Christopher Wiles, an anesthesiology resident from the University of Connecticut.[4] This face mask is a simple 3-part design (ie, mask, filter box, and filter), with files for the mask available in multiple sizes to accommodate different face sizes, including large narrow, large wide, small narrow, small wide (Figure 1). At the time of this publication, the Wiles design has been tested and cleared for community use when fabricated as instructed in the design specifications, but designers have not completed outgassing tests to meet full requirements for use in a clinical setting.

Using the NIH 3D print exchange, we selected the 3DVerkstan 3D printed face shield headband design[5] developed by a group in Sweden. This is a simple, headband frame for holding plastic protective sheets and is universal in size to accommodate many head

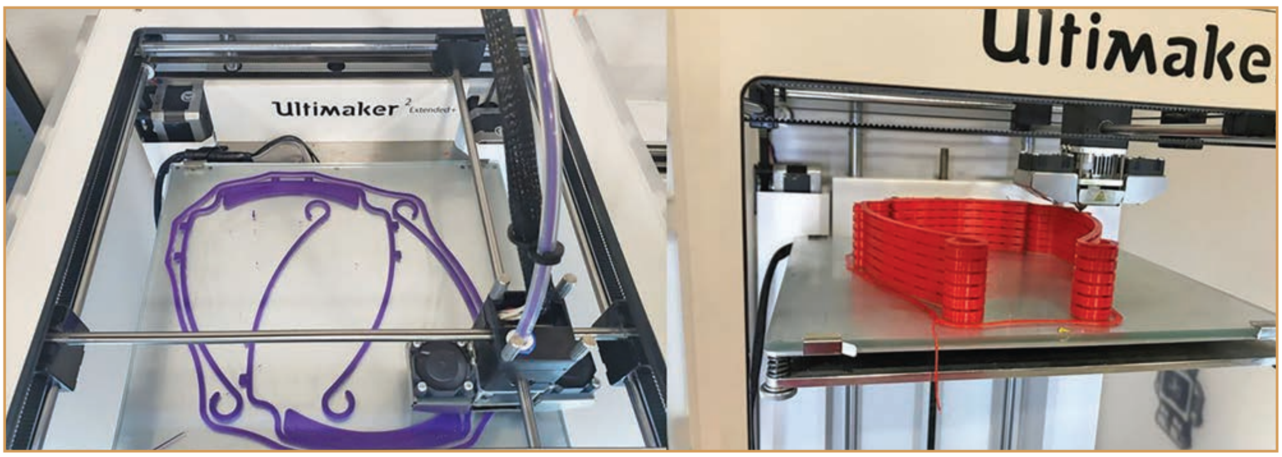


Figure 2. The 3DVerkstan 3D printed face shield headband design printed with polylactic acid filament. This design is universal in size and was primarily distributed to first responders and healthcare providers. (Left) A single layer of two headbands printed simultaneously. (Right) A modified stereolithography (.stl) to print stacked headbands for increased productivity and print efficiency.

Table 1. *Onsite 3D print range parameters for face masks, filter cartridges, and headbands for face shields.*

Item	Printer Type	Material	Filament Size (mm)	Slicer		Layer thickness (mm)	Nozzle temp (°C)	Bed temp (°C)	Print Speed (mm/min)	Fill pattern	Outline Overlap (%)	Extrusion Multiplier	Extrusion Width (mm)	Retraction Distance (mm)	Fan (%)
Mask	Lulzbot Taz Pro	TPU	2.85	Simplify 3D	0.5	0.25	250	65	4000		40	1.00	0.55	1.7	0
Filter Cartridge	Lulzbot Taz Pro	PLA	2.85	Simplify 3D	0.5	0.25	215	60	4000		20	1.0	0.70	1.9	0
Filter Cartridge	Lulzbot Taz Workhorse	PLA	2.85	Simplify 3D	0.5	0.35	215	70	4000		20	1.0	0.70	1.9	0
Filter Cartridge	Ultimaker 2e	PLA	2.85	Cura	0.8	0.2	210	60	2400	line	25	1.0	0.70	2.0	100
Filter Cartridge	Ultimaker 3	PLA	2.85	Cura	0.8	0.2	210	60	3000	line	25	1.0	0.70	2.0	75
Headband	Ultimaker 2e	PLA	2.85	Cura	0.8	0.2	210	60	2400	line	25	1.0	0.70	2.0	100
Head-band	Ultimaker 3	PLA	2.85	Cura	0.8	0.2	210-215	60	3000	line	25	1.0	0.70	2.0	75

PLA, Polylactic Acid; TPU, Thermoplastic Polyurethane sizes (Figure 2). At the time of this publication, this design has undergone a review in a clinical setting and is deemed appropriate when fabricated according to the specifications on the website.

According to the FDA guidance mentioned in the previous section, our 3D printed masks fall under the definition of a "face mask," which is defined as a mask, with or without a face shield, that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels. This classification required us to adhere to guidelines[2] in section C, which states that face masks are intended for medical purposes and are not intended to provide liquid barrier protection. This guidance requires product labeling as a face mask as opposed to a surgical mask or respirator, contains a list of body contacting materials, includes recommendations against use in surgical settings or where risk of infection is high, and does not include particulate filtration claims (although this testing was completed and included in a later section). We opted to maintain classification as a face mask to expedite distribution to the communities most affected in our state.

Per the aforementioned FDA guidance, our 3D printed shield headbands fall under the definition of a "face shield," which is defined as device used to protect the user's eyes and face from bodily fluids, liquid splashes, or potentially infectious materials. This classification required us to adhere to guidelines[2] in section D, which states that face shields are intended for a medical purpose. This guidance requires adequate labeling as a face shield, includes a list of body contacting materials, and does not contain flammable materials.

FACE MASK 3D PRINTING

Masks are printed on LulzBot Taz Pro 3D printers (Aleph Objects Inc, Loveland, CO) with thermoplastic polyurethane (TPU), a filament material that is pliable and can easily and comfortably fit to the contours of each individual's face. The use of TPU makes our masks unique. Most other designs utilize rigid polymer filament that cannot contour to the user's face and requires additional interfacing material such as foam or weatherproofing rubber to provide a secure and comfortable fit. The filter boxes are printed on a variety of 3D printers using a rigid polylactic acid (PLA) polymer filament. The filter boxes snap directly to the masks upon assembly. We use Cura (open-source software) and Simplify3D (Simplify3D, Cincinnati, OH) slicer software to convert the stereolithography (.stl) files to g-code files for each printer type. Due to the large print beds on the LulzBot Taz Pro models, five to eight masks can be fabricated per printer in a 12-hour window depending on the mask size. Additionally, we can print twelve filter boxes at a time on the larger printers and four on the smaller print beds. A team of engineering students, staff, and faculty are working 8 hour shifts, 7 days a week, 24 hours per day, which amounts to more than 600 masks and more than 700 filter boxes printed weekly. The printed components are then sanded down using belt and Dremel sanders, and head straps (tourniquet material) are added. Table 1 provides details of printer specifications used for fabrication of face masks, filter boxes, and headbands for the face shields printed at the COSMIAC research facility.

FACE SHIELD 3D PRINTING

Headbands for face shields are printed on a variety of 3D printers using rigid PLA and n-gen polymers. The 3D printing specifications enable printability with nozzles up to 1 mm and layer heights up to 0.5 mm. We can print two headbands per printer in a single layer setting, but we have created files that allow stacks of up to ten headbands per print. Because of the simple design, widely used polymer filament types, and broad printer specification that can be used, we have enlisted help from our community to print headbands for this purpose; we provide printer filament and the g-code files, and they return printed headbands. This partnership enables us to reduce production of headbands and increase production of masks. Our printers are among the only printers in the state currently 3D printing PPE that are capable of printing with TPU, thus enabling us to increase face mask production from our facility.

FACE MASK HIGH EFFICIENCY FILTRATION

Filters consist of two layers of hospital grade, high efficiency particulate air (HEPA) filter material without fiberglass: a flat 3M Filtrete MPR 1500 layer and a Honeywell Elite Allergen Pleated FPR 10 layer folded in an accordion manner to increase filtration surface area. Each layer has a minimum efficiency reporting value of 13, which captures large particles like dust, small particles like bacteria, and other virus carrying particles. Particle filtration efficiency testing has been completed on the sandwiched filters. Kaolin (clay mineral) aerosol was generated using a fluid bed generator (Model 3400A, TSI Inc, Shoreview, MN) and delivered to a mixing chamber. A real time aerosol monitor (Model 8533 DustTrak DRX, TSI Inc, Shoreline, MN) measured chamber concentration. A probe delivered the Kaolin to a 47 mm filter holder containing the sandwiched filters. Samples from the filter holder were extracted upstream and downstream and measured using an aerosol particle spectrometer (Model 3340 Laser Aerosol Spectrometer, TSI Inc, Shoreview, MN). Filter collection efficiency was calculated as: Efficiency (%) = 100*[1-(downstream conc./upstream conc.)]. Results of efficiency testing are shown in Figure 3. The filters achieved a particle capture efficiency of 95% at 270 nm (0.27 microns). For comparison, N95 respirators that are recommended in COVID-19 aerosolizing environments are commonly tested to ensure 95% particle capture efficiency at 300 nm (0.3 microns).

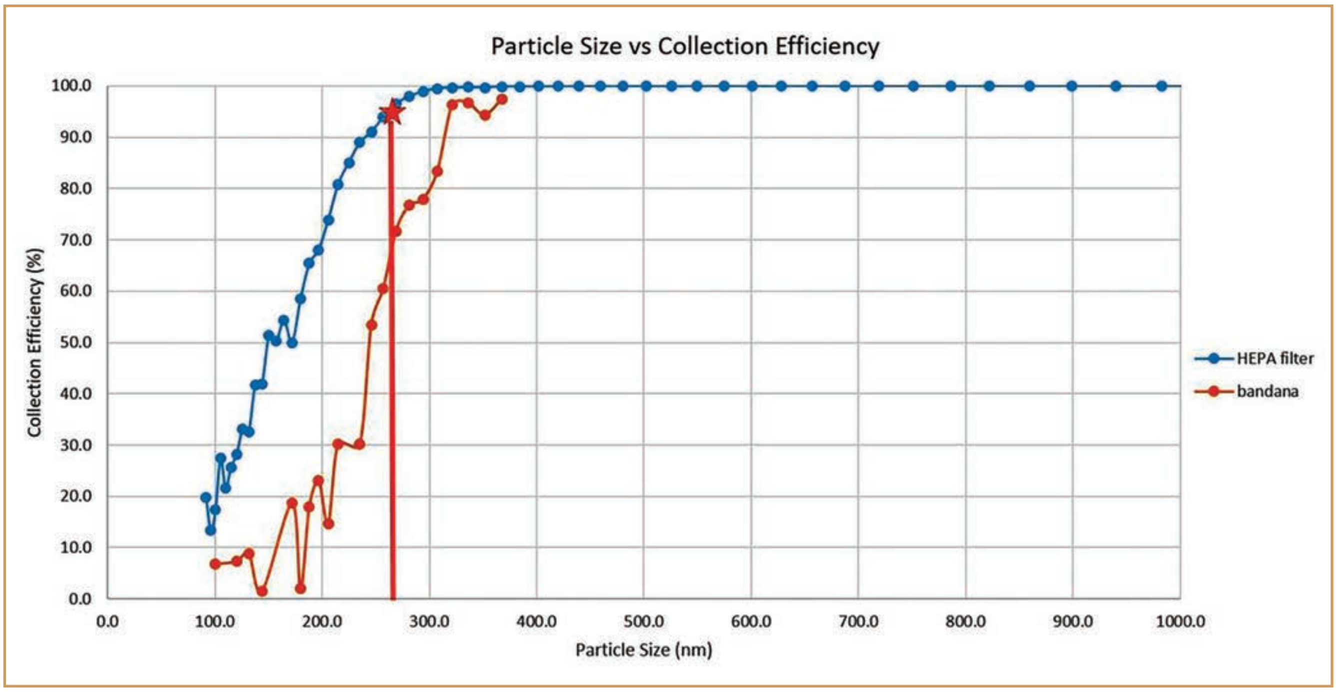
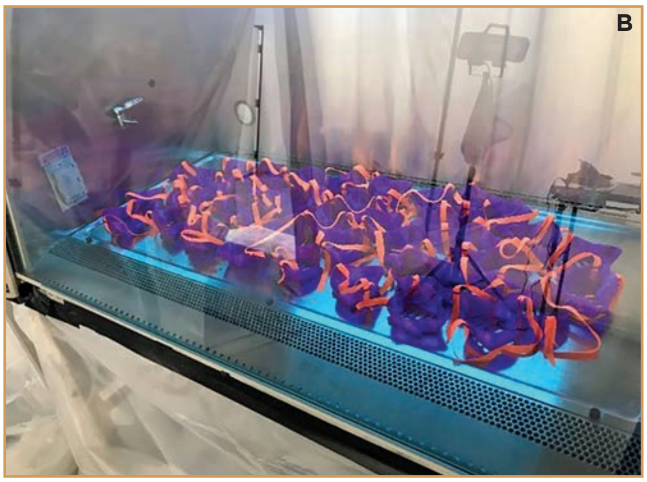


Figure 3. *Particle capture efficiency testing of the HEPA filters used in the face masks. The two filters were sandwiched together for testing. Upstream and downstream data were used to calculate capture efficiency of a range of aerosolized Kaolin particles from 100 to 1000 nanometers (0.1 to 1.0 microns) in size. A reference plot was generated from data collected of particle efficiency testing of a household bandana folded in half (2 layers) in order to show the effectiveness of the filters. Note that the red star indicates 95% particle capture efficiency of the filters at approximately 270 nanometers.*



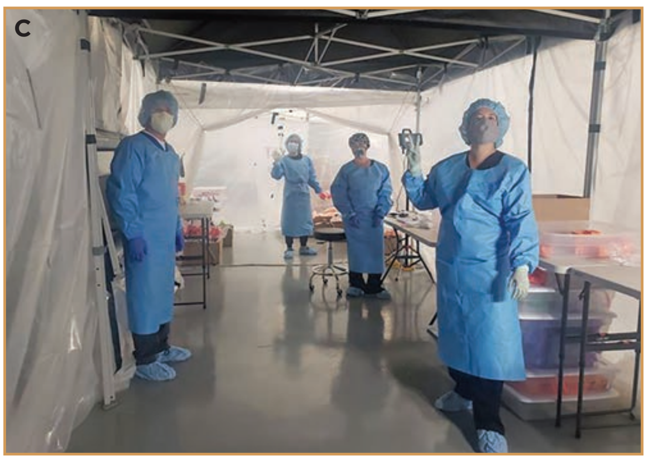


Figure 4. *A) Clean room facility modeled after disaster relief and emergency response shelters. This facility was used for sterilization, assembly, and packaging of face masks and shields. B) Biosafety cabinet with ultraviolet light used for post-processing sterilization of masks, filter boxes, and headbands for face shields. C) Nurses, paramedics, and other volunteers (primarily from the healthcare industry) staffed the clean room to ensure an aseptic environment.*

Figure 5. *Packaged masks and face shield headbands with appropriate labeling as directed by the United States Food and Drug Administration.*

FACE MASK STERILIZATION, ASSEMBLY, AND PACKAGING

Completed 3D printed masks, filter boxes, and headbands for shields are then transferred to a room for sterilization, assembly, and packaging. Using four adjacent 10 ft x 10 ft canopies completely enclosed in large plastic sheeting, we developed a portable "clean room" facility modeled after temporary emergency response and disaster relief shelters (Figure 4). Inside this facility, we maintain two Biosafety Level 1 cabinets with HEPA filtration and ultraviolet germicidal lamps with 40 µw/cm^2 intensity. The clean room is staffed by volunteers, primarily nurses and paramedics, employed in New Mexico at various hospitals and healthcare companies. We specifically selected trained medical personnel to work in this capacity because they are most familiar with working in an aseptic environment that was necessary for these tasks. Volunteers work 4 to 8 hours per day, comply with strict PPE requirements in the clean room, and assist with distribution of supplies across the state.

3D printed materials are first exposed to 15 to 20 minutes of ultraviolet light per side using the biosafety hoods. At the next station, volunteers hot glue the flat filter against the inner surface of the filter box ensuring a proper seal across all edges. At the third station, the accordion layer of filter material is added to the filter box. Mask and filter boxes are then snapped together and vacuum sealed in packs of four to six with FDA labeling corresponding to the mask (Figure 5). Headbands for face shields are exposed to ultraviolet light and then vacuum sealed in packs of 20 to 25.

AUTHORIZATION FOR DISTRIBUTION AND LESSONS LEARNED

As a state institution, it was necessary for us to ensure that anything fabricated by our students, staff, or faculty was safe for external distribution. The Governor of New Mexico, Michelle Lujan Grisham, requested that we complete three tasks prior to distribution:
1) ensure adherence to the FDA guidelines described in prior sections, 2) prepare a memorandum of agreement (MOA) with all FDA guidelines clearly delineated for any recipients, and 3) obtain approval from the state Medical Advisory Team (MAT). We consulted our university's legal team in order to prepare tasks 1 and 2. The legal team enlisted the assistance of an external lawyer with FDA experience to ensure we met all FDA guidelines. With the FDA instructions clearly defined and after a series of drafts and revisions, the university approved an MOA for external distribution of our masks and shields. Exactly 2 weeks from the fabrication of our first mask, on April 24, 2020, the state MAT approved the MOA, the FDA guidance, and the design of our masks. On April 28, 2020, the first MOA was approved by the McKinley County, NM manager, and we completed our first distribution to McKinley County Fire Department that day. We quickly faced a limitation on widespread distribution of our masks and shields. In order for the MOA to be official, a notary was required to witness signing of the document remotely online. Due to the lack of electrical power and limited Internet access of the most affected communities in our state, we were unable to complete this essential task. For the following week, we dispatched a notary to various regions of our state for in-person signing of the MOA. This enabled us to increase distribution to more regions, but unnecessarily risked exposure to our notary. We sought an alternative path toward widespread distribution. On May 5, 2020, we received broad approval from the New Mexico Department of Homeland Security (DHS) Secretary, Kelly Hamilton, to distribute our masks and shields freely across NM and in states adjacent to NM, with the only requirement to track the dispensing of our PPE and notify the DHS of these distributions.

IMPACT ON THE STATE OF NEW MEXICO

To date we have distributed 3,679 face masks and 2,395 face shields to the eastern parts of NN in NM (Newcomb, San Juan, Upper Fruitland, Burnham, Hogsback, Nenahnezad, and Crownpoint) and Arizona (Fort Defiance and Chinle); to other Native American pueblos in NM (Zuni, Zia, and Santo Domingo); and to the community and healthcare providers in cities that serve these Native American communities (Rehoboth McKinley Medical Center and Miyamura Alternate Care Facility in Gallup, NM). These distributions also included delivery to the Field Operations Officer for Emergency Operations for the Eastern NN, which covers Red Mesa, Arizona and Shiprock, Tohachi, Crownpoint, Torreon, and Tohajiilee, NM.

Furthermore, we have partnered with the New Mexico COVID-19 Emergency Supply Collaborative (www.nmcovid19.org) to increase understanding of the needs of communities, first responders, and healthcare providers in our state. We have planned distributions to San Felipe Pueblo and to all remaining chapters of the eastern parts of NN. Our aim is to continue to provide masks and shields to the communities disproportionately affected in NM and Arizona and to areas that continue to lead the entire US in per capita infections. We hope to saturate these communities with enough masks that we will only need to provide replacement filter boxes and filters to satisfy the 3 month suggested lifespan of the HEPA filters.

CONCLUSION

After identifying a need within our state during the COVID-19 pandemic and concluding that utilization of 3D printing resources could help this cause, we were able to effectively create a system for production, fabrication, and distribution of 3D printed face masks and shields by collaborating across institutions and governing bodies within our state. Although our efforts have resulted in distribution of 3D printed PPE to regions of NM and surrounding areas in great need, there continues to be a disproportionate rate of infection and death in northwestern NM counties. Despite this trend, NM is moving forward with the gradual reopening of businesses and restaurants in various regions of the state and decreasing restrictions on travel and mandatory stay at home quarantine. It is essential during this return to normalcy, that all NM citizens, first responders, and healthcare workers have access to proper PPE including N95 masks. Our hope is that the knowledge we have learned and the connections we have made throughout this ordeal, both advance technologies for 3D printed PPE and better prepare us for helping with a similar situation, should it arise, in the future.

Specifically, we aim to evaluate the face masks to determine whether they meet the classification requirements to be designated a "surgical mask intended to provide liquid barrier protection." These requirements include: standard test method for resistance of medical face masks to penetration by synthetic blood per ASTM F1862; flammability requirements per 16 CFR 1610 (unless labeled with a recommendation against use in the presence of a high intensity heat source); labeling that accurately describes the product as a surgical mask; and labeling that does not include uses for antiviral protection or particulate filtration claims. The addition of a liquid barrier fabric to the inner surface of the filter boxes, such as that used for surgical sterilization, would enable a reclassification of these masks. This would allow us to distribute them to a greater number of healthcare facilities for use in areas where liquid exposure is a risk. At this time, the FDA has not issued guidance for 3D printing devices meant to be classified as "filtering face piece respirators," even in the presence of this continued healthcare crisis.

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