
M E M O R A N D U M

April 15, 2020

To: Governors' Offices
From: Bill McBride, Executive Director
Re: The Additive Manufacturing Response to COVID-19

Introduction

As the COVID-19 pandemic disrupts global supply chains and manufacturing operations, the medical community faces a critical shortage of certain devices and personal protective equipment (PPE), particularly those essential for treating respiratory diseases like COVID-19: test swabs, respirators, ventilators and face shields. One potential solution to help bridge the gap between healthcare systems and their suppliers is the additive manufacturing community. Also known as 3D printing, additive manufacturing (AM) is a digitalized production process that layers material to build up a component into a finished product. The 3D printing process is a flexible approach to manufacturing, with labs small and mobile enough to be established in a basement if necessary.

With thousands of labs scattered around the country needing only the appropriate design blueprints and material to begin producing, AM has the potential to be a rapid, localized response option for healthcare systems in need. The AM community is proactively seeking ways they can support the crisis response, including creating and distributing head bands for face shields, ventilator splitters, test swabs and replacement parts for ventilators and respirators. As the AM community increasingly looks to serve as a stop-gap measure to bridge the equipment shortage, state governments should be aware of any sterilization and quality control issues surrounding deployment, potential legal concerns, and how they can assist in scaling production and distribution.

Action Steps for Governors

Amplify Need for Critical Equipment and Design Information: Governors can take the lead in calling for state solidarity in responding to the medical device shortages due to COVID-19. For 3D printing specifically, governors can announce the need for a central depository for design information and equipment manuals. Each state contains hundreds of AM labs, each potentially needing only a design blueprint to begin production. The AM community is often decentralized, and any gubernatorial announcement can centralize authority, synchronize efforts and target aid to healthcare providers based on need.

Advance Cross-Sector Mobilization: As the primary voice of state authority, governors have the unique ability to pull together disparate institutions for a common purpose. The shortage in critical medical equipment, combined with the interruption in manufacturing operations, necessitates a cross-sector response involving state emergency management, public health, education and commerce staff to work with the state's AM community to reduce roadblocks and find stop-gap measures.

Current Efforts

Both foreign and domestic additive manufacturers have already taken steps to support hospitals during the current crisis. The response can be separated into two categories: 1) production of critical equipment and devices, and 2) leveraging the AM community's widespread network to crowdsource designs and help match hospitals with local 3D printers.

Production: Many labs across the country are focusing on producing head bands for protective face shields as they are in high demand, require relatively less regulatory validation than other devices, and are technically feasible for most 3D labs. The PPE and other devices produced (including specially-crafted plastic objects for

use in opening doors and pushing elevator buttons) offer assistance beyond hospitals and healthcare organizations, protecting first responders, staff and residents in long-term care facilities, and essential workers.

- Colorado Governor Jared Polis created the Innovation Response Team Task Force to address critical COVID-19 issues, including production of PPE.¹ His administration is working with a local plastics facility to collaborate with other 3D printers to mass produce head bands for face shields.²
- Tennessee Governor Bill Lee is working with the state's Higher Education Commission to mass produce 10,000 3D-printed head bands for face shields by eight of the state's postsecondary institutions.³ The Tennessee Emergency Management Agency is collecting and distributing the items to local hospitals.
- Kansas Governor Laura Kelly and Secretary of Health and Environment Dr. Lee Norman announced that local 3D printers are helping address the critical shortage of nasopharyngeal (NP) testing swabs.⁴ The low number of swabs available is the limiting factor preventing the state's ability to conduct widespread testing. The state is working with local technology labs, universities, and dental offices to 3D print NP swabs at scale. Dental offices are uniquely suited to assist as most already use onsite 3D printers for molds and equipment and are largely available to assist given the cessation of non-emergency treatments.
- Ohio Governor Mike DeWine announced that Ohio State University's Wexner Medical Center designed a 3D printing program for test swabs. The medical center is working with a Toledo-based manufacturer on producing 15,000 swabs.⁵
- The West Virginia National Guard, in collaboration with researchers from West Virginia University, academia, and business and industry leaders, announced a coordinated effort to address personal protective equipment shortages via the 3-D printing of N95 masks.⁶
- The State University of New York and The City University of New York are 3D printing face shields for New York healthcare personnel.⁷

Leveraging Networks: Despite its decentralization, the AM community is also attempting to organize itself to scale production and map medical suppliers and local printers to healthcare providers.

- Massachusetts-based 3D printing company Formlabs launched a support service that attempts to match healthcare systems with the company's network of 3D printers. The company is working with healthcare providers, local government, and a volunteer network to design, prototype, and produce parts to be tested and adopted.⁸
- Addressing a looming ventilator shortage, residents at Massachusetts General Hospital drafted and released plans for a virtual, open competition—COVENT-19—which calls for inventors and designers to collaborate with medical experts to design a 3D-printed machine ventilator in 90 days.⁹
- North Dakota's Information and Technology Department, in partnership with the state university system, the Gateway to Science Museum and Microsoft, has launched the Personal Protective Equipment Portal to source designs for 3D-printed PPE.¹⁰

¹ <https://www.colorado.gov/governor/news/gov-polis-colorado-leading-example-and-taking-action-address-covid-19>

² <https://denver.cbslocal.com/2020/03/24/coronavirus-greeley-genesis-plastics-masks-3d-printed/>

³ <https://www.tn.gov/governor/covid-19/covid-19-daily-bulletin/2020/3/23/covid-19-bulletin-4---march-23--2020.html>

⁴ <https://governor.kansas.gov/newsroom/videos/>

⁵ <https://governor.ohio.gov/wps/portal/gov/governor/media/news-and-media/covid-19-update-april-15>

⁶ <https://governor.wv.gov/News/press-releases/2020/Pages/Gov-Justice-WV-National-Guard,-WVU-researchers-collaborate-with-community-and-technical-colleges,-businesses-to-address-PP.aspx>

⁷ <https://www.governor.ny.gov/news/amid-ongoing-covid-19-pandemic-governor-cuomo-issues-executive-order-requiring-all-people-new>

⁸ <https://formlabs.com/covid-19-response/>

⁹ <https://www.coventchallenge.com/>

¹⁰ <https://gatewaytoscience.org/nd-covid19/>

FDA Guidance

The U.S. Food and Drug Administration (FDA), the primary regulator for medical suppliers,¹¹ recently released guidance for industry on the regulatory process for ventilators and other respiratory devices during the current public health emergency.¹² While the FDA urges that wherever possible, healthcare facilities should use FDA-cleared ventilators or devices subject to the Emergency Use Authorization (EUA), it acknowledges that practices allowing for wider availability and flexibility may be required. The EUA authority allows the FDA to fast-track the availability and use of medical countermeasures during public health emergencies.¹³ The FDA will not object to limited modifications to the production process of ventilators and related respiratory devices. The guidance has two purposes: 1) to aid suppliers in adding production lines, and 2) to encourage alternative production sites to reduce bottlenecks in the supply line. The guidance also requests that any facility looking to produce medical devices but lacks previous experience in the field should send the FDA information on the product for an expedited review for an EUA.

Governors should be aware that while the FDA recognizes the potential for 3D printing to support the medical supply shortage, it maintains that certain 3D-printed equipment may be less suited for medical use. The agency recommends printers to work with the relevant device manufacturers where possible and to use original parts or those with the same specifications, dimensions and performance.¹⁴ The agency is amenable to discussing issues with manufacturers and facilities and offers an email address devoted to manufacturing questions.¹⁵

Fitness for Use Concerns

Technical Limitations: While 3D printing can help produce face shield bands and NP test swabs, there are concerns, especially with sterilization, about printing ventilator valves and respiratory devices, such as the N95 mask.¹⁶ 3D-printed PPE are best designed to provide physical barriers, but are less effective as a fluid barrier and lack sufficient air filtration quality, particularly as compared to FDA-approved N95 masks.¹⁷ Even with reusable face shields, the high-temperature required for sterilization may damage the shield.¹⁸

Quality Control: By its nature, the AM community is decentralized, and if hospitals receive 3D-printed material piecemeal from several sources, challenges may arise in protecting users and patients from defective material.¹⁹ Most 3D-printed PPE are designed for single use, significantly increasing quantity demanded, and as scale rises, concerns emerge on implementing safeguards and certifications, especially with volunteer or in-home facilities. Contamination risk is a concern under normal printing conditions, let alone the current environment posed by COVID-19, and only increases with storage, handling, and distribution processes that may be unfamiliar to many printers, especially those lacking experience manufacturing PPE at scale.

¹¹ The FDA released guidance in 2017 on 3D printing for medical devices. The guidance listed technical considerations on five areas: 1) materials used; 2) validation of the process from design to post-printing; 3) printing characteristics and parameters; 4) physical and mechanical assessments of final product; and 5) biological considerations of final devices, including cleaning and sterility. See <https://www.fda.gov/media/97633/download>

¹² <https://www.fda.gov/media/136318/download>

¹³ <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

¹⁴ <https://www.fda.gov/medical-devices/3d-printing-medical-devices/faqs-3d-printing-medical-devices-accessories-components-and-parts-during-covid-19-pandemic>

¹⁵ For additional information, email COVIDManufacturing@fda.hhs.gov.

¹⁶ Some healthcare additive manufacturers voice concern that the resolution required to manufacture a N95 mask is higher than most 3D printers can provide. Likewise, valves should be sourced from original manufacturers so components can be sterilized at specific heats and pressure levels. See <https://formlabs.com/covid-19-response/>

¹⁷ <https://www.fda.gov/medical-devices/3d-printing-medical-devices/faqs-3d-printing-medical-devices-accessories-components-and-parts-during-covid-19-pandemic>

¹⁸ <https://www.additivemanufacturing.media/blog/post/3d-printing-and-coronavirus-us-additive-manufacturers-share-their-experiences>

¹⁹ *Ibid.*

Legal Considerations: As 3D printers shift towards producing medical devices and other PPE, they may face potential legal liability issues—especially for those printers with no prior experience manufacturing medical devices. These liability issues are twofold. First, because many needed supplies and devices have patent-protected components, printers may worry they could be blocked from producing them or later sued for patent infringement.²⁰ Second, printers may worry that, in the event any supplies—particularly if brought rapidly into production—do not function properly against COVID-19, they might be held liable for illness or injury suffered by healthcare providers or patients.²¹ Federal and state governments, however, may possess avenues to address some of these liability concerns during emergency periods.²²

In the U.S., neither the Patent Act nor common law provides a full defense against patent infringement based on emergency or medical necessity; however, there are both legal and practical factors mitigating the risk of suit or significant damages.²³ Still, printers should be cautious of direct and indirect patent infringement considerations for creators of 3D printing files, distributors of such files, and printers that do the actual printing. Similar questions and considerations are raised around product liability, particularly when determining who should be liable if the device fails (e.g., the designer, machine manufacturer, printer). Ultimately, the legal liability issues facing 3D printers are novel and complex, and states interested in considering these avenues should continue to consult with private sector partners.

For questions or concerns related to the contents of this memo, please contact NGA staff:

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²⁰ <https://www.law.com/newyorklawjournal/2020/03/30/there-may-be-liability-concerns-for-a-private-sector-willing-to-step-up-to-produce-sorely-needed-medical-supplies-to-fight-covid-19-but-states-can-address-the-problem/>.

²¹ *Ibid.*

²² For example, the U.S. Department of Health and Human Services' March 17th declaration granted liability immunity with respect to certain treatments, devices, or equipment that the Secretary designates as countermeasures for the pandemic. See <https://www.govinfo.gov/content/pkg/FR-2020-03-17/pdf/2020-05484.pdf>. Another federal avenue could be through the Defense Production Act: "The Defense Production Act (DPA) provides the President with broad authority in times of national emergency to direct private industry to accept and prioritize performance of government contracts or to purchase essential materials or supplies. President Trump invoked the DPA on March 18. The President can now at any time issue "rated orders" to anyone with a suitable 3D printer, immediately turning those with 3D printers into government contractors, and requiring prompt production of the required supplies." Legal experts also note that state governments could attempt to provide manufacturers immunity for purposes of meeting supply shortfalls caused by COVID-19 through executive action. See <https://www.jdsupra.com/legalnews/covid19-ip-update-can-3d-printing-be-13183/>.

²³ "The value of assisting in the ongoing crisis and any associated goodwill is likely higher than exposure to risk. Nevertheless, these extraordinary circumstances likely limit the remedies available to a patent holder. The immense risk of public relations backlash against a litigious plaintiff could also serve as a natural limitation on true risk." See <https://www.jdsupra.com/legalnews/covid19-ip-update-can-3d-printing-be-13183/>.