

March 21, 2020

The Honorable Stephen Hahn, MD
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Hahn,

As local supplies of medical and other spare parts are exhausted, and the supply chain continues to degrade as more protective measures are put in place, there is an opportunity to fill gaps with locally manufactured (e.g. 3d-printed and other advanced manufactured) parts. We recognize that in situations such as this, part availability can make all the difference in life or death situations. The additive manufacturing industry is in a unique position to assist in solving supply chain shortages and is dedicated to working with our partners to quickly ensure these needs are met with quality and safe products.

America Makes serves as the national additive manufacturing innovation institute. As such, we are actively communicating with our members (hundreds of organizations), stakeholders and industry partners to assess capabilities and readiness to meet the needs of America's health care workers on the front lines of the COVID-19 crisis.

Many are answering that call and ready to assist, however the following critical roadblocks need to be overcome immediately before the community can respond effectively:

1. **Part Shortages:** Which PPE, parts, components are most needed in the next 10, 30, and 60 days.
2. **Consolidation of Designs:** There are currently many "unvalidated" designs for masks and other equipment from numerous sources on the internet. Producers/manufacturers need a single, reliable, accessible source to access "trusted" designs. The NIH 3D Print Exchange (<https://3dprint.nih.gov/>) could be the single repository for these "trusted" designs.
3. **Direction from FDA:** Manufacturers are eager to print masks and other medical equipment but want to do so according to proper standards/protocols so as to "do no harm." There is currently no directive for manufacturers to follow.
 - a. **Design** – Need some national authority to validate the N95 or other design for use (for medical, first responders, other clients). Otherwise these local manufacturers have no direction.
 - b. **Material** – Need material guidance on specific alloys, chemistries, polymers, and/or approved grades. If this information is not readily available, direction from regulatory authorities or medical personnel on desired characteristics, use, operating conditions (cleaning process, sterilization, etc.), and/or desired performance.

- c. **IP/Legal** – We need assurance that if we engage the 3D print community to make parts, they will not be sued. We are acting as Good Samaritans. This will limit our participation by manufacturers.
- 4. **Distribution Channels:** Manufacturers (additive and otherwise) require organized, efficient ways to distribute printed equipment to hospitals and other points of care. Currently, no procedure or protocol is in place.

America Makes is in a unique position to provide valuable counsel and direction to the many across the additive manufacturing industry looking to help and promote safe and appropriate designs that meet FDA standards for health care workers.

Without them there is too much risk that any of the dozens of open source designs and blueprints circulating now could be ineffective, or worse unsafe, wasting valuable time. We are urging the FDA to issue universal standards for additive manufacturers to follow when producing parts for front line health care workers.

Thank you. We look forward to discussing this very important issue with you further and are ready to assist in the effort to meet the needs of America's health care workers.

Sincerely,



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cc: The Honorable Lamar Alexander, United States Senate
The Honorable Sherrod Brown, United States Senate
The Honorable Rob Portman, United States Senate
The Honorable Tim Ryan, United States House of Representatives
The Honorable Haley Stevens, United States House of Representatives
The Honorable Anna Eshoo, United States House of Representatives
The Honorable Mike DeWine, Governor of the State of Ohio
Karas Gross, FDA
Suzanne Schwartz, FDA
Matthew DiPrima, FDA
James Coburn, FDA