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Manufacturing and Distributing Personal Protective Equipment in Response to COVID-19: What Higher Education Institutions Need to Know

SUMMARY

In response to widespread shortages of protective masks, face shields and other medical devices and device components (e.g., ventilators and ventilator parts) in light of COVID-19, some colleges and universities with the engineering and technological capacity are beginning to take advantage of 3D printing and other specialized equipment on campus to manufacture and distribute these products.

Those understandably laudable (and necessary) actions have often been undertaken under emergency circumstances and at the request of government or health care officials. Although liability concerns have not and should not take precedence, when time permits it is still important to consider the regulatory regimes that govern the manufacturing, distribution and marketing of protective equipment and medical devices that could apply to them as well as the risk of potential future product liability claims that go hand-in-hand with such “Good Samaritan” efforts. This alert discusses the current climate’s relaxed regulatory burdens, including the limited immunity afforded under the federal PREP Act, as well as general recommendations associated with warnings, warranties, disclaimers and other instructions associated with the manufacture, distribution and marketing of COVID-19 protective products.

Introduction and Purpose

As the unprecedented international demand for personal protective equipment (PPE) continues to rise, there is a pressing need for the manufacturing and supply of face masks, ventilators, face shields and the like to combat the escalating COVID-19 cases around the world. Colleges and universities with the capabilities to provide PPE are – generously so – eager to aid in the effort. Some institutions may even feel as though they have the “moral responsibility” or “obligation” to assist in such a time of crisis and need. In response to these pressures, many institutions are working to serve health care professionals by providing PPE using campus resources, facilities and pertinent technology. Additionally, institutions with 3D printers available on their campuses are providing PPE face shields and ventilators needed for health care professionals. And in the case of career and technical education programs, Secretary DeVos announced on April 15, 2020 that those programs can donate or loan PPE purchased with federal funds to public health agencies, private nonprofit hospitals and other licensed healthcare providers.

By way of a few examples, media reports indicate that a state’s public university and community college system signed a memorandum of understanding with that state’s Emergency Management Agency, and are currently providing PPE to hospitals statewide, either directly or through the Agency. Other public institutions are manufacturing hand sanitizer, sending masks and gloves and a professor at one of the colleges created a device on a 3D printer that can allow multiple patients to be treated with one ventilator. Likewise, another state’s Higher Education Commission announced that the public postsecondary institutions across the state would use existing 3D printers to manufacture medical supplies.

However, with these advanced capabilities and capacity to assist comes the concern that higher education institutions could be held liable if something goes wrong with one of their manufactured PPEs or if people using them get sick anyway.

Ensuring Regulatory Compliance While Filling Unmet Needs During COVID-19

Federal regulators are responding to the increased demand for medical devices and PPE with guidance that institutions should keep in mind. On March 26, 2020, the U.S. Food and Drug Administration (FDA or the Agency) issued answers to some frequently asked questions (FAQs) on [“3D Printing of Medical Devices, Accessories, Components, and Parts During the COVID-19 Pandemic.”](#)

Interestingly, but not unsurprisingly, the FDA does not address directly in the FAQ responses what, if any, liability a manufacturer would face for non-compliant manufacturing of medical devices during the COVID-19 crisis. The Agency has been issuing COVID-19-related [guidance](#) in a number of areas in order to support rapid disease response efforts. Generally, such guidance documents suggest eased regulatory burdens and enforcement discretion until the end of the pandemic. However, that latitude has limits, and the FDA and its federal agency counterparts have not been shy about taking enforcement action (e.g., for making unsubstantiated claims, for price gouging and for supply hoarding). For those entities donating their services and supplies altruistically, it is expected that regulatory agencies will not aggressively enforce regulatory requirements as long as minimum standards are met and unsubstantiated claims by manufacturers and those in the product supply chain are not made.

For colleges and universities thinking about 3D printing products to fill unmet needs, here are some important considerations:

- Not all products in need are regulated medical devices. For instance, face masks that are not intended for a medical purpose are not medical devices. As the FDA indicates in its [Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease \(COVID-19\) Public Health Emergency](#), face masks and respirators are devices when they are intended for a medical purpose, such as prevention of infectious disease transmission (including uses related to COVID-19). Face masks and respirators are not devices when they are intended for a non-medical purpose, such as for use in construction. When considering whether these products are intended for a medical purpose, among other considerations, the Agency will look at whether:
 - They are labeled or otherwise intended for use by a health care professional;
 - They are labeled or otherwise for use in a health care facility or environment; and
 - They include any drugs, biologics, or antimicrobial/antiviral agents.

For schools manufacturing face masks, it is important to not make warranties or representations about the products or suggest that they are suitable for use by a health care professional or in a health care facility or environment. Inadequate or misleading instructions about the functionality or intended use of the mask can create exposure to regulatory enforcement actions, and private actions for negligence and other product liability claims resulting from personal injury, as well as potential commercial claims for breach of warranty of fitness for a particular purpose. When possible, appropriate instructions should accompany each unit in an effort to optimize the end-user's receipt of the limited intended functions of the product.

- [Consider whether 3D printing is appropriate for the type of product being made.](#) As the FDA indicates in its FAQ responses, while it is possible to use 3D printing to make certain PPE, there are technical challenges that have to be overcome in order for PPE to be as effective as necessary. For example, 3D-printed PPE may provide a physical barrier, but 3D-printed PPE are unlikely to provide the same fluid barrier and air filtration protection as FDA-cleared surgical masks and N95 respirators. Again, insufficient or misleading warnings about PPE raises product liability and regulatory enforcement concerns. For example, indicating that a 3D-printed mask is comparable to an N95 respirator, without appropriate product testing and FDA vetting, could subject the institution to the claims and risks described above.
- [Avoid offering unsubstantiated information.](#) If a recipient of products 3D printed at your institution asks you questions about whether they should use the products, what kind of protection they offer, and what they should do when using your 3D-printed products, refer them to information published by the FDA and/or CDC, or consider creating an appropriate warning or disclaimer by consulting with experienced counsel. While it is tempting to be as helpful as possible during these difficult times, information offered in response to such questions could increase your institution's potential liability, both from regulatory compliance and litigation perspectives. If possible, schools should consider including warranty disclaimers and ensuring that the product labeling is consistent with its intended purpose.
- [Not all medical device components, parts, and accessories should be 3D printed.](#) If institutions are considering printing device components, parts, and accessories, the Agency points out in its FAQ responses that entities should use original parts or those with the same specifications, dimensions, and performance, if available. While it is possible to use 3D printing to print certain accessories, components, and parts, some complex products (e.g., working pumps, electronics) are not easily 3D printed. The FDA suggests that it may help to use plans from original parts when available and verify that any 3D-printed products fit and work properly before they are used in a clinical setting, working with relevant medical device manufacturers.
- [Contact the FDA if you are considering printing an entire medical device.](#) While the Agency understands that 3D printing may occur to fill unmet needs during the COVID-19 public health emergency, some devices are more amenable to 3D printing than others. The FDA encourages manufacturers to contact the Agency at COVIDManufacturing@fda.hhs.gov to engage with regulators on this point.

Again, while regulators are expected to take a more hands-off approach to altruistic (and perhaps some commercial) product manufacturing during COVID-19, it is important to ensure products meet minimum standards and are not labeled misleadingly.

Assessing and Limiting the Risk of Potential Future Liability

In addition to following minimum standards to ensure compliance with federal regulations, colleges and universities should take steps to minimize liability associated with the manufacture and distribution of PPE.

Product liability laws vary from state to state and their complexities are beyond the scope of this Alert, but product liability claims generally fall into three main categories: warnings (failure to warn or inadequate warnings), design defects, and/or manufacturing defects. Both strict liability and negligence concepts apply to each of the theories of liability. In addition, purchasers of the products may bring commercial claims for breach of warranty.

In an effort to protect colleges and universities from increased liability, the federal government has passed legislation to provide limited immunity related to the manufacture and distribution of PPE. Additionally, higher education institutions can implement quality controls, testing protocols, and labeling best practices to minimize risk.

Public Readiness and Emergency Preparedness Act (PREP Act) Declaration

In response to the COVID-19 crisis, the Secretary of Health and Human Services issued a Declaration on March 19, 2020 pursuant to the Public Readiness and Emergency Preparedness Act (the "PREP Act") for certain medical countermeasures. Except in cases of willful misconduct, the PREP Act provides limited immunity to colleges and universities manufacturing and distributing PPE in response to the COVID-19 pandemic.

The PREP Act (42 U.S.C. §247d-6d), which was passed in 2005, provides that "a covered person shall be immune from suit and liability under federal and state law with respect to all claims for loss" related to the "design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use" of "covered countermeasures" to a pandemic and epidemic. The PREP Act is highly detailed, and this section of the Alert is intended to introduce the main relevant provisions.

"Covered persons" includes manufacturers, distributors, "program planners", and licensed health professions authorized to prescribe, administer, or dispense the countermeasure. "Person" under the Act includes individuals, partnerships, corporations, associations, entities, or public or private corporations, including federal, state, or local government agencies or departments. Manufacturers, distributors, and "program planners" are broadly defined under the Act to include:

- **Manufacturers:** (a) a contractor or subcontractor of a manufacturer; (b) a supplier or licensor of any product, intellectual property, service, research tool, or component or other article used in the design, development, clinical testing, investigation, or manufacturing of a "covered countermeasure"; and (c) all parents, subsidiaries, affiliates, successors and assigns.
- **Distributor:** persons or entities engaged in the distribution of drugs, biologics, or devices, including manufacturers, repackers, common carriers, contract carriers, air carriers, own-label distributors, private-label distributors, jobbers, brokers, warehouses and wholesale drug warehouses, independent wholesale drug traders and retail pharmacies.
- **Program Planner:** a state or local government (including employees) supervising or administering a program with respect to the administration, dispensing, distribution, provision, or use of a "covered countermeasure", including persons establishing requirements, providing policy guidance, or supplying technical or scientific advice or assistance to administer or use the "covered countermeasure".

A "covered countermeasure" broadly includes drugs, biological products and devices designed to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic.

"Loss" under the Act includes (i) death, (ii) physical, mental, or emotional injury, illness, disability, or condition; (iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and (iv) loss of or damage to property, including business interruption loss.

The Act's limited immunity applies only if the covered countermeasure was administered or used during the effective period of HHS' declaration and used for the category(ies) of diseases and health conditions specified in the Declaration. For program planners and licensed health professions, the covered countermeasure must be administered or used by an individual who is in a population specified by the Declaration and was physically present or had a connection to the area specified in the Declaration. The Declaration currently went into effect on February 4, 2020 and extends through October 1, 2024.

Warnings and Disclaimers

Higher education institutions that manufacture and/or distribute PPE should also keep in mind the use of warnings, disclaimers, and

instructions on their manufactured products and equipment. While a warning label or disclaimer written on the institution's PPE may not provide a complete defense to a product liability claim, such a statement will inform users of the potential risks inherent in the use of the equipment. For example, institutions may want to consider providing a warning label on face masks that informs the reader that the institution's mask may not provide sufficient air filtration to prevent transmission of infectious agents. Consulting with counsel experienced in the drafting and defense of warnings is advised, particularly in this regulated environment.

By way of a real-world example and for illustrative purposes only, the Harvard Medical School Teaching Hospital and the Boston Children's Hospital shared a joint video about making a homemade reusable respirator mask in order to help individuals in need of masks during the shortage. In order to protect itself from liability, the video included the following legal disclaimer:

The device created as part of this publication should NOT be used as a replacement for conventional and approved Personal Protective Equipment. The device has not been industry tested nor has it been NIOSH approved. The publication of this article shall not constitute or be deemed to constitute any representation by the authors, their affiliates, and Boston Children's Hospital and is intended for educational purposes only. The decision to use this device is solely your own.

Providing a highly visible warning or disclaimer on institution-manufactured PPE will help mitigate the risk of product liability lawsuits, putting the end user on notice that the products may not be designed to perfection or insulate the user from COVID-19.

Indemnity Agreements with Medical Service Providers

Lastly, colleges and universities may want to consider entering into indemnification or similar agreements with hospitals or other partner health care institutions, whereby the providers agree to indemnify or hold the institutions harmless from potential claims arising from the PPE.

Concluding Thoughts

As the pandemic continues to create a national shortage of PPE and medical devices, higher education institutions are stepping up to manufacture, distribute and innovate new PPE to combat the virus and assist their community health care partners. Universities and colleges benefit from the limited immunity afforded by the PREP Act, and should continue to mitigate risk of product liability claims by examining existing quality controls and implementing product warning protocols.

Saul Ewing Arnstein & Lehr attorneys have combined experience representing colleges and universities and navigating this highly-regulated arena. If you have any questions, or need additional information, please reach out to Jonathan Havens, Steven Appelbaum or the other authors of this Alert. Jonathan began his legal career at FDA, where he served as a regulatory counsel and focused on promotion, advertising, and labeling, and currently serves as the co-chair of Saul Ewing Arnstein & Lehr's Manufacturing, Distribution and Retail Practice. Steven Appelbaum is a member of the Firm's Product Liability Practice and its Higher Education Practice.

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