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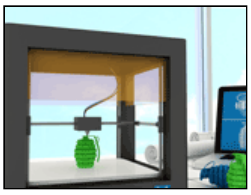
3-D PRINTING

The Food and Drug Administration recently updated its guidance on the design and manufacturing of 3-D printed medical products. Attorneys at Nutter McClennen & Fish analyze how the guidance will shape product liability law.

3D Printing

How the FDA's New 3-D Printing Guidance Informs Product Liability



Robyn S. Maguire and Valérie Imparato

Robyn S. Maguire is a partner in Nutter's litigation department and a member of the firm's product liability and business litigation practice groups. She may be reached at (617) 439-2493 or rmaguire@nutter.com.

Valérie Imparato is an associate in Nutter's litigation department and a member of the firm's product liability and business litigation practice groups. She may be reached at (617) 439-2138 or vimparato@nutter.com.

Introduction

In December 2017, the Food and Drug Administration issued final guidance applicable to prescription drugs and medical devices manufactured with 3-D printing technology, or additive manufacturing (AM). The FDA's recommendations are based on a review of 100 medical products made with AM that are currently on the market, as well as feedback from stakeholders in the AM industry. The recommendations follow draft guidance that the agency first promulgated in May 2016. In the words of FDA Commissioner Scott Gottlieb, the final guidance "provide[s] a comprehensive technical framework to advise manufacturers creating medical products on 3D printers." In a nutshell, the guidance suggests extensive device testing for AM products and internal checks preventing users from exceeding pre-established device specifications. It also recommends that users archive device files in standardized AM-specific formats and that they document materials used extensively.

Background

The guidance defines AM as "a process that builds an object by sequentially building 2-dimensional (2D) layers and joining each to the layer below, allowing device manufacturers to rapidly produce alternative designs without the need for retooling, and to create complex devices built as a single piece." This manufacturing process is used extensively in the aerospace, architecture, consumer products, and, more recently, medical industries.

The guidance is broadly organized into two topic areas: design and manufacturing considerations, and device testing considerations. The former provides designers and manufacturers with valuable information that will allow them to avoid some of the common pitfalls related to creating AM products. The latter relates to standards regarding the information that is required in pre-market submissions to the FDA involving AM products. In this article, we are primarily focused on the design and manufacturing considerations for AM products, and how those considerations will shape product liability law.

Guidance

The design and manufacturing section of the FDA guidance provides "technical considerations that should be addressed as part of fulfilling Quality System requirements for a regulated device made in whole or in part by AM." These recommendations are particularly useful for patient-matched device (PMD) designers and manufacturers, or manufacturers that customize devices to match patients anatomies.

First, the FDA recommends that designers and manufacturers compare the desired feature sizes of the finished printed product to the minimum possible feature sizes of individual AM machines. In making this recommendation, the FDA cautions designers to ensure that the particular AM machine being used is compatible with the design of the device.

Second, for custom devices, the FDA recommends that designers set clinically-relevant parameters within which a particular device design can be altered to fit a patient's anatomy without resulting in a change that would render the device defective. Accordingly, when those other than the designers seek to customize a device (such as clinicians), they will know what parts of the design can be customized, and what parts of the design can't. The FDA also notes that the designer of medical devices based on anatomical images should pay attention to image quality and resolution, any smoothing or image-processing algorithms that may alter the dimensions of the image, the rigidity of the anatomic features being imaged, and the clarity of the anatomic image—again, to ensure that the original design of the device or product is not altered in such a way that renders it defective.

Finally, the FDA notes that given that the AM process can involve interaction between several different types of software, designers should maintain standardized digital formats in order to avoid design defects that might result from file conversions. Designers and manufacturers should also extensively document all aspects of the AM process, from identifying CAD image file formats to describing the software validation process to documenting all materials used in the AM process.

In making these recommendations, the FDA recognizes that designers and manufacturers of 3-D printed products are particularly susceptible to liability, because the final printed product is based on a digital design that a third party will "manufacture" by use of a 3-D printer. Thus, unlike the proverbial Acme Corp., in the 3-D printing context there is no "manufacturer" in the traditional sense. Rather, any alteration to the digital design of a product after it leaves the designer's facility could lead to a product defect, even before the actual "product" is printed. These concerns are even further elevated in the medical context, where digital designs are routinely altered to become customized to individual patient anatomy. Accordingly, medical device designers and manufacturers are particularly susceptible to liability in the product liability context, where plaintiffs may bring claims against multiple parties under a theory of joint and several liability.

Considerations for Medical Device Companies

Given the FDA's guidance, as well as the threat of joint and several liability, manufacturers and designers of medical devices using AM should improve their processes in two areas: by tightening internal protocols regarding the design files, and by providing clear and accurate warnings to potential users. Specifically, attorneys should counsel medical device designers using AM to:

- work closely with clinicians on custom devices to be sure that the device designs are customized within the expected parameters;
- document all aspects of the digital design extensively, as any change to the CAD file that goes beyond the customizable parameters for a medical product can render it defective;
- provide users with information (in warnings and other promotional material) concerning the software that should be used in the AM process, to ensure that design file formats are compatible with the user's software; and
- standardize and/or specify the types of printer(s) compatible with the device design (in warnings and other promotional material) to ensure the product is made using a printer that is capable of accurately printing the manufacturer's design.

Conclusion

Given the dearth of case law in the AM context, it is still unclear how traditional product liability principles will be applied to this new area of medical device design and manufacturing. Nevertheless, in releasing the guidance, the FDA is clearly thinking about how patient care might be affected by this novel technology and how manufacturers can best ensure that their products maintain patient safety, especially when those products are customized to patients' anatomies. In the future, the FDA plans to release additional information and guidance concerning the role of nontraditional manufacturing facilities (such as hospital operating rooms, universities, and laboratories), as well as bio-printing of biological materials. Counsel, as well as medical device designers and manufacturers, should stay abreast of these issues as medical technology continues to evolve.

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