# Medical Devices Law & Industry Report<sup>™</sup>

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### **3D Printed Medical Devices: More Lawsuits and More Questions**







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hree-dimensional printing ("3D printing"), also known as additive manufacturing, has been in existence since the 1980s, but only recently has gained industry attention. Notably, in 2013, there was an estimated \$1.2 billion market for healthcare-related 3D printing. By 2018, this market is expected to explode to more than \$4 billion in this one narrow field. <sup>1</sup> 3D printing is expanding in the medical field because the technology has driven favorable outcomes via new and

<sup>1</sup> See http://tinyurl.com/md2zmpx.

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Appreciating the utility of 3D printing and the growing market, many hospitals now have their own 3D printers. Over the long run, in-house printing is expected to drastically reduce hospital costs associated with implants; while a hospital might have to spend significant dollars upfront to purchase the printer, it will subsequently be able to print devices at the cost of the raw materials. <sup>2</sup>

This increase in in-house printing of medical devices will likely subject hospitals to increased products liability litigation. Hospitals may face suits that sound in strict liability and suits applying a lower negligence standard. Moreover, hospitals might be more carefully scrutinized by FDA if their 3D printed devices result in negative outcomes. This article discusses the potential liability and regulatory questions surrounding in-house 3D printing and offers solutions in light of the changing landscape.

## Might a hospital be strictly liable for manufacturing a 3D printed medical device?

Traditionally, hospitals have not been subject to suit under theories of strict liability because they never have been considered a "manufacturer" or a "commercial seller" of medical devices. But, under some states' laws, hospitals might qualify as a manufacturer or commercial seller of medical devices similar to the Medtronics,

 $<sup>^2</sup>$  Kyle J. Trout and Justin N. Mullen, 20 Westlaw Journal Medical Devices 1 (2013).

Strykers and Depuys of the world if they opt make their own implants. This classification would result in significantly more litigation exposure.

Under current strict liability regimes, as encapsulated by the Third Restatement of Torts, "[o]ne engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect."" Strict liability will "not apply to a noncommercial seller or distributor of such products . . . [but] it is not necessary that a commercial seller or distributor be engaged exclusively or even primarily in selling or otherwise distributing the type of product that injured the plaintiff, so long as the sale of the product is other than occasional or causal." Illustrating this distinction, the Restatement explains that "a service station that does mechanical repair work on cars" but also sells tires would be a commercial seller, but "the occasional sale of surplus equipment by a business does not" qualify.

While 3D printed medical devices were initially created to address unique problems, hospitals will likely begin using them with more regularity as the technology gains popularity. More frequent printing could render hospitals "commercial sellers." A hospital who occasionally prints medical devices (unique or traditional) appears more analogous to the repair shop who occasionally sells tires than an outfit that occasionally sells surplus equipment. For this reason, it is possible that hospitals who print devices in-house might be subject to strict liability in the future. Given there are fewer defenses to strict liability, a hospital who prints its devices in-house would be well-served to examine its available indemnity and potentially procure extra products liability-specific insurance from its carrier to safeguard against possible litigation.

### Will hospitals see more negligence suits regarding 3D printed devices because a lower pleading standard will apply?

Another question raised by in-house printing of medical devices is what pleading standard will apply to the hospitals if they are sued for an alleged negligently designed printed device? In many jurisdictions, when doctors or hospitals are sued in negligence, a plaintiff must meet a higher pleading burden. This higher burden ensures that doctors are not so busy fending off medical malpractice lawsuits that they cannot perform, or will be deterred from performing, their jobs. For example, in Georgia, a complaint sounding in medical malpractice must be accompanied by an affidavit from a qualified expert (i. e. a doctor, nurse, etc. ) that sets forth at least one negligent act or omission committed by the defendant. <sup>4</sup> This higher pleading standard applies if the negligence suit "calls into question the conduct of a professional [e. g. a doctor] in his area of expertise. "5

Whether the heightened pleading standard will apply to a negligence claim premised on the design of a 3D printed device will likely hinge on a court's interpretation of the level of skill required to produce the device. In some instances, a medical professional might have to "design" the custom 3D printed device. For example, in the case of Kaiba Gionfriddo, doctors took a CT scan of his lungs in order to create the customized 3D printed device. While a technician without a medical degree could enter the CT scan information into the printer, that technician could not have conceptualized or "designed" the splint. As 3D printing becomes more popular and focuses on traditional devices, though, it is possible that hospitals will need little to no physician input to create a device. Accordingly, a heightened pleading standard might not apply to negligent design of a device if it becomes mechanized and routine like traditional device manufacturing.

Given this open question, hospitals should ensure that they extensively consent patients who receive 3D printed devices. Specifically, doctors should (1) ensure that patients are aware that the device was printed, (2) describe how the device compares to any potential alternative devices and (3) detail the potential risks unique to the printed device (e.g. potential diminished antimicrobial properties of the material used).

### Do hospitals need to do more to ensure that they comply with FDA regulations for 3D printed devices?

The recent surge of 3D printing in medical applications also has regulatory implications. But the breadth of those implications is still in flux. To date, the FDA has cleared several types of 3D printed devices including patient matched implants (e.g. skull plates, orthopedic implants, emergency and custom devices), orthopedic devices (e.g. hip cups, spinal cages, knee trays), patient matched surgical guides (e.g. craniofacial, knee, ankle) and dental devices (e.g. temporary bridges, reconstructive surgery support). Currently, these 3D printed devices are reviewed by the FDA through the existing regulatory pathways. However, the FDA is actively gathering information to address and regulate the area.

Notably, in October 2014, the FDA held a public workshop on 3D printing "to provide a forum for FDA, medical device manufacturers, additive manufacturing companies, and academia to discuss technical challenges and solutions of 3D printing."<sup>6</sup> While this workshop largely focused on the printing process, multiple participants echoed that the FDA needed to pay close attention to quality control and process validation issues potentially created by these devices. Therefore, hospitals should expect the FDA to issue future guidance and possible regulations that will address these issues and others as the use of 3D printing increases.

While nothing in the regulatory arena has officially changed to this point, hospitals should consider taking a couple steps to ensure compliance with FDA regulations as 3D printing increases. First, hospitals should consider engaging their institutional review board (IRB) even when it is not required. For example, "custom devices" do not require review and approval. A "custom device" is a device that, among other things, "is intended for use by an individual patient named in the order form of a physician or dentist, and is to be made in

<sup>&</sup>lt;sup>3</sup> RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 1 (1998).

<sup>&</sup>lt;sup>4</sup> See O.C.G.A. § 9-11-9.1.

<sup>&</sup>lt;sup>5</sup> Knight v. Sturm, 212 Ga. App. 391, 392 (1994); Baskette v. Atlanta Ctr. for Reprod. Med., LLC, 285 Ga. App. 876, 881 (2007); see also O.C.G.A. § 9-3-70.

<sup>&</sup>lt;sup>6</sup> http://www.fda.gov/medicaldevices/newsevents/ workshopsconferences/ucm397324.htm.

a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice."<sup>7</sup> Some 3D printed devices clearly fall into this category. While a hospital's IRB need not review devices for custom use, a hospital should consider having its IRB review its 3D printed custom devices. Further, hospitals should consider consulting with the FDA when planning on printing devices that will be produced on a larger scale. Early interaction with IRBs and the FDA will allow hospitals to spot issues before spending significant monies on printing.

### Conclusion

In the future we are likely to see increased litigation and regulation in the area of 3D printed medical devices. In addition to tracking these developments, hospitals would be well-served to examine their governing contracts to ensure that their current insurance coverage, indemnity agreements and informed consent procedures contemplate potential increased litigation in this arena. Hospitals should also seek preliminary guidance from their IRBs and the FDA when launching 3D printing projects to ensure compliance with current and future regulations.

<sup>&</sup>lt;sup>7</sup> http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm127067.pdf.