# The Liability of Hospitals and Doctors Printing 3D Medical Devices

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As 3D printing becomes more accessible, it will present significant liability questions for those injured by these devices. If a traditional manufacturer creates a 3D-printed device, that manufacturer is subject to products liability claims. But, when a hospital or doctor prints the device at their own facility, who is responsible if that device causes a patient harm? This article will provide a very brief overview of the existing legal landscape for those injured by medical devices printed by doctors and hospitals, but will not address the liability issues that arise when the 3D printer itself is defective.

## The Additive Process

The 3D-printing process involves building solid, three-dimensional objects from digital models, using an additive process in which successive layers of material are assembled on top of one another to build the desired device. The 3D printer can layer materials such as metal, plastic, medication and even human tissue, until that material matches the original digital model. Customized devices are printed for a variety of medical uses including surgery preparation, medical devices such as prosthetics, hearing aids, braces, casts and may one day create organs. Several companies specialize in 3D manufacturing and that number is growing. These companies use a conventional distribution process by receiving patient specifications, printing the 3D device in their own plant and shipping the device directly to the doctor or hospital.

3D printers, however, are becoming more and more accessible, and health care providers are taking advantage of the capability to print medical devices in-house, removing many of the tight controls that exist in these manufacturing facilities. When this happens, determining who is responsible to victims injured by a 3D-printed device becomes a more complicated question, as does determining which theory of liability will apply.

## Tort Liability

**• Strict Liability**

Currently, applying products liability principals to hospitals and doctors printing their own custom 3D

medical devices will prove difficult. Under the basic principals of products liability law, anyone injured by a defective product can hold the manufacturers and sellers of the product strictly liable as long as they engaged in the business of selling the product. But who is the manufacturer of a product created by a 3D printer, and can that manufacturer be a hospital or a physician? Currently, doctors and hospitals cannot be held strictly liable as suppliers of medical products. They are considered to be akin to a consumer or user of a product when the product's use is incidental to the provision of medical services, and are shielded from being held strictly liable. Additionally, if there is a defect in the product traceable to the software code, the predominant view is that software codes are not considered "products," and software designers are not responsible for the defects in the design of 3D products. This brings tremendous safety concerns for the patients that are on the frontier of this new technology.

As hospitals and doctors begin to print 3D devices in bulk quantities and sell them to their patients, the line distinguishing manufacturer and service provider will become increasingly blurred. Many believe that, eventually, public policy will favor imposing strict liability on doctors and hospitals that manufacture 3D devices. Until that happens, doctors and hospitals will continue to be shielded from strict liability claims for injury or death caused by medical devices that they design and print.

**• Negligence**

As the law stands now, victims injured by defective devices printed by doctors and hospitals will be relegated to a simple negligence cause of action. In strict liability, the manufacturer is liable for product defects regardless of fault; negligence is a fault-based doctrine and more difficult to prove. Victims will have the burden to prove breach of duty, causation and damages. This is a more difficult burden and the newness of the technology may present additional obstacles regarding the standard of care and causation. Location of expert witnesses could prove difficult, as the pool of experts who understand 3D printer best practices is likely to be very small at this stage of 3D innovation.

**• Malpractice Claims**

If a hospital or medical professional recommends or supervises the use of a defective 3D device, patients injured by that provider may file a medical malpractice claim. Medical negligence can be asserted when a procedure is performed incorrectly using a 3D-printed device, if there has been improper training for the use of the device, or there is a failure to provide informed consent with respect to the use and risks associated with the device.

The proper standard of care for a physician is that he must have and use the same knowledge and skill and exercise, and the same care normally used in the medical profession. If the physician is a specialist, then the standard of care is even higher in that the physician who professes to be a specialist in a particular field of medicine must have the same knowledge and skill and use the same care as others in that same medical specialty. Hospitals can be liable under a corporate negligence theory arising from the policies, actions or inactions of the institution itself.

**• Regulation**

The Food and Drug Administration (FDA) is the most visible regulator of medical device safety, and our robust tort liability laws serve as a backup to its regulatory powers. FDA approval can pre-empt state tort law claims and can impact defenses asserted in products liability claims. But, 3D-printed medical devices present challenges for the FDA, and many issues remain unclear. These medical devices are bespoke, made for a specific patient, surgery or procedure, and their customized

nature could mean that 3D-printed items may not be classified as medical devices by the FDA, or they may be considered Class I devices, negating the need for FDA approval, clearance or exemption. Other devices will have to seek 510(k) clearance, premarket approval, a humanitarian device exemption (HDE) or a custom device exemption. To date, the FDA has granted clearance though its 510(k) process for more than 85 3D-printed devices; no devices have gone through the FDA's more rigorous premarket approval process (PMA). Since all 3D-printed medical devices on the market thus far have been cleared by the FDA as substantially equivalent to existing, traditionally manufactured devices, they have had no impact on products liability pre-emption.

**• The Future**

There is a paucity of case law involving 3D-printed devices and tort liability, but there is genuine concern that these devices may cause harm to patients, especially those who are on the frontier of this new technology. Since it is widely anticipated that hospitals and doctors will significantly increase their production of 3D medical devices on-site, patients injured by these 3D devices will face legal hurdles. Strict liability theories are currently not a viable legal option, and victims will be forced to file negligence claims and medical malpractice claims, which carry heavier burdens. The FDA will have to continue to ensure that these products are safe, as well as properly regulated, until the law catches up with this rapidly evolving technology. •

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