New Liability and Compliance Issues?

3-D Printing of Medical Devices

By Michael P. Bruyere and Amanda Kunz Hall

3-D printing in the medical device arena has the potential to have as profound of an effect on product liability law as it does on medicine.

Innovation and excitement are alive and well in the health care industry. Rapid developments in additive manufacturing, or three-dimensional (3-D) printing, are driving phenomenal improvements in patient care. Yet the process of 3-D printing medical devices raises issues, specifically how will courts apply traditional product liability law to these devices should a defect occur.

Three-dimensional printing was invented over 30 years ago by a brilliant engineer, Chuck Hull. At its most fundamental level, 3-D printing began when an ink printer was modified to use various materials as the "ink" or powder and so it could build vertical levels of a design. In successive passes of the build process, the printing jet is slightly raised, and the printed material is added onto the previous layers. Understandably, the vertical printing process raised new and complex issues of design, geometry, layer adhesion, and material compatibility, to name only a few. There are myriad applications for 3D printing technologies, including architecture, construction, mechanical engineering, industrial design, the automotive industry, aerospace, military, the dental and medical industries, biotech (human tissue replacement), fashion, footwear, jewelry, eyewear, education, geographic information systems, and food. Three-dimensional printers are even being manufactured for home use now. While the cost per item is higher than conventionally manufactured items, setup expenses are far lower. For example, one aerospace firm cut its construction time by 70 percent and overall costs by 80 percent when it switched to manufacturing cable housing by 3-D methods rather than using conventional manufacturing.

Another benefit to the technology is the ability to customize a product to its end user's requirements. For example, custom-built hearing aids designed to fit the customer's ear canals, based upon photographs, can now be built in a matter of

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hours. In fact, scientists and engineers have developed design, material, and manufacturing processes and equipment that are bringing 3-D printing into the mainstream of health care delivery and the doctor-patient relationship. Among areas garnering significant media attention has been the additive manufacturing of prosthetic devices and components. Three-dimensional printing promises to build products faster, lighter, cheaper, with lower capital equipment costs and more personalized product production than those currently available through mass means. Additionally, this technology is pushing the production of the products themselves from the factory floor to a health care provider's office or facility.

By enabling medical providers to produce rapidly devices such as customized artificial limbs, dental devices, and exterior bracing such as the braces used to treat scoliosis, the availability of high-quality and low-cost devices has spread geographically and throughout the health care industry. Three-dimensional printing applications are currently in use or in development for pumps, stents, coils, surgical guides, and a host of orthopedic applications. Additive manufacturing is also pioneering the field of rapid prototyping, transforming practices for health care providers. For example, prototyping technology can translate an electronic imaging of a patient's brain tumor into a physical 3-D model of the brain and the tumor. This allows surgeons to hold and examine an exact model of the area upon which they will operate, thereby enabling a previously unknown level of detailed presurgical planning and practice to occur before a patient reaches a surgical suite. Three-dimensional printing is not, however, limited to inanimate structures.

Indeed, a subindustry known as "bioprinting" or "bio-manufacturing" is revolutionizing patient treatments. Using "ink" that contains living cells and other biocompatible materials (sometimes including the patient's own cells), it is now possible to print products made of living organisms. Life sciences additive manufacturers have successfully printed human skin and tissues for the bladder, urethra, and vagina. Additionally, printed living cell constructs for blood vessels, heart valves, livers, fingers, nerves, muscle, eyes, and other living structures are currently under development. One goal of this technology eventually is to print whole organs that could be implanted into a patient. While challenges with micro-vascularity suggest that we may be decades away from fully functional and implantable human organs, these products nevertheless hold promise for patient-specific implants and applications. Additionally, devices such as printed livers may offer alternatives to human and animal testing of drugs and medical devices. It should be no surprise, therefore, that the estimated market for bio-printed products is expected to reach $600 million within 10 years to over $10 billion in 30 years.

The regulatory and liability issues associated with additive manufacturing are evolving with the technology. At first blush, it would appear that there is no difference from a product liability perspective between a 3-D-printed device and one produced by traditional means. However, production of heavily regulated medical devices with this technology may result in new legal liability and regulatory compliance issues.

Traditional Product Liability Law

The basic tenet of product liability law is that "[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." Restatement (Third) of Torts, Products Liability, §1. There are several public policy considerations that underlie this area of the law. Manufacturers and sellers of products are in a better position than consumers to analyze and to inspect products to make sure that they are safe for their intended use. In addition, if something does go wrong, a manufacturer or a seller is in a better position to pay the costs associated with an injury or a death caused by a defective product than the consumer is. Indeed, a manufacturer or a seller of a product should not be allowed to profit from the sale of products without incurring the risk of having to pay for a consumer's injury or death in the event that the product is defective. Finally, product liability lawsuits and the threat of such litigation give manufacturers and sellers an incentive to provide safer products and to recall dangerous ones.

There are two basic theories of liability in product liability law: (1) strict liability and (2) negligence. In a strict liability claim, a product liability defendant can be held liable for injury or death caused by a defective product regardless of whether the defendant acted negligently. A product liability plaintiff simply has to prove that the product was defective and that this defect proximately caused the injury or death. The concept of "fault" is therefore absent because the focus is not on the actions or conduct of a defendant, but rather the design, development, and marketing of the defendant's product.

In a negligence claim, on the other hand, a product liability defendant can be held liable if it had a duty to exercise reasonable care, and it failed to fulfill that duty, and the breach of that duty proximately caused injury or death. Negligence consists of doing something that a person of ordinary prudence would not do under the same or similar circumstances or failing to do something that a person of ordinary prudence would do under the same or similar circumstances. In a negligence claim, a plaintiff essentially alleges that a product liability defendant's negligence resulted in a defective product.

In both strict liability and negligence claims, a product liability plaintiff must prove a product had a defect. A product is considered defective when it is unreasonably dangerous for its intended purpose. Under the Restatement (Third) of Torts, Products Liability, §2, there are three types of potential defects in the product liability realm. A manufacturing defect occurs when a product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product. A design defect occurs when the foreseeable risks of harm posed by a product could have been reduced or avoided by the adoption of a reasonable alternative design, and the omission of the alternative design renders the product not reasonably safe. Finally, a warning defect occurs when the foreseeable risks of harm posed by a product could have been reduced or avoided by reasonable instructions or warnings, and the omission of the instructions or warnings renders the product not reasonably safe. A defect must exist in a product "at the time

of sale or distribution." Restatement (Third) of Torts, Products Liability, §2.

The Restatement (Third) of Torts, Products Liability, §6 discusses defects in medical devices specifically. Under that section, a manufacturer of a medical device that sells or otherwise distributes a defective medical device is subject to liability for injury or death to a product liability plaintiff caused by the defect. As with all products, a medical device can be defective because of a manufacturing defect, a design defect, a warning defect, or a combination of these. For purposes of the Restatement, a manufacturing defect with respect to medical devices is the same as that for products in general—the medical device departs from its intended design even though all possible care was exercised in the preparation and marketing of the product. A medical device suffers from a design defect if the foreseeable risks of harm posed by the medical device are sufficiently great in relation to its foreseeable therapeutic benefits in such a way that a reasonable health care provider, weighing the foreseeable risks and therapeutic benefits, would not prescribe the medical device to any class of patients. A medical device is not reasonably safe due to inadequate warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to (1) the prescribing or other health care providers who are in a position to reduce the risks of harm in accordance with the warnings, or (2) the patient, if the product liability defendant knows or has reason to know that the health care providers will not be in a position to reduce the risks of harm in accordance with the warnings.

Applying the Law to a 3-D-Printed Product

Under traditional theories of product liability, the persons or entities responsible for a defective product are those who manufactured or sold the product. Historically, the same has been true for medical devices. Three-dimensional printers, however, require careful analysis to determine how traditional product liability law would apply to strict liability, breach of warranties, and negligence for medical devices manufactured with them. If an end user, for example, is injured by a defective product manufactured using 3-D printing, whom would he or she sue? The person who manufactured the defective product may, for instance, not be a commercial seller—as is often required by traditional product liability doctrines. The manufacturer of the 3-D printer, on the other hand, may have manufactured a perfectly well-functioning 3-D printer that created a defective product due to some other error in the process, thus limiting its liability under traditional principles. Perhaps the problem was with the CAD (computer-aided design) developer who created the 3-D product blueprint. Maybe the software designer who developed the software used to create the CAD and print the 3-D product should be held responsible. Perhaps the physician or other health care professional who produced the product using the 3-D printer made a mistake. Or should the owner of the 3-D printer, which will most likely be a hospital or a clinic, be held liable when a medical device created with a 3-D printer is defective? As you can see, the factors involved in liability for medical devices produced by 3-D-printing technology raise many questions and potential issues.

To determine whether any of the above parties could be held liable under a theory of strict liability or negligence or both, two primary considerations must be made. First, a person injured by a product created with a 3-D printer needs to determine if the person or the entity that he or she seeks to hold responsible can be considered a commercial seller because only commercial sellers can be held strictly liable under product liability law. A negligence theory, on the other hand, may apply to a potentially responsible individual or entity regardless of whether the individual or entity is engaged in commercial sale.

Second, a person injured by a product created with a 3-D printer must determine whether the potentially liable person or entity provided a "product." Under the Restatement (Third) of Torts, Products Liability, §19, a product is tangible personal property distributed commercially for use or consumption. Services, even when provided commercially, are not products. Without a product, there is no product liability claim, whether in strict liability or in negligence.

3-D Printer Manufacturer

A 3-D printer manufacturer is a commercial seller of a product, and thus could arguably be held liable in strict liability or negligence for a defective product produced by its printer. Although the 3-D equipment manufacturers do not control the use of their devices, they have a responsibility to design and manufacture equipment that can be relied upon to produce the designed product properly. Potential exposures for the printer manufacturers may focus on the clarity of the instructions provided with the initial setup of a printer, including the quality of the input material, accessibility of the troubleshooting protocol, and the product maintenance instructions.

Traditionally, inventors and designers have not been subject to strict product liability claims.

A person injured by a medical device created with a 3-D printer would face many challenges, however, in seeking to hold the manufacturer of the 3-D printer liable for the defective medical device that the 3-D printer manufacturer produced. First, although a defect in a 3-D printer could result in a defective end product, establishing proximate cause will likely be a challenge in light of all other possible contributing factors.

Second, any defect in a product must exist at the time of its sale or distribution. Therefore, a person injured by a medical device created with a 3-D printer will have to show that the 3-D printer was defective not only at the time that the defective end product was created, but also at the time that the 3-D printer left the printer manufacturer's possession and control. This could be difficult to show for printers with frequent use or numerous users.

Finally, if the U.S. Food and Drug Administration chose to regulate 3-D printers, making them subject to premarket approval, claims against 3-D printer manufacturers could be subject to an argument that potential state law tort claims were preempted by federal law—specifi-

cally, the U.S. Food and Drug Administration regulations.

CAD Developer and Software Designer

As explained above, a software designer develops the software used to create the CAD, and the CAD developer creates the CAD that is the 3-D product blueprint. Thus the CAD developer and the software designer each write the code that is fed into the printer to create the product. Can either of these parties be held liable in product liability under a strict liability or negligence theory for their roles in the chain that results in a 3-D product?

Both the CAD developer and the software designer could likely defeat an argument that they are "commercial sellers" for the purposes of strict liability by asserting that they are merely the product designers or inventors, not manufacturers. Traditionally, inventors and designers have not been subject to strict product liability claims. *Christain v. 3M*, 126 F. Supp. 2d 951 (D. Md. 2001).

Additionally, software designers and CAD developers could argue that they have no liability because there is no "product" involved. A software designer may attempt to argue that he or she has simply provided a service, not a product. Whether this argument prevails will likely depend on whether the software was custom designed. Marketed, non-custom software is typically considered to be a "product." Custom-designed software, however, may be considered a service.

A CAD developer, on the other hand, may argue that he or she is merely a "content" creator, and "content" does not meet the "tangible personal property" standard for a "product" within the Restatement. As one author suggested, the CAD "code" can be compared to the information contained in a book, and a number of cases hold that such "content" is not a "product" for product liability purposes. *See* Nora Freeman Engstrom, *3D Printing and Product Liability: Identifying the Obstacles*, U. Penn. Law Review, Vol. 162, no. 35 (2013) (citing *Winter v. G.P. Putnam's Sons*, 938 F.2d 1033 (9th Cir. 1991)).

Hospitals and Doctors

Finally, a person injured by a medical device created with a 3-D printer may seek to hold the hospital or doctor liable. Traditionally, hospitals and doctors are not held liable in product liability cases under strict liability or negligence theories. They are not considered to be commercial sellers of medical devices. As the Restatement (Third) of Torts, Products Liability, §20, comment d acknowledges, "in a strong majority of jurisdictions, hospitals are held not to be sellers of products they supply in conjunction with the provision of medical care, regardless of the circumstances." Instead, hospitals and doctors are viewed as service providers even if a defective product passed through their hands. As one court noted, "the contractual relationship between a hospital and a patient is not one of sale but is one of service; that during treatment in the hospital [medical products] for which additional charges are made may be transferred from the hospital to the patient; and yet the transfer is an incidental feature of the transaction and not a sale." *Howell v. Spokane & Inland Empire Blood Bank*, 785 P.2d 815, 821 (WA 1990).

Public policy supports this product seller as opposed to service provider distinction with respect to most medical devices. Hospitals and doctors are not in a position to make a better "product" for the typical medical device. Therefore, product liability litigation and the threat of such litigation against hospitals and doctors would do little to make medical devices safer. Given the fact, however, that 3-D-printed medical devices can be created at a hospital—with significant input from a doctor—the lines between manufacturer or seller on the one hand and service provider on the other will be much more blurred than with products manufactured in other ways, and public policy considerations may weigh more heavily in favor of imposing liability against hospitals and doctors for 3-D printed products.

Hospitals and doctors will likely have to anticipate and to address these public policy arguments to avoid liability for injuries caused by 3-D-printed medical devices. In addition, hospitals and doctors would benefit from instituting minor changes to their protocols to avoid liability for defective products produced by 3-D printers. For example, to strengthen the argument that they are service providers rather than commercial sellers of a product, hospitals should be wary of itemizing for the 3-D-printed product. Both hospitals and doctors may further benefit from indemnity agreements with either the software developer or the CAD designer of a 3-D printer.

Comparative Negligence

Questions also exist about how these products will affect a comparative negligence calculus. Traditionally, under strict liability, responsibility is pushed up the chain to a manufacturer. But, as discussed above, it is yet to be seen who will be considered the manufacturer when this type of equipment is used—the manufacturer of the 3-D printer or the manufacturer of the end product created by the 3-D printer. It is rare for an injured party to go after the company that made the machine that was used to produce the defective product in a typical product liability case.

Traditional risk-sharing doctrines such as "joint and several" liability that protect an injured party when some but not all of the tortfeasors can satisfy a judgment have been significantly weakened by tort reform in recent years. Someone can imagine a number of situations in which significant numbers of injured claimants are unable to recover for their injuries because products were manufactured by uninsured private parties using 3-D printers. Will this burgeoning industry force changes in tort liability doctrines or cause new laws to be enacted to clarify financial responsibility?

Conclusion

The effect that technological advances in manufacturing, including 3-D printing, will have on traditional product liability theories is difficult to predict. The main effect appears to be that 3-D printing will insert layers of possible defendants, specifically the 3-D printing equipment manufacturers and those who choose to produce products using these devices. The U.S. Food and Drug Administration has begun to conduct workshops for manufacturers of 3-D printer-produced devices to address a range of these and other evolving topics. What is clear now is that 3-D printing and other technological advances in the medical device arena have the potential to have as profound an effect on product liability law as they do on medicine. FD