LEGAL ISSUES OF 3D PRINTING TECHNOLOGY

By: Suzanne Billam

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Three-dimensional (3D) printing is generating quite the excitement in the health care industry, and the technology is moving rapidly. 3D printing, also known by the more technical term "additive manufacturing," was invented over 30 years ago by engineer Chuck Hull[1], but the technology significantly evolved in recent years. The prices of 3D printers have dropped substantially, with 3D printers even being manufactured and available for home use. 3D printing technology has tremendous innovative potential for many applications, including dental and medical, automotive, aerospace, military, fashion, eyewear, and construction, and even food. Due to this rapid growth, President Obama launched the National Additive Manufacturing Innovation Institute in August 2012, in an effort to foster collaboration and provide support for 3D printing technologies and products.[2]

The technology's capability of personalized product production is especially attractive in the medical industry. For medical devices, physicians are be able to customize medical devices to meet patients' needs, and in the future, print those devices on demand at a hospital or at the physician's own office, creating more treatment options than ever before. Another exciting

[1] http://www.cnn.com/2014/02/13/tech/innovation/the-night-i-invented-3d-printing-chuck-hall/
[2] http://manufacturing.gov/nnmi.html

prospect and radical way that 3D printing is shaping the medical industry is bio-printing, the 3D printing of human tissues by depositing cells layer-by-layer to grow organs.

In August 2015, the U.S. Food and Drug Administration approved the country's first prescription drug product made through 3D printing. This 3D-printed pill – Spritam® – is created and sold by Aprecia Pharmaceuticals®, is a dissolvable tablet used to treat certain types of seizures caused by epilepsy. Aprecia's proprietary 3D printing process, known as the ZipDose® Technology platform, binds the final drug formation without compression, creating a porous structure that rapidly disintegrates with the sip of a liquid, even at high dose loads.[3] It literally melts in your mouth with just a sip of water or other liquid, making it easier to swallow. Spritam® isn't available until early 2016, and then only by prescription.

Aprecia has now become the first major pharmaceutical company to print drugs, but the technology is sparking wide-spread innovation and excitement throughout the medical community. We may soon see medications and drugs customizable for specific patients and users – no more of the one-size-fits all approach, or even 3D printing that could potentially enable patients to print their own medicines at home. The pharmaceutical industry could eventually witness a transition from prescriptions to algorithms. Doctors could hand off an algorithm for patients to go print at home on a 3D printer rather than jotting down "take 2 and call me in the morning" on a sheet of paper.

But as access to the technology expands, so do concerns of legal issues surrounding regulation and product liability.

REGULATORY ISSUES

[3] *See* Aprecia Pharmaceuticals Press Release (Aug. 3, 2015), https://aprecia.com/pdf/2015_08_03_Spritam_FDA_Approval_Press_Release.pdf.

The FDA seems remarkably open to the idea of 3D printing, even while it acknowledges that the regulatory hurdles could be considerable. Before it approved the 3D printed pill, the agency had already approved the first 3D printed prosthetic[4], and has cleared numerous medical devices made using 3D printing additive manufacturing processes.

But many pressing unanswered regulatory issues associated with 3D printing include:

-How FDA intends to approach non-traditional device "manufacturers?"

-Will the FDA regulate the 3D printer or just the end product?

-Will the FDA view shared design files as the unauthorized promotion of the device if the device's benefits and risks are not disclosed?

-Will the design files of FDA Premarket Approved devices be available through the open source community, such that anyone can modify the design file to 3D print nonapproved devices?

-To what extent might FDA exercise its enforcement discretion for 3D products?

-When would a 3D printed device be considered a "custom device" that is exempt from premarket approval requirements and mandatory performance standards?

-What effect, if any, will any of these issues have on FDA's programs of inspection to ensure assurance with QS and GMP requirements and standards?

-If the FDA begins to regulate 3D printers, could potential state law tort claims be preempted by federal law?

TORT LIABILITY

[4] http://www.oxfordpm.com/news/article/2014-08-19_oxford_performance_materials_receives_fda_clearance_for_3d_printed_osteofab_patient-specific_facial_device.php

3D printing further presents challenges with regard to potential tort liability. The basic tenant 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. But, the rise of three-dimensional printers requires complex analysis in determination of how traditional product liability law would apply to theories of strict liability, breach of warranties, and negligence. The 3D printing process raises various scenarios of liability, including (1) defective original product used to create the digital design; (2) defective original digital design; (3) defective digital file; (4) corrupted copy of downloaded digital file; (5) defective 3D printer; (6) defective bulk printing material used in 3D printer; (7) human error in implementing the digital design; and (8) human error in using the 3D printer and/or materials. Product end users seeking to recover for injuries resulting from a 3D printed product could be left wondering: who is liable?

Whether an end-user can recover for injuries under a strict liability theory will depend on a number of factors, including whether the "seller is engaged in the business of selling" the product.[5] Could hospitals and healthcare facilities - which generally are not strictly liable for personal injuries arising from product defects – become considered a "seller" or "manufacturer" for purposes of either strict liability or negligence strictly liable as they begin to incorporate 3D printing in house? Would a hobbyist who occasionally uses 3D printing to make medication for a neighbor, which then injures a consumer, be subject to strict liability?

The challenges associated with asserting a strict liability claim in the context of 3D printing, may leave plaintiffs left having to pursue negligence claims. To prevail on a negligence

[5] *See* Restatement (Second) of Torts § 402A(1)(a) (1964); see also Restatement (Third) of Torts § 402A (1998); Drug and Device Law, Feb. 5, 2015, http://druganddevicelaw.blogspot.com/2015/02/some-ideas-about-3d-printing.html

theory, one must prove the existence of a duty of care, breach of that duty, proximate causation, and resulting damages. But then, who owes a duty of care to the plaintiff?

The precise effect of these technological advances on traditional product liability law is difficult to predict. But it is abundantly clear, that as 3D printing continues to unsettle traditional manufacturing, products liability law will likely evolve to accommodate the new, and ever growing, technology.