3D Printed Pharmaceuticals and Devices Article Series: Assessing, Managing, and Insuring Against Risk in the Next Era of Drugs and Medical Devices – Part 2

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The prior installment of this three-part series gave an overview of the 3D printing industry and process and how the FDA is beginning to approach the regulation of 3D printed drugs and medical devices. This second installment outlines some of the risks and uncertainties with respect to liability for 3D printed drugs and devices. The third article in the series will discuss insurance considerations and best practices, in light of these risks and uncertainties.

Naturally, how the FDA treats a drug or medical device has implications for product liability. Under *Riegel v. Medtronic, Inc.*, 522 U.S. 312 (2008), *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 512 (1996), and related cases, some state law tort claims regarding medical may be preempted—and therefore barred--under the Medical Device Amendment of 1975. Devices cleared by the FDA under the less rigorous "substantial equivalence" standard under the 510(k) process generally are not immune from tort claims under principles of federal preemption. Thus, how 3D printed drugs or devices are classified will be crucial to assessing potential liability for product liability. Companies bringing a 3D printed product to market should consider the advantages and disadvantages of the FDA approval, clearance, or exemption options available for the product—including the advantages and disadvantages for tort liability protections. These entities should also contemplate the parameters of a document retention policy that will span the life of the 3D printed product and any related liability claims.

How Will 3D Printed Drugs and Devices be Treated Under the 50 States' Product Liability Law?

Uncertainty regarding strict liability

3D printing raises both philosophical and logistical questions with respect to product liability law. On the philosophical side, the imposition of strict liability on product manufacturers and sellers has often been justified by contending: (1) product manufacturers and sellers (often large companies) are better able to absorb and distribute the losses associated with the social costs of accidents arising from product defects than injured individuals; (2) enterprises are better able to respond to safety incentives posed by liability rules than individuals; and (3) it is 'only fair' that those who profit from the imposition of risk should bear the costs of accidents caused by defects in their products.[1]

But 3D printing is a fundamentally democratizing technology, allowing a whole host of new entities (including doctors, hospitals, and patients themselves) to create products. This means strict liability may apply beyond the traditional manufacturers and sellers that have profited from the product or that are most capable of absorbing costs and responding to liability. That prospect raises philosophical questions of whether strict liability should apply. The more pressing question for stakeholders is the likelihood that courts (and possibly legislatures) *will* apply it, whether it makes philosophical sense or not.

[1] *See* Nora Freeman Engstrom, 3D Printing and Product Liability: Identifying the Obstacles, 162 U. PA. L. REV. ONLINE 35, 41 (2013); *Greenman v. Yuba Power Prods., Inc.*, 59 Cal 2d 57 (Cal. 1963).

The various states may apply strict liability to any number of parties in the product's chain of distribution: (1) the manufacturer; (2) the manufacturer of a component part; (3) the seller or distributor; and (4) the assembler or installer. Some may extend liability even to designers. 3D printers, themselves, fit fairly well within standard paradigms for product liability. But the 3D printing process—where a non-commercial manufacturer or seller creates or distributes a product that began with a software file—challenges the traditional understanding of designer, manufacturer, seller, and even product.

Strict liability was originally the creation of the California Supreme Court, which first held that manufacturers could be liable without fault for injuries caused by a defective product.[2] Strict liability was then included in the Restatement (Second) of Torts and widely adopted thereafter.[3] In pursuing claims in strict liability it is critical to identify the commercial manufacturer, seller, and the product. These elements are so critical; in fact, that some have conjectured that there could be many instances in which no one is strictly liable for an injury caused by a 3D printed product because the commercial manufacturer, seller, or product cannot be sufficiently identified.[4] But this prediction may assume product liability law is more static than it is—or at least than it has been in the past. At this stage, the compatibility of 3D printing and product liability law might simply be better viewed as a series of questions than answers.

What is the product?

The first question in strict liability is what, exactly, is the "product." A 3D printed drug or device begins with a computer file. So does this software become a product for purposes of product liability? So far the answer is no, but this could certainly change. Courts addressing the question in other contexts have concluded that software is not a product.[5] Similarly the Ninth Circuit held that information in a book is not a product for the purposes of product liability.[6] Electronic code also does not constitute a product under the Restatement (Third) of Torts, which defines a product as "tangible personal property distributed commercially for use or consumption."[7]

But this is unsettled and likely evolving. At least three courts have concluded that intangible items, like electricity, qualify as products for the purpose of strict liability.[8] Aeronautical maps and charts have also qualified as products for the purposes of strict liability.[9] And even the dictum in *Winter* suggested that computer software could in some circumstances be considered a "product."[10]

Has the product undergone a substantial change?

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[2] *Greenman*, 59 Cal 2d 57 (1963).
[3] Restatement (Second) of Torts § 402A (1965).
[4] Engstrom, *supra* note 13, at 37.
[5] *See, e.g.*, *U.S. v. Aleynikov*, 676 F.3D 71, 73 (2d Cir. Apr. 11, 2012) (reversing a criminal conviction under the National Stolen Property Act because the stolen computer source code was not a stolen "good" within the meaning of the statute); *ClearCorrectOperating, LLC v. Int'l Trade Comm'n.*, No. 2014-1527, 2015 WL 6875205 (Fed. Cir. Nov. 10, 2015) (concluding 3D printed files are not material things).
[6] *Winter v. G.P. Putnam's Sons*, 938 F. 2d 1033, 1039 (9th Cir. 1991); *see also Lewin v. McCreight*, 655 F. Supp. 282, 284 (E.D. Mich. 1987) (holding a publisher did not have a duty to warn of defective ideas provided by third party authors); *Way v. Boy Scouts of America*, 856 S.W.2d 230, 239 (Tex. App. 1993) (holding that the information contained in a magazine and supplement was not a product within the meaning of the Restatement (Second) of Torts).
[7] Restatement (Third) of Torts: Prods. Liab. § 19 (2015).
[8] *Smith v. Home Light and Power Co.*, 695 P.2d 788, 789 (Colo. 1984); *Schriner v. Pa. Power & Light Co.*, 501 A.2d 1128, 1133 (1985); *Stein v. So. California Edison Co.*, 7 Cal. App.4th 565, 571 (1992).
[9] *See Brockesby v. U.S.*, 767 F.2d 1288, 1295 (9th Cir. 1985) (holding an aeronautical chart was defective); *Saloomey v. Jeppesen & Co.*, 707 F.2d 671, 676-77 (2d. Cir. 1983) (holding navigational charts were defective).
[10] *Winter*, 938 F.2d at 1036.

Next, assuming a plaintiff can establish that the software at issue is a product, the question is whether the product has substantially changed. Software itself cannot physically cause harm—only the drug or device that is created from the software design could do that. And The Second Restatement requires that the product reach the consumer without substantial change.[11] Courts may, as they have in the context of architecture plans, view the transformation of a digital design to a tangible drug or device as a substantial change in the product that prevents the plaintiff from prevailing by arguing the defendant's strict liability.[12] But if courts begin to expand their notions of products wide enough to include software, they will likely also adjust their analysis regarding what constitutes substantial change.

Who is a commercial seller?

Finally, there is a lingering question regarding who, exactly, constitutes a commercial seller. For states that have adopted the Second Restatement, strict liability applies only to commercial sellers and not occasional ones. For 3D printed products, there are myriad potential non-traditional sellers (such as doctors or hospitals) that may not ultimately qualify as commercial sellers. Hospitals, for example, are typically viewed as service providers and not product sellers for the purposes of strict liability.[13] And tracing the chain of distribution back to the software may offer little reprieve. Independent designers of products are generally not held strictly liable for defects in their designs.[14]

However hospitals or providers who print their own drugs or devices may see their status shift if they begin doing so in higher volume or providing the products to more than just their own patients. And designers, who are presently unlikely to be deemed a manufacturer or product seller and who most states don't treat as part of the chain of distribution for purposes of strict liability, may also see their status change—and their potential liability expand--as this technology evolves.

Liability questions regarding negligence claims

Because of the potential challenges in applying strict liability to 3D printed products, plaintiffs may try to assert negligence claims. Rather than needing to identify commercial sellers or manufactures and a recognizable product, a claim alleging negligence focuses on the duty that potential defendants may owe to the injured party. Under a negligence standard, a plaintiff must prove that the defendant owed the plaintiff a duty of care, breached that duty of care by failing to act at the level of care of an ordinarily prudent person, and that the plaintiff's injuries were proximately caused by the breach of duty.[15] Negligence is a viable alternative to strict liability, but poses its own challenges. Establishing the standard of care for the various entities or persons involved in the ultimate production of a 3D printed drug or device, and solidifying the expert testimony in support of that standard, may be a winding road for plaintiffs who seek to establish claims against new types of defendants in these cases.

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[11] See Restatement (Second) of Torts § 402A(1)(b) & cmt. P.
[12] *See, e.g.*, *K-Mart Corp. v. Midcon Realty Grp. Of Conn. Ltd.*, 489 F. Supp. 813 (D. Conn. 1980).
[13] *See, e.g.*, Restatement (Third) of Torts, Products Liability, § 20 (2015) ("[I]n a strong majority of jurisdictions, hospitals are not to be sellers of products they supply in conjunction with the provision of medical care, regardless of the circumstances."); *Cafazzo v. Central Medical Health Serv.'s, Inc.*, 668 A.2d 521, 532 (1995) (reasoning that hospitals are suppliers of services rather than products by stating "The thrust of the inquiry is thus not on whether a separate consideration is charged for the physical material used in the exercise of medical skill, but what service is being performed to restore or maintain the patient's health.").
[14] Melissa Evans Buss, *Products Liability and Intellectual Property Licensors*, 27 WM. MITCHELL L. REV. 229, 313-14 (2000).
[15] *See* Restatement (Third) of Torts: Liability for Physical Harm § 3.

On the other hand, stakeholders in the 3D printing process for a product may face an expanded field of potential negligence claims. The democratizing nature of 3D printing poses unique hazards that may lead to expanding theories of liability. In contrast to other types of manufacturing in the medical device and pharmaceutical arenas, for example, there is a much higher likelihood that many 3D printed products or variations of products may be manufactured by novice, untrained producers (such as health care providers). This may give rise to heightened duties to warn, instruct, and even train than courts have previously entertained. The placement of a 3D printer in a health care facility, for use by its personnel, may also give rise to greater duties to inspect, maintain, and repair the printer on a regular basis—and to safeguard against misuse.

Finally the democratizing nature of production poses unique challenges for recalling a flawed design, once distributed. Given how 3D printers, design files, and their products can be widely distributed, stakeholders will likely face unique challenges in recalling products that were disseminated beyond the original purchaser and, potentially, beyond the borders of the United States.

The Potential Claims Ramifications of an Unorthodox Supply Chain

One of the greatest uncertainties regarding 3D printed pharmaceuticals and medical devices may be the future treatment of health care providers who are found to be the ultimate "manufacturer" of the product. If courts continue the current course, and do not treat health care providers as manufacturers or sellers, those who pursue negligence claims against doctors or hospitals may face either heightened pleading standards for professional negligence or limits on recoverable damages. Both may drive claimants who would otherwise confine their claims to allegations against the doctor or hospital to pursue theories of liability against other stakeholders in the supply chain. On the other hand, if doctors or hospitals no longer enjoy the current protections of heightened pleading standards or damages limitations, the increased exposure may trigger a greater number of cross-claims for indemnity and contribution.

The Interplay Between Shifting Theories of Liability and Existing Product Liability Legal Doctrines

As courts begin to address the concepts of product and manufacturer in the context of 3D printed drugs and medical device, other tenets of product liability law may offer guidance to defendants. For example, the first federal court to examine the issue confirmed that the learned intermediary doctrine will continue to apply to such claims (This doctrine states that a manufacturer of a product has fulfilled his or her duty of care by providing all necessary information to a "learned intermediary" who then interacts with the end user of that particular product). In *Buckley v. Align Technologies Inc.*, the district court held that the manufacturer of custom orthodontic aligners had no duty to warn the patient that the aligners would not treat malocclusions.[16] The court concluded that the learned intermediary rule barred the plaintiff's claims against Align because she had not alleged that Align somehow misled the plaintiff's dentist (the "learned intermediary").[17] And defendants involved in the chain of distribution for a 3D printed drug or device that is a copy of a non-3D-printed drug or could also argue they are analogous to manufacturers of generic drugs, which enjoy preemption protections. The software designer, or even the manufacturer of a 3D printer itself, might also argue that they are akin to component parts suppliers, which in many states are not liable in strict liability for finished products that incorporate their components.[18]

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[16] *Buckley v. Align Tech., Inc.*, No. 5:13-CV-02812-EJD, 2015 WL 5698751 (N.D. Cal. Sept. 29, 2015).
[17] *Id.*
[18] *See, e.g.*, *Taylor v. Elliot Turbomachinery Co., Inc.*, 171 Cal.App.4th 564 (2009).

Having now given an overview of 3D printed drugs and medical devices, early regulatory treatment, and the risks and uncertainties facing stakeholders in the chain of distribution, the third installment of this three-part series will discuss potential best practices for risk mitigation and insurance considerations for this dynamic industry.

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