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STRICT LIABILITY AND 3D-PRINTED MEDICAL DEVICES

By: Eric Lindenfeld & Jasper L. Tran. December 11, 2015.

The 3D printing of medical devices is now a reality. The rapidly expanding field allows for incredible improvements in patient care, especially with regard to cost-effectiveness, productivity, and a greater democratization and collaboration of design and manufacturing. 3D printing technologies have also expanded capabilities for mass customization of products.^[i] For example, using only photographs, custom-fit hearing aids can now be designed in a matter of hours to mold perfectly to a patient's ear canals. This same type of customization is occurring regularly on artificial limbs, dental implants, and exterior spinal bracing used in patients with scoliosis or paralysis. A related field, 3D bioprinting, has already made it possible to cure previously untreatable conditions by allowing for the implantation of human tissue on diseased bladders, tracheas, and hearts.^[ii] Given the incredible potential for these technologies, it is unsurprising that the market for 3D-printed devices is expected to be worth \$2.16 billion by 2020, with the bio printing market worth nearly \$6 billion.^[iii]

The Problem

Despite the strong promise of 3D printing for healthcare's future, there are critical concerns and unknowns regarding the framework for potential tort liability. While to date there has been only a single product liability lawsuit involving a 3D-printed product,^[iv] there are fears that 3D printing will present significant safety concerns for the first wave of consumers.^[v] Consumers faced with significant injuries as a result of 3D-printed products will have significant medical bills but no real opportunity to be made whole. This problem becomes increasingly troublesome when one considers that adequate safety principles, standards, and quality necessarily lag behind in any new advent or technology. 3D printing, in effect, will serve as one of the first technological advances to disrupt the product liability regime first envisioned, and eventually instituted, by Justice Roger Traynor of the California Supreme Court.^[vi]

Applying traditional product liability principles to 3D printing represents a complicated task. For example, under basic principles of product liability law, those injured by defective products are able to hold those who sold or manufactured the product strictly liable as long as they "engaged in the business of selling such a product."^[vii] The questions then arise: who is the manufacturer of a product created by a 3D printer for the purposes of liability under the Restatement? Could a hospital be considered a manufacturer of a defective 3D-printed product or as "engaged in the business" of selling the product? Thus far, courts have held that hospitals cannot be held strictly liable as "suppliers" of medical products.^[viii] Another possibility is holding the manufacturer of the 3D printer itself liable. However, imposing such excessive liability on the manufacturer for any future equipment the 3D printer may make would be inconsistent with prior case law dealing with analogous manufacturers.^[ix] For example, manufacturers of welding torches or industrial robots used to create automobiles have not been held responsible under strict liability for everything created by that equipment.^[x] More importantly, holding 3D printing manufacturers strictly liable would place a stranglehold on the 3D printing industry just as it is beginning to blossom. Given that 3D-printed technologies in the medical realm are poised to transform nearly every sector of the industry, it would be ill advised to suppress the technology as its benefits have barely begun to be realized.^[xi] The final option would be to hold the CAD software designer liable for a defective product created from a 3D printer.^[xii] However, so far, courts have also taken a strong stance on the issue, ruling that in most situations product designs, especially software codes, are not "products" as contemplated by the Second Restatement.^[xiii]

Given the tremendous challenges with asserting strict liability claims, and absent any concerted change by courts, plaintiffs will eventually be relegated to simple negligence causes of action. To succeed on a negligence cause of action, the plaintiff has a burden of proving duty, breach of duty, causation and damages. Although negligence in the 3D printing context itself poses new difficulties regarding duty of care and causation, negligence has traditionally been a much harder cause of action to prove.

The Solution

To avoid such an undesirable result, it is imperative that courts make a concerted effort to redefine the boundaries of product liability law to account for new technologies and make room for liability to those supply chains that do not engage in traditional manufacturing. More specifically, the most realistic approach to the problem would be for courts to uniformly hold CAD software designers responsible for the defects related to design of the 3D-printed products.

The rationales articulated by Justice Traynor for imposition of strict liability for product defects are equally applicable for the CAD software designers of medical products. For example, Justice Traynor emphasized that the underlying policy motivations of strict liability are threefold: (1) the difficulty in proving negligence in defective products, (2) the manufacturer's position to best absorb and redistribute costs, and (3) the incentive for greater caution in producing safe goods.^[xiv] Indeed, the complexity surrounding CAD blueprints' design and its associated computer software makes it extremely difficult to show that there was an absence of due care in CAD software's design. A CAD software designer could also easily absorb and spread these costs of risk in the form of higher fees, or through the purchase of malpractice insurance. Most importantly, increased risk of liability upon CAD software designers will impose significant pressure on them to take due care to investigate the most devastating defects—those relating to a product's design. A close investigation of the landscape dealing with designers or similar products also suggests that courts would not be required to make such a huge leap in finding CAD software designers strictly liable for defects in its blueprints.^[xv] For example, courts in the past have been willing to find that information contained in aeronautical^[xvi] and navigational charts^[xvii] are products under strict liability principles.

For these reasons, courts should not balk when faced with the perplexing legal questions related to an application of 3D-printed products to traditional product liability principles. Otherwise deserving plaintiffs should not be relegated to the defendant-friendly negligence cause of action when there is viable legal option in strict liability. Holding a CAD software designer strictly liable ultimately does not conflict with the policy considerations underlying strict liability and fault apportionment, but will place the burden upon those who are in the best position to prevent the injury in the first place.

[i] See generally Jasper L. Tran, *The Law & 3D Printing*, 31 J. Info. Tech. & Privacy L. 505 (2015).

[ii] See Jasper L. Tran, *To Bioprint or Not to Bioprint*, 17 N.C. J.L. & Tech. 123,138 & n.13 (2015).

[iii] *3D Printing Medical Devices Market Worth 2.13 Billion USD by 2020*, Market Watch (Sept. 9, 2015 5:31 AM EST), <http://www.marketwatch.com/story/3d-printing-medical-devices-market-worth-213-billion-usd-by-2020-2015-09-09-5203318>; David R. Schilling, *Global 3D Bio-Printing Market to Reach \$150 Billion by 2030*, Ind. Tap

(June 30, 2015), <http://www.industrytap.com/global-3d-bio-printing-market-reach-150-billi...> ("According to a number of research reports, the global 3D bio-printing market in the healthcare industry is set to grow at a compound annual growth rate (CAGR) of nearly 15% to about \$6 billion by 2020.")

[iv] Buckley v. Align Technology, Inc., No. 5:13-cv-02812-EJD, 2015 U.S. Dist. LEXIS 133388 (N.D. Cal. Sept 29, 2015).

[v] Tran, *To Bioprint, supra* note 2, at 141-46.

[vi] Escola v. Coca Cola Bottling Co., 150 P.2d 436, 441 (Cal. 1944) (Traynor, J., concurring) ("Those who suffer injury from defective products are unprepared to meet its consequences. The cost of an injury and the loss of time or health may be an overwhelming misfortune to the person injured, and a needless one, for the risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business.")

[vii] Restatement (Second) of Torts, Products Liability § 402 (2015).

[viii] Restatement (Third) of Torts, Products Liability § 20 (2015) ("[I]n 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."); *see also id.* at § 20, cmt. d ("[I]n 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.")

[ix] James A. Henderson, Jr., *Echoes of Enterprise Liability in Product Design and Marketing Litigation*, 87 Cornell L. Rev. 958, 973 (2002) ("Courts have rejected attempts by plaintiffs to extend strict liability to commercial enterprises that supply machinery, vehicles, and other equipment to those who themselves engage in activities deemed abnormally dangerous."); *see also* Cropper v. Rego Distribution Ctr., Inc., 542 F. Supp. 1142, 1147-49 (D. Del. 1982) (finding no strict liability for the manufacturer of machinery utilized to store and transport hazardous chemicals even though the purchaser of the machinery utilized it as part of an abnormally dangerous activity); Cavan v. Gen. Motors Corp., 571 P.2d 1249, 1251 (Or. 1977) ("Historically, the strict liability rule ... is applied when an activity creates an abnormally dangerous condition, or by its nature presents extraordinary risk of harm It has no applicability in a products case.")

[x] *See Some Ideas About 3D Printing*, Drug & Device L. Blog (Feb. 5, 2015), <http://druganddevicelaw.blogspot.com/2015/02/some-ideas-about-3d-printing.html> ("Imposing strict liability on the printer manufacturer for any product the printer could be configured to produce would be like imposing crashworthiness liability on the makers of the industrial robots used to make automobiles, or more generally on makers of a welding torches or plastic extrusion molders for everything that such equipment might be used to make.")

[xi] Spencer Thompson, *3D Printing Is Coming – so Let’s Not Strangle the Industry at Birth*, The Guardian (Oct. 16, 2012 8:00 EDT), <http://www.theguardian.com/commentisfree/2012/oct/16/get-ready-for-3d-printing>.

[xii] For a discussion of CAD software, see generally Kyle Dolinsky, *CAD’s Cradle: Untangling Copyrightability, Derivative Works, and Fair Use in 3D Printing*, 71 Wash. & Lee L. Rev. 591, 600 (2014).

[xiii] *See, e.g.,* In re Minnesota Breast Implant Litig., 36 F. Supp. 2d 863, 872 (D. Minn. 1998) (ruling that "if 3M played no role in the manufacture or sale of Plaintiffs’ breast implants, 3M cannot be strictly liable"); Christian v. Minnesota Mining & Manufacturing Co., 126 F. Supp.2d 951, 958 (D. Md. 2001) (finding developer of product, that no longer manufactured it, not strictly liable).

[xiv] *See, e.g.,* Greenman v. Yuba Power Prods., Inc., 377 P.2d 897 (Cal. 1963); *see also* Brooks v. Beech Aircraft Corp., 902 P.2d 54, 56 (N.M. 1995) (discussing four primary policies supporting imposition of strict products liability).

[xv] Cf. Patrick T. Miyaki, Comment, *Computer Software Defects: Should Computer Software Manufacturers Be Held Strictly Liable for Computer Software Defects?*, 8 Santa Clara Computer & High Tech. L.J. 121, 122-23 (1992) (arguing for strict liability in computer software defects).

[xvi] *E.g.,* Fluor Corp. v. Jeppesen & Co., 170 Cal. App. 3d 468, 474 (Ct. App. 1985) (finding charts as "products" for purposes of strict liability); Brockelsby v. U.S., 767 F.2d 1288, 1295 (9th Cir. 1985) (finding an aeronautical chart as "a defective product for purposes of analysis under section 402A").

[xvii] *E.g.,* Saloomey v. Jeppesen & Co., 707 F.2d 671, 676-77 (2d Cir. 1983) (holding that navigational charts were products under section 402A, and that mass production and marketing of charts required that the defendant bear the costs of accidents proximately caused by the charts).

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