

# **3D PRINTING OF MEDICAL DEVICES: CAD DESIGNERS AS THE MOST REALISTIC TARGET FOR STRICT, PRODUCT LIABILITY LAWSUITS**

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Abstract

*The potential framework for tort liability for the 3D printing of medical devices is highly questionable. Strict liability, which is traditionally applied in the products liability landscape, is not easily applied in the context of 3D printing of medical products. This problem becomes increasingly troublesome when one considers that experts predict that the first wave of consumers will suffer grave injuries as a result of defects in these medical products. This paper proposes that the CAD designer of a CAD blueprint should be held strictly liable for defects arising out of its designs. Hospitals and 3D Printer Manufacturers should be held liable only under negligence standards.*

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## INTRODUCTION

3D printing of medical devices is now a reality. The rapidly expanding field is currently allowing for incredible improvements in patient care, especially as it relates to cost-effectiveness, increased productivity, and a greater democratization and collaboration of design and manufacturing.<sup>1</sup> 3D printing technologies have also expanded capabilities for mass customization of products.<sup>2</sup> For example, custom-fit hearing aids can now be designed in a matter of hours to mold perfectly to a patient's ear canals, using only photographs.<sup>3</sup> This same type of customization is being utilized regularly to create artificial limbs, dental implants, and exterior spinal bracing in patients with scoliosis, or with paralysis.<sup>4</sup> 3D printing is also having rippling effects on the world of surgical prototyping.<sup>5</sup> That is, surgeons are now utilizing 3D printing to create realistic physical models of patients' various organs.<sup>6</sup> This allows surgeons to better conceptualize and plan for complicated and delicate procedures.<sup>7</sup>

There is no doubt that 3D printing of medical devices is likely to revolutionize the medical field.<sup>8</sup> Despite the promise of the new technology, there are deep concerns that the technology will present significant safety concerns for the first wave of consumers.<sup>9</sup> While an application of traditional product liability

<sup>1</sup> C. Lee Ventola, *Medical Applications for 3D Printing: Current and Projected Uses*, 39 PHARMACY AND THERAPEUTICS 704, 704 (2004), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4189697/pdf/ptj4910704.pdf>.

<sup>2</sup> Jasper L. Tran, *The Law and 3D Printing*, 31 J. MARSHALL J. INFO. TECH. & PRIVACY L. 505, 508 (2015) (“3D printers can print out anything, from a lithium-ion microbattery to a human kidney, and can print in materials like plastic, metal, ceramic, cement, wood, food, and human cells.”); Jasper L. Tran, *3D-Printed Food*, 17 MINN. J.L. SCI. & TECH. 855, 857-60 (2016) (discussing different variety of 3D-printed foods); *New Trends in 3D Printing—Customized Medical Devices*, ENVISIONTEC (Dec. 15, 2015), <http://envisiontec.com/trends-in-3d-printing-of-customized-medical-devices/>.

<sup>3</sup> Estie Neff, *3D Print Your Future Digital Hearing Aids*, AUDICUS (Oct. 8, 2014), <https://audicus.com/3d-print-your-future-digital-hearing-aids/>.

<sup>4</sup> See Jerome Groopman, *Print Thyself: How 3D Printing is Revolutionizing Medicine*, THE NEW YORKER (Nov. 24, 2014), <http://www.newyorker.com/magazine/2014/11/24/print-thyself> (discussing the most recent developments in 3D printing of medical devices).

<sup>5</sup> See TE Halterman, *Researchers Use 3D Printed Models to Save Lives with Delicate Ventricular Surgery*, 3DPRINT (Jan. 30, 2015), <http://3dprint.com/40946/3d-printed-models-save-lives>; Tyler Koslow, *3D Printing Comes to the Aid of India's Pediatric Surgeons*, 3D PRINTING INDUSTRY (Nov. 20, 2015), <http://3dprintingindustry.com/2015/11/20/62375>.

<sup>6</sup> Koslow, *supra* note 5.

<sup>7</sup> Halterman, *supra* note 5.

<sup>8</sup> Roberto Ascione, *How Can 3D Printing Revolutionize Healthcare?* HEALTHWARE (Oct. 12, 2015), <http://www.healthwareinternational.com/blogpost/how-can-3d-printing-revolutionize-healthcare-411>. Cf. Jasper L. Tran, *Press Clause and 3D Printing*, 14 NW. J. TECH. & INTELL. PROP. 75, 77 (2016) (positing that 3D printing falls under the First Amendment's manufacturing right).

<sup>9</sup> See Allison Harris, *The Effects of In-home 3D Printing Printing on Product Liability Law*, 6 J. OF SCI. POL'Y & GOVERNANCE (Feb. 2015), [http://www.sciencepolicyjournal.org/uploads/5/4/3/4/5434385/harris\\_new\\_ta1\\_1.2.2015\\_lb\\_mg.pdf](http://www.sciencepolicyjournal.org/uploads/5/4/3/4/5434385/harris_new_ta1_1.2.2015_lb_mg.pdf)

principles may seem to be straightforward, those familiar with the framework realize that an application of those principles to 3D printing is complicated and unique.<sup>10</sup> Given the tremendous challenges with asserting strict liability claims, and absent any concerted change by courts, plaintiffs will eventually be relegated to difficult-to-prove negligence cause of actions.<sup>11</sup> Because of this, many deserving plaintiffs will ultimately be prevented from receiving any compensation for their injuries.<sup>12</sup>

This paper proceeds in five parts. Part I explains the technology of 3D printed medical products, introducing the major players in the industry, safety concerns of 3D products and potential targets for strict liability lawsuits. Part II then explains the early history and evolution of strict liability for defective products and the manner in which courts grappled with concepts such as distribution of costs and product safety. Next, Part III explores in-depth the Second and Third Restatements of Torts, and how their drafters codified the growing trend of courts in applying strict liability for defectively designed products. The different types of product “defects” will be explained, as well as the requirements that there be a “product” and a “seller” in order for strict liability principles to apply. Part IV then explains the doctrinal difficulties in applying strict liability to hospitals, 3D printer manufacturers, and CAD designers, and argues that these difficulties will lead to otherwise deserving plaintiffs from being unable to receive any form of compensation.

Having established the difficulties in applying the traditional model, Part V argues that holding CAD designers strictly liable for defects originating in their designs will offer a large majority of plaintiffs the ability to be made whole. In doing so, the policies underlying strict liability will be investigated and applied to the CAD designer landscape. The section will also argue that it would not be a huge leap for courts to find CAD designers strictly liable for defects originating in their products. Finally, the paper argues that applying strict liability principles to hospitals or 3D printer manufacturers is economically inefficient, will cause the price of healthcare to skyrocket, and will most likely place a stranglehold on a budding industry before it had the opportunity to truly blossom and prove its enormous potential benefits.

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f. For a discussion of technologies in digital right management, see generally Jasper L. Tran, *A Primer on Digital Rights Management Technologies*, in *DIGITAL RIGHTS MANAGEMENT: A LIBRARIAN'S GUIDE* (Catherine Lemmer & Carla Wale eds., 2016).

<sup>10</sup> Life Sciences Health Industry Group, *3D Printing of Medical Devices: When a Novel Technology Meets Traditional Legal Principles*, REED SMITH 1, 2 (2015) [http://www.reedsmith.com/files/Publication/130448b9-7565-4295-a697-5c5d7c6eb516/Presentation/PublicationAttachment/9ba9b53c-2009-488d-ba91-5cc5a19a38f7/3d-printing-white-paper\\_79444049.pdf](http://www.reedsmith.com/files/Publication/130448b9-7565-4295-a697-5c5d7c6eb516/Presentation/PublicationAttachment/9ba9b53c-2009-488d-ba91-5cc5a19a38f7/3d-printing-white-paper_79444049.pdf) [hereinafter *LSHIG White Paper*].

<sup>11</sup> *Id.* at 17-18.

<sup>12</sup> *Id.* at 18.

## I. THE TECHNOLOGY

### A. 3D Printing of Medical Devices

There are approximately twenty-four 3D printing processes, all using different printing technologies, speeds, bonding techniques, resolutions, and materials.<sup>13</sup> However, all of these 3D processes are designed to build a 3D object that is defined by a computer-aided design software program (CAD).<sup>14</sup> Typically, the 3D printer slices the CAD design into small horizontal cross-sections, producing a subset of many digital 2D pieces.<sup>15</sup> These 2D pieces are then printed, aggregated and bonded, ultimately forming the 3D object originally specified by the CAD design.<sup>16</sup> In the case of medical device products, hospitals usually send patient specific data to a 3D device manufacturer and subsequently receive a shipment of a personalized product.<sup>17</sup> Often however, a hospital will have its own 3D printing facility with patient specific data provided by its radiologists, and other departments within the hospital are utilized to create a personal, 3D printed medical device.<sup>18</sup>

### B. 3D Bio-printing

The biggest promise for 3D printing is sure to lie in the future of “bio-printing.” Bio-printing is the production and manufacturing of living organisms using ink made of living cells.<sup>19</sup> The advent has already made it possible to cure previously untreatable conditions by allowing for the implantation of human tissue in diseased bladders, tracheas, and hearts.<sup>20</sup> The creation of fully functional organs through bio-printing is not yet a reality as it has been estimated that we

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<sup>13</sup> Ventola, *supra* note 1, at 705.

<sup>14</sup> Steven Leckart, *How 3-D Printing Body Parts Will Revolutionize Medicine*, POPULAR SCIENCE (Aug. 16, 2013), <http://www.popsci.com/science/article/2013-07/how-3-d-printing-body-parts-will-revolutionize-medicine/>.

<sup>15</sup> See Harris, *supra* note 9.

<sup>16</sup> *Id.*

<sup>17</sup> See Ashok Khanna et al., *3D Printing: New Opportunities for the Medical Devices Industry*, TATA CONSULTANCY SERVICES 7, 10 (2015), [http://www.tcs.com/SiteCollectionDocuments/White%20Papers/3D-Printing-New-Opportunities-for-Medical-Device-Industry\\_0315-1.pdf](http://www.tcs.com/SiteCollectionDocuments/White%20Papers/3D-Printing-New-Opportunities-for-Medical-Device-Industry_0315-1.pdf).

<sup>18</sup> *Id.* For a discussion on data and right to privacy, see generally Jasper L. Tran, *The Right to Attention*, 91 IND. L.J. 1023, 1029, 1033 (2016).

<sup>19</sup> See Jasper L. Tran, *To Bioprint or Not to Bioprint*, 17 N.C. J.L. & TECH. 123, 138 (2015), <http://ssrn.com/abstract=2562952>.

<sup>20</sup> See Bertalan Mesko Thu, *12 Things We Can Print in Medicine Right Now*, 3D PRINTING INDUSTRY (Feb. 26, 2015), <http://3dprintingindustry.com/news/12-things-we-can-3d-print-in-medicine-right-now-42867>.

are twenty years from printing a fully functional 3D heart.<sup>21</sup> However, constructs for blood vessels, heart valves, fingers, nerves, muscles and other lower-level biological entities are currently under development and could be available within 3 to 5 years.<sup>22</sup> Bio-printing also shows great promise for the creation of low-cost and high efficiency pharmaceutical drugs.<sup>23</sup> For example, the technology will make it possible to print replicas of a patient's tissue in the form of a strip which can be used to test what medications are effective, or potentially harmful to a patient.<sup>24</sup>

Like non-biological 3D printing, bio-printing utilizes many types of printing technologies to create a product from the ground up to replicate a blueprint in a CAD model.<sup>25</sup> However, compared to non-biological 3D printing, 3D bio-printing contains additional complexities such as the choice of materials, bonding techniques, as well as sensitivities and construction of human cells.<sup>26</sup> Significant hurdles also remain in regards to the ethical implications of 3D printed biomaterials and the impending FDA regulatory scheme, which is sure to impose harsh guidelines on manufacturers of such products.<sup>27</sup> Despite some of the challenges facing 3D printing of medical devices, the future is bright for the

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<sup>21</sup> See *3D Printing of Biomaterials: Analyzing the Revolution in Healthcare*, 3DPRINTING.COM, (Oct. 9, 2015), <http://3dprinting.com/bio-printing/3d-printing-of-biomaterials-analyzing-the-revolution-in-healthcare/> ("In the next 20 years, we can witness a 3D printed heart functioning properly without rejection by the body."). But see Philip Ross, *3D-Printed Hearts From Human Fat Cells? Scientist Says 'Bioprinting' Organs Possible 'In 10 Years,'* INT. BUS. TIMES (Nov. 23, 2013), <http://www.ibtimes.com/3d-printed-hearts-human-fat-cells-scientist-says-bioprinting-organs-possible-10-years-1483568> (forecasting that we are actually less than 10 years from fully functional hearts).

<sup>22</sup> See Lyndsey Gilpin & Jason Hiner, *3D Bioprinter to Reproduce Human Organs, Change the Face of Healthcare: The Inside Story*, TECH REPUBLIC, <http://www.techrepublic.com/article/new-3d-bioprinter-to-reproduce-human-organs/> (last visited Dec. 15, 2015).

<sup>23</sup> Dominic Basulto, *Why it Matters That the FDA Just Approved the First 3D-printed Drug*, THE WASHINGTON POST (Aug. 11, 2015), <https://www.washingtonpost.com/news/innovations/wp/2015/08/11/why-it-matters-that-the-fda-just-approved-the-first-3d-printed-drug/>; see also Jasper L. Tran, *Patenting Bioprinting*, HARV. J.L. & TECH. DIG. (Sept. 23, 2015), <http://jolt.law.harvard.edu/digest/patent/patenting-bioprinting> (discussing the patentability of bioprinting).

<sup>24</sup> See Ventola, *supra* note 1, at 711 ("It may also be possible to print out a patient's tissue as a strip that can be used in tests to determine what medication will be most effective.").

<sup>25</sup> *Id.* at 704.

<sup>26</sup> Sean V. Murphy & Anthony Atala, *3D Bioprinting of Tissues and Organs*, NATURE BIOTECHNOLOGY (Dec. 15, 2015), <http://www.nature.com/nbt/journal/v32/n8/abs/nbt.2958.html>.

<sup>27</sup> Lucas Mearian, *Bio-printing Human Parts Will Spark Ethical, Regulatory Debate*, COMPUTER WORLD. (Dec. 15, 2015), <http://www.computerworld.com/article/2486998/emerging-technology/bio-printing-human-parts-will-spark-ethical-regulatory-debate.html?page=2>. For a discussion on the FDA's regulatory scheme, see generally Jasper L. Tran & Derek Tri Tran, *(De)Regulating Neuroenhancement*, 37 U. LA VERNE L. REV. 179, 187-89 (2015).

industry, and it is expected to grow at a nearly 15% rate to about \$2.13 billion by 2020, with the bio-printing market worth nearly \$6 billion.<sup>28</sup>

### C. Safety Concerns

Despite the strong promise that 3D printing holds for the future of healthcare, there are critical concerns, and deep unknowns regarding the safety of 3D printed products and product liability law.<sup>29</sup> Potentially devastating injuries can occur as a result of syntax errors, semantic errors as well as “unit changes, geometry formation, inaccurate geometric alignment, and poorly generated models.”<sup>30</sup> And while the availability and accessibility to a variety of CAD files on open source domains could assist in the collaboration of design, complications can arise when a 3D printer utilizes a CAD file that was intended for a different type of 3D printer. In other words, a design created for production on one 3D printer can produce a product on a different 3D printer, which alters significantly from the intended product.<sup>31</sup> It is also common knowledge that adequate safety principles, standards and quality necessarily lag behind in any new advent or technology.<sup>32</sup> Therefore, it is impossible to know with any degree of certainty the entire extent of problems which may arise from defective 3D printed medical products before they have actually become a problem.<sup>33</sup>

To date, there has been only a single product liability lawsuit involving a 3D printed product.<sup>34</sup> That 2015 case involved the 3D printing of customized “Invisalign” braces, in which the manufacturer was alleged to have failed in its duty to warn the patient directly regarding the potential ineffectiveness of its

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<sup>28</sup> *3D Printing Medical Devices Market Worth 2.13 Billion USD by 2020*, MARKET WATCH (Sept. 9, 2015 5:31 AM), <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*, INDUSTRY TAP (June 30, 2015), <http://www.industrytap.com/global-3d-bio-printing-market-reach-150-billion-2030/29692> (“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.”).

<sup>29</sup> See generally Harris, *supra* note 9 (explaining the transforming consumer-manufacturer relationship, which has potential to evolve beyond the bounds of traditional product liability law).

<sup>30</sup> *Id.* See also Michael H. Park, *For A New Heart, Just Click Print: The Effect on Medical and Products Liability from 3-D Printed Organs*, 2015 U. ILL. J.L. TECH. & POL'Y 187, 191 (2015) (“Another limitation is the possibility of failure of the object created. When printing in layers, each layer has the potential to fail manufacturing standards. Considering that products are made up of multiple layers, the potential for flaws is multiplied by the number of layers needed to complete the product. This is in contrast to conventional manufacturing which does not require multiple layers.”).

<sup>31</sup> See Harris, *supra* note 9.

<sup>32</sup> See generally Ventola, *supra* note 1, at 710 (explaining the origin, development, potential, and dangers of unregulated 3D printing).

<sup>33</sup> See *id.*

<sup>34</sup> See *Buckley v. Align Tech., Inc.*, No. 5:13-cv-02812-EJD, 2015 U.S. Dist. LEXIS 133388, at \*1 (N.D. Cal. Sept. 29, 2015).

product.<sup>35</sup> While the suit was eventually dismissed on the grounds that the manufacturer was only required to warn the doctor regarding the dangers, and not the patient, product safety experts suggest that the first wave of product liability lawsuits involving severely disfigured patients is on the horizon.<sup>36</sup> And while an application of traditional product liability principles may seem to be straightforward, those familiar with the framework realize that an application of those principles to 3D printing is complicated, unique, and is likely to test the boundaries of all existing product liability law.<sup>37</sup> To fully understand the difficulties associated with application of the existing framework, the origins and formation of the modern product liability regime must be investigated.

## II. THE HISTORY AND EVOLUTION OF STRICT LIABILITY

### A. The Shift Away From Privity

The American court system has been offering redress for those harmed by defective products since its inception.<sup>38</sup> Initially, injured plaintiffs were restricted to negligence cause of actions, having to prove duty, breach of duty and causation.<sup>39</sup>

These plaintiffs also were restricted by the rule of privity, and were permitted to file suit against a manufacturer only where there was a direct contractual agreement with the manufacturer.<sup>40</sup> Recognizing the great injustice posed upon injured plaintiffs who were unable to recover from manufacturers insulated far along the supply chain, the New York Court of Appeals, in 1852, dispensed of the privity requirement in situations where the product involved was “imminently dangerous to human life.”<sup>41</sup> Soon, gunpowder, nitroglycerine and poisonous drugs were exempted from the privity requirement, having also been established as “intrinsicly dangerous” products.<sup>42</sup>

It was not until the beginning of the twentieth century that courts began to realize the need for a completely new standard for product liability law. In 1916, the Court terminated the privity requirement altogether when they held that

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<sup>35</sup> *Id.* at \*3.

<sup>36</sup> See Paul L. Knobbe, *3-D Printing Raises a Host of Product Liability Issues*, PRODUCT LIABILITY PLAYBOOK (Dec. 3, 2015), <http://gsriskmitigationblog.com/3-d-printing-raises-a-host-of-product-liability-issues/> (“Several recent news articles highlight some of the risks and issues that have come to the forefront with respect to 3-D printing, including a recent study which found that some 3-D printed parts may leach toxic chemicals.”).

<sup>37</sup> See *infra* Part IV.

<sup>38</sup> Frank J. Vandall & Joshua F. Vandall, *A Call for an Accurate Restatement (Third) of Torts: Design Defect*, 33 U. MEM. L. REV. 909, 911-12 (2003).

<sup>39</sup> David G. Owen, *The Evolution of Products Liability Law*, 26 REV. LITIG. 955, 962 (2007).

<sup>40</sup> *Id.*

<sup>41</sup> *Thomas v. Winchester*, 6 N.Y. 397, 408 (1852).

<sup>42</sup> *Lebourdais v. Vitriified Wheel Co.*, 80 N.E. 482, 483 (Mass. 1907). See *Curtain v. Somerset*, 21 A. 244, 245 (Pa. 1891).



the privity requirement was inapplicable in cases where “the nature of [the product] is such that it is reasonably certain to place life and limb in peril when negligently made.”<sup>43</sup> The broader, newer standard essentially swallowed the previous “inherently dangerous” rule, as most, if not many of the products under suit could be considered as placing life and limb in danger if negligently made.<sup>44</sup> Some high level courts soon took note of the decision in *MacPherson* and adopted similar standards, with others terminating their privity requirements altogether.<sup>45</sup>

### B. The Shift Towards Strict Liability

Subsequent to *MacPherson*'s shift to a non-privity landscape, negligence remained the primary vehicle to bring suits when injured by a defective product.<sup>46</sup> Plaintiffs, who have the difficult burden of showing how a party in the supply chain had failed to exercise due care, were often unable to recover despite the existence of a legitimate defect and significant injuries.<sup>47</sup> Frustrated by the shortcomings of the existing system, and encouraged by the writings of noted tort scholar William Prosser, courts began to allow plaintiffs to bring suit under implied and express warranty theories.<sup>48</sup> While warranty theories ensured that a seller would be strictly liable for the safety of his product even though he had exercised all reasonable care, plaintiffs were still required to prove reliance upon the warranty, that they were injured as a result of reliance, and that notice of the defect was given in reasonable time.<sup>49</sup> In this respect, “consumers continued to lose cases that-based on the equities-they should have won.”<sup>50</sup>

Finally, in 1963, Justice Traynor established what would be the new standard when he held that strict liability, as opposed to any contract theories, would govern product liability law.<sup>51</sup> Faced with a claim for personal injuries resulting from a defective power tool, the court opined that “[a] manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being.”<sup>52</sup> Traynor reiterated that this type of strict liability would best “insure that the costs of injuries resulting from defective products are borne by

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<sup>43</sup> *MacPherson v. Buick Motor Co.*, 111 N.E. 1050, 1051 (1916).

<sup>44</sup> See generally W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 97, at 690 (5th ed. 1984) (detailing the expansion of liability for those selling to the ultimate consumer).

<sup>45</sup> See *id.*

<sup>46</sup> Kyle Graham, *Strict Products Liability at 50: Four Histories*, 98 MARQ. L. REV. 555, 579 (2014).

<sup>47</sup> *Id.* at 568-69.

<sup>48</sup> *Id.* at 570-71.

<sup>49</sup> KENNARD NEAL, GEORGIA PRODUCTS LIABILITY § 1:1 at 3 (4th ed. 2015).

<sup>50</sup> Adam F. Trupp, Comment, *A Step Backwards in Products Liability Law: The Utah Supreme Court and Comment k*, UTAH L. REV. 101, 104 (1992).

<sup>51</sup> *Greenman v. Yuba Power Products, Inc.*, 377 P.2d 897, 901 (Cal. 1963).

<sup>52</sup> *Id.* at 900.

the manufacturers...,” that put such products on the market rather than by the injured persons who are powerless to protect themselves.<sup>53</sup> The ruling soon gained acceptance and was eventually echoed in the Second Restatement of Torts only two years later.<sup>54</sup>

### III. RESTATEMENT SECOND 402A

Section 402A of the Second Restatement of Torts is the modern standard in products liability law.<sup>55</sup> In relevant part, Section 402A states that a seller is liable for physical harm caused by a product if it is sold in “defective condition unreasonably dangerous to the user or consumer or to his property.”<sup>56</sup> In this respect, liability under 402A is “strict” because sellers are subject to liability regardless of whether they were negligent, and whether or not they exercised due care.<sup>57</sup> Notwithstanding that liability is strict, 402A is careful to limit its reach to those sellers who are “engaged in the business of selling such a product” and to those products which are expected to reach the consumer “without substantial change in the condition in which it is sold.”<sup>58</sup> Causation and damages, of course, are also required elements under 402A.<sup>59</sup>

#### A. Types of Defects

While 402A does not explicitly differentiate between types of strict products liability claims, courts applying the standard have generally differentiated between design, warning, and manufacturing defect claims.<sup>60</sup> And although much of the Third Restatement of Torts has been slow to catch on with the courts,<sup>61</sup> its drafters have also attempted to demarcate the precise boundaries

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<sup>53</sup> See Trupp, *supra* note 50, at 107.

<sup>54</sup> Eric Lindenfeld & Jasper L. Tran, *Prescription Drugs and Design Defect Liability: Blanket Immunity Approach to the Increased Costs and Unavailability of Prescription Medication*, 64 DRAKE L. REV. 111, 117 (2016).

<sup>55</sup> Trupp, *supra* note 50, at 211.

<sup>56</sup> RESTATEMENT (SECOND) OF TORTS § 402A(1) (AM. LAW INST. 1965).

<sup>57</sup> See *id.* at § 402A(2); Charles M. Key, *Toward A Safer Health System: Medical Injury Compensation and Medical Quality*, 37 U. MEM. L. REV. 459, 486 n. 97 (2007) (“The phrase ‘strict liability’ already has an established use, however, referring to the liability of a seller for injury arising out of the use of its defective or unreasonably dangerous product, regardless of the seller’s exercise of due care.”).

<sup>58</sup> RESTATEMENT (SECOND) OF TORTS § 402A(1)(a)-(b) (AM. LAW INST. 1965).

<sup>59</sup> See, e.g., *Bockrath v. Aldrich Chem. Co.*, 980 P.2d 398, 403 (Cal. 1999) (noting that plaintiff must show causation between injuries and a defendant’s conduct under any tort theory); *Dow Chem. Co. v. Mahlum*, 970 P.2d 98, 107 (Nev. 1998) (discussing that plaintiff must prove causation under both negligence and strict liability theories).

<sup>60</sup> See Lindenfeld & Tran, *supra* note 54, at 118.

<sup>61</sup> See George W. Conk, *Punctuated Equilibrium: Why Section 402A Flourished and the Third Restatement Languished*, 26 REV. LITIG. 799, 800 (2007).

of these claims.<sup>62</sup> Design defects are those that in which the “foreseeable risk of harm posed by the product could have been reduced or avoided by . . . a reasonable alternative design. . . .the omission of [which] . . . renders the product not reasonably safe.”<sup>63</sup> Warning defects are those in which the manufacturer failed to warn of dangers of the product that are “not generally known, or if known, is one which the consumer would reasonably not expect to find in the product.”<sup>64</sup> Finally, manufacturing defects are those which result from some type of flaw in the manufacturing process which make the product more dangerous than it was designed to be.<sup>65</sup> Strict liability is imposed for manufacturing defects absent any failure to comply with any type of reasonableness standard, and as such, it has been held to be the only “true” strict liability standard under the 402A regime.<sup>66</sup>

### B. What Is a Product?

Since 402A’s inception, courts and legal scholars have grappled over what constitutes a “product” for purposes of strict liability, although most agree that it should not be expanded to apply to services.<sup>67</sup> While comment d to Section 402A does offer a brief list of products that would fall under the auspices of the section,<sup>68</sup> the drafters of the section give no further guidance on whether more obscure items, such as electricity, farm animals, real property, navigational maps, computer software, human tissue and blood are considered products subject to strict liability.<sup>69</sup> To be fair, the Third Restatement has since taken note of some of

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<sup>62</sup> See David G. Owen, *Defectiveness Restated: Exploding the "Strict" Products Liability Myth*, U. ILL. L. REV. 743, 778 (1996).

<sup>63</sup> RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2(b) (AM. LAW INST. 1998). A determination of whether a product contains design defect usually entails a court using one of two tests. First, the “consumer expectations” test, assesses whether the design meets the safety expectations of users and consumers. See Lindenfeld & Tran, *supra* note 54, at 118-19. Alternatively, the “risk-utility” test assesses whether the safety benefits of designing away a foreseeable danger exceed the resulting costs. *Id.*

<sup>64</sup> RESTATEMENT (SECOND) OF TORTS § 402A cmt. j (AM. LAW INST. 1965).

<sup>65</sup> See John Riper, Note, *Strict Liability in Hybrid Cases*, 32 STAN. L. REV. 391, 391 n.2 (1980).

<sup>66</sup> See Owen, *supra* note 62 at 744.

<sup>67</sup> See Charles E. Cantu, *The Illusive Meaning of the Term "Product" Under Section 402A of the Restatement (Second) of Torts*, 44 OKLA. L. REV. 635, 639 (1991).

<sup>68</sup> RESTATEMENT (SECOND) OF TORTS § 402A cmt. d (AM. LAW INST. 1965) (“The rule stated in this Section is not limited to the sale of food for human consumption, or other products for intimate bodily use, although it will obviously include them. It extends to any product sold in the condition, or substantially the same condition, in which it is expected to reach the ultimate user or consumer. Thus the rule stated applies to an automobile, a tire, an airplane, a grinding wheel, a water heater, a gas stove, a power tool, a riveting machine, a chair, and an insecticide. It applies also to products which, if they are defective, may be expected to and do cause only ‘physical harm’ in the form of damage to the user’s land or chattels, as in the case of animal food or a herbicide.”).

<sup>69</sup> See Cantu, *supra* note 67, at 658-59 (“[T]ransactions involving traditional services, houses, land, blood, electricity, component parts, water, computer software, and ideas have all been held in one

perplexities surrounding many of these items, defining “products” as “tangible personal property”, and has attempted to give more comprehensive answers in regards to real property, human tissue, blood and electricity.<sup>70</sup> However, the Third Restatement has notoriously avoided discussing certain minority jurisdictions and trends, and there still remains conflicting authority and heavy scholarly debate over items such as computer software.<sup>71</sup> Even more perplexing are the varying approaches taken when dealing with “hybrid” scenarios, in which products and services are sold in the same transaction.<sup>72</sup>

### C. Who Is a Seller?

As discussed, Section 402A states that only those “who sell” and those who are “engaged in the business of selling” or otherwise distributing such a product are liable under the regime.<sup>73</sup> Illustrating this concept, the Second Restatement explains that strict liability will not apply “to the housewife who, on one occasion, sells to her neighbor a jar of jam or a pound of sugar.”<sup>74</sup> The Third Restatement contains the same “business of selling” language, and further states that strict liability will “not apply to a noncommercial seller or distributor of such products . . . [but] [i]t is not necessary that a commercial seller or distributor be engaged exclusively or even primarily in selling or otherwise distributing the type of product that injured the plaintiff, so long as the sale of the product is

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form or another to constitute a product.”).

<sup>70</sup> See RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 19(a), (c) (AM. LAW INST. 1998) (categorizing cases that have applied the framework to real property, human tissue, blood and electricity).

<sup>71</sup> See, e.g., Patrick T. Miyaki, *Computer Software Defects: Should Computer Software Manufacturers Be Held Strictly Liable for Computer Software Defects?*, 8 SANTA CLARA COMPUTER & HIGH TECH. L.J. 121, 130 (1992) (arguing that computer software developers can, but should not be held liable under strict liability standards); Kevin R. Pinkney, *Putting Blame Where Blame Is Due: Software Manufacturer and Customer Liability for Security-Related Software Failure*, 13 ALB. L.J. SCI. & TECH. 43, 70 (2002) (arguing for the applicability of strict liability standards for computer software); cf. Jasper L. Tran, *Software Patents: A One-Year Review of Alice v. CLS Bank*, 97 J. PAT. & TRADEMARK OFF. SOC’Y 532, 534-40 (2015) (discussing the landscape of software patents in 2015); Jasper L. Tran, *Two Years After Alice v. CLS Bank*, 98 J. PAT. & TRADEMARK OFF. SOC’Y \_\_ (2016) (discussing the landscape of software patents in 2016). For an in-depth treatment on patents, see generally Jasper L. Tran, *Timing Matters: Prior Art’s Age Infers Patent Nonobviousness*, 50 GONZ. L. REV. 189, 194-98 (2014-2015) (discussing patent nonobviousness and prior art); Jasper L. Tran, *Rethinking Intellectual Property Transactions*, 43 S.U. L. REV. 149, 152-57 (2015) (discussing patent licensing).

<sup>72</sup> While courts allow plaintiffs to utilize strict products liability principles in hybrid transactions involving nonprofessional sellers/service providers, they often refrain from holding medical professionals engaged in hybrid transactions from being held strictly liable. See Richard L. Cupp, Jr., *Sharing Accountability for Breast Implants: Strict Products Liability and Medical Professionals Engaged in Hybrid Sales/Service Cosmetic Products Transactions*, 21 FLA. ST. U. L. REV. 873, 877 (1994); see also *infra* Section IV.A.

<sup>73</sup> RESTATEMENT (SECOND) OF TORTS § 402A(1)-(1)(a) (AM. LAW INST. 1965).

<sup>74</sup> See *id.* at cmt. f.

other than occasional or casual.”<sup>75</sup> In illustrating this point, the Third Restatement explains that “a service station that does mechanical repair work on cars” but also sells tires would be a commercial seller.<sup>76</sup> However, the “occasional sale of surplus equipment by a business does not” qualify as a commercial seller.<sup>77</sup>

#### IV. DIFFICULTIES IN APPLYING TRADITIONAL MODEL

The uniqueness of the 3D printing of medical devices, especially as it relates to the manufacturer-consumer relationship, poses serious and perplexing legal issues for those injured by 3D printed medical products.<sup>78</sup> Assuming that a hospital utilizes a 3D printer to create a customized prosthetic limb for a patient which eventually fails, causing serious injury, who would be liable under the typical, strict product liability regime? While a 3D printed device almost certainly can be considered a “product” under existing case law, it is less certain that a hospital be considered as the “seller” of the customized device, or as sufficiently “engaged in the business” of selling such a product. What about the manufacturer of the 3D printer? While this party is a “seller” of a “product”, it is less certain that a court would find that it was responsible for all defectively made products made by its defective-less printer. Finally, could a CAD blueprint be considered a sufficiently tangible “product” to implicate the CAD designer under the strict liability regime? Clearly, traditional liability factors as applied to 3D printed products are likely to raise many perplexing legal questions.

##### A. Hospitals

The majority of jurisdictions are of the opinion that a hospital that sells medical products in conjunction with the services they provide are not “seller[s] of the product[s]” as contemplated by the Second Restatement, and thus are not liable under strict liability principles.<sup>79</sup> These courts have almost unanimously held that the primary objective of hospitals is to provide services, and therefore, any sale of medical products is simply ancillary to that primary objective.<sup>80</sup>

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<sup>75</sup> RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 1 cmt. c (AM. LAW INST. 1998).

<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

<sup>78</sup> Scott J. Grunewald, *Liability and Legal Issues May Derail the Future of 3D Printed Medication*, 3DPRINT.COM (Nov. 13, 2015), <https://3dprint.com/105447/liability-3d-print-medication/>.

<sup>79</sup> See RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 20 cmt. d (AM. LAW INST. 1998).

<sup>80</sup> See, e.g., *San Diego Hospital Ass’n v. Superior Court*, 35 Cal. Rptr. 2d 489, 493 (Cal. Ct. App. 1994) (“The hospital is not in the business of selling or even leasing, bailing or licensing equipment to the physician. It is in the business of providing medical services to its patients . . . The fact the hospital provides equipment for the physician’s use is incidental to the overriding purpose of providing medical services.”); *Gile v. Kennewick Public Hospital Dist.*, 296 P.2d 662, 666 (Wash. 1956) (“[T]he 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

Similarly, since hospitals are typically not affiliated with the manufacturer of the device, nor have hospitals played an integral role in the production or marketing of the product, they have generally not been held to be liable under the strict liability regime.<sup>81</sup> Rarely has separate consideration given to the hospital from the patient led to the hospital being found a “seller of a product.”<sup>82</sup> It is for these reasons a hospital will most likely not be held strictly liable for an injury caused by a 3D printed medical product.

It is conceded that as more hospitals begin bringing 3D printers on-site, and as doctors play an increasingly more integral role in the design, formation and implantation of the device, the typical distinction between seller and service provider may begin to blur.<sup>83</sup> While this may bring hospitals one step closer to being held liable under strict liability principles, injured litigants still have to overcome the almost insurmountable task of showing that a hospital “was in the business” of selling the 3D printed device and that it was more than an “occasional seller.”<sup>84</sup> Indeed, section 402A notes that while strict liability “applies to any person engaged in the business of selling products for use or consumption,” it will not apply to the “occasional seller” of a product “who is not engaged in that activity as a part of his business.”<sup>85</sup> James Beck, leading medical device and pharmaceutical liability scholar has recently noted that “even if [hospitals] have a few 3D printers, [hospitals] will still be considered not to be in ‘the business’ of manufacturing medical devices with them. The same service/sale and public policy issues that drive the general rule that hospitals aren’t subject to strict liability would still be there.”<sup>86</sup> Therefore, it appears, at least initially, the injured will have a difficult time bringing strict liability claims against hospitals for defective 3D products.

## B. 3D Printer Manufacturers

Another possibility is to hold the manufacturer of the 3D printer strictly liable for design or warning defects originating from medical device products. A 3D printer is a “product”, and its manufacturer is clearly a “seller” as contemplated by the Second Restatement, however, posing such extensive liability on a manufacturer of a 3D printer for anything and everything it may make would be extremely excessive and inconsistent with prior case law dealing

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feature of the transaction and not a sale.”).

<sup>81</sup> See *Hector v. Cedars-Sinai Med. Ctr.*, 225 Cal. Rptr. 595, 599, 602 (Cal. Ct. App. 1986).

<sup>82</sup> See James M. Beck, *Hospital Strict Liability – A 50-State Survey*, DRUG AND DEVICE LAW (Nov. 16, 2012), <http://druganddevicelaw.blogspot.com/2012/11/hospital-strict-liability-50-state.html>.

<sup>83</sup> See *LSHIG White Paper*, *supra* note 10.

<sup>84</sup> Donald M. Zupanec, Annotation, *When Is Person “Engaged in the Business” for Purposes of Doctrine of Strict Tort Liability*, 99 A.L.R. Fed. 3d 671, § 2 (1980).

<sup>85</sup> RESTATEMENT (SECOND) OF TORTS § 402A, cmt. f (AM. LAW INST. 1965).

<sup>86</sup> James M. Beck, *Some Ideas About 3D Printing*, DRUG & DEVICE LAW (Feb. 5, 2015), <http://druganddevicelaw.blogspot.com/2015/02/some-ideas-about-3d-printing.html>.

with analogous manufacturers.<sup>87</sup> 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.<sup>88</sup> While other claims against 3D manufacturers, couched in transparency of instructions, quality of provided materials, or product maintenance instructions may prove to be minimally more successful, they will probably fail on proximate cause grounds.<sup>89</sup> This is because there are a host of other contributing factors, making it almost impossible to sufficiently prove that the absence of such instructions or materials led to the plaintiff's injury.<sup>90</sup> Lastly, under strict liability principles, a defect must exist at the time of sale or distribution. Therefore, a plaintiff must show that the 3D printer was defective not only at the time that it printed the 3D medical device, but also at the time of the 3D printer's sale.<sup>91</sup> This can be exceedingly difficult to prove considering the volume of prints and users utilizing a single printer per year.<sup>92</sup>

### C. CAD Designers

The final option would be to hold the designer of the CAD blueprint strictly liable for a defective medical devices created by a 3D printer.<sup>93</sup> As discussed, a CAD designer utilizes specialized software to create a CAD blueprint of the 3D medical device.<sup>94</sup> Theoretically, a plaintiff could assert that the CAD blueprint was defectively designed, causing the end product 3D medical

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<sup>87</sup> 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, 1156 (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.”).

<sup>88</sup> *See* Beck, *supra* note 86 (“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.”).

<sup>89</sup> *LSHIG White Paper*, *supra* note 10, at 18.

<sup>90</sup> *Id.*

<sup>91</sup> *See* Nora Freeman Engstrom, *3-D Printing and Product Liability: Identifying the Obstacles*, 162 U. PA. L. REV. ONLINE 35, 38 (2013).

<sup>92</sup> *See id.* at 36 (“3-D printing seems poised to transform the goods we buy, the products we use, and the world we inhabit.”).

<sup>93</sup> *See* Eric Lindenfeld & Jasper L. Tran, *Beyond Preemption of Generic Drug Claims*, 45 Sw. U. L. REV. 241 (2016) (discussing claims against non-manufacturers).

<sup>94</sup> *See supra* Section I.A.

device to be unreasonably dangerous to the consumer.<sup>95</sup> However, the CAD designer will likely be able to defeat a lawsuit on the grounds that they are simply the designers or inventors of products, as opposed to “sellers” as required by the Second Restatement.<sup>96</sup> Indeed, so far, courts have taken a strong stance on the issue, ruling that in most situations inventors, designers or suppliers of information are not “sellers” and are not strictly liable under product liability law.<sup>97</sup>

Additionally, the CAD designers may successfully argue that what they supply are not “products” as contemplated by the Restatement. Traditionally, courts have been receptive to these arguments, holding that product designs are not “products” as contemplated by the Second or Third Restatements.<sup>98</sup> This issue was heavily litigated in breast implant failure cases, where courts overwhelmingly found that the designer of the breast implants could not be held strictly liable for products if they played no role in the manufacturing process.<sup>99</sup> And while there are a limited number of cases in which courts have been asked to apply strict liability principals to computer software, scholars have increasingly forecasted that courts will rule along similar lines.<sup>100</sup> These scholars have advocated for finding that software is most comparable to a “service” as opposed to a “product” and subject to negligence standards as opposed to any form of strict liability.<sup>101</sup>

## V. CAD DESIGNERS AS THE MOST REALISTIC TARGET

Given the tremendous challenges with asserting strict liability claims, and absent any concerted change by courts, plaintiffs will eventually be delegated to simple negligence cause of actions. In order to succeed on a negligence cause of action, the plaintiff has a burden of proving duty, breach of duty, causation and damages.<sup>102</sup> Despite the fact that negligence in the 3D printing context itself poses unique difficulties regarding duty of care and causation, negligence has

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<sup>95</sup> See *LSHIG White Paper*, *supra* note 10, at 15.

<sup>96</sup> *Id.* at 18.

<sup>97</sup> *Id.*

<sup>98</sup> *Id.* at 15.

<sup>99</sup> See, e.g., *Christian v. Minn. Mining & Mfg. Co.*, 126 F. Supp. 2d 951, 957 (D. Md. 2001) (holding that the developer of product who no longer manufactured cannot be found strictly liable); *In re Minn. Breast Implant Litig.*, 36 F. Supp. 2d 863, 872 (D. Minn. 1998) (designer held not to be liable under strict liability principles).

<sup>100</sup> See David W. Lannetti, *Toward A Revised Definition of "Product" Under the Restatement (Third) of Torts: Products Liability*, 55 *BUS. LAW.* 799, 816 (2000) (“[M]any scholars have advocated the inclusion of computer software under the aegis of section 402A products.”).

<sup>101</sup> *Id.* at 834.

<sup>102</sup> David G. Owen, *The Five Elements of Negligence*, 35 *HOFSTRA L. REV.* 1671, 1674 (2007).



traditionally been a much harder cause of action to prove.<sup>103</sup> Injured consumers, who will undoubtedly be faced with significant injuries as a result of 3D products, will be faced with significant medical bills, but no real opportunity to be made whole. This problem becomes increasingly troublesome when one considers the fact that adequate safety principles, standards, and quality necessarily lag behind in any new advent or technology.<sup>104</sup> 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 Traynor.

In order 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 to make room for liability to those supply chains which do not engage in traditional manufacturing. More specifically, the most realistic approach would be for courts to uniformly hold CAD designers strictly liable for defects in 3D printed products. This approach is most consistent with the policy objectives of strict liability law, and would not be an excessive leap for the courts.<sup>105</sup> Most importantly, an imposition of strict liability to hospitals or 3D printer manufacturers would be economically inefficient, would cause the price of healthcare to skyrocket, and would most likely place a stranglehold on a budding industry before it had the opportunity to truly blossom.

#### **A. Strict Liability for CAD Designers Is Most Consistent with the Policy Objectives**

Public policy considerations have historically been the primary motivating factor for the imposition of strict liability in products liability law.<sup>106</sup> These same policy considerations are also used as the guiding light in determining how far the regime should expand.<sup>107</sup> For these reasons, only by isolating and closely examining these public policy rationales can one determine whether a particular manufacturer or product properly falls under the auspices of the strict liability regime. Justice Traynor, founder of modern product liability law, gave one of the first elucidations of the public policy considerations

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<sup>103</sup> See Melissa Moore, Comment, *Strict Liability Claims Against Hospitals Under 402a*, 29 DUQ. L. REV. 109, 118 (1990) (“[F]ault or negligence is difficult to prove in a defective product context.”).

<sup>104</sup> See *supra* Section I.A.

<sup>105</sup> See *supra* Section I.B.

<sup>106</sup> See, e.g., Seldon J. Childers, Note, *Don't Stop the Music: No Strict Products Liability for Embedded Software*, 19 U. FLA. J.L. & PUB. POL'Y 125, 135-36 (2008) (arguing several policy reasons that support the imposition of strict products liability in various scenarios).

<sup>107</sup> See Joseph L. Reutiman, Note, *Defective Information: Should Information Be A "Product" Subject to Products Liability Claims?*, 22 CORNELL J.L. & PUB. POL'Y 181, 183 (2012) (“Public policy considerations have driven the widespread adoption of liability in tort for product-caused harm. Beyond recognition of products liability as a distinct field of tort, public policy has also played a significant role in determining how far liability under this system should extend.”).

underlying strict liability for defective products in a concurrence of *Escola v. Coca-Cola Bottling Co.*<sup>108</sup> In *Escola*, a plaintiff was injured when a Coca-Cola bottle she was handling exploded, causing severe injuries to her hand.<sup>109</sup> While the majority opinion ultimately found the defendant guilty under negligence and *res ipsa loquitor* theories, Justice Traynor suggested that strict liability principles should govern product liability law going forward.<sup>110</sup> In his concurrence, Traynor famously articulated three separate policy justifications for strict liability for defective products.

Traynor first emphasized that the difficulty in proving negligence in defective product cases is an unduly burdensome standard for a plaintiff who “is not ordinarily in a position to refute such evidence or identify the cause of the defect.”<sup>111</sup> Second, Traynor proffered an economic efficiency approach, arguing that the risk of the product should be borne by the manufacturers, as they are in the best position to absorb it and redistribute it “among the public as a cost of doing business.”<sup>112</sup> Finally, Traynor underscored product safety, arguing that strict liability would incentivize manufacturers to take the utmost care to prevent disastrous injuries to consumers.<sup>113</sup> “Even if there is no ‘fault’ involved in the damage caused by a product, strict liability ensures that risky activities that are inherent in certain types of businesses and industries will be curtailed to a certain extent.”<sup>114</sup> Commentators have since offered additional policy justifications which courts have found compelling, such as the “justice of imposing the loss” on the manufacturer who created the risk and reaped the profit,<sup>115</sup> as well as “the disparity in position and bargaining power which forces the consumer to depend entirely on the manufacturer.”<sup>116</sup>

The rationales articulated by Justice Traynor for imposition of strict liability for product defects are equally applicable for the CAD designers of medical products. First, like mass produced products, negligence will be extremely hard to prove for those injured by defective CAD designs because the complexity surrounding the design of CAD blueprints and its associated computer software makes it impossible, or at best, extremely difficult to show that there was an absence of due care in the design of the CAD blueprint.<sup>117</sup>

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<sup>108</sup> *Escola v. Coca Cola Bottling Co. of Fresno*, 150 P.2d 436, 440 (Cal. 1944) (Traynor, J., concurring).

<sup>109</sup> *Id.* at 437.

<sup>110</sup> *Id.* at 441-42.

<sup>111</sup> *Id.*

<sup>112</sup> *Id.*

<sup>113</sup> *Id.* at 442.

<sup>114</sup> T. Randolph Beard et al., *Tort Liability for Software Developers: A Law & Economics Perspective*, 27 J. MARSHALL J. COMPUTER & INFO. L. 199, 206 (2009).

<sup>115</sup> *Suvada v. White Motor Co.*, 210 N.E.2d 182, 186 (Ill. 1965).

<sup>116</sup> *Immergluck v. Ridgeview House, Inc.* 368 N.E.2d 803, 804 (Ill. App. Ct. 1977).

<sup>117</sup> See Miyaki, *supra* note 71, at 139 (arguing that it will be extremely difficult for a consumer, who knows little about the inner-workings of the software, to identify the lack of due care by the manufacturer).

Moreover, the highly technical, complicated and mathematical nature of CAD coding for the 3D printed products such as heart valves and spinal braces suggests that a small technical error or bug could cause a significant injury, yet not meet the threshold of negligence under traditional tort principles. For example, because negligence principles focus on the reasonableness of the actor's conduct,<sup>118</sup> CAD designer's conduct may be considered reasonable in cases where only a close reading of millions of lines of code would have revealed the error.<sup>119</sup> Early on in the development of software coding, the Eighth Circuit recognized the highly complicated nature of computer coding and the resulting difficulty of proof in negligence causes of actions by adopting a higher standard of due care upon computer software designers.<sup>120</sup>

The second justification for strict liability can apply to CAD designers, who in the near future will most likely be associated with large hospitals, or large thirty-party 3D printing vendors, and will be in a significantly better position to absorb the costs of injury and redistribute them to the consumers of their products. Considering that the design flaw of the CAD model for a medical device could have tragic and costly consequences for its end user, it is most equitable to spread possible liability costs evenly upon those who profit from its sale and those who benefit from the product.<sup>121</sup> A CAD designer could also easily spread these costs of risk in the form of higher fees, or through the purchase of malpractice insurance.<sup>122</sup> At least one legal scholar has argued that design professionals, such as architects, are the most capable of bearing and spreading the losses incurred by the end user for defects in its designs.<sup>123</sup> Interestingly, this commenter also acknowledges that the risk allocation could be redistributed indirectly.<sup>124</sup> In the case of 3D CAD designs for medical products, the CAD designer would pass these costs on to the clinic or hospital, with these entities then passing these costs equally among their customers.

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<sup>118</sup> See DOUGLAS DANNER & LARRY L. VARN, 4 *Pattern Discovery Products Liability* 3d § 39:3 (Feb. 2016) ("Rather than focus on the behavior of the manufacturer, as in a negligence action, strict liability focuses on the product itself.").

<sup>119</sup> See Frances E. Zollers et al., *No More Soft Landings for Software: Liability for Defects in an Industry That Has Come of Age*, 21 SANTA CLARA COMPUTER & HIGH TECH. L.J. 745, 770 (2005) ("In a program that contains millions of lines of code, it may be that the presence of a few bugs will not qualify as negligence and relieve the producer of liability for any injuries.").

<sup>120</sup> See *Diversified Graphics, Ltd. v. Groves*, 868 F.2d 293, 297 (8th Cir. 1989) (holding computer software consultants to a professional standard of care).

<sup>121</sup> See Lannetti, *supra* note 100, at 835 ("[A]s new technologies emerge in response to the needs of society, it only makes sense that any losses incurred as a result of technological defects should be spread among all who benefit from the advances.").

<sup>122</sup> See generally Jeff Sobel, *Architect Tort Liability in Preparation of Plans and Specifications*, 55 CALIF. L. REV. 1361 (1967) (arguing that architects can spread the risk by increasing their fees and are more likely to purchase malpractice insurance than are their clients).

<sup>123</sup> See *id.* at 1362.

<sup>124</sup> *Id.* at 1363-64.

Most importantly, increased risk of liability upon CAD designers will impose significant pressure on them to take due care to investigate potential failures with its designs. It is frequently stated by courts that consumer safety is the primary motivating factor behind strict liability.<sup>125</sup> No longer insulated by difficult-to-prove negligence standards, CAD designers will be motivated to provide adequate warnings and detailed instructions to physicians and 3D printer vendors regarding potential pitfalls of its designs.<sup>126</sup> It is conceded that a CAD designer can only minimize those injuries which they are in control of, such as the defects in the coding, warnings and instructions and other defects, such as those strictly relating to the 3D printer itself. Negligence on the part of its operator or the physician, cannot be curbed by an imposition of liability upon the CAD designer. Nevertheless, strict liability should be expected to act as a deterrent to some of the most potentially devastating injuries of defective products – those relating to the design itself.

### **B. Strict Liability for CAD Designers Would Not Be a Big Leap for the Courts**

A close investigation of the relevant landscaping dealing with similar factual cases to CAD designers suggests that courts would not be required to make such a huge leap in finding CAD designers strictly liable for defects in its blueprints. For one thing, the Third Restatement is mistaken in asserting that tangibility dictates whether something is a “product” under strict liability principles.<sup>127</sup> For example, courts have often ruled that non-tangible items such as electricity, as well as information contained in aeronautical and navigational chart are products under strict liability principles.<sup>128</sup> Most notably, the Ninth

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<sup>125</sup> *Escola v. Coca Cola Bottling Co. of Fresno*, 150 P.2d 436, 440 (Cal. 1944) (Traynor, J., concurring).

<sup>126</sup> *See Pinkney, supra* note 71, at , 70 (“When software manufacturers are strictly liable they bear all the costs of accidents they will take due care to investigate potential software failure when preventing the failures is less costly than paying for the resulting harm.”). For a discussion on the current cybersecurity regime, see generally Jasper L. Tran, *Navigating the Cybersecurity Act of 2015*, 19 CHAP. L. REV. 483 (2016).

<sup>127</sup> *See* RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 19 (AM. LAW INST. 1998).

<sup>128</sup> *See, e.g., Brockelsby v. U.S.*, 767 F.2d 1288, 1295 (9th Cir. 1985) (holding that an aeronautical chart “was a defective product for purposes of analysis under section 402A.”); *Saloomy 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); *Fluor Corp. v. Jeppesen & Co.*, 170 Cal. App.3d 468, (Cal. Ct. App. 1985) (finding that such aeronautical charts were products for purposes of strict liability); *Hanus v. Texas Utilities Co.*, 71 S.W.3d 874, 877 (Tex. App. 2002) (holding that electricity is “product” when in a form usable by consumers because it can be manufactured, transported and sold like other goods); *Ransome v. Wis. Elec. Power Co.*, 275 N.W.2d 641 (Wis. 1979) (categorizing electricity as a product for strict liability purposes because it can be produced, confined, controlled, transmitted and distributed in the stream of commerce).

Circuit has completely dispensed of the tangible/intangible distinction, instead choosing to rely on whether the defective information was meant to be used as a “highly technical tool.”<sup>129</sup> And while computer software injury lawsuits have thus far not been routinely litigated, there is some authority which suggests that software could also potentially be considered a product under strict liability principles, regardless of whether or not the code itself is stored on a tangible medium.<sup>130</sup> This dispensation of the tangible/intangible distinction has generated acclaim by legal scholars, many of whom contend that courts cannot adequately support the tangible/intangible distinction, and instead argue that all commercially sold information should be considered products.<sup>131</sup>

Second, while most courts refrain from finding architects and engineers strictly liable, there is at least some authority which suggests that those engaged in design related services could be considered “sellers” as opposed to “service providers” under the Second Restatement.<sup>132</sup> In *Schipper v. Levitt & Sons, Inc.*, the New Jersey Supreme Court found that the designer of homes could be held liable under strict liability theories for defects originating in his design.<sup>133</sup> Similarly, in *Abdul-Warith v. Arthur G. McKee & Co.*, a United States District Court found that an engineer of a skip bridge could be held strictly liable for injuries resulting from defects originating in his bridge design as long as the engineer also had a role in implementing the bridge design.<sup>134</sup> While the *Abdul* decision is unhelpful for those courts that wish to impose strict liability on CAD designers whose sole function is the design of the device, it offers significant support for those courts ruling on situations in which a CAD designer played a dual role in the actual printing of its designs.<sup>135</sup> This scenario will most frequently be seen in hospitals that have incorporated the full spectrum of 3D software, printers and skilled CAD designers into their facilities.<sup>136</sup>

Finally, most of the courts that reject strict liability for designers, do so on the grounds that their products are “custom” and not “mass marketed,” and thus do not fall within the ambit of the strict liability regime.<sup>137</sup> Interestingly,

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<sup>129</sup> See *Winter v. G.P. Putnam's Sons*, 938 F.2d 1033, 1036 (9th Cir. 1991) (suggesting that the tangible distinction should be dispensed of in favor of a “technical” distinction).

<sup>130</sup> See Reutiman, *supra* note 107, at 195-96.

<sup>131</sup> *Id.* at 203.

<sup>132</sup> *Schipper v. Levitt & Sons, Inc.*, 207 A.2d 314, 317 (N.J. 1965).

<sup>133</sup> *Id.*

<sup>134</sup> *Abdul-Warith v. Arthur G. McKee & Co.*, 488 F. Supp. 306, 312 (E.D. Pa. 1980) *aff'd sub nom. Abdulwarith v. Arthur G. McKee & Co.*, 642 F.2d 440 (3d Cir. 1981).

<sup>135</sup> *Id.* at 313.

<sup>136</sup> See Meribah Knight, *3-D Printing is Revolutionizing Surgery*, CRAIN'S CHICAGO BUSINESS (Mar. 22, 2014), <http://www.chicagobusiness.com/article/20140322/ISSUE01/140229904/3-d-printing-is-revolutionizing-surgery> (discussing various hospitals that have begun implementing 3D printing labs within their facilities).

<sup>137</sup> See, e.g., *Oliver v. Superior Court*, 259 Cal. Rptr. 160, 161 (Cal. Ct. App. 1989) (holding that the theory of strict liability does not apply to custom or non-mass produced items); Jonathan K. Gable, *An Overview of the Legal Liabilities Facing Manufacturers of Medical Information Systems*,

nowhere in Justice Traynor's articulation of product liability principles, nor in the drafter's comments of the Second Restatement does it suggest that mass production or distribution is a prerequisite to support a determination that a particular item qualifies as a "product."<sup>138</sup> In fact Traynor, the drafters of the Second Restatement, and other prominent tort scholars have repeatedly argued that the primary justification for strict liability relates to "public interest in human life, health and safety."<sup>139</sup> Based on this justification, it should make little difference whether or not a product is custom-made for a customer or if it was produced in mass quantities. Rather, the primary focus should be on whether the implementation of a strict liability regime upon a specific subset of items would further the policy objectives underlying strict liability.<sup>140</sup> Along these lines, some tort scholars have suggested that an appropriate line to draw should be whether "the defendant is an integral part of the composite business enterprise responsible for placing the product in the stream of commerce."<sup>141</sup>

### C. Strict Liability for Hospitals or 3D Printer Manufacturers Is Undesirable

As discussed, the imposition of strict liability for CAD designers for defects originating in its designs is justified by the policy arguments underlying the doctrine.<sup>142</sup> At first blush, these same policy justifications seem to also apply to hospitals, 3D printer manufacturers, or software designers because these entities, which appear to stand in a substantially similar position to that CAD designer, would also be in a better position to more equitably distribute costs relating to injuries that arise out of its products.<sup>143</sup> Additionally, the difficulties facing plaintiffs who wish to prove negligence actions against a hospital or medical professional are well documented and despite some of the similarities,

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5 QUINNIPIAC HEALTH L.J. 127, 147 (2001) (noting that courts look to the custom or mass-manufactured nature of the product in determining whether to hold designers strictly liable).

<sup>138</sup> See *Munhoven v. Northwind Marine, Inc.*, 353 F. Supp. 2d 1072, 1074 (D. Alaska 2005) (noting that there is nothing in Alaskan law, nor the Restatement, imposing a mass-production requirement for the imposition of strict liability principles).

<sup>139</sup> See William L. Prosser, *Assault Upon the Citadel*, 69 YALE L.J. 1099, 1121-22 (1960); see also Robert A. Prentice Mark, "Tort Reform" and the Liability "Revolution": *Defending Strict Liability in Tort for Defective Products*, 27 GONZ. L. REV. 251, 273 (1992) (noting that the two most important policies underlying the doctrine of strict liability are creating incentives for safety and risk-spreading.); Gerald F. Tietz, *Strict Products Liability, Design Defects and Corporate Decision-Making: Greater Deterrence Through Stricter Process*, 38 VILL. L. REV. 1361, 1415-16 (1993) ("Creating incentives for safety is one of the most important policies underlying strict products liability law.").

<sup>140</sup> See Reutiman, *supra* note 107, at 203 (Arguing the typical distinction, instead opting for a case-by-case analysis which "differentiates between those software manufacturers that satisfy the policy grounds for imposition of strict liability and those that do not satisfy the policy grounds.").

<sup>141</sup> CHARLES J. NAGY, JR., AM. L. PROD. LIAB. 3d § 5:24 (Feb. 2016).

<sup>142</sup> See *supra* Section V.A.

<sup>143</sup> See Lannetti, *supra* note 100, at 835.

there are critical differences between these entities and which warrant caution in applying strict liability.<sup>144</sup>

The imposition of strict liability upon hospitals for injuries which arise out of rendered 3D medical services is likely lead to an unacceptable increase in the price of health care. In *Magrine v. Krasnica*, a New Jersey court aptly noted the “relevant considerations” in application of strict liability include the spreading of risk and increased product safety.<sup>145</sup> However, the court also stressed that these policy considerations are “not nearly enough when laid beside other more basic considerations” such as the adverse effect strict liability would have upon the price of healthcare.<sup>146</sup> Similarly, in *Newmark v. Gimbel's, Inc.*, another New Jersey court stressed that the policy considerations underlying strict liability applied with less force in the context of the medical professional because the health and general welfare of the people outweigh the doctor’s imposition.<sup>147</sup> Indeed, commentators have noted the strong qualitative basis that “holding health care providers strictly liable for defects in prosthetic devices . . . would likely result in higher health care costs.”<sup>148</sup> Affordable healthcare, which continues to remain out-of-reach for many Americans, must remain the main priority for lawmakers.<sup>149</sup> Access to basic healthcare must not be outweighed by our desire for cutting edge products.<sup>150</sup>

Besides for the increased costs of health care, there are significant concerns that an imposition of strict liability on hospitals for 3D products would dissuade hospitals from utilizing 3D printed products and technologies in their facilities.<sup>151</sup> For example, in 1994, the California Court of Appeal ruled that a hospital was not strictly liable for defects arising out of the use of a cutting-edge surgical laser, stressing that would “ill serve the public good by discouraging hospitals that feared expanded liability from providing equipment utilizing recent

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<sup>144</sup> See generally Moore, *supra* note 103 (exploring state court decisions and their rationales).

<sup>145</sup> *Magrine v. Krasnica*, 227 A.2d 539, 545 (N.J. Super. Ct. Law Div. 1967).

<sup>146</sup> *Id.* at 546. For a discussion of the current healthcare crisis, see generally Eric Lindenfeld, *Moving Beyond the Quick Fix: Medical Malpractice Non-Economic Damage Caps a Poor Solution to the Growing Healthcare Crisis*, 41 T. MARSHALL L. REV. 109 (2015).

<sup>147</sup> See *Newmark v. Gimbel's, Inc.*, 258 A.2d 697, 703 (N.J. 1969).

<sup>148</sup> See *Royer v. Catholic Med. Ctr.*, 741 A.2d 74, 78 (N.H. 1999); see also *Ayyash v. Henry Ford Health Sys.*, 533 N.W.2d 353, 356 (Mich. Ct. App. 1995) (holding that an imposition of strict liability for hospitals would “place an unrealistic burden on the physicians and hospitals of this state to test or guarantee the tens of thousands of products used in hospitals by doctors.”).

<sup>149</sup> See *Medical Cost Trend: Behind the Numbers 2016*, PWC, <http://www.pwc.com/us/en/health-industries/behind-the-numbers/behind-the-numbers-2016.html> (last visited Dec. 15, 2015).

<sup>150</sup> Another legal scholar challenges the application of strict liability principles to hospitals, asserting that the resulting increase in hospitalization costs “could be devastating to the national economy.” See Frank J. Vandall, *Applying Strict Liability to Professionals: Economic and Legal Analysis*, 59 IND. L.J. 25, 34 (1984) (“Since most patients would not consider a small amount determinative, it is unlikely that the application of strict liability will cause a substantial decrease in the demand for medical services.”).

<sup>151</sup> See generally Cupp, *supra* note 72.

technological advances.”<sup>152</sup> Finally, due to the unique nature of the manufacturer-consumer relationship, there will be no large name medical device manufacturers whom hospitals can pass off liability to in the form of indemnification agreements.<sup>153</sup>

Holding 3D printer manufacturers strictly liable for product defects will place a stranglehold on a budding industry before it has had the opportunity to blossom.<sup>154</sup> As explained earlier, the imposition of liability upon 3D printing manufacturers for any and all defects which exist in the end product would be an absurd proposition, and far exceed strict liability principles as envisioned by Justice Traynor.<sup>155</sup> However, this paper also urges that 3D printer manufacturers should be shielded from strict liability for defects which are alleged to have originated in the 3D printer itself, at least for the time being.<sup>156</sup> This type of strict liability immunity, and “legal nurturing” for “infant industries” is not new and many legal historians suggest that the nineteenth century judges replaced a form of strict liability with the negligence standards in order to protect infant industries in the United States.<sup>157</sup> More recently, courts and legislators have implemented strict liability carve-outs for products such as bloods and vaccines, recognizing the massive social benefits of these products exceeds any justifications underlying strict liability.<sup>158</sup> Other commentators have suggested that the benefits of strict liability, such as the “risk spreading” rationale cannot be realized in immature industries that cannot readily obtain insurance against risks.<sup>159</sup>

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<sup>152</sup> San Diego Hospital Ass’n. v. Superior Court, 35 Cal. Rptr.2d 489, 493 (Cal. App. 1994).

<sup>153</sup> See Bartolo, *Tales of Informed Consent: Four Years on an Institutional Review Board*, 2 HEALTH MATRIX 193, 206 (1992) (discussing indemnification agreements between hospitals and device manufacturers as a method for hospitals to avoid institutional liability).

<sup>154</sup> See generally Spencer Thompson, *3D Printing Is Coming – So Let’s Not Strangle the Industry at Birth*, THE GUARDIAN (Oct. 16, 2012), <http://www.theguardian.com/commentisfree/2012/oct/16/get-ready-for-3d-printing>.

<sup>155</sup> See *supra* Section IV.B.

<sup>156</sup> See *Woods v. Luertzing*, 400 A.2d 562, 566 (N.J. Super. Ct. Law Div. 1979) (holding that “[s]trict . . . liability during the attempt to find out what a product can and cannot do, is senseless and can only deter the development of new products and processes.”).

<sup>157</sup> See MORTON J. HORWITZ, *THE TRANSFORMATION OF AMERICAN LAW, 1780-1860* 99-101 (1977) (discussing how the shift from strict liability to negligence subsidized infant industry.); see also Childers, *supra* note 106, at 172 (“The concept that nascent industries deserve some protection from tort liability has an impressive pedigree. The development of strict products liability doctrine was delayed at the beginning of the industrial revolution, largely to give the new industrial technologies time to “get off the ground” and to mature before subjecting them to the additional externalities imposed by tort liability.”).

<sup>158</sup> Suppliers of blood and vaccines escape liability through statutes implemented to shield manufacturers from liability. See Richard C. Ausness, *Unavoidably Unsafe Products and Strict Products Liability: What Liability Rule Should Be Applied to the Sellers of Pharmaceutical Products?*, 78 KY. L.J. 705, 747 (1990).

<sup>159</sup> Childers, *supra* note 106, at 173.



### CONCLUSION

The Supreme Court has repeatedly stated that it is “axiomatic that the common law is not immutable but flexible, and by its own principles adapts itself to varying conditions.”<sup>160</sup> It is imperative that courts implement this long-standing principal by imposing strict liability on entities in the supply chain which traditionally have not been held strictly liable. Specifically, holding CAD designers strictly liable for defects originating in 3D designs would relieve much of the burden facing plaintiffs seeking redress from significant personal injuries caused by 3D printed medical products. This model is consistent with the policies underlying strict liability, nor would it require courts to make overly ambitious jumps in legal reasoning, and most importantly, it would not impose excessive costs upon a budding industry.

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<sup>160</sup> *Mullen v. United States*, 263 F.2d 275, 279 (D.C. Cir. 1958).