Masthead Logo

Santa Clara High Technology Law Journal

Volume 35 | Issue 3

Article 2

4-2-2019

DEFECTIVE COMPUTER-AIDED DESIGN SOFTWARE LIABILITY IN 3D BIOPRINTED HUMAN ORGAN EQUIVALENTS

Jamil Ammar

DEFECTIVE COMPUTER-AIDED DESIGN SOFTWARE LIABILITY IN 3D BIOPRINTED HUMAN ORGAN EQUIVALENTS

By Jamil Ammar [†]

Three-dimensional (3D) bioprinting offers the exciting prospect of printing 3D multicellular human organs by combining a host of specialisms, including software development, biotechnology and tort law. 3D bioprinting methods rely on highly specialized computer software that incorporates computer-aided design (CAD). Optimizing development of CAD software is paramount to the quality of the final bioprinted organ. This optimization is computationally intensive, and its success plays a critical role in regulating key aspects of the final bioprinted organ, such as mechanical and cell growth properties of the scaffold, behavior, and cell differentiation.

Policies underlying strict product liability law are highly relevant to 'defective' CAD software. Given the potentially life threatening impact of defective software, this article proposes that the U.S. rethinks its approach to liability of such defective software. This article proposes a policy-based approach that could be adapted to determine which aspects of the manufacturing process of a bioprinted human organ justify the added consumer protection provided by strict product liability.

†Academic Associate, Faculty of Social Science and Humanities, Ontario University Institute of Technology, Jamil.Ammar@uoit.ca.
An earlier version of this article was presented to Osgoode Hall Law School seminar series. Special thanks to Giuseppina D'Agostino, Saptarishi Bandopadhyay, and John N. Davis for commenting on, providing feedback or supporting this article. For financial support, the author would like to thank the Institute of International Education (IIE-SRF), New York.

CONTENTS

INTRODUCTION

Three-dimensional (3D) bioprinting is an emerging industry that offers the exciting prospect of printing, in 3D, multicellular human organ equivalents (organ equivalent devices or 'OEDs') for use in a clinical disease setting.[1] Such 3D bioprinting methods rely on computer-aided design (CAD) and computer aided manufacturing (CAM) in order to design, and manufacture OEDs. First, specialized executable CAD software must be created by the CAD developer. This CAD software is then used by the 'CAD user' to create a bespoke (patient-specific) 3D CAD model of the patient's organ that can be used for bioprinting (the 'CAD print file'); this CAD print file is typically derived from 3D image data obtained from methods such as computed tomography (CT) or magnetic resonance imaging (MRI).[2]

---

[1] Sean Murphy & Anthony Atala, *3D Bioprinting of Tissues and Organs*, 32 NATURE BIOTECHNOLOGY 773 (2014).

[2] Wei Sun, Binil Starly, Jae Nam & Andrew Darling, *Bio-CAD modeling and its applications in computer-aided tissue engineering*, 37 COMPUTER-AIDED DESIGN 1097 (2005).

The creation of the CAD print file presents two key technical challenges: (i) replication of intricate organ micro-architecture and (ii) organization of multiple cell types at a resolution that is sufficient to manufacture a fully functional organ.[3] A typical human organ consists of multiple cell types, including specific functional, structural, and supportive cells.[4] Finally, the CAD print file is used to manufacture the final OED using bioprinting methods.

Creating the optimum CAD print file is paramount to successful OED bioprinting, since the design of that file plays a key role in determining the mechanical properties of the OED's cell scaffold (the structure providing support to 3D bio-printed cells to multiply), cell growth, cell dynamics and differentiation.[5] The final use of the CAD software, via the CAD print file, therefore, has an indisputably specific set of characteristics that must be taken into account when assessing the concept of liability during CAD software design and development. While offering enormous benefits, methods of CAD software development may carry generic risks for which liability rests with the developer.[6] This is particularly significant for OED manufactures, since OED quality relies heavily, albeit not exclusively, on CAD software quality.

In the medical 3D bioprinting field, three theories are, in principle, relevant to the protection of the patient against injuries that are attributable to defective CAD software: (i) medical malpractice (a subset of negligence law),[7] (ii) breach of warranty under the Uniform Commercial Code (UCC),[8] and (iii) strict liability. None of these theories, however, adequately address the range of injuries that could potentially arise due to use of defective CAD software. This article will explore these issues in the framework of the ongoing conflict between negligence, breach of warranty, and strict liability. In this context, 3D bioprinting creates the possibility of extending theories of liability; redefining the parameters of tort liability where healthcare providers

---

[3] Murphy & Atala, *supra* note 1, at 773-85.

[4] Murphy & Atala, *supra* note 1, at 780.

[5] Dong-Woo Cho, Jung-Seob Lee, Jinah Jang, et. al., ORGAN PRINTING 5-2 (Morgan & Claypool Publishers) (2015).

[6] Broadly speaking, absent a consensual agreement to the contrary, the manufacturer of a given product, including medical devices, is liable for its quality, reliability and safety and thus might be held accountable for any resulting damages.

[7] Malpractice is a type of negligence occurs when a licensed professional (like a doctor, lawyer or accountant) fails to provide services as per the standards set by the governing body ('standard of care'). Negligence is a failure to exercise the care that a reasonably prudent person would exercise in like circumstances. It applies to harm caused by carelessness, not intentional harm.

[8] *See e.g., Motorola Mobility, Inc. v. Myriad France SAS*, 850 F. Supp. 2d 878 (N.D. III. 2012) (alleging defective software pleaded as a breach of warranty).

provide both semi-traditional manufacturing and healthcare services. The definitions of software developer, fabricator, or manufacturer (rather than healthcare provider), and, equally important for our discussion here, the products versus services dichotomy, will be scrutinized.

From the perspective of product liability, courts in the U.S. consider computer software to be a service rather than a product. To date, courts have been reluctant to extend theories of product liability to software.[9] In the same context, the near-unanimous common wisdom and current holding of courts is that the primary function of hospitals and other healthcare providers is to provide services rather than to sell products.[10] This creates a technical dichotomy that to date has created an immunity for healthcare providers and medical professionals against strict liability claims for the effects of products used 'incidentally' in the provision of healthcare. The manufacturers of those products, however, may still be subject to strict liability law.

Product liability is a critical policy issue in the field of 3D bioprinting. It is necessary to reconsider the premise that software developers, especially in a healthcare setting, are not intrinsically subject to strict liability rules in relation to the software they provide. Such an extensive immunity, while justified in a conventional health care setting, is poorly-suited to the 3D bioprinting age for which software errors can cause actual physical injury to patients. Liability regimes currently consist of a collection of different legal systems that do not properly fit the needs of OED manufactures due to the fact that OED bioprinting combines both products and services.[11] Healthcare professionals, medical device manufacturers, and medical software developers have, traditionally, been clearly separated; this is no longer the case, particularly when OED design and bioprinting are carried out by the same entity.

---

[9] *See generally, ClearCorrectOperating, LLC v. Inter'l Trade Comm'n*, 810 F.3d 1283 (Fed. Cir. 2015); *Sanders v. Acclaim Entm't*, 188 F.Supp. 2d 1264 (D. Colo. 2002)("holding that computer games are not products for strict liability purposes"); *Wilson v. Midway Games, Inc.*, 198 F.Supp.2d 167, 173 (D. Conn. 2002)(indicating that interactive "virtual reality technology" is not a "[product] for the purposes of strict products liability"); *James v. Meow Media, Inc.*, 90 F.Supp. 2d 798, 810 (W.D. Ky. 2000) (stating that "[w]hile computer source codes and programs are construed as 'tangible property' for tax purposes and as 'goods' for UCC purposes, these classifications do not indicate that intangible thoughts, ideas, and messages contained in computer video games, movies, or internet materials should be treated as products for purposes of strict liability"), aff'd, 300 F.3d 683, 700–01 (6th Cir. 2002) (software makers and website operators did not deal in "products").

[10] *Perlmutter v. Beth David Hospital*, 123 N. E. 2d 792, 795 (N.Y. 1954) (arguing that medical care provider provides patients with services not goods).

[11] Murphy, *supra* note 1.

The significance of CAD software to the bioprinting process originates from three notable characteristics. First, unlike the case of electronic and mechanical assemblies, software failures always arise due to development or engineering defects.[12] Second, a software-based medical device is generally more complicated and technically demanding than software used to produce other conventional electronics. The overwhelming majority of 'conventional' software cannot be fully tested for every combination of potential pathway through the software source code.[13] It follows that not all 3D bioprinting software defects can be fully tested for every combination of potential pathways through the software source code either; this has potentially far-reaching significance given the importance of CAD software in determining the quality of the final bioprinted OED. Thirdly, from a welfare standpoint, apart from the potential costs of human harm or even death, it is considerably cheaper to correct software defects early rather than late in the development lifecycle.[14] Using this welfare argument, it can be argued that strict liability could be extended to aspects of CAD development given the fact that the CAD developer is in a strong position to discourage the development of defective software through arguments of cost-effectiveness.

In this context, one should ask how the law should treat suits brought by victims of defective CAD software in the field of OED manufacturing. In this article, we shall look for liability on the part of two potential defendants: (i) healthcare providers that use CAD print files, both organizing and controlling the bioprinting processes within their premises (CAD users), and (ii) non-manufacturing developers of CAD print files (a CAD developer who produces an executable CAD program but does not herself use the CAD program to create OEDs or files to print OEDs).

The main article will be structured as follows. First, we will discuss how and why the OED bioprinting industry presents serious legal and technical challenges in the fields of professional and product liability, especially regarding defective CAD development. We will then investigate the possibility of extending liability for defective CAD software to manufacturing and non-manufacturing healthcare providers; here we will highlight the need to clearly set out the general obligations of the CAD developer, alongside the obligations of the healthcare providers that use the CAD software during OED

---

[12] David Vogel, MEDICAL DEVICE SOFTWARE VERIFICATION, VALIDATION, AND COMPLIANCE 27 (Artech House, 2011).

[13] *See generally*, *Id.*, at 27.

[14] *Id*. at 34.

manufacturing. These discussions will be guided by the hypothesis that the majority of relevant regulations and guidance documents have been developed with conventional medical devices firmly in mind.[15] We will conclude by suggesting a promising approach for addressing the liability challenge in the context of defective software development.

I. REGULATORY REGIMES FOR 3D BIOPRINTING OF OEDS: A BRIEF INTRODUCTION

There is not currently a set of specific regulations that adequately meet the quality, safety and efficacy requirements of OED manufacturing. Depending on how a manufactured OED is ultimately characterized, the OED itself falls under a vast body of law, regulations, and guiding documents, none of which adequately covers the liability issues that might arise from use of defective CAD software. The U.S. Food and Drug Administration (FDA) draft guidance titled "Technical Considerations for Additive Manufactured Devices", as an example,[16] clearly states that it does not address the use or "incorporation of biological, cellular, or tissue-based products in AM (additive manufacturing)."[17] Here, it is useful to keep in mind that a 3D bioprinted OED is an implantable surgically invasive medical body part equivalent; in other words, OEDs are intended to be surgically introduced into the human body. Therefore, OEDs must be 'designed' and bioprinted (manufactured) in such a way that, when implanted under suitable conditions and for the defined purpose, they do not compromise the clinical condition or safety of the patient.

---

[15] None of the currently applicable regulations and guidance documents apply to 3D bio-printing of human organs. Examples include, *The Technical Considerations for Additive Manufactured Devices: Draft Guidance for Industry and Food and Drug Administration Staff*, U.S. DEP'T HEALTH & HUM. SERVICES (May 10,2016). Page 2 explicitly excluded manufactured tissues and organs. The Recital 13 of Regulation 2017/745 of the European Parliament (April 5, 2017) also excludes products containing viable tissues or cells of human or animals origin from the scope of this Regulation. *Recital 8 and Article 2 (c) exclude human organs from the scope of Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells*, (OJ) L. 102/48 7.4.2004 (2004).

[16] *Technical Considerations for Additive Manufactured Devices: Draft Guidance for Industry and Food and Drug Administration Staff*, U.S. DEP'T HEALTH & HUM. SERVICES (May 10,2016), http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm499809.pdf.

[17] *Id.* at 2. *See also*, *Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue Based Products: Minimal Manipulation and Homologous Use, Guidance for Industry and Food and Drug Administration Staff*, FDA (2017), https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/cellularandgenetherapy/ucm585403.pdf.

Based on the risks that OEDs present, the current regulatory regime in the U.S. establishes various levels of oversight for 'conventional' and 3D printed medical devices. Devices that are purported or represented to be used in "supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," (Class III) or that present a "potential unreasonable risk of illness or injury" are subject to the most rigorous testing process and federal oversight.[18] A manufacturer of a Class III device must submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness; these studies should have been published or should reasonably be known to the applicant. Among other requirements, the applicant must also provide a 'full statement' of the device's "components, ingredients, and properties and of the principle or principles of operations."[19] Only once the device's safety and effectiveness are reasonably assured is it possible to grant approval.[20] The FDA must "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use."[21]

In summary, the result of this regulation is that the FDA can approve a device that presents significant risk as long as it also offers sufficient patient benefit in the context of available alternatives.[22] Class III devices are subject to reporting requirements.[23] Thus, any new clinical or scientific studies concerning the device that the applicant is aware of or should reasonably be aware of, as well as incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred, must all be reported to the FDA.[24]

Broadly speaking, satisfying the safety criterion is a matter of risk-benefit analysis; effective medical devices are rarely risk-free. The FDA, which is responsible for protecting the public health by assuring the safety, efficacy, and security of biological products, employs two

---

[18] Examples include replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators; Classification of Devices Intended for Human Use, 21 U.S.C § 360c (2017).

[19] 21 U.S.C § 360e(c)(1)(B) (2017).

[20] 21 U.S.C § 360e(d)(2) (2017).

[21] 21 U.S.C § 360c(a)(2)(C) (2017).

[22] For example, the FDA approved a ventricular assist device for children with failing hearts, even though the survival rate of children using the device was less than 50 percent. *See* FDA, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, *Debakey VAD Child Left Ventricular Assist System-H030003, Summary of Safety and Probable Benefit* 20 (2004), http://www.fda.gov/cdrh/pdf3/H030003b.pdf.

[23] 21 U.S.C § 360i (2017).

[24] 21 C.F.R § 814.84(b)(2) (2013),

specific regulatory tools: (i) the Federal Food, Drug and Cosmetic Act (as amended), and (ii) Regulation 21 CFR (800-1299). Of particular significance to our discussion is Part 820 of the Code (Quality System Regulations).[25] In the U.S., Section 351 of the Public Health Act and Title 21, Part 1271 of the CFR (Human Cells, Tissues, and Cellular and Tissue-Based Products) are also relevant. The latter regulates stem cell-based medical devices (often referred to as somatic cell therapies or biologics).[26] Other voluntary initiatives are also utilized, including FDA guidelines, industry standards and information reports.

A device that is manufactured from or that incorporates human tissues is typically regulated as a human cell, tissue, or cellular- or tissue-based product (HCT) under 21 CFR Parts 1270 and 1271.[27] Both Parts require tissue establishments to, among other things, test donors and prepare and follow written procedures for the prevention of the spread of disease. [28] It should be noted that vascularized human organ transplants, such as kidney, liver, and heart transplants, are not regulated under this part; instead, transplantations are overseen by the Health Resources Services Administration (HRSA). [29] It is yet to be decided if OEDs will be classified as tissue-based products. In the meantime, this vast body of law, regulations and guiding documents are, at best, partially applied.

A. Intersection between Traditional Tort Liability and CAD Software

Here we will survey the U.S. legal framework for software development liability. Our goal is not to provide an exhaustive review of the minutiae of black letter liability law, but rather to identify the building blocks for moving forward. U.S. tort liability laws consist of a conglomeration of legal regimes that include negligence, strict liability or a combination of the two.[30] Negligence is a fault-based system whereby a customer who has suffered loss or damage resulting

---

[25] 21 C.F.R § 820.30 (2019) applies to medical device software professionals. 21 C.F.R §§ 820.30, 820.70 are Design Control Regulations (regulating how a medical device, designed, developed, reviewed, tested, and documented). Section 820.70 regulates production and process controls. 21 C.F.R § 820.70 (2019).

[26] 21 C.F.R § 1271.10 (2014).

[27] Examples include, bone, skin, corneas, heart valves, and hematopoietic stem/progenitor cells derived from peripheral all fall under this category.U.S. FOOD AND DRUG ADMINISTRATION, *Tissue & Tissue Products* (2018), https://www.fda.gov/biologicsbloodvaccines/tissuetissueproducts/default.htm.

[28] *Id*.

[29] *Id*.

[30] RESTATEMENT OF TORTS §§ 281-503 (1934); RESTATEMENT OF TORTS §§ 504-24 (1938).

from defective software can bring an action in negligence against the software developer;[31] defective software development typically falls under this broad category. This common form of legal action will be discussed briefly later. In contrast, the strict liability doctrine is based on the notion that a manufacturer is liable for product defects, regardless of fault.[32] For reasons that will become clear shortly, neither strict liability nor negligence regimes can be applied adequately to software development in the field of OED manufacturing. Here, we will solely examine the possibility of extending the liability of the CAD developer under the uncommon strict liability path. In this context, 3D bioprinting methods create a number of liability-related challenges that are yet to be addressed.

In the U.S., common-law strict liability standards rely on either the Restatement (Second) of Torts[33] or Restatement (Third) of Torts.[34] Under the Restatement (Second) of Torts, the task of establishing a product defect includes an analysis of consumer expectation, risk utility, and manufacturing quality.[35] In contrast, the test to determine whether a product is defective under Restatement (Third) of Torts raises three interrelated sources of defect: (i) manufacturing defects, (ii) development defects, and (iii) defects related to inadequate user instructions or warnings.[36] A key point to note here is that integrating different components into a product might introduce certain dangers for which liability rests with the patient. Provided that the supplied components are not defective and the component supplier has not participated in the product design, the component supplier is normally under no duty to warn end-users of any dangers in the product in which their components are incorporated.[37] In all cases, strict liability does not apply unless the said defective product was sold by a person or entity engaged in the 'business of selling'.[38] Manufacturers, wholesalers, retailers, and distributors are all considered to be involved

---

[31] This common form of legal action will be briefly addressed here.

[32] David Owen & Mary Davis, PRODUCTS LIABILITY §5:29 (4th ed. 2016).

[33] RESTATEMENT (SECOND) OF TORTS §402A (Am. Law inst.1965).

[34] Patrick Comerford & Erik Belt, *3DP, AM, 3DS and Product Liability*, 55 SANTA CLARA L.REV. 821, 825-30, 832, 835- 36 (2015).

[35] RESTATEMENT (SECOND) OF TORTS §402A reads: "(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if (a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold".

[36] RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY. § 1- 2 (AM. LAW INST. 1998).

[37] RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY § 5; *see also*, Comerford, *supra* note 34 (discussing supplier's duty to warn under the third restatement of torts).

[38] RESTATEMENT (SECOND), *supra* note 35, §402A (1) (A).

in the 'business of selling'.[39] Strict liability, however, does not apply to occasional sales.[40] Nonetheless, a seller need not be exclusively engaged in selling the product category that caused injury to the plaintiff for liability to attach.[41]

Computer software is commonly characterized as a service rather than a product. To date, courts have been reluctant to extend product liability theories to defective software.[42] The Restatement (Third) of Torts defines a product as a 'tangible' property.[43] In *ClearCorrect Operating, LLC v. International Trade Commission*[44], the Federal Circuit pointed out that a digital 3D printing file (CAD) is not an 'article' under the Tariff Act of 1930 because digital files are not "material things and thus not articles." Software that was developed specifically for a customer's needs is considered to be a service.[45] The Restatement (Third) of Torts, however, lists electricity as an intangible item that qualifies as a product for the purposes of tort liability.[46] *Brocklesby v. United States* [47] followed a similar path, holding that an aeronautical chart was a defective 'product' under Section 402A. The Court in *Fluor Corp. v. Jeppesen & Co.* also concluded that an instrument approach chart was a 'product', and hence subject to strict liability.[48] The Restatement (Third) of Torts, however, clearly and categorically excludes human tissue, even when provided commercially, from the scope of strict liability.[49]

Here one should ask whether 3D bioprinting renders parts product liability obsolete, but we believe that parts of product liability are not necessarily obsolete. In *Winter v. G.P. Putnam's Sons*,[50] the Ninth Circuit drew an analogy between defective computer software and

---

[39] RESTATEMENT (SECOND) OF TORTS, §402A (1964).

[40] RESTATEMENT (THIRD) OF TORTS, PRODUCT LIABILITY; *see also*, Comerford, *supra* note 34.

[41] *Id.*

[42] *James v. Meow Media, Inc., supra* note 9 at 810.

[43] RESTATEMENT (THIRD) OF TORTS, *supra* note 36, § 19.

[44] *ClearCorrect Operating, LLC v. International Trade Com'n*, 810 F.3d 1283, 1287-1294 (Fed. Cir. 2015).

[45] *Advent Sys. Ltd. v. Unisys Corp*, 925 F. 2d 670 (3d Cir. 1991); *Data Processing Serv. v. L.H. Smith Oil Corp*, 492 N.E.2d 314 (Ind. Ct. App. 1986).

[46] 'When the context of their distribution and use is sufficiently analogous to the distribution and use of tangible personal property'. *See Smith v. Homes Light*, 695 P.2d (Colo. App. 1984); *Brocklesby v. United States*, 767 F.2d 1288 (9th Cir. 1985); *see also*, *Winter v. G.P. Putnam's*, 938 F. 2d 1033, 1036 (9th Cir. 1991). The Restatement (Third) of Torts states: "Human blood and human tissue, even when provided commercially, are not subject to the rules of this Restatement." RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY § 19(c) (Am. Law Inst. 1998).

[47] *Brocklesby v. U.S.*, 767 F.2d 1288, 1295 (9th Cir. 1985).

[48] *Fluor Corp. v. Jeppesen & Co.*, 216 Cal. Rptr. 68, 70-71 (Cal. Ct. App. 1985).

[49] RESTATEMENT (THIRD) OF TORTS, *supra* note 36, § 19(c).

[50] *Winter v. G.P. Putnam's Sons*, 938 F.2d 1033, 1036 (9th Cir. 1991).

defective products, suggesting that defective software and defective products might be equitable for the purpose of strict product liability.[51] Another interesting view is offered by *Corley v. Stryker Corp*., in which a single-use cutting guide was designed and manufactured from a 3D model of a patient's anatomy using computer software (Class II medical device).[52] In this case, the plaintiff's allegation that the software was defective because the cutting guide that was used during surgery was "unreasonably dangerous in design due to the alleged software defects" survived a motion to dismiss. [53]

The imposition of strict liability, however, can be avoided by invoking the unavoidably unsafe product defense. Restatement (Second) of Torts §402A, comment k (1965), acknowledges that some products are "quite incapable of being made safe for their intended and ordinary use." The seller of such products is not to be held to strict liability for "unfortunate consequences attending their use." [54] This defense under §402A applies to 'design defects' rather than manufacturing defects; [55] it is intended to protect products that cannot be designed to be more safe from strict liability.[56] It is not yet determined whether OEDs will fall within this category of unavoidably unsafe products.

B. Designer or Manufacturer: What's in a Name?

CAD software plays an integral and vital role in the overall design and manufacturing of an OED. The OED design (CAD print file) plays

---

[51] *Id.* at 1036. Where the court reasoned that: "Aeronautical charts are highly technical tools. They are graphic depictions of technical, mechanical data. The best analogy to an aeronautical chart is a compass. Both may be used to guide an individual who is engaged in an activity requiring certain knowledge of natural features. Computer software that fails to yield the result for which it was designed may be another. In contrast, The Encyclopedia of Mushrooms is like a book on how to use a compass or an aeronautical chart. The chart itself is like a physical "product" while the "How to Use" book is pure thought and expression".

[52] *Corley v. Stryker Corp.*, 2014 WL 3375596 *1 (W.D. La. 2014).

[53] *Id.* at 3-4.

[54] RESTATEMENT (SECOND) OF TORTS §402A, comment k (1965).

[55] *Toner v. Lederle Laboratories*, 732 P. 2d 297 (Idaho Supreme Court 1987) at 305; *See also Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 657 (1st Cir. 1981); *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276 (5th Cir.), *cert. denied*, 419 U.S. 1096, 95 S.Ct. 1096, 42 L.Ed.2d 688 (1974); *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121, 128-29 (9th Cir. 1968); *Yarrow v. Sterling Drug, Inc.*, 263 F. Supp. 159, 163 (D. S.D. 1967), *aff'd*, 408 F.2d 978 (8th Cir. 1969); *Kearl v. Lederle Laboratories*, 172 Cal. App.3d 812, 218 Cal. Rptr. 453, 465 (1985); Feldman v. Lederle Labs., 479 A.2d 374, 384 (N.J. 1984); *See also* Victor Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment K*, 42 WASH. & LEE L.REV. 1139, 1141 (1985); Sidney Willig, *The Comment k Character: A Conceptual Barrier to Strict Liability*, 29 MERCER L.REV. 545, 575 (1978).

[56] Wilig, *supra* note 55, at 575.

a key role in regulating the scaffold's mechanical properties, cell growth, behavior, and differentiation.[57] A sophisticated CAD print file almost eliminates waste of printing materials and, thus, reduces costs significantly.[58] While materials, and processes used in OED 3D bioprinting can still be approved by the current regulatory system, the nature of the role that a CAD print file plays raises many new issues, the most pertinent of which is establishing who should technically take the title of 'OED manufacturer'. Given the undisputed impact of the CAD software, should the producer of the CAD print file (CAD user) be considered as the manufacturer or semi-manufacturer of the OED? The FDA defines a manufacturer as "any person who designs, manufactures, fabricates, assembles, or processes a finished device."[59] The term 'manufacturer' includes, but is not limited to, those who perform the functions of "contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions." [60] When regulating Mobile Medical Apps, the guidance document of the FDA provides that a Mobile Medical App manufacturer is "anyone who initiates specifications, designs, labels, or creates a software system or application for a regulated medical device in whole or from multiple software components."[61] Should developers who produce CAD software exclusively for the purpose of bioprinting OEDs, without engaging in the manufacturing methods, be considered manufactures (fabricators)? Following on from that question, how should CAD users who are engaged with the bioprinting process (manufacturing) be considered?

It is not yet clear whether CAD developers will be subject to design claims under strict liability rules. As mentioned before in this article, computer software is generally considered to be a service rather

---

[57]Cho, *supra* note 5, at 5-2.

[58] Mathew Varkey & Anthony Atala, *Organ Bio printing: A Closer Look at Ethics and Policies*, 5 WAKE FOREST J.L. & POLICY 275, 277 (2015).

[59] The Federal Food, Drug, and Cosmetic Act defines a medical device as: "[A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article . . . *intended for use in the diagnosis of disease* or other conditions, or in the *cure*, *mitigation*, *treatment*, or prevention of disease, in man or other animals, or *intended to affect the structure* or any function of the body of man or other animals". 21 U.S.C. § 321(h) (2006).

[60] 21 C.F.R.§820.3(o) (2017).

[61] FOOD AND DRUG ADMINISTRATION, *Mobile Medical Applications*, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH 9 (Feb. 9, 2015) (available at: https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf).

than a product;[62] though it is possible to treat mass-marketed software as a product under the UCC.[63]

Cases seeking compensation for damage caused by allegedly defective software are increasingly proceeded as breach of warranty under the UCC. *Motorola Mobility, Inc. v. Myriad France SAS* is a good example of a case in which it was pleaded that defective software constituted a breach of warranty.[64] In the context of defective CAD print files, however, injury will most likely be suffered by non-purchasing third parties, such as patients, rather than the healthcare provider that actually purchased the defective software. While the plaintiff might allege that their injury was caused by defective CAD print file design, it may be difficult to ascertain the true cause of injury.[65] If the software is licensed, the plaintiff has the option to bring suit against the manufacturer of the OED designed using CAD software who, in turn, can seek contribution or indemnification from the CAD software provider under breach of warranty and other contract-based theories.[66] An interesting question is whether a healthcare provider can be vicariously liable for the actions of a CAD user who fails to meet industry standards, even where the CAD user was acting as an independent contractor.[67] This is particularly important given that non-manufacturing software developers are not liable for defects in their software. The healthcare provider also must ensure that the CAD print file is properly uploaded to the bioprinting machinery and that the

---

[62] *Sys. Am., Inc. v. Rockwell Software, Inc.*, No. C 03-02232 JF (RS), 2007 WL 218242 (N.D. Cal. 2007); *Pearl Invs. LLC. v. Standard I/O, Inc.*, 257 F. Supp. 2d 326, 352–53 (D. Me. 2003).

[63] *See* e.g., *Advent Sys. Ltd. v. Unisys Corp*, 925 F. 2d 670 (3rd Cir. 1991), *Data Processing Serv; v. L.H. Smith Oil Corp*., 492 N. E. 2d 314 (Ind. Ct. App. 1986). *Rottner v. AVG Techs. USA, Inc.*, 943 F. Supp. 2d 222, 230-31 (D. Mass. 2013); *Sys. Design & Mgmt. Info., Inc. v. Kan. City Post Office*, 788 P.2d 878 (Kan. App. 1990). However, the 2005 revisions to UCC §§ 9-102 and 2-105 exclude information from the definition of goods and also define computer software as including any support information provided in connection with the transaction. *See* U.C.C.§§9-102, 2-105(1) (2005). Though, UCC cases focus on products as goods involving economic losses rather than personal injuries. *Advent Sys. Ltd.*, 925 F.2d at 672; *RRX Indus., Inc. v. Lab-Con, Inc.*, 772 F.2d 543, 544 (9th Cir. 1985); *Wachter Mgmt. Co.*, 144 P.3d 747, 749-50 (2006); *Olcott Int'l &Co., Inc. v. Micro Data Base Systems, Inc.*, 793 N.E. 2d 1063, 1068 (2003); *Sys. Design & Mgmt. Info., Inc. v. Kansas City Post Office Employees*, 788 P.2d 878, 879 (1990); *Rottner*, 943 F. Supp. 2d at 224.

[64] *Motorola Mobility, Inc. v. Myriad France SAS*, 850 F.Supp. 2d 878 (N.D. III. 2012).

[65] A notable case in this context is *In re Toyota Motor Corp- Unintended Acceleration Mktg.*, 2013 WL 5733178 (C.D. Cal. 2013).

[66] *See generally*, David Vladeck, *Machines without Principles: Liability Rules and Artificial Intelligence*, 89: 117 WASH. L. REV. 146 (2013).

[67] Unless the hospital explicitly informs patients that the designer of the CAD files is not hospital employee. In this case, the hospital might not be held liable. *See Gilbert v. Sycamore Mun. Hosp*; 622 N.E.2d 788, 793-94 (III. 1993) (the hospital is liable for the negligent act of an emergency room physician because the public could reasonably assume that the physician was an agent of the hospital).

bioprinting process runs correctly. Assuming that OED bioprinting can be supervised by a technician – the person in charge of the department that does the bioprinting or a physician, the healthcare provider might be held liable for bioprinting-related defects, since it has a duty to supervise the quality of the 3D bioprinting processes administered in its premises.

In addition to the production of the CAD print file, the sale of biological and other solvable and non-solvable materials, such as synthetic polymers and natural polymers, is not a discrete isolated event in 3D bioprinting. A 3D bioprinted OED cannot sensibly be subject to expectations of uniformity. After all, even natural organs sometimes suffer catastrophic failure. Due to the complexities of the manufacturing and utilization process, therefore, in the absence of fault on part of the healthcare professional, the source of a defect in a bioprinted OED cannot always be traced to a single component of manufacture, be it the CAD print file (defective software might work seemingly well), the biomaterials, the bioprinting methods, or the advanced professional skills needed to productively bring these efforts together.

Determining what is a proper test to detect a CAD software defect is an unresolved and contentious issue. Limited jurisprudence permits assertion of implied warranty against healthcare providers whenever there is a sale of a product under the UCC.[68] In all cases, identifying the manufacturer is an important first step. Characterizing the CAD user as a manufacturer, even where the CAD print file production and bioprinting methods are performed by the same entity, might not be tenable. Due to the peculiar nature of healthcare provision, the overwhelming majority of courts are reluctant to abandon the malpractice concept and, thus, are unwilling to extend the principle of strict liability to healthcare providers on grounds that the "utility of and the need for them, involving as they do, the health and even survival of many people, are so important to the general welfare as to outweigh in the policy scale any need for the imposition on dentists and doctors of the rules of strict liability in tort."[69]

Measured against these principles, should the principle of exempting the developers of customized software from the rules of strict liability apply to software developers and healthcare providers alike? *Whitehurst v. American National Red Cross* provides interesting

---

[68] *See*, e.g., *M.C. Skelton v. Druid City Hosp. Bd.*, 459 So. 2d 818, 823 (Ala. 1984).

[69] *Brody v. Overlook Hosp.*, 317 A.2d 392, 396 (N.J. Super. Ct. App. Div. 1974); *See also Feldman v. Lederle Labs.*, 479 A.2d 374, 381 (N.J. 1984); *Hoven v. Kelble*, 256 N.W.2d 379, 392 (Wis. 1977); *Cafazzo v. Cent. Med. Health Servs., Inc.*, 668 A.2d 521, 527 (Pa. 1995).

insight. The plaintiff in this case sought to recover damages for injuries that she sustained when she contracted homologous serum hepatitis,[70] alleging that the furnishing of impure blood constituted a sale within the Uniform Sales Act.[71] The Court of Appeals rejected this argument, adding that an extra charge for blood is not indicative of a sale.[72] The court stated that administering a blood transfusion is "not a sale from which an action for breach of implied warranty will lie."[73] Incidental use of a product, such as placing a prosthesis in a patient's mouth, does not constitute a 'sale' of a device, as required for a cause of action sounding in product liability.[74] Hospitals, as healthcare providers, are not engaged in the 'business of distributing' products.[75] One of the requisites, which the Restatement prescribes for the imposition of strict liability, the court reasoned, is that "the seller is engaged in the business of selling such product."[76] Hospitals are not subject to strict liability for "latently defective product[s] supplied . . . by another for . . . use in rendering treatment."[77] With the above descriptions in mind, two important issues must be considered. First, it seems that the production of a CAD print file by a healthcare provider constitutes the performance of a medical 'service'.[78] Does it follow, however, that the performance of such a service by a healthcare provider categorically does not give rise to an action for breach of warranty? If so, who bears liability for claimed defects in a CAD print file that was made exclusively under the control of a healthcare provider and used in clinical procedures within its premises? The answers to these questions rest, among other issues, on the level of personalization by the CAD user that is needed to create a CAD print file, which is used by a manufacturer, to bioprint an OED. A personalized CAD print file is unlikely to be subject to strict liability rules.

The personalization of OED bioprinting clearly blurs the line between the principles of negligence and strict liability. In this context,

---

[70] *Whitehurst v. Am. Nat'l Red Cross*, 402 P.2d 584, 584 (Ariz. Ct. App. 1965). A similar conclusion was reached in *Koenig v. Milwaukee Blood Center, Inc*., 23 Wis. 2d 324, 329 (1964). Maintaining a steady stream of blood supply was the rationale behind the rulings of those cases. *See, Murphy v. E.R. Squibb & Sons, Inc.*, 40 Cal. 3d 672, 680 (1985).

[71] *Whitehurst*, *supra* note 70, at 585.

[72] *Id.* at 586.

[73] *Id.*

[74] *See Goldfarb v. Teitelbaum*, 540 N.Y.S.2d 263, 264 (N.Y. App. Div. 1989).

[75] *Pierson v. Sharp Mem'l Hosp., Inc.*, 264 Cal. Rptr. 673, 676 (Cal. Ct. App. 1989).

[76] *Hartman v. Miller Hydro Co.*, 499 F.2d 191, 192 fn 1; *see also* RESTATEMENT (SECOND) OF TORTS § 402A (AM. LAW INST. 1965).

[77] *Snyder v. Mekhjian*, 582 A.2d 307, 313 (N.J. Super. Ct. App. Div. 1990).

[78] *See* Koenig v. Milwaukee Blood Ctr., Inc., 127 N.W.2d 50, 53 (Wis. 1964).

it is the hospital, (healthcare provider) that is likely to handle most of the bioprinting process, including the CAD print file production.

C. To Regulate or Not to Regulate?

The complexity of using CAD software for 3D bioprinting is likely to place a strain on the current infrastructure of software development regulation. Agency theory teaches us that, although certain innovations can disrupt existing industries, traditional rulemaking and adjudication are, nonetheless, not the best answer to face this disruption.[79] Tim Wu argues that 'threats', when posed in guidance documents, are a more suitable means of seeking to avoid premature regulation than poorly formed or premature laws.[80] In essence, fears regarding economic growth and regulation compliance might ultimately be the most effective means to persuade healthcare providers to adopt a 'workable', albeit incoherent, up-to-date quality design. A recent study conducted by the FDA revealed that compliance with medical regulations does not necessarily ensure the highest possible quality of final health outcome for the patient.[81] Similarly, having well-formed legal/technical definitions in the design documents of source code of the CAD software does not necessarily guarantee fault-free software; defective CAD software can sometimes result from sound technical definitions in the CAD source code.[82] While clear industry standards would help in early identification of potential coding defects,[83] it is unusually challenging for a government agency to be sufficiently omniscient to be able to predict scenarios that may require legal attention in advanced technology industries such as 3D bioprinting.

Despite its advantages described above, a 'threats' policy brings the risk of suboptimal long-term regulation;[84] the software-based medical device industry is a notable example. For almost three decades, the FDA has struggled to develop a comprehensive regulatory initiative for innovative medical products.[85] A prominent example is the Therac-

---

[79] *See generally*, Tim Wu, *Agency Threats*, 60 DUKE L. J. 1841, 1842 (2011).

[80] *Id.* at 1851.

[81] FOOD AND DRUG ADMINISTRATION (FDA), Center for Devices and Radiological Health, *Understanding Barriers to Medical Device Quality* 3-4 (Oct. 31, 2011).

[82] Vogel, *supra* note 12, at 5.

[83] *Id*.

[84] Nathan Cortez, *Regulating Disruptive Innovation*, 29 BERKELEY TECH L. J.:175, 179 (2014).

[85] Historically, the medical device industry flourished with minimal regulation. Legislators most often have taken a reactive rather than proactive regulatory approach to incidents in the medical field that noticeably raised public concern. For example, in the United States, the Food Drug and

25 incident in 1986-87, which led to a number of legislative and regulatory initiatives.[86] Following this incident, in 1987 the FDA published its Draft Policy Guidance for the Regulation of Computer Products.[87] Despite the growing and critical role of software in patient safety, the FDA never finalized their draft guidance, thus failing to transform it into a long term strategy; the draft guidance was finally abandoned, 18 years later, in 2005.[88] In 2013, the FDA published another guidance document that this time addressed issues related to software devices embodied in smartphones.[89] Thus, the FDA's 'threats' policy has been used as a long-term strategy to address software-related issues in the medical field,[90] partially replacing rulemaking and adjudication. Given the highly uncertain nature of software innovations and the associated risks of embarking on premature regulatory exercises, the FDA's conventional wisdom has been to rely on guidance documents rather than decisive regulation.[91] The FDA continues on this path despite the ever-increasing number of critical safety incidents that involve software defects, with as many as a few hundred patients injured in radiation incidents that were caused by either software or user error, just as happened in the Therac-25 case around thirty years ago.[92]

There is no reason to believe that the FDA's regulatory approach to OED manufacturing and use will be any different to that taken for software in general. The FDA is likely to rely on its tentative, short-

---

Cosmetic Act of 1938 was a reaction to increasing public concern and dissatisfaction with ineffective and sometimes unsafe medical device. Today's premarket approvals for drugs (PMAs) came into being on the aftermath of the Thalidomide medical disaster struck in Europe. Again, after the Dalkon Shield Instrauterine device caused injuries to thousands of women, legislators responded to the disaster by the creation of the Medical Device Amendments; requesting medical devices to be premarket approved. *See*, U.S. FOOD AND DRUG ADMINISTRATION, Sulfanilamide Disaster, FDA CONSUMER MAGAZINE (June 1981), (Sulfanilamide killed almost a 100 people). *See also*, Vogel, *supra* note 12, at 14.

[86] A number of cancer patients received massive X -ray overdoes during radiation therapy which led to a number of inquiry to identify potential faults and things that could go wrong with software. *See* Vogel, *supra* note 12, at 15.

[87] *Draft Policy Guidance for Regulation of Computer Products*, 52 FED. REG. 36, 104 (Sept. 25, 1987)

[88] *Annual Comprehensive List of Guidance Documents at the Food and Drug Administration*, 70 FED. REG. 824, 890 (Jan. 5, 2005); *see also* Cortez, *supra* note 84, at 181.

[89] *Mobile Medical Applications. Guidance for Industry and Food and Drug Administration Staff*, U.S. FOOD AND DRUG ADMINISTRATION (Feb. 9, 2015), http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm263366.pdf.

[90] *Annual Comprehensive List of Guidance Documents at the Food and Drug Administration*, *supra*, note 88; *See also* Cortez, *supra* note 84, at 181.

[91] Cortez, *supra* note 84, at 181.

[92] Walt Bogdanich, *Radiation Offers New Cures, and Ways to Do Harm*, NEW YORK TIMES: HEALTH (Jan. 23, 2010).

term approach and publish a number of draft guidance documents to regulate CAD software in the 3D bioprinting field; these documents will likely be used, by default, in the long-term, ultimately leading to suboptimal regulation for this emerging industry.[93] The public interest in human healthcare demands, however, that regulators maintain their efforts in the face of disruptive 3D biotechnologies. While avoiding technological initiatives that would discourage innovation in this field is paramount, some kind of regulatory intervention is also needed, particularly for industries in which consumers cannot themselves assess quality by personal inspection or experience.

II. RETHINKING SOFTWARE DEVELOPMENT LIABILITY

The following proposal seeks to leverage the legal developments in the fields of 3D bioprinting of OEDs and product liability in order to improve the U.S.'s approach to the regulation of software design in the medical sector. The proposal remains committed to the policy decisions underlying the U.S. healthcare system while offering many benefits to patients. Furthermore, it will lead to improved predictability and lower costs for all involved parties, and minimize the incentive for producing defective software.

A. The Need to Abandon the Products/Services Dichotomy

This section investigates the viability of adopting a policy-based approach to determine whether the development of CAD software deserves the protection of strict product lability. In a series of cases in the U.S., a common law doctrine of strict liability in the medical field has been developed. According to this series of cases, it is possible to extend the scope of strict liability to certain pre-determined aspects of CAD development. Under this approach, however, courts should be willing to look beyond the traditional products/services dichotomy that has, so far, shielded software development against strict liability law.

Clay v. Yates was the first case to examine mixed sales-services transactions, albeit outside the context of 3D bioprinting.[94]. This case involved labor as well as the necessary 'incidental' use of cloth and paper, both of which would be incorporated in the final product: a book. In this context, the court approached the interface between products

---

[93] *See*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue Based Products*, FOOD AND DRUG ADMINISTRATION (2017) https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/cellularandgenetherapy/ucm585403.pdf.

[94] *Clay v. Yates*, 156 Eng. Rep. 1123 (1856).

and services by pointing out that "the true criterion is, whether work is the essence of the contract, or whether it is the materials supplied."[95]

A more contemporary interpretation of this principle was provided by the Eighth Circuit in *Bonebrake v. Cox*.[96] Here, the predominant factor test was framed in the following manner:

> The test for inclusion or exclusion is not whether [products and services] are mixed, but… whether their predominant factor, their thrust, their purposes,… is the rendition of services, with products incidentally involved… or is a transaction of sale, with labor incidentally involved.[97]

This significant policy-based statement, that a mixed transaction should be assessed in its 'essence', could have a potent implication in the CAD print file production process. More specifically, courts and legislators will have to determine what is the essential quality of the bioprinted organ: the CAD print file, bioprinting materials, bioprinting methods, or some combination of the three.

In *Greenberg v. Michael Reese Hospital*, the court noted that it is a "distortion to take what is a sale and turn it into a service, perhaps to reach the desired result."[98] The court stated that "[i]n cases involving products and other tangible physical materials which are in some way bad, imposition of liability unquestionably enhances the public interest in human life and health."[99]

In *Johnson v. Sears*,[100] a Wisconsin federal district court unequivocally rejected the technical and artificial products/services distinction as a basis for not imposing strict liability rules on hospitals for the services they provide; the court stated that hospitals could be held strictly liable for the 'administrative rather than professional' services they render. [101] How to best distinguish between professional medical and administrative services, however, remains to be determined; this is a distinction that should be made on an ad hoc basis.[102] The New Jersey Supreme Court also held that "the distinction between a sale and the rendition of services is a highly artificial one."[103] A similar conclusion was reached *in Hoffman v. Misericordia Hospital of Philadelphia*, where the Supreme Court of Pennsylvania

---

[95] *Id.* at 1125.

[96] *Bonebrake v. Cox*, 499 F.2d 951 (8th Cir. 1974).

[97] *Id.* at 960.

[98] *Greenberg v. Michael Reese Hospital*, 83 Ill.2d 282, 284 (1980).

[99] *Id.* at 394.

[100] *Johnson v. Sears, Roebuck & Co.*, 355 F. Supp. 1065 (E.D. Wis. 1973).

[101] *Id.* at 1067.

[102] *Id.* at 1067-68.

[103] *Newmark v. Gimbels, Inc*., 54 N.J. 585, 258 A.2d 697, 700 (1969).

contended that it did "not feel obligated to hinge any resolution of the very important issue… raised [in this case] on the technical existence of a sale."[104] Before that, the court in *Cunningham v. MacNeal* Memorial Hospital also held that a hospital could be held strictly liable for provision of contaminated blood.[105]

Differentiating between products and services for the purposes of product liability requires a policy-based test. In *Lowrie v. City of Evanston*[106], the court stressed that the policy reasons underlying "product liability . . . should be considered in determining whether something is a product . . . rather than . . . the dictionary definition of the word."[107] When determining whether something constitutes a product for purposes of strict lability, the following policy reasons should be considered: (i) the public interest in human life and health,[108] (ii) the invitations and solicitations of the manufacturer to purchase the product,[109] (iii) the justice of imposing a loss on a manufacturer who created a risk and reaped a profit,[110] and (iv) the superior ability of the commercial enterprise to distribute the risk of injury proximately caused by the defective condition of its product by passing the loss onto the public as a cost of doing business.[111]

This interpretation is in accordance with the Restatement (Third) of Tort, which does not seem to discard such a possibility. When considering the case of *Winter v. G.P. Putnam's Sons* in relation to the use of computer software, it would appear that the reporters were leaning towards extending strict lability to software, pointing out that: "When a court will have to decide whether to extend strict liability to computer software, it may draw an analogy between the treatment of software under the UCC and under product liability law."[112]

The Restatement (Third) provides that, even when provided commercially, services are not products.[113] Personalized software-based products, biological tissues, biological materials and human organs are not considered products for the purposes of strict lability.

---

[104] *Hoffman v. Misericordia Hospital of Philadelphia*, 267 A.2d 867, 870 (1970).

[105] *Cunningham v. MacNeal Memorial Hospital*, 47 Ill.2d 443, 266 N.E.2d 897 (1970).

[106] *Lowrie v. City of Evanston*, 365 N.E.2d 923, 928 (Ill. App. Ct. 1977).

[107] *Id.*

[108] *Suvada v. White Motor Co.*, 32 Ill.2d 612, 619, 210 N.E.2d 182, 186 (1965).

[109] *Id.*

[110] *Id.*

[111] *Trent v. Brasch Mfg. Co., Inc.*, 87 Ill.Dec. 784, 787, 477 N.E.2d 1312, 1315, *cited in Bastian v. Wausau Homes Inc.*, 620 F.Supp. 947, 950 (N.D. Ill. 1985).

[112] RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY § 19 (1998), comment d, Reporters' Notes, at 277-79.

[113] *Id.* at § 19.

The provision of a software-based product that is created at the request of a specific patient, such as a CAD print file, is likely to be considered as a service provision. In this context, customization means developing software whose output is a software-based product for use by a single or a small group of individuals. In the 3D bioprinting field, therefore, the fate of defective CAD print files rests, among others, on two dominant factors: (i) the level of customization required to fit a patient's specific needs; and (ii) the identity of the CAD user.

B. Against Extending Strict Liability Rules to Defective CAD Print Files

This section raises the question of whether imposing strict liability, rather than negligence, on facilities that produce defective CAD print files is an efficient method to force CAD developers (in the field of OED fabrication) to produce defective CAD software.

The theory of strict liability is based upon many economic policy considerations.[114] Most jurisprudences refrain from applying strict product liability to software developers and medical professionals; traditionally, medical professionals have only been liable for negligent conduct. Apart from a few exceptions, courts in the U.S. have followed *Perlmutter v. Beth David Hospital* [115] by exempting blood products from the scope of strict liability. *Cunningham v. MacNeal Memorial Hospital*, however, rejected Perlmutter's interpretation and held that a hospital could be held strictly liable for providing a patient with contaminated blood.[116] This ruling led subsequently to the passing in the U.S. of the so-called 'blood shield statutes' in which both warranty and strict liability are inapplicable to blood transfusions. In accordance with this approach, the Wisconsin Supreme Court stated that providing medical services should not be equated with the task of selling products: "Medical and many other professional services tend often to be experimental in nature, depending on factors beyond the control of the professional, and devoid of certainty or assurance or result. Medical services are an absolute necessity to society, and they must be readily available to the people."[117]

Health care facilities are precluded from the scope of strict liability for defective medical implants used within their premises for

---

[114] *Challoner v. Day & Zimmerman, Inc.*, 512 F.2d 77, 84 (5th Cir 1975).

[115] *Perlmutter v. Beth David Hospital*, 123 N.E.2d 792, 795 (N.Y. 1954) (arguing that medical care providers provide patients with services and not products).

[116] *Cunningham v. MacNeal Memorial Hospital*, 47 Ill. 2d 443, 266 N.E.2d 897 (1970).

[117] *Hoven v. Kelble*, 256 N.W.2d 379, 391 (Wis. 1977).

good reason; with *Cafazzo v. Central Medical Health Services, Inc*[118] and *Hoff v. Zimmer, Inc*[119] being just two of many notable examples of such reasoning. Imposing strict liability on healthcare-related services will increase the costs of providing those services and hamper progress in developing new treatments and interventional techniques, thus risking them becoming unaffordable to many patients.[120] Policy considerations that favor the application of the strict liability doctrine on CAD software could be significantly undermined and outweighed by the need for ready accessibility of essential healthcare services.[121] These two arguments are, however, rebuttable.[122] Analogously, essential products, such as pharmaceuticals, are subject to strict liability. Categorically exempting medical software development from the scope of strict liability can only be justified where doing so would discourage software developers from doing their jobs well, or where the price of medical services would increase.[123] Both of these assumptions are yet to be substantiated quantitatively.

To summarize, applying stringent strict liability as a theory of recovery in the software development setting might be counterproductive. Under such a scenario, CAD developers might be more willing to produce safe, yet not quite effective, software. In the words of the Supreme Court of the United States: "State tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect."[124] The Court stressed that a cost-benefit analysis should be conducted to determine, for example, how many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm.[125]

C. The Need for a Third Approach?

Conventional OED bioprinting involves a vast array of materials, services, and products, often used in combination; examples include

---

[118] *Cafazzo v. Central Medical Health Services, Inc.,* 635 A.2d 151, 152-54 (Pa. Super. Ct. 1993)(holding that a hospital was not strictly liable for defective temporomandibular joint implant).

[119] *Hoff v. Zimmer, Inc.*, 746 F.Supp. 872, 874-76 (W.D. Wis. 1990)(finding a hospital not liable for defective hip prosthesis).

[120] *Hoven v. Kelble,* 256 N.W.2d 379, 391 (Wis. 1977).

[121] *Newmark v. Gimbels, Inc*., 54 N.J. 585, 258 A. 2d 697 (1969).

[122] Michael Greenfield, *Consumer Protection in Services Transactions Implied Warranties Strict Liability in Tort*, 1974 UTAH L. REV. 661, 688-696 (1974).

[123] *Id.*

[124] *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008).

[125] *Id.*

services by healthcare professionals, bio-ink, human tissue, biological and non-biological materials, bioprinters, imaging facilities, patient image data, and highly specialized CAD software, which is the focus of this article. Can a healthcare provider be held liable for producing defective CAD print files for use in 3D bioprinting? Common wisdom and virtually unanimous holding of the courts is that defective CAD software and CAD print files that are produced by a healthcare provider are typically beyond the scope of strict liability.[126] Here, one should ask if a defective CAD print file supplied by a non-manufacturing entity falls under the scope of strict liability. In this context, a distinction must be made between standardized and personalized CAD print file production. There might be room for advancing strict lability claims against the producer of standardized CAD print files under the UCC. However, customized CAD print files are typically exempt from the scope of strict liability, even when sold commercially.[127] If the producer of the defective CAD print file and the manufacturer of the OED are not the same entity, the distributor of the defective CAD software might also be exempted from strict liability. Conventional wisdom dictates that a 'non-manufacturing' seller or licensor of a defective product is not strictly liable for harm caused by that defective product.[128]

The only viable remaining option is recovery based upon the theory of malpractice.[129] Under negligence claims, four conditions must all be met: duty of care, breach of duty, causation, and damages. Here it is useful to ask whether the developer of CAD software used to bioprint the OED should have a duty of care towards a specific patient. It is possible that they should have a duty of care provided that two conditions are met: (1) the patient suffers economic injury,[130] and (2) the CAD developer and the fabricator of the OED are the same individuals/entity.[131] This creates a new problem: while the

---

[126] *Budding v. SSM Healthcare System*, 19 S.W.3d 678 (2000).

[127] RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY § 19(c) (Am. Law Inst. 1998).

[128] For example, RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 14 reads" The licensor, who does not sell or otherwise distribute products, is not liable under …this Restatement".

[129] In such a case, the following conditions are to be satisfied: the plaintiff has to prove that a professional duty was owed to the patient, breach of said duty, injury, damages, and causation.

[130] Since software developers do not have a duty of care to avoid intangible or emotional distress. *See* for example, *In re Sony Gaming Networks & Customer Data Sec. Breach Litig.*,903 F.Supp. 2d 942, 967–68 (S.D. Cal. 2012); *Shema Kolainu-Hear Our Voices v. Provider Soft, LLC*, 832 F. Supp. 2d 194, 205–08 (E.D.N.Y. 2010); *Hou-Tex, Inc. v. Landmark Graphics*, 26 S.W.3d 103, 107 (Tex. App. 2000); *Huron Tool &Engineering Co. v. Precision Consulting Serv., Inc.*, 532 N.W.2d 541, 543–44 (Mich. Ct. App. 1995).

[131] Product designers who were not also manufacturers of products very often are not help strictly

manufacturer of a conventional product has a legal duty to use 'reasonable care' to mitigate foreseeable risks of injury to others, it is unusually difficult for the CAD developer to predict all of the 'reasonable dangers' associated with the use of the OED, or to predict the 'unreasonable dangers' for which they owe a duty to warn. In this context, setting an industry standard of care is unusually difficult; the full risks and benefits may not become apparent for many years. It is not currently clear if it is tenable to impose a strict standard of care on OED design and development processes in order to mitigate against the manufacture of intrinsically dangerous OEDs. This lack of clarity is due to the heavy burden of proof that is needed to demonstrate that OED's defects are attributable to negligence under traditional theories of negligence. It is confounded by the large number of different hypotheses, information, and conflicting literature.[132] To complicate this issue further, the benefits of the elaborate safety precautions that are incorporated into CAD development may or may not always outweigh the inhibiting effects on innovation, let alone the human cost and development delay.

Satisfying the high threshold requirement of causation could constitute an exceptionally challenging legal hurdle. Latent design or bioprinting defects could take weeks, months or years to negatively impact patient health. This issue is complicated by the fact that it is not always possible to associate organ failure with bioprinting methods (manufacture), defective CAD software, or defective biomaterials.

For these reasons, the complexities of proving causation and negligent conduct in 3D bioprinting design defect cases could be powerful disincentives to pursuing a claim. The limits of clinical trials in predicting adverse effects over time are a potent factor that further complicates the process of establishing negligence. The use of 3D bioprinted organs introduces unique challenges that severely limit the potential to undertake clinical trials. For example, it is difficult to perform a randomized clinical trial on patients who have received personalized OEDs since each OED is designed to treat the specific clinical circumstances of only that single patient; this makes it difficult to provide a reliable control group. Furthermore, inconsistent evidence standards applied to conventional medical devices, along with diverse regulatory standards, could inadvertently introduce avoidable risks to patients in need of 3D bioprinted organs. Such an unpredictable

liable for product defect. See, James Beck & Anthony Vale, Drug & Medical Device Product Liability Desk Book §8.09 (2016).

[132] These same issues were faced in the medicinal products field. *See*, Dodds-Smith, M Spencer, & J Bore, PRODUCT LIABILITY FOR MEDICINAL PRODUCTS IN CLINICAL NEGLIGENCE 24.78 (4th ed., Bloomsbury Professional 2008).

environment also sends strong disincentives to investors in this emerging field. The general medical condition of the patient in need of a bioprinted OED can pose acute evidential difficulties. So, too, can uncertainty over the appropriate defendant(s), be it the CAD user, the physician(s) monitoring the bioprinting methods, the healthcare provider responsible for bioprinting the organ or a combination of these individuals/entities.

III. MOVING FORWARD: AN AD HOC APPROACH TO EXTEND THE LIABILITY OF DEFECTIVE CAD DESIGN

Neither strict nor negligence theories of liability seem to properly fit the needs of the OED software. Applying a stringent strict liability to CAD design and development processes can lead CAD developers to deploy safe, but not necessarily effective, software. Proving professional negligence, on the other hand, is likely to be an unusually strenuous legal process. For these reasons, this article proposes a third policy-based approach as a basis for imposing liability on the developers of defective CAD software.[133] Under this approach, instead of making the artificial distinction between products/services, liability rules ought to be based on whether the step performed or service rendered is administrative/technical or professional (a purely medical service).[134] Only administrative and technical services should to be subject to strict liability rules. The distinction between professional and non-professional (administrative and technical) services is a consideration that should be made on an *ad hoc* basis. The next section will use a set of economic and technical justifications to make the case for this *ad hoc* approach.

A. Economic Considerations

The rationale of economic efficiency is frequently used to justify the imposition of strict liability.[135] It is believed that, once identified, liability should be placed on the party that was most capable of preventing the defect in the first place. In *Escola v. Coca Cola Bottling Co.*,[136] in his concurring opinion, Justice Traynor outlined this economic rationale, pointing out that "even if there is no negligence, however, public policy demands that responsibility be fixed wherever it well most effectively reduce the hazards to life and health inherent in

---

[133] The distinction between administrative and technical services was first made by the court in Johnson v. Sears, *supra* note 100, at 1067.

[134] *Id.*

[135] *Escola v. Coca Cola Bottling Company*, 24 Cal.2d 453, 460-461 (1944).

[136] *Id.*

defective products that reach the market."[137] Reducing the defect rate to an acceptable level, therefore, necessitates two interrelated requirements: (1) identification of a cost-effective action that can be used to prevent the defect and (2) identification of the party that was most 'effectively capable of preventing' the defect in the first place.[138] In other words, the party with the greatest control and knowledge of the product should bear ultimate responsibility for its defects.

Since software defects originate from the development process,[139] it is perhaps logical to focus our attention on the design and development stages of CAD software. From a policy standpoint, it is 100 times cheaper to correct software defects early rather than late in the development lifecycle,[140] irrespective of the potential cost of human harm or even death. From this perspective, adequate penalties should be imposed on CAD developers in the hope that this will deter serious misconduct more effectively than imposing a fault-based system, provided that two conditions are met: (1) there is an unacceptably high incidence of defective CAD software development, and (2) there are economically viable penalties for developing defective CAD software available.

Under this welfare argument, an acceptable reason to extend strict liability to the 'administrative/technical' aspects of CAD software development is that the developer is in an enormously strong position to cost-effectively discourage the development of defective software. The position of the developer is so strong that a commercial software development company can realistically discourage the production of defective software at relatively low cost. Strict lability law could serve its many goals by extending its scope to administrative/technical design as well as the development of CAD software in the 3D bioprinting field. In contrast, if the cost of extending strict liability to these steps were to be unacceptably high, or where doing so would sustainably restrict access to affordable healthcare in other ways, other reward approaches should be considered.

B. Technical Considerations

Software power is ubiquitous. The use of advanced software today extends into the medical field and impacts on our daily health, with OEDs being an excellent example. The consequences of using

---

[137] *Id.* at 462.

[138] George Priest, *The Current Insurance Crisis and Modern Tort Law*, 96 YALE L. J. 1521, 1537 (1987).

[139] *See* in general, Vogel, *supra* note 12, at 28.

[140] *Id.* at 34.

defective software in the medical field can be far reaching, especially in cases where patients suffer real physical harm. As demonstrated by the experience of the North American Space Agency (NASA) on July 22, 1962, a small coding error can lead to serious consequences- a missing hyphen, among other reasons, led the Mariner spacecraft to spin wildly out of control.[141] In fact, defective software development is the single most important for software failure. Currently, a host of software defect mitigation methods are implemented; of particular interest are software verification and validation methods.[142] In the context of OED manufacture, software verification focuses on providing 'objective evidence' that the design outputs of a particular piece of CAD software meets all specified requirements for proper OED bioprinting, ensuring consistency, completeness, and correctness of the bioprinting methods. In contrast, software validation focusses on examination and provision of objective evidence that the final bioprinted OED meets patient requirements and expectations. Software validation goes beyond mere software testing to address issues related to best engineering practices, software development, and testing. [143]

A significant and likely challenge in the field of OED bioprinting will be to establish how much 'evidence' is required to verify and validate CAD software whose output is a CAD print file for use in OED manufactureing. The complexity of a validation system for CAD software of this nature should be commensurate with the risk posed to the patient by automated bioprinting, in addition to the risks imposed by other factors, such as the use of synthetic and organic material. Ultimately, the quality of a 3D bioprinted OED is strongly dependent on the complexity of the CAD software, the CAD print file design, and bioprinting methods (manufacture).

An interesting question is whether mathematical modeling used to optimize the print file and predictions before bioprinting should be accepted as 'documented evidence' that the manufactured OED is likely to 'consistently lead to the expected results' and, thus, comply with relevant regulations. This is important for two reasons: (1) 3D bioprinting relies on mathematical modeling to optimize CAD print file design before bioprinting;[144] and (2) a significant number of medical

---

[141] *NSSDC Master Catalog: Spacecraft, Mariner 1*, NATIONAL SPACE SCIENCE DATA CENTER, (last accessed March 31, 2019)
https://nssdc.gsfc.nasa.gov/nmc/spacecraft/display.action?id=MARIN1.

[142] For more information about software validation in general, *see* CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, *General Principle of Software Validation*, FOOD AND DRUG ADMINISTRATION 6 (Jan. 11, 2002).

[143] For general information about software validation, *see* Vogel, *supra* note 12, at 31.

[144] Fabien Guillemot, Vladimir Mironov & Makoto Nakamura, *Bioprinting is coming of age*, 2

device recalls in the U.S. are due to defective software.[145] In fact, more than 50 percent of all medical device recalls are reportedly due to failures in product design and manufacturing process control.[146] This issue is likely to become even more acute given the critical role of CAD software in 3D bioprinting.

In 3D bioprinting, CAD software validation requirements should reflect the stated or implied needs of the patient receiving the OED. In this respect, testing that uses only mathematical modeling is unlikely to satisfy the full validation requirements. The overwhelming majority of software cannot be fully tested for every potential pathway combination through the source code.[147] It follows, therefore, that not all 3D bioprinting CAD software defects can be fully tested for every potential pathway combination through the source code. For this reason, a combination of other 3D bioprinting-related verification techniques that take into consideration the OED development environment, the application, and the risk to patients are likely required to ensure comprehensive validation. This is extremely important given that software defects usually occur without warning, where latent defects may be hidden until long after the software is reached in the market.[148]

C. Why CAD Print File?

A scientist or medical device engineer commences the analysis of software-based medical devices with a statement of the following nature: "I don't trust software…software -any software- is probably going to fail in some way when I use it, and probably when I need it most. I'm rarely disappointed in that regard."[149] Software development

---

BIOFABRICATION 1 (March 2010); Vladimir Mironov, et. al., *Biofabrication: A 21st century manufacturing paradigm*, 1 BIOFABRICATION 2 (June 2009).

[145] Between 1992 and 1998, 242 recalls were attributed to software failure. CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, *General Principles of Software Validation*, FOOD AND DRUG ADMINISTRATION 1, 11 (Jan. 2002) https://www.fda.gov/downloads/medicaldevices/.../ucm085371.pdf.

[146] CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, *Understanding Barriers to Medical Device Quality* 3, FOOD AND DRUG ADMINISTRATION (Oct. 2011) https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM277323.pdf.

[147] *See generally*, Vogel, *supra* note 12 at 27.

[148] This is due to a feature of software called "branching"; the ability to execute alternative series of commands, based on differing inputs. One of the most significant features of software is branching, i.e., the ability to execute alternative series of commands, based on differing inputs. This feature makes the testing process of even short programs very complex and difficult to fully understand. For this reason, testing alone cannot fully verify that software is complete and correct. *See, General Principle of Software Validation*, *supra* note 145, at 8.

[149] Vogel, *supra* note 12, at xv.

for medical devices is more technically demanding than software development for consumer electronics[150] since the frequently short lifecycle of consumer electronics often allows consumer acceptance of lower standards of software robustness.

The important function of CAD software lends it an indisputably specific character. It is challenging to determine whether an OED-related injury is caused by either defective CAD software or bioprinting hardware. It is not clear whether it would be possible to accept that a bioprinted OED defect was caused by defective CAD software without establishing that the same CAD software used to bioprint an OED for person A (without defect) also resulted in the defect of which person B complains. This raises the pivotal question of when, if at all, an implantable OED can be regarded to be defective when it does not belong to a group that has a proven and significant risk of failure, or in which a significant number of examples of the same model product have been defective, as is the case when assessing defects in conventional medical devices. This is why the concept of defective software is fundamental to the application of specific rules governing strict liability to a pre-determined administrative/technical aspect of CAD software development. In cases whereby defective CAD software causes patient injury, and where it is unreasonably challenging to attribute fault to a particular party, forming a response that best serves the collective interests of all affected stakeholders is an important first step. Under the malpractice regime, it is difficult, if not impossible, to satisfy the high legal threshold that a physician failed to comply with the local standard of care, or that the CAD software was defective. For example, a patient would have to demonstrate that defective CAD software would benefit from incremental modifications that would improve the quality of the final 3D bioprinted OED, and that the value of the resultant improvements to patient health would be equal to, or more than, the added cost of the modified CAD software; this requires a quantifiable economic to be placed on patient health. Furthermore, it would be unusually challenging to prove that the suggested improvement to the CAD software would, in reality, yield the expected improvement to patient health. Here, the patient would need to employ an expert software developer to demonstrate that the improved software is technologically feasible.

It is fair to argue and even to assume that the safety and efficacy of CAD software that is used in OED manufacturing is paramount to patient health, and it should outweigh time-to-market considerations. However, despite the already heavy regulation of invasive medical

[150] Vogel, *supra* note 12, at 13.

devices, where regulatory oversight covers the development stages as well as the final product, safety and efficacy are sometimes influenced by other pertinent factors. Ideally, OED manufacture requires reasonably lengthy and onerous evaluation to ensure safety, quality, and effectiveness; this is unlikely to be well received by the 3D bioprinting industry. Lengthy evaluation shortens the most lucrative period for a heavily patented industry; although granted U.S. patents have a 20 year term in the case of devices (supplementary protection certificates however are available for some pharmaceuticals and agrochemical),[151] methods, or printing methods, the period during which a 3D bioprinted invention can be marketed is normally much shorter, due to the lengthy development period. Enforcing rigorous safety standards takes valuable time and, thus, risks compromising the economic value of the patented product. For these reasons, it is likely that the 3D bioprinting industry will push hard to obtain shorter review times and decreased administrative requirements for individually licensed OEDs.[152] Furthermore, broader policy issues are raised by commercial priorities, as well as the extent to which the private sector controls research, production, and marketing of 3D bioprinted OEDs. As already mentioned, the use of 3D bioprinted OEDs introduces challenges that render randomized controlled clinical trials difficult due to the inherent personalization of each individual OED. The unavoidably commercial incentives might encourage CAD developers to end software testing prematurely at the detriment of patient wellbeing. For these reasons, the formation of a system of strict liability, completely uncoupled from notions of fault or malpractice, for a selected group of administrative and technical CAD development steps is desirable.

CONCLUSION

Cadaveric donors are currently the main source of human transplant organs.[153] With the exception of cornea transplantations, transplant timing is critically tight; for example, donor hearts and lungs are viable for transplantation for fewer than six hours.[154] Alternative

---

[151] 35 U.S.C. § 154 (2015).

[152] A similar problem was faced by the pharmaceutical industry. *See* Joel Lexchin, *Transparency in Drug Regulation: Mirage or Oasis* , CANADIAN CENTER FOR POLICY ALTERNATIVES 9 (Oct. 2004) https://www.policyalternatives.ca/sites/default/files/uploads/publications/National_Office_Pubs/transparency.pdf.

[153] ORGANDONOR.ORG., https://www.organdonor.gov/about/what.html (last accessed on Apr. 10, 2019).

[154] UNIVERSITY OF MICHIGAN TRANSPLANT CENTER, *TransWeb.org* http://www.transweb.org/about/index.shtml (last visited March 31, 2019).

options to whole organ transplants include the possibility of transplanting cells directly into the target area to replace damaged tissue; this option is currently problematic due to the often high rate of transplanted cell death, which can be as high 50-90 percent in cases of ischemic cardiac disease cell transplant. Indeed, more than 90 percent of transplanted cells usually die within one week of transplantation for a number of reasons.[155] In this context, 3D bioprinted OED implants might be regarded as a cure when conventional therapies have failed, are unavailable, or are unsuitable. Thus, it is important that the growth of innovative 3D bioprinting is encouraged.

Effective 3D OED bioprinting offers the promise of bridging the current shortage of donor organs, thus enhancing patient quality of care. Creating a streamlined approach to assessing the requirements of effective, reliable, and high-quality CAD software is an important first step.

This article concludes by suggesting a potentially promising approach for addressing the liability challenge for defective CAD software in the context of 3D bioprinted OEDs. The proposed solution would enable the public to bring tort actions against CAD developers. To allow a claim however, courts should move beyond the superficial differentiation of products and services; courts must allow stakeholders to use the potential of tort law effectively and, equally importantly, to curb the introduction of defective CAD software. Furthermore, a new test for setting the boundaries and limits of strict liability in the field of OED bioprinting is proposed. The strict liability regime offers several advantages relative to negligence and/or malpractice regimes, which can be utilized to enhance patient safety. The proposed approach avoids the nearly impossible task of proving a breach in standard of care, allowing stakeholders to benefit from clearer and lower evidentiary standards. Equally significant, the cost factor of our proposal does not, in principle, lead to an overreliance on technology, which would risk defective outcomes or a reduction in the creation of would-be optimal solutions.

---

[155] Rafael Lozano, et. al., *Global and regional mortality from 235 causes of death for 20 age groups in 1990 and 2010: a systematic analysis for the Global Burden of Disease Study 2010*, 380 THE LANCET 2095 (Dec. 2012); THE AMERICAN HEART ASSOCIATION CIRCULATION, *Heart Disease and Stroke Statistics–2014 Report*, 129 CIRCULATION e28 (Dec. 2013); Wolfram-Hubertus Zimmermann, et. al., *Engineered heart tissue grafts improve systolic and diastolic function in infarcted rat hearts*, 12 NATURE MEDICINE 452 (2006).