

A BRAVE NEW WORLD: ALGORITHMS AND 3-D PRINTING AND THE IMPLICATION ON MEDICAL PRODUCTS LIABILITY LAW

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Emergent Medical Technology and Product Liability Law

Jeffrey Hines and Emmit Kellar

As medical technology pushes faster and faster into the future, regulation and legal authority has remained alarmingly stagnant. Without guidance from legislators or the courts, manufacturers of cutting edge-medical devices are left without guidance or, perhaps more importantly, restrictions. This article looks at 3D printing and medical algorithms, two of the fastest emerging technologies in medicine, and asks where gaps are in the current regulations and what sort of challenges do these gaps present in the context of product liability law.

3D Printing and Redefining the Medical Manufacturer

Three-dimensional printing is one of the most bleedingedge and quickly emerging technologies in the field of medicine. The applications of 3D printing are limited only by the imagination of the users and have already begun to penetrate various areas of the industry, including custom prosthesis, surgical implants, and even pharmaceuticals. However, each technological leap achieved by 3D printing is accompanied by an almost equal lag in legal precedent. The following discusses the current and upcoming applications for 3D printing and the legal ramifications it will continue to have on the various players in the healthcare market.

3D Printing – The Process, Players, and Pieces.

3D printing is an interesting but complex process that presents incredible possibilities for medicine as well as a critical need for regulation and legal guidance. 3D printing or "additive manufacturing, is a process by which a custom device (or medication) can be made using a patient's individual specifications.

Importantly, the process of 3D printing is unique to the typical medical manufacturing cycle. Typically, the medical 3D printing process begins with a care provider collecting input data either manually or through diagnostic testing, such as an MRI.¹ That data is sent to a computer programmer who creates a "computer aided design" or a "CAD file" that acts as a blueprint for the 3D printer.² The actual printing process can be accomplished through various different techniques, including bonding hundreds of small layers or sheets of material to form an object, using a liquid bonding agent to form powdered material into a specific shape, or whittling down larger blocks of material until the desired product is formed.³ The physical materials used for 3D printing can also vary greatly, which further expands the options for the medical industry.4 Not only can objects be printed using various plastics and metals, but new materials such as silicone, carbon fiber, graphene and even biomaterials are creating new design opportunities in the already boundless field of 3D printing.⁵

Because of this, the practical applications for 3D printing in the medical field are already revolutionizing the industry. Surgeons are able to use 3D printing to

¹ Richard Rubenstein & Juanlin Song, 3-D Printed Implants Pose Challenge for Product Regulators, Law 360 (Jan. 10, 2018), https://www.law360.com/articles/1000475.

² Id.

³ James A. Beck and Matthew D. Jacobson, 3D Printing: What Could Happen to Products Liability When Users (and Everyone Else In Between) Become Manufacturers, 18 Minn. J.L. Sci. & Tech. 143, 149-50 (2017).

⁴ Id. at 150-51.

⁵ ld.

customize surgical implants and create 3D models to prepare and practice for procedures.⁶ Care providers can create patient-matched medical devices and prosthesis on demand with 3D printers onsite at hospitals or practices.⁷ As mentioned above, the emerging ability to print with biomaterials makes creating replacement organs out of living cells a plausible idea rather than a science fiction fantasy.⁸ Overall, the 3D printing niche looks promising and is estimated to grow into a multibillion dollar marketplace in the near future.⁹ However, one of the biggest obstacles for 3D printing is how it will be regulated in the legal community.

FDA Regulation of 3D Printing.

One of the most reliable sources and highest authorities in medicine that courts and litigants look to for legal guidance is the U.S. Food and Drug Administration ("FDA"). However, because 3D Printing is an emergent technology, FDA regulation has not had the opportunity to catch up and is, in fact, falling increasingly further behind.¹⁰ The FDA website is indicative of this. The latest FDA guidance on 3D printed devices comes in the form of the "Technical Considerations for Additive Manufactured Devices," which was published in 2016.¹¹ The website discusses that, although the FDA is still determining its evaluation criteria for 3D printed products, it plans to continue grouping 3D printed products into the same regulatory classifications used for standard medical devices.¹²

Looking to the Guidelines themselves, the FDA states upfront that the document "represents the current thinking of the [FDA]" and "does not establish any rights for any person and is not binding on FDA or the public."¹³ The Guidelines acknowledge that 3D printing is a rapidly growing technology that is finding application in a broad range of areas in the medical field.¹⁴ The FDA also discusses various relevant considerations for 3D printed medical devices, such as interruptions to typical product workflows, design models versus individually patientmatched devices, the critical role of computer software, and the need to regulate printing materials.¹⁵ While the Guidelines adequately apprise the medical industry of what will be regulated in the future, they offer little insight as to what specific benchmarks the medical industry are currently expected to adhere to.

This has led to a unique situation: despite not having binding rules and regulations in place, the FDA has already begun classifying and regulating certain 3D printed medical devices.¹⁶ For instance, the approval of Spiritam, a seizure prevention drug by Aprecia Pharmaceuticals Co., represented the FDA's first approved 3D printed medication.¹⁷ Other devices- such as hearing aids, surgical implants, and bone replacements- have been approved by the 501(k) premarket notification process.¹⁸ While many of 3D printed devices may be considered "custom devices," some have also fallen into the threetiered FDA classification system, in which the regulatory controls increase according to what class the product falls into.¹⁹ The versatility of 3D printed devices will undoubtedly present new issues for these classifications, given that the system was developed to regulate medical products that are more rigidly defined.²⁰

Product Liability of 3D Printing - Novel Products Create Novel Problems.

The lag in the FDA's reaction to 3D printing is mirrored by a lag in product liability law. As product liability law has evolved, the need for privity with a manufacturer has evaporated and the general sentiment has moved towards strict liability theory for manufacturers.²¹ Essentially, as seen under the Restatement (Second) of Torts, a product manufacturer may be held liable for selling products in "a defective condition unreasonably dangerous to the user or consumer or to his property."²²

Although there are differing views on how to prove that a product is "defective," the crux of strict liability theory is to more easily hold manufacturers accountable for the products that they are putting out on the market.²³ Essentially, the theory shifts a plaintiff's burden from proving that a defendant breached a standard of care to merely requiring proof that the defendant was a "seller" of

18 Id.

20 Adams-Hess, et al., supra note 17.

- 22 Id. at 154 (quoting RESTATMENT (SECOND) OF TORTS § 402A (Am. Law Inst. 1998).
- 23 Id.

⁶ Id. at 151.

⁷ Id.

⁸ Eric Lindenfeld, 3D Printing of Medical Devices: CAD Designers as the Most Realistic Target for Strict Product Liability Lawsuits, 85 UMKC L. Rev. 79, 83 (2016).

⁹ ld.

¹⁰ Rubenstein, supra note 1.

¹¹ FDA's Role in 3D Printing, U.S. Food & Drug Administration (Mar. 27, 2019, 3:43 PM), https:// www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/3DPrintingofMedicalDevices/ ucm500548.htm

¹² Id.

¹³ U.S. Food & Drug Admin., Technical Considerations for Additive Manufactured Medical Devices 1 (2017).

¹⁵ Id. at 5, 8-10, 11, 15-17.

^{16 3}DPrintingofMedicalDevices, U.S.Food&DrugAdministration(Mar.27,2019,3:43PM), https:// www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/3DPrintingofMedicalDevices/ default.htm.

¹⁷ $\,$ Lindsey Adams-Hess, et al., Law and Regulation of 3-D Printed Medical Devices, Law 360 (Mar. 31, 2016).

¹⁹ U.S. Food & Drug Administration, supra note 11.

²¹ Beck and Jacobson, supra note 3 at 152-54

a defective product.24

In medical device and pharmaceutical cases, liability is not simply limited to manufacturers. For instance, the learned intermediary theory only obligates manufacturers to "warn a prescribing doctor about the risks [of a product], rather than an end user."²⁵ Thereby looping prescribing care providers in as potential targets for failure to warn claims.²⁶ However, this liability calculus becomes more difficult to grasp thanks to the radically new supply chain presented by 3D printing.

As mentioned above, the typical process for 3D printing naturally involves more parties than the standard medical manufacturing lifecycle. In 3D printing, doctors and technicians are often responsible for obtaining the exact specifications for a 3D printed medical product. Next, software programmers will likely be looped in for creating the CAD file on which the printer will base its "image." Obviously, the printer manufacturer could also become a potential new source of liability, as would employees that are tasked with operating the machine.

All of these new potential sources of liability beg the question: who is a "manufacturer" in the 3D printing supply chain? This question does not have a definite answer, but there are certainly indicators for what courts may eventually say. Although 3D printer companies may seem like a logical defendant due to their deep pockets, plaintiffs will need to show a flaw with the printer itself, which will likely be more difficult to prove.²⁷ Likewise, medical professionals are more prone to negligence liability rather than product liability in the 3D printing context because it will be more difficult to construe them as "sellers" of the products rather than prescribing care providers.²⁸ This is likely true even where the care providers are operating a 3D printer onsite.²⁹ In this new supply chain, the most likely source of liability for a defective 3D printed medical device would be the CAD developers given the control they have over the final product and the leeway for plaintiffs to argue a developer's ability to affect the overall manufacturing process.³⁰

However, 3D printing also raises novel issues about the definition of a "product" for the purposes of strict liability. In this new supply chain, is the 3D printer output the true product, or is it the CAD file on which the output is

28 Id. at 92.

based? Can a CAD designer escape liability by arguing he is not a seller of the final output or product? Can a manufacturer argue its exculpation based on the fact that the manufacturer has no control over the CAD file inputs? The key to these inquiries is getting a definitive answer as to whether an electronic CAD file can constitute a "product" for liability purposes. Currently, the Restatement (Third) defines products as "tangible personal property distributed commercially for use or consumption."31 However, although courts have yet to address CAD files in the product liability context, case law has been gradually expanding the Restatement's narrow definition of a "product."32 For instance, a 2014 District Court decision grazed the field of 3D printing when it found that the software used to create a patient-matched cutting guide for knee replacement surgery could be lumped into the definition of the product as "a necessary part of the cutting guide."33 Decisions like these will only become more frequent as the use of 3D printing becomes more prevalent.

On the other hand, Courts have already started to weigh in on a 3D printing's effect on the duty to warn end users or patients. The Northern District of California ruled that CAD developers and 3D printer manufacturers are involved in the customization of 3D printed medical devices.³⁴ However, the learned intermediary exception expands to these parties so that they need only warn the care providers of the risks associated with 3D printed products.³⁵ Nonetheless, the Buckley case is a very basic application of 3D printing, and it will be interesting to see where courts assign liability as the practical uses of 3D printing become increasingly complex.³⁶ At this stage, however, there is still much work to be done for product liability law to catch up to 3D printing technology.

Medical Algorithms and the Challenge of Holding Software Legally Responsible

Like 3D printing, medical algorithms present one of the most promising areas of medicine while also widening the void between medical technology and regulation. Algorithms can already be found in several on-themarket products that are used every day. As algorithmic technology progresses, products will be able to make more decisions autonomously, creating less need for medical provider supervision and greater accessibility

²⁴ Id.

²⁵ Id.

²⁶ Id.

²⁷ Lindenfeld, supra note 8 at 93.

²⁹ The logic being that, while the care provider is capable of operating the printer, s/he is not in the business of selling 3D printers or 3D printed products. Id. at 92-93.

³¹ Restatement (Third) of Torts: Prod. Liab. § 19(a)

³² For instance, some courts have recently held that intangible items, such as electricity, can be considered a "product" for liability purposes. Michael D. Scott, Tort Liability for Vendors of Insecure Software: Has the Time Finally Come?, 67 Md. L. Rev. 425, 435-36 (2008).

³³ Corley v. Stryker Corp., 2014 WL 3375596 at *4 (W.D. La. May 27, 2014).

³⁴ Buckley v. Align Technology, Inc. 2015 WL 5698751 at *3-4 (N.D. Cal. Sep. 29, 2015).

³⁵ Id.

³⁶ Beck and Jacobson, supra note 3 at 202.

to medical care for consumers. The difficulty lies in regulating this type of smart technology when problems occur. This is another area where the legislature and the judiciary have not made significant headway.

Algorithms in Healthcare – Decisions Through Programming.

Algorithms are emerging as a pivotal and interesting part of the medical industry. The layman's definition of an algorithm is a piece of computer coding that is capable of "machine learning", dynamically learning to solve problems by constantly absorbing external data.³⁷ Examples of this would include the software behind selfdriving cars, search engines like Google that market products based on your queries, and banking algorithms that determine how money markets will trend in the near and long term future.³⁸

This sort of self-learning technology has already found its way into the highly-regulated field of medicine. Medical algorithms have found useful applications in a number of fields, including spotting DNA mutations that lead to tumors, getting out in front of heart failure, and predicting changes in ICU patient conditions before they occur.³⁹ Private companies, like Apple, have begun marketing this type of predictive medical technology directly to end users as a way to maintain health in between visits to the doctor's office.⁴⁰ These products typically rely on consumer input data either through interactive questionnaires, separate devices that can be synced with the software, or functionalities of the actual device such as a smartphone camera or a heart rate sensor built into a smartwatch.⁴¹

Learning algorithms have a near limitless potential in the medical industry. For instance, promising cognitive disease technology is using algorithms to detect conditions like Alzheimer's at their early stages by analyzing speech and language patterns over time. Technology similar to the omnipresent in-home A.I.⁴² is being utilized to listen for and detect the human cough in children to help diagnose asthma, tuberculosis, pneumonia, and other lung diseases.⁴³

37 Andrew Tutt, An FDA for Algorithms, 69, 85 Admin. L. Rev. 83 (2017).

38 Id.

Interestingly, and somewhat alarmingly, the rapid growth and tremendous potential for self-learning medical algorithms has led many companies to avoid the cumbersome approval process of the FDA.⁴⁴ The industry's lightning quick development and the legal community's failure to react has resulted in a gap between the traditional liability rules for the medical industry and the evolving practical concerns for patients, practitioners and manufacturers.

FDA Regulation of Healthcare Algorithms or Lack Thereof.

One of the largest potential hazards for healthcare algorithms is that the FDA has yet to properly address them. Currently, algorithms generally are not beholden to any specific regulatory authority.⁴⁵ At this point, the FDA maintains a much tighter ability to regulate medical devices in general rather than the software behind them.⁴⁶ Ironically, this has allowed the FDA to make more headway towards regulating algorithms in the consumer marketplace by categorizing healthcare apps and software marketed directly to end users as consumer "medical devices."⁴⁷ However, even this framework is in its developmental stages.⁴⁸

That is not to say that the FDA has not placed regulations on device algorithms in the past. For example, the FDA technically regulates the algorithms behind "disease detection" devices, including the data referenced by the software, the scoring methods for disease detection, processing mechanics and other intricate details.49 However, as of now, medical algorithms are being addressed on an ad hoc basis and are seen as a component to a larger product that fits more neatly into the current FDA classification scheme.⁵⁰ At current, the FDA has acknowledged that this piecemeal method is not sufficient and is seeking better ways of addressing and regulating healthcare algorithms consistently.51 Nonetheless, keeping pace may become increasingly difficult as algorithms become more prevalent and more powerful with technological development.

48 Id.

³⁹ Top Smart Algorithms in Healthcare, The Medical Futurist (Feb. 5, 2019), https:// medicalfuturist.com/top-ai-algorithms-healthcare.

⁴⁰ Nathan G. Cortez, et al., FDA Regulation of Mobile Health Technologies, 4 N. Engl. J. Med. 371, 372 (2014) (discussing the emerging FDA regulation of mHealth).

⁴¹ Id.

⁴² Jonathan Kay, How Do You Regulate a Self-Improving Algorithm?, The Atlantic (Oct. 25, 2017), https://www.theatlantic.com/technology/archive/2017/10/algorithms-future-of-health-care/543825/.

⁴⁴ ld.

⁴⁵ See generally, Tutt, supra note 37.

⁴⁶ Paul A. Mathews, The Next Wave: Federal Regulatory, Intellectual Property, and Tort Liability Considerations for Medical Device Software, 2 J. Marshall Rev. Intell. Prop. L. 259, 265 (2003)

⁴⁷ $\,$ Cortez, et al., supra note 40 at 373-74 (discussing the emerging FDA regulation of mHealth).

⁴⁹ See e.g., U.S. Food & Drug Admin., Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data – Premarket Notification [501(k)] submissions 1 (2012).

⁵⁰ Id.

⁵¹ Dave Muoio, Roundup: 12 healthcare algorithms cleared by the FDA, Mobile Health News (Nov. 15, 2018), https://www.mobihealthnews.com/content/roundup-12-healthcare-algorithms-cleared-fda.

Liability Implications – Who Is to Blame When Skynet Goes Bad?

The lack of regulation on medical algorithms will become a more obvious problem as medical technology becomes increasingly complex. Practically speaking, without regulation, algorithms represent an immensely powerful tool that a very small percentage of people truly understand. Moreover, even now, a single medical device may utilize numerous intertwined algorithms, the failure of which could lead to catastrophic results. Lack of meaningful regulation means a lack of meaningful accountability when a failure occurs.

It is interesting to consider the novel problems presented by imposing liability for a failed algorithm. Initially, although we have well-defined standards for "what it means for a person to act negligently or otherwise act in a legally culpable manner, []we have no similarly welldefined conception of what it means for an algorithm to do so."⁵² For instance, in a malpractice setting, we can more easily determine what is a reasonable dose of insulin for a doctor to give a patient under defined circumstances. However, when a machine is dosing the patient using algorithms based on a strict set of data inputs, the law has no baseline for parsing those facts.

Secondly, the legal community is currently ill-equipped to analyze algorithms from a causation standpoint. Because algorithms are essentially making decisions based on input data, tracing an algorithmic failure to its origin may require a master's degree in computer engineering. Identifying whether the algorithm reacted properly to "signal" data or was improperly triggered due to other data "noise" is a key inquiry that is not easily understood by a layperson.⁵³

Finally, even though algorithms are built to behave autonomously, the human element of the software will not be easily removed. Keep in mind that programmers often copy and paste code sections from one algorithm to the next, leading to the possibility for human error.⁵⁴ To that end, companies also engage in the buying and selling of software and algorithms in the same way that products are made up of components manufactured by several different vendors.⁵⁵ How to untangle the software behind these products is something that has not been addressed by either the courts or the FDA.

This creates a new frontier of product liability law that

55 Id.

is becoming harsher on product liability plaintiffs by the day. Currently, the Restatement (Third) considers a medical device defective for strict liability purposes if it "provides net benefits to no class of patients."56 This presents a particularly high standard for plaintiffs to prove that "reasonable, informed health-care providers would not prescribe [the device or drug] to any class of patients." Moreover, while software designers have been named as parties in past product liability suits, courts have consistently held that a software designer who does "not 'substantially participate' in the design of the marketed product is excused from liability."57 "Substantial participation" is a fact-based inquiry that will likely depend on the algorithm's role in the overall product.58 However, as mentioned above, parsing this role and assigning responsibility could prove nearly impossible without existing legal guidance.

However, policy also disfavors holding medical care providers liable in lieu of the developers of the algorithms used in medical devices. Notably, even in the current medical device market, healthcare providers have no real choice other than to rely on a manufacturer's word that a product will function the way it is intended.⁵⁹ Moreover, it is unreasonable to expect care providers to undergo the extensive training that would be necessary to understand how the software behind a device functions.⁶⁰ Normally, practitioners rely on the FDA to "validate" devices for use on their patients but, as discussed supra, the lag in FDA regulation has left practitioners without guidance on medical device software. Therefore, this accelerating area of medical technology has created a blind spot for both the industry and the legal community alike.

Conclusion

Emerging medical technologies such as 3D printing and self-learning algorithms have exposed a tremendous need for courts and legislators to modernize product liability law. As it stands currently, the strict liability model of the Restatement is ill-equipped to define who is ultimately liable as a manufacturer of 3D printed medical devices that cause injuries. Moreover, there are significant blind spots in the law surrounding medical algorithms that are making healthcare decisions autonomously from the care providers and companies who prescribe them. Although the FDA has acknowledged the need to address these types of emerging technologies, the exponential growth in the medical industry presents an ever-present problem for lawmakers to keep up the pace.

⁵² Tutt, supra note 37 at 105.

⁵³ Id.

⁵⁴ Id. at 106.

⁵⁶ Restatement (Third) of Torts: Prod. Liab. § 6 comment f (1998)

⁵⁷ Mathews, supra note 46 at 293-94.

⁵⁸ Id.

⁵⁹ Id. at 296

⁶⁰ Id.

A Brave New World

Algorithms and 3-D Printing

And the Implication on Medical Products Liability Law



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Living In Westworld





3-Dimensional Printing

In Westworld: Hi-Tech robotics are used to assemble indistinguishable copies of people, animals, props, and items.

In Reality: 3D printing AKA "Additive Manufacturing" builds objects *iteratively* by stacking and joining multiple 2-dimensional layer prints.

- Printers build from Computer Aided Design files ("CAD Files")
 - <u>CAD Files</u>: "virtual blueprints" that are customizable
- Currently Available at retail in all shapes and sizes
 - Price Ranges from \$300 to upwards of \$100,000





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Powder Bed Fusion 3D Printer



3D Printing – Advantages

Printing Materials:

- Range of building applications Polymers, Plastics, Ceramics, Metals
- Development of new materials as concept continues to progress
- Elimination of waste/biproduct/excess inventory

Design/Manufacturing:

- CAD files allow customized design changes on the fly
- Complex and detailed structures without the need for overly expensive tools
- Designs can be custom-tailored to end user



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Emerging Applications of 3D Printing in the Medical Industry





3D Printing







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FDA REGULATION

FDA CHALLENGES:

- Patient Matched Devices
 - Interrupt standardized workflow
 - Require customization on backend
- Diverse Printing Capabilities
 - Not all regulations will apply to all products
 - Impossible to standardize
- Bio Printing NOT YET
 - · FDA punts on this issue entirely



FDA Powder Bed Fusion Printer



FDA EVALUATION OF 3D PRINTED PRODUCTS

3D PRINTED DEVICES "EXEMPT"

- ٠ Dozens already exempt
- Typically "Class II" items ٠
- Approved via 501(k) premarket ٠ process
- None approved via "more arduous" Premarket Approval (PMA) process
 - 4 step review that culminates in published FD "approval"

	Date	Product	Manufacturer
t	5/16/2018	Patient Specific 3d Printed Bone Segments	Additive Orthopedics, LLC
	4/25/2018	Unid Patient Specific 3d Printed Cage	Medicrea International S.A.
	3/27/2018	Mpact [®] 3d Metal™ Implants and Augments	Medacta International SA
DA	8/8/2017	Trumatch Cmf Titanium 3d Printed Implant System	Materialise NV
	5/4/2017	Foundation 3d Interbody	CoreLink, LLC



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FDA EVALUATION OF 3D PRINTED PRODUCTS





- Pharmaceutical Products Are Up and . Coming
 - 2015 FDA approves Spritam, the first 3D printed medication to treat epilepsy
 - Created by Aprecia Pharmaceuticals
 - Providers can print using the powdered medication and binding fluid
 - 3D printing allows porous design of pill









3D Printing – Who is liable?

Hospitals and Healthcare Providers?

- Viewed as <u>Service</u> providers
 - Public policy favors protecting Healthcare
- On-site printing Will provider be "in business of" 3DP or "occasional seller" under Rest. 402(a)?
- Trending towards on-site labs where techs/providers can customize designs







Can CAD Files Be Products?

Restatement: <u>Unlikely</u>

 Restatement Second §402a comment d: "any product sold in the condition, or substantially the same condition, in which it is expected to reach the ultimate consumer"

Drafted in 1965 (examples include a grinding wheel, gas stove, insecticide, etc.)

 Restatement Third §19: "tangible personal property distributed commercially for use or consumption"

Case Law: <u>On the Horizon</u>

- Courts have held that intangible items (i.e. electricity) can be "products."

- Has not addressed whether the code for 3D printing designs constitute a "product"
- <u>Corley v. Stryker Corp., 2014 WL 3375596 (W.D. La. May 27, 2014</u>: "software used in creating each cutting guide was a necessary part of the cutting guide."



CAD Files: Data Risks



- 3D Printing is an Open Source Industry

 Can the market place be regulated?
- Patient Specific Devices

 Customization by end user/provider
- Manufacturer and Patient Info at Stake
 - Piracy of designs
 - Patient medical/personal data breaches



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3D Printing – Duty To Warn?

Current Duty to Warn

- · Manufacturer must warn about risks associated with:
 - Proper use of the product
 - Improper uses of the product which are reasonably foreseeable
- Learned Intermediary Doctrine:
 - Protects manufacturers
 - Need only provide warnings to healthcare professionals.



3D Printing – Duty To Warn?

Effect of 3D Printers on Duty to Warn

- Buckley v. Align Technology, Inc., 2015 WL 5698751 (N.D. Cal. Sep. 29, 2015)
 - Learned Intermediary applies to 3D manufacturers
 - Involved in customization but no need to warn individual patients about uses/risks.
- End users able to customize products Duty to Warn?
 - Inherently Safe Product → Customization → Becomes Dangerous
 - Fact based inquiry (Foreseeability)



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In Westworld: Algorithms allow "Hosts" to react to their environment in real time and adjust their behavior on the fly as they encounter new situations.

In Reality: Algorithms have become an essential part of predictive programming. With a variety of uses, algorithms utilize real time data to make output adjustments automatically.

- Common Examples Include:
 - Trading Algorithms for Financial Institutions
 - SEO Marketing and Online Advertising
 - Safety Features for Automobiles (Self-Parking)



Algorithms





Current Algorithms in the Healthcare Sector



Home Healthcare

- Medication administration
 - · ie. Automatic insulin pumps
- AppStore, Md.
 - Apple Watch/Apple Health
 - Third party heart monitoring apps







Looking to the Future

Self-Learning Algorithms

- As opposed to "static" algorithms, create "new operational products" each time data is added.
 - CloudDX Lung Disease Detection
 - WinterLight Labs Cognitive Diagnosis through Speech Analysis
- Difficult to regulate
 - Parameters are not static or quantifiable
 - Many products fit in between health sector and "general wellness"
- Lack of Acceptance by Medical Community





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FDA Regulation of Algorithms

Currently NO Regulation/Guidance

 Broad application of algorithms has driven away regulators

FDA Offers Commentary on Specific Subjects

- ie. Detection specifications for radiology
- Commentary indicates comprehensive regulation:
 - Algorithm design & function
 - Processing mechanics
 - Databases referenced
 - Reference standards
 - Scoring Methodology







Medical Algorithms – Proof Issues

- No current baseline Cannot gauge effectiveness or determine whether algorithms are "faulty"
 - Restatement Third creates high standard Liability only to devices that provide NO BENEFIT to ANY identifiable class of patient.
 - Current FDA Scheme Manufacturers must demonstrate that their devices are both safe and effective *before* gaining approval
 - The question on standards remains an open issue in most jurisdictions.
 - Practical Concerns
 - Many devices use MULTIPLE software systems with intertwined algorithms
 - Medical professionals do not completely understand algorithms involved in products.



Medical Algorithms – Proof Issues

- Regulating medical algorithms conflicts with FDA policy to not regulate *practice* of medicine.
- Courts have been reluctant to blame software for medical injuries.
 - Although software designers have been named as culpable parties in other contexts, medical products liability remains relatively untouched.
- Current technology still requires some human interaction.
 - Medical Software *helps* decision making process, but ultimate decision still rests with providers
 - What happens when providers rely on technology they do not full comprehend to make decisions?
- · Can algorithms be used to impeach experts and standards?



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Hacking & Piracy of Medical Algorithms

Hacking and Tampering

- Altering data skews outputs
- Infringement on IP Can be difficult to distinguish/prove

Data Security Concerns

- Medical Algorithms rely on patient data
 Could be susceptible to piracy
- Implications with other privacy laws -HIPPA







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Mr. Hines joined the firm as a partner in 2003. Prior to joining Goodell DeVries, he was the managing principal of a regional law firm's District of Columbia and Virginia offices. Mr. Hines is licensed in Maryland, the District of Columbia and Virginia, and has represented clients in trials and appeals in all three jurisdictions. His areas of practice include professional malpractice, toxic tort and environmental litigation, pharmaceutical litigation, product liability, and commercial, securities and employee litigation. Mr. Hines is the firm's General Counsel and serves on the three person Executive Committee.

Practice Areas

- Product Liability
- Pharmaceutical and Medical Device Litigation
- Toxic Tort and Environmental Litigation
- Professional Liability
- Employment Litigation
- FINRA and Securities
- Accounting Malpractice

Professional Associations

- The Defense Research Institute
- American Bar Association: Section of Litigation, Mass Torts and Litigation Committees
- Maryland State Bar Association
- The Network of Trial Law Firms, Inc.

Honors and Awards

- Best Lawyers in America "Lawyer of the Year" Award for Baltimore Legal Malpractice Law Defendants (2014)
- Best Lawyers in America "Lawyer of the Year" Award for Baltimore Mass Tort Litigation/Class Actions Defendants (2013)
- Best Lawyers in America "Lawyer of the Year" Award for Baltimore Legal Malpractice Law Defendants (2012)
- AV Preeminent Rated, Martindale Hubbell (1994 2016)
- Best Lawyers in America Legal Malpractice Law, Defendants (Baltimore, Maryland 2003 2017)
- Best Lawyers in America Legal Malpractice Law- Defendants Legal Ethics (Baltimore, Maryland 2011 2014)
- Best Lawyers in America Mass Tort Litigation/Class Actions Defendants (Baltimore, 2013-2017)
- Best Lawyers in America Product Liability Litigation Defendants (Baltimore, Maryland;2011 2017)
- Maryland Super Lawyers Product Liability Defense (2009 2011, 2014-2019)

Education

- University of Maryland (B.S., 1981)
- University of Maryland, School of Law (J.D., with Honors, 1985)