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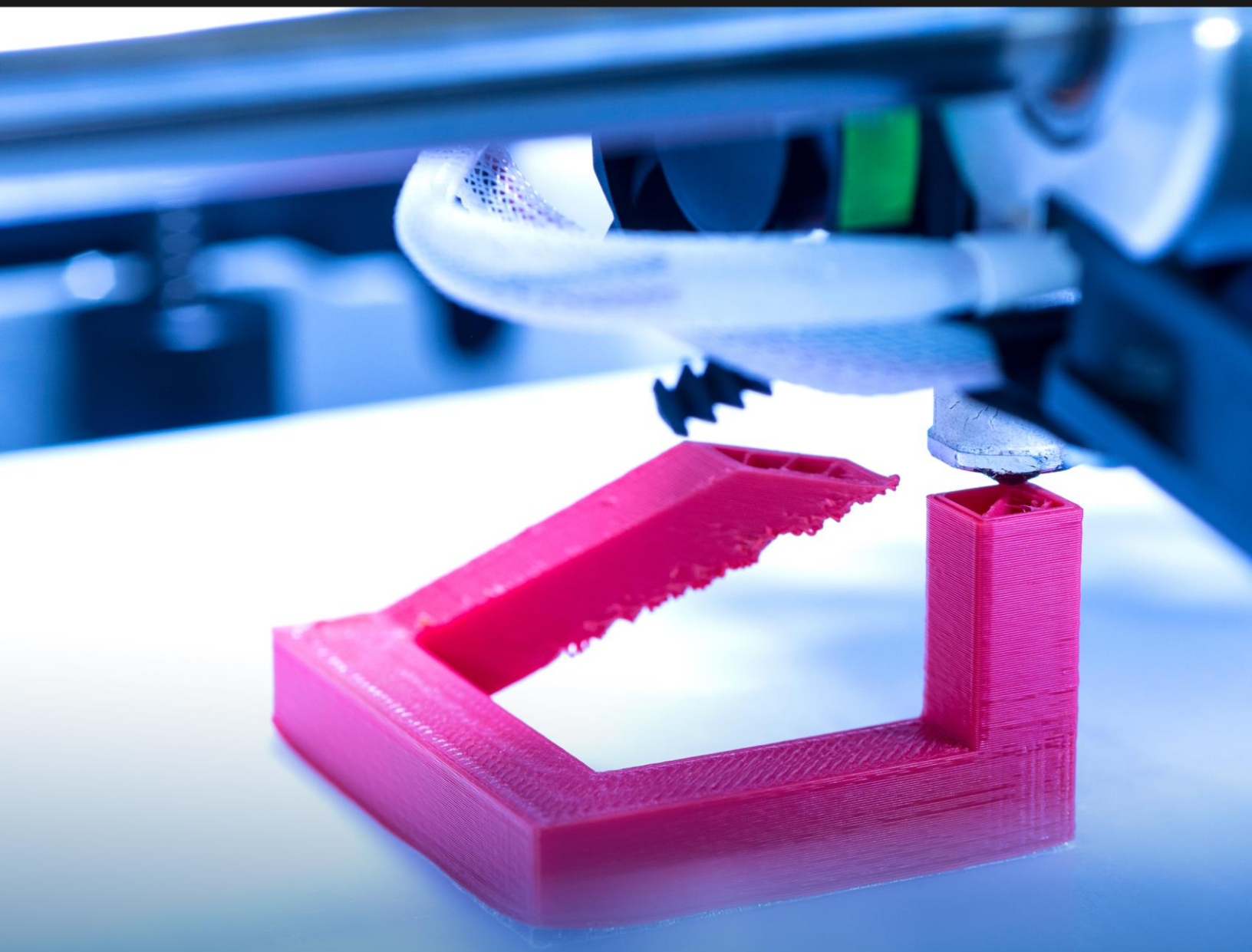


3D Printing of Medical Devices: When a Novel Technology Meets Traditional Legal Principles

First Edition

Letter from the Editors

This white paper – *3D Printing of Medical Devices: When a Novel Technology Meets Traditional Legal Principles* – explores the legal ramifications and risks of the rapidly increasing use of 3D printing of medical devices. 3D printing technology has the potential to radically transform the way medical devices are used to treat patients and save lives, a potential that is already beginning to be felt. One can foresee numerous potential benefits to patients as this technological trend continues – but at the same time, unknown risks and consequences exist.

What follows is an overview of what 3D technology is and how it is being used to print medical devices for patient treatment or use. In addition, an overview of a wide range of developing legal issues is provided, including:

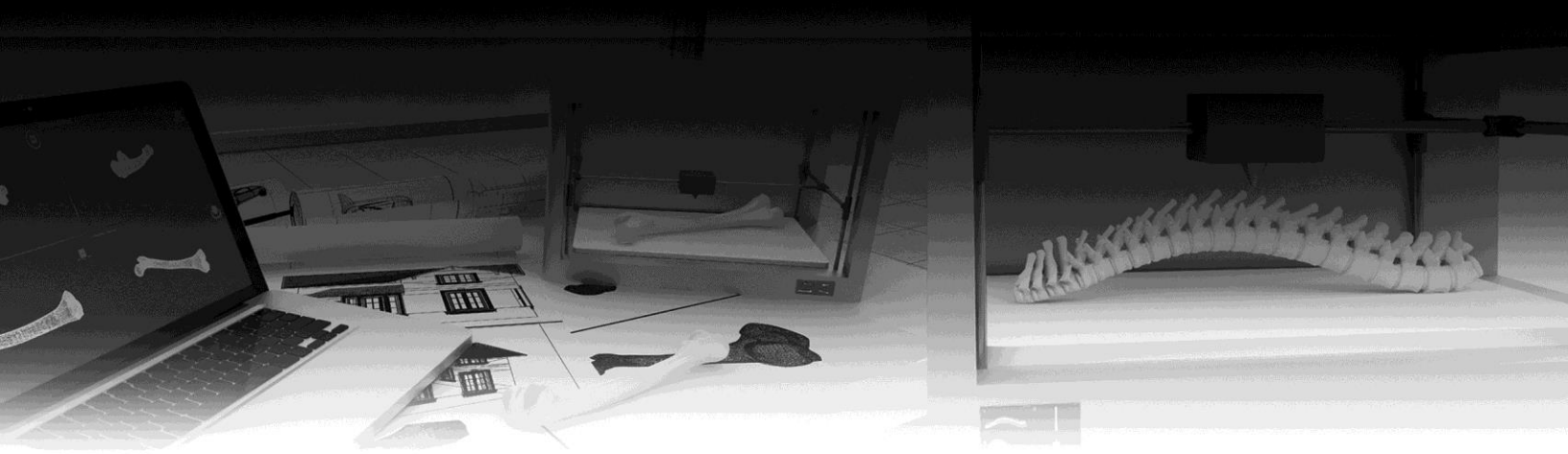
- Regulatory Issues
- Intellectual Property
- Tort Liability
- Environmental Effects and Health Risks in the Work Place
- Insurance Issues
- Reimbursement
- Litigation

This is a truly collaborative work with contributions of a Reed Smith 3D Printing task force including chapter editors Jim Beck, Celeste Letourneau, Kevin Madagan, Todd Maiden, John Schryber, Tracy Quinn, and Gail Daubert. A special thank you to Reed Smith attorneys Matt Jacobson and Farah Tabibkhoei, who worked tirelessly on drafting, editing and compiling.

We predict continued rapid change in the medical arena as the use of 3D technology grows. Even as this white paper was going to print, Aprecia Pharmaceuticals Company announced that the FDA granted approval for the first ever 3D printed drug tablet for use in the treatment of epilepsy. Aprecia's proprietary 3D printing technology allows it to make porous tablets that rapidly disintegrate when taken with water, thereby aiding patients who struggle to take large, hard-to-swallow medications. As the legal environment surrounding 3D technology evolves, as well as the technology itself, this white paper will be updated to offer a comprehensive, up-to-date resource.

We hope that *3D Printing of Medical Devices: When a Novel Technology Meets Traditional Legal Principles* provides readers with valuable guidance as the medical use of this evolving technology continues. We welcome any comments or questions, which can be sent to 3Dprintingmedicaldevices@reedsmith.com.

Thank you,
Colleen Davies, Lisa Baird, Matthew Jacobson and Farah Tabibkhoei
Editors



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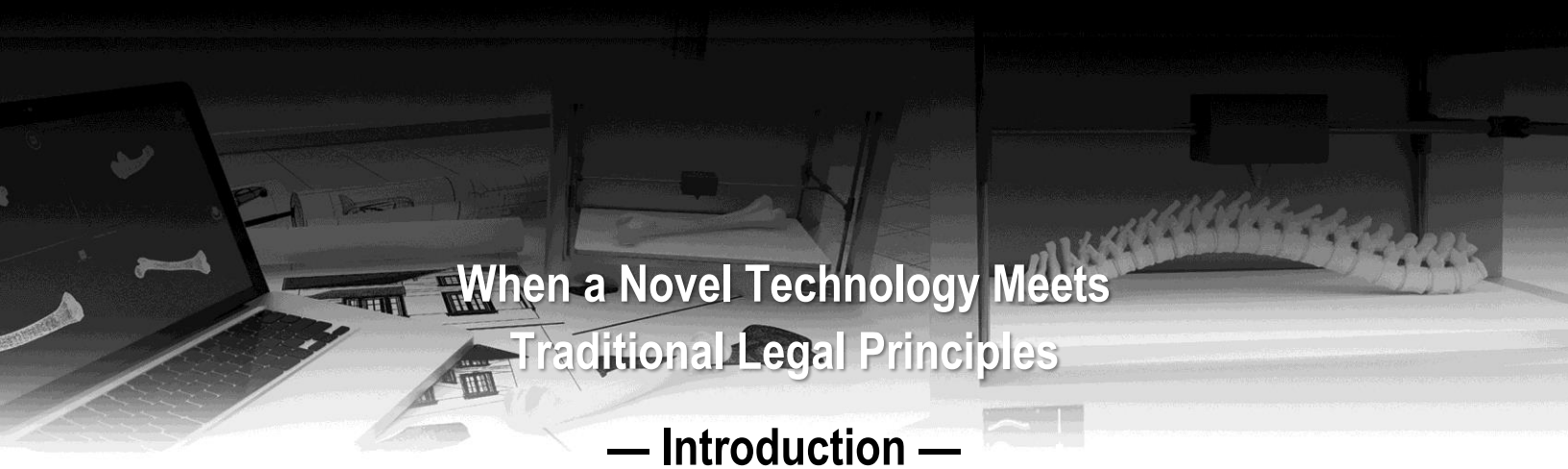

When a Novel Technology Meets Traditional Legal Principles

— Introduction —

Your 6-week-old child has stopped breathing. You rush her to the emergency room and learn she has a rare birth defect called tracheobronchomalacia (TBM), which causes her windpipe to collapse and block air flow. But then you learn the doctor is able to *print* a splint that will replicate your child's windpipe, and keep it open until she outgrows the need for it, and the splint will be resorbed by the body.

Although this sounds like something straight out of a science fiction novel, doctors at the University of Michigan have already done this at least three times.[1] This surgery would not be possible without the advent of 3D printing. But what exactly is 3D printing—and what are the legal ramifications that flow from 3D printing of implanted medical devices, or otherwise using 3D printed items in the delivery of health care?

Overview of 3D Printing: What Is 3D Printing And How Does It Work?

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3D printing is quite possibly the next greatest chapter in the industrial revolution, and the technology is moving rapidly. 3D printing, also known by the more technical term "additive manufacturing," has been around since the 1980s. In the past few years, however, the technology has developed rapidly and the prices of 3D printers have dropped substantially, with 3D printing becoming a significant industry with tremendous innovative potential for many applications, from dental[2] and medical[3], to automotive[4], aerospace[5], military[6], fashion[7], food[8], eyewear[9], and construction[10]. Because of this rapid growth of 3D printing, President Obama launched the National Additive Manufacturing Innovation Institute in August 2012, an effort to foster collaboration among industry, universities, and the federal government, and provide infrastructure that will support innovation regarding 3D printing technologies and products.[11]

Although the term "3D printing" is the most common and colloquial term used for the additive manufacturing process, the term "additive manufacturing" actually encompasses seven different types of manufacturing. In an effort to categorize these different types of additive manufacturing, the American Society for Testing and Material (ASTM) has drafted standards for each:

- Material extrusion—material is selectively dispensed through a nozzle or orifice
- Material jetting—droplets of build material are selectively deposited
- Binder jetting—a liquid bonding agent is selectively deposited to join powder materials
- Sheet lamination—sheets of material are bonded to form an object
- Vat photopolymerization—liquid photopolymer in a vat is selectively cured by light-activated polymerization
- Powder bed fusion—thermal energy selectively fuses regions of a powder bed
- Directed energy deposition—focused thermal energy is used to fuse materials by melting as the material is being deposited[12]

The technical aspects of how a particular 3D printer works depend on multiple factors, including the type of additive manufacturing process, material, and printer being used; but the basic concept of additive manufacturing is that components are built up layer by layer—even though each layer may be on a very, very small scale.[13] And behind the scenes, controlling the shape that a given 3D printer will produce, is an electronic file (usually a computer aided design (CAD) file or an image file created by scanning an object) containing the data the printer needs to give shape to the physical object being printed.[14]

In many respects, additive manufacturing is the inverse of traditional subtractive manufacturing

processes, where blocks of material are whittled down until a final shape emerges (as when a marble statue or ice sculpture is carved from a block). The basic principal of subtractive manufacturing is to start with too much and remove what is not needed. But because additive manufacturing only uses materials that are needed for the final object, the process can be more efficient and cost-effective, and waste can be reduced.

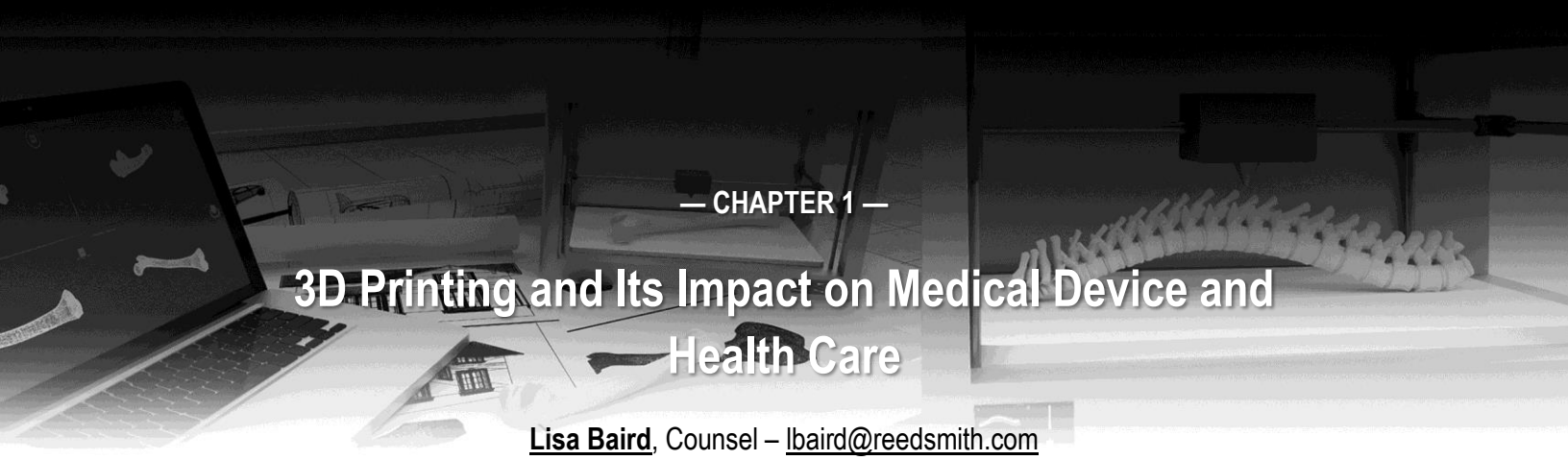
There are other benefits from additive manufacturing as well. Manufacturing products layer by layer results in products that can be made in one integrated piece, so that no final assembly is required.[15] Current 3D printers can use different materials, including plastics, metal, ceramics, and wood.[16] In addition, 3D printing can produce shapes not even possible using traditional manufacturing techniques.[17]

3D printing is revolutionary in other respects too. It allows products to be customized to an individual's needs or tastes, a drastic departure from today's factories, which focus on mass production and aim to produce identical, standardized products in bulk.[18] 3D printing additionally allows for the manufacture of customized components or replacement parts.[19]

Forecasters also predict that 3D printing will democratize manufacturing, allowing every individual with the means to buy one, the ability to become a manufacturer, potentially with the ability to market his or her products to others as well.[20] Already, individuals can upload their design to 3D printing websites like Shapeways, which will market the product, print ordered products with its 3D printer, and deliver it to the purchaser.[21] For medical devices, physicians will be able to customize medical devices to meet patients' needs, and in the future, print those devices on demand at a hospital or even at the physician's own office, giving the physician more treatment options than ever before.[22]

3D printing is likely to also facilitate the concept of "open design," which will make it easier for the design of products to evolve. Once a digital product design file is made available to the public, others may modify the design.[23] Existing items can be scanned to create a CAD or image file, opening the door to potentially unlimited copying.

Simply put, 3D printing is a potentially disruptive technology, and we undoubtedly have not yet envisioned all the changes it will bring. That said, the use of 3D printing in providing health care has perhaps the greatest potential to benefit human lives and health, even if the exact nature of those developments is hard to predict. What assuredly can be foreseen, however, is that 3D printing will present legal challenges in areas ranging from product liability to intellectual property. This white paper accordingly focuses on the legal issues of 3D printing of medical devices and other uses of 3D printing in the health care setting, and attempts to set out a framework for analyzing and addressing such issues as they arise.



— CHAPTER 1 —

3D Printing and Its Impact on Medical Device and Health Care

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3D printing will impact health care in many ways, including implantable and non-implantable medical devices, as well as cost-effective customizable devices. One of the most exciting prospects and radical ways that 3D printing is shaping the medical industry is bioprinting, the 3D printing of human tissues by depositing cells layer-by-layer to grow organs. Should the promise become fully realized, the ability to print organs on demand will mean more lives will be saved, particularly those of patients currently waiting on lists and in desperate need of organ transplants. Gone will be the day when immunosuppressants are needed to prevent rejection of transplanted organs, because the organs will be printed using the patients' own stem cells.[24] Patients will be able to receive the organ they need, when they need it, and one that is "customized" to their body.

Developments in this area are progressing rapidly. In March 2011, Anthony Atala, director of the Wake Forest Institute for Regenerative Medicine, gave a TED talk regarding the future of bioprinting and held in his hands a 3D printed kidney prototype.[25] Four years later, a company named Organovo has announced the first 3D printed human kidney tissue, a key development toward the treatment of kidney diseases and one step closer to making printing implantable kidneys a reality.[26]

In addition, 3D printing of tissues has the potential to reduce the need for experimentation and testing of drugs, cosmetics, and medical devices on animals.[27]

3D printing holds promise for improving health care in other ways as well. In addition to customized 3D printed medical devices, physicians now can use 3D printed models of a particular patient's organ or body part to better plan out and practice for complex surgeries, and thus reduce surgery times, costs and risks associated with it, and improve outcomes. Whether a complicated heart surgery or an attempt at facial reconstruction, the longer the patient's internal tissue is exposed during surgery, the greater the risk of tissue damage.

But 3D printed cells, tissues and organs, and 3D printed medical models, are only two types of examples of 3D printed objects that are, or could be, used to improve health care and outcomes for patients. Custom 3D printed medical devices are another, more mature, use of this technology. For example, prosthetic limbs are now being made to mirror the size and shape of the patient's corresponding limb through 3D scanning technology. An image is first taken of the patient's sound-side limb and existing prosthetic. The image of the sound-side limb is then laid over the former image to create a design for the fairing that is then 3D printed and fitted to the patient, restoring symmetry to the patient's body and resulting in increased function, comfort and mobility.[28] Some such uses are no longer investigational. To date, the U.S. Food and Drug Administration (FDA) has granted clearance through the 510(k) process for several 3D printed medical devices, some implantable. These include hearing aids[29], dental crowns[30], bone tether plates[31], skull plates[32], hip cups[33], spinal cages[34], knee trays[35], facial implants[36],

screws[37], surgical instruments[38], and Invisalign® braces.[39]

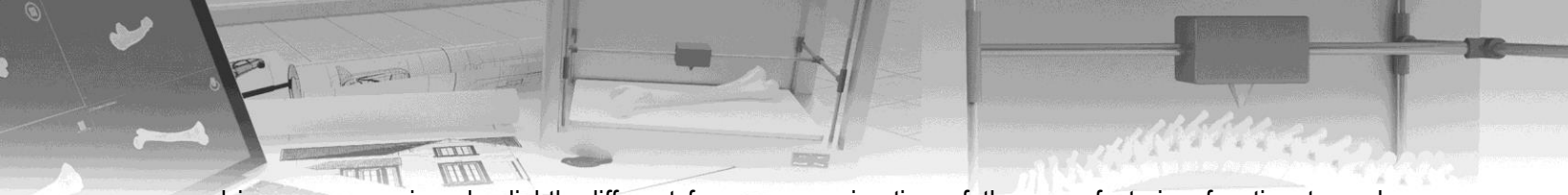
Some of these—like Invisalign® braces—are 3D-printed at a central facility and then shipped to the prescribing health care provider, reflecting a more traditional distribution system. However, the non-traditional devolution of the manufacturing function that 3D printing promises has also made its way to the medical device sphere. The tracheal splints discussed in the Introduction are being printed on-site at the health care facility. Either way, by using 3D printing, these devices can be easily and rapidly customized for each patient.[40]

After digitally scanning the area to be operated on, surgeons can print 3D models to scale—sometimes with mixed colors and media to reflect different structures—to map out the planned procedure or to confirm that implants will fit as expected.

Describing some of the relatively new companies leading the way in innovation of 3D printed medical devices provides just a glimpse of the possibilities that exist:

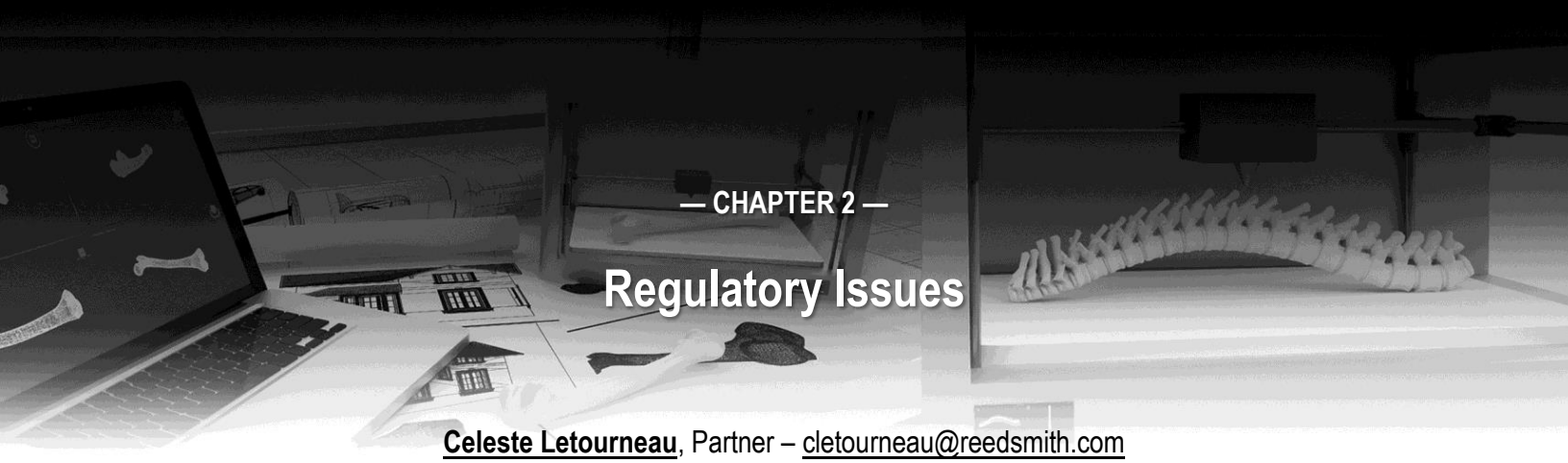
- **Clear Correct, LLC** uses 3D printers to manufacture clear plastic braces. First, a patient's teeth are scanned and then a computer model of the patient's teeth is created, showing the teeth's current alignment and desired alignment. Next, a 3D printer is used to create a series of models of the teeth, which represent a progression of the teeth's current alignment to a straight alignment. Traditional manufacturing techniques can then be used to create the aligners. The aligners and 3D printed models are then sent to the patient's dentist, who can utilize the 3D printed model to assist the dentist in fitting the patient with the appropriate aligners.
- **MedShape, Inc.** develops and commercializes orthopedic devices using proprietary shape memory technology. On December 18, 2014, the FDA granted 510(k) clearance to MedShape's Class II implantable medical device, the FastForward™ Bone Tether Plate, which is created through the 3D printing of medical grade titanium alloy, which allows fabrication of devices with complex and customizable geometries. The plate serves as the primary component in the FastForward Bunion Correction System, a new approach for surgical correction of hallux valgus deformities that preserves and protects the native bone anatomy. (510(k) Number: K141420).
- **Oxford Performance Materials (OPM)** announced August 19, 2014, that it received 510(k) clearance for its 3D-printed OsteoFab® Patient-Specific Facial Device, the first and only FDA-cleared 3D printed polymeric implant for facial indications, and follows FDA clearance of the first and only 3D printed polymeric implant, OPM's OsteoFab Patient-Specific Cranial Device, which was granted in February 2013.[41] Both products are Class II medical devices (510(k) Numbers: K133809 and K121818).
- **Renovis Surgical Technologies, Inc.** supplies orthopedic implants to surgeons and hospitals for adult spinal joint reconstruction, and trauma surgery applications. Renovis received 510(k) clearance for its Tesera™ Stand-alone ALIF Cage, a titanium implant that uses additive manufacturing to create porous surfaces that aid bone in-growth from the vertebral endplates.[42] (510(k) Number: K132312).

These are only a few of the companies that are now using additive manufacturing technology to create medical devices. Each of these companies receives patient specifications (often through a scanned image sent in by a physician or dentist) and prints the medical device to those specifications. Printing the devices at a central facility allows these companies to regulate quality, biocompatibility of materials, and sterility,



and in many ways is only slightly different from how medical device manufacturers traditionally have produced their products, with the main difference being cost.

As the technology develops further and 3D printers become ever more accessible, increased migration of the manufacturing function toward on-site printing is inevitable, as with the tracheal splints discussed in the Introduction. This migration of manufacturing to non-traditional and dispersed locations will undoubtedly present numerous additional technological, regulatory, and legal complications.



— CHAPTER 2 —

Regulatory Issues

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With the emergence of three-dimensional (3D) printing technology, and the corresponding innovation resulting in decreased time for design and manufacture of increasingly complex products, the regulatory landscape governing this technology will need to evolve. For FDA-regulated products, the process for change is already underway. In August 2015, for instance, FDA approved the first 3D printed drug product. The product uses 3D technology to bind the final drug formation without compression.[43] The output is a porous structure (in final drug form) that rapidly disintegrates with the sip of a liquid, even at high dose loads.[44]

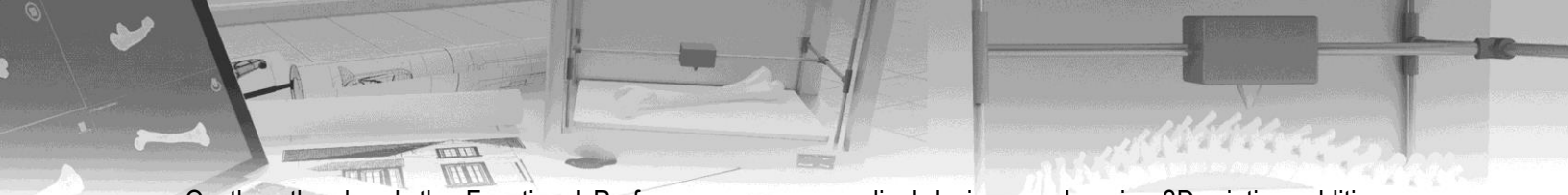
Although FDA is currently reviewing marketing applications utilizing 3D printing technology (also known as additive manufacturing), it is also working toward developing a sound understanding of the technology involved through its own research. For industries with products regulated by FDA, 3D printing offers immense potential. There are, however, many unanswered regulatory issues that need to be addressed to inform the framework under which FDA will regulate the commercial use of products developed with such additive manufacturing processes, as that technology evolves and the innovative products are brought to market.

FDA Investment in Additive Manufacturing Research

FDA has a history of researching innovative technologies to generate first-hand knowledge and experience with that technology, while continuing to protect public health. The research for innovative technology of 3D printing is no exception. Currently, FDA is researching 3D printing to obtain the knowledge and experience necessary to assess the safety, effectiveness, quality and performance of FDA-regulated products developed through additive manufacturing processes.[45] This research further includes an assessment of the advantages and challenges associated with the technology.[46]

In particular, two laboratories within the FDA's Office of Science and Engineering Laboratories (OSEL) are studying the future potential effects of 3D technology on medical device manufacturing—FDA's Laboratory for Solid Mechanics and FDA's Functional Performance and Device Use Laboratory.[47]

FDA's Laboratory for Solid Mechanics is studying the effect of different printing techniques and processes on the durability and strength of various medical device materials. This research is anticipated to help inform the "development of standards and establish parameters for scale, materials, and other critical aspects that contribute to product safety and innovation."[48]



On the other hand, the Functional Performance and Device Use Laboratory is working on computer-modeling methods. The focus of this research is to help FDA understand how changes to the design of medical devices potentially impact safety and performance in differing patient populations.[49] These computer-modeling methods allow FDA to research changes in a device design, and then evaluate the effect of those changes.

The FDA recognizes that with the continued innovation of the technical processes associated with 3D printing, new issues implicating everything from the design to the final production of the medical device will arise and must be addressed to ensure patient safety and promote innovation.[50] Matthew Di Prima, a materials scientist in the Division of the Applied Mechanics in OSEL, underscores the importance of this research by noting that "not all devices or additive manufacturing technologies have the same risks or degrees of concern."[51] As such, there will not be a "one size fits all" set of requirements. FDA is working toward addressing these issues both through its own research and in collaboration with industry stakeholders.

Current Review Pathways

Drug and medical device manufacturers are already incorporating 3D printing into marketing applications for review by FDA. So far, this approach is working and it may largely be because FDA views 3D printing/ additive manufacturing as another form of advanced manufacturing.[52] As such, FDA makes a benefit-risk determination of such products incorporating advanced manufacturing, like 3D printing, as well as an evaluation for safety and effectiveness of the products.[53]

Although as of the date of this publication FDA has approved one 3D printed drug, the following discussion focuses on the current review pathways for medical devices because the FDA has reportedly so far cleared no fewer than 85 medical devices made using 3D printing additive manufacturing processes.[54] From a brief review of FDA's Premarket Notification (510(k)) and Premarket Approval Application (PMA) databases, we have identified, in **Table A**, 15<cleared 510(k) applications for products incorporating 3D printing technology. However, in most of the identified 510(k) applications, it is impossible to tell – either from FDA's 510(k) database or the accompanying clearance letter – how the 3D processes are implicated. We confirmed that the applicant considers the device to include 3D technology by researching the company's press release or journals.

All of the products identified in Table A are FDA's Class II devices, which are higher-risk devices requiring greater regulatory controls to provide reasonable assurance of the device's safety and effectiveness.[55] The general categories of the devices that so far incorporate 3D printing technology include tracheal splints, skull plates, hip prosthetics, spinal cages and dental or bone reconstruction products. Accordingly, the route for marketing authorization of these devices has largely been through the 510(k) pathway. Under the 510(k) pathway, applicants must demonstrate that their device is at least as safe and effective; that is, substantially equivalent, to a legally marketed, or predicate, device.[56] Essentially, applicants must compare their device with one or more commercial devices, and provide data to support the claim of substantial equivalence. If FDA agrees, the product is "cleared" for commercial use.

Importantly, a proposed 510(k) device must not be classified as a high-risk product (i.e., Class III) requiring PMA. Such high-risk products will require FDA's scientific and regulatory review of the full complement of scientific evidence to support a finding that the product is safe and effective. If such safety and efficacy is demonstrated, the product is "approved." As of May 2015, it is not clear if any PMAs for devices using additive manufacturing technology have been submitted to FDA, but as of that date, FDA

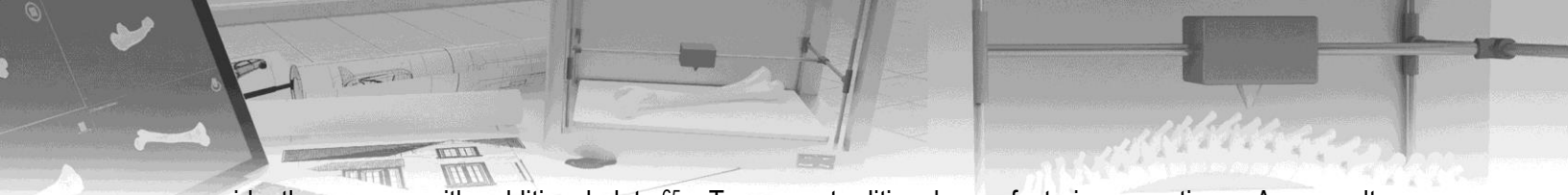
has not yet approved any PMAs for 3D printed medical devices.[57] This is likely because the development of truly innovative medical devices using 3D printing technology is still underway. According to Steven K. Pollack, director of OSEL, the FDA is "still waiting for devices that we haven't been able to make before, and that's when we're going to see the PMAs."[58] Thus, the products that incorporate 3D technology so far are not new and innovative *per se*. Rather, they are products of a type already in use, albeit developed with 3D printing technology, where the benefit may be that the devices are customizable to the needs of the patient.

In addition to the traditional review pathways for marketing approval, FDA may permit the use of abbreviated pathways, other than a 510(k) pathway, to allow for the use of 3D printing of certain medical devices. These pathways include the compassionate use, custom device exemption and emergency use pathways.

- ***Compassionate Use Pathway*** – This abbreviated pathway, unlike the Emergency Use pathway, requires prior FDA approval. The sponsor is required to submit an Investigational Device Exemption (IDE) supplement that allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data. The IDE supplement should include: "(i) a description of the patient's condition and the circumstances necessitating treatment; (ii) a discussion of why alternatives therapies are unsatisfactory and why the probable risk of using the investigational device is no greater than the probable risk from the disease or condition; (iii) an identification of any deviations in the approved clinical protocol that may be needed in order to treat the patient; and (iv) the patient protection measures that will be followed."[59]
- ***Custom Device Exemption Pathway*** – This exemption is approved in situations where the specific device needed is "created or modified in order to comply with the order of an individual physician….and is not generally available in the United States in finished form through labeling or advertising by the manufacturer or distributor, for commercial distribution."[60]
- ***Emergency Use Pathway*** – In an emergency situation, FDA may allow a physician to treat a patient with an unapproved medical device, manufactured with 3D printing, if the physician concludes that: "(i) the patient has a life-threatening condition that needs immediate treatment; (ii) no generally acceptable alternative treatment for the condition exists; and (iii) because of the immediate need to use the device, there is no time to use existing procedures to get FDA approval for the use."[61]

For example, in 2013, the Institutional Review Board of the University of Michigan received an approval, through FDA's emergency-use exemption pathway, to use a 3D manufactured tracheal splint on a newborn with tracheobronchomalacia. With the help of high-resolution imaging and biomaterial 3D printing technology, the researchers at the university created this anatomically specific tracheal splint to help the baby breathe better.[62] These non-traditional pathways may offer an alternative for certain devices and should be considered by applicants as the 3D printing technology evolves.

Based on its track record so far, the FDA is reviewing and approving marketing applications for 3D printing medical products. And, according to Susan Laine of the FDA's Office of Media Affairs, "the review process for these devices will remain as it is for all medical devices – with safety and effectiveness of the device being paramount."[63] FDA will focus on the specific issues based on the device and type of technology being used to manufacture the device.[64] And, based on the complexity of the device, FDA may require manufacturers to



provide the agency with additional data.[65] To facilitate review, FDA recommends that manufacturers looking to market 3D printed devices should participate in pre-submission meetings with FDA review teams to help FDA reviewers get a better understanding of the technology involved in manufacturing the device.[66] The list of medical devices utilizing 3D printing technology in Table A will continue to be updated as more information becomes available.

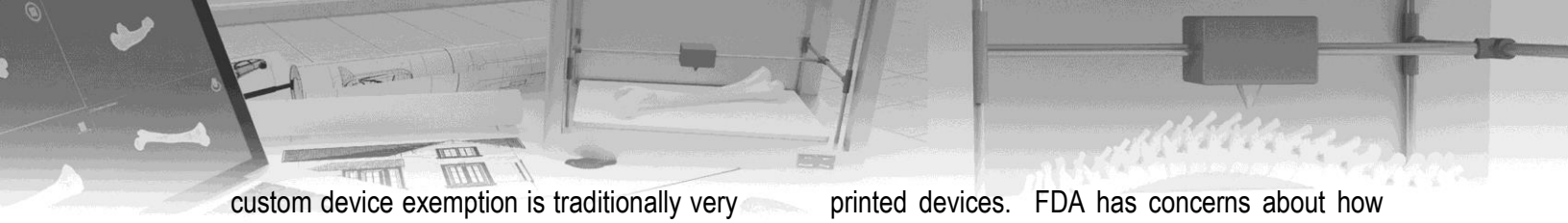
FDA – Next Steps and Unresolved Issues

As noted above, additive manufacturing is increasingly entering mainstream use in medical devices, both as an alternative device production method for traditional components and as a method to create finely tuned, patient-matched devices. The advent of additive manufacturing takes patient-specific device manufacturing to another level.[67] Looking forward, we believe 3D technology will cause a surge over the next decade of demand-based manufacturing at health care facilities and practitioner offices.[68] But for this to occur, the health care industry needs guidance from FDA about how the agency's current system for oversight and regulation of medical device manufacturing, processing and distribution applies to 3D printing. FDA knows this and has been working proactively with many stakeholders to develop a policy for regulating the commercial use of products developed with additive manufacturing processes.

One pressing unanswered regulatory issue associated with 3D printing is how FDA intends to approach non-traditional device "manufacturers." As background, under the existing FDA regulatory framework, a "manufacturer" is defined broadly to include "any person who designs, manufactures, fabricates, assembles, or processes a finished device."[69] With 3D printers becoming increasingly accessible, a person (or entity) with a 3D printer does not need the financial capital, infrastructure or resources historically associated with traditional manufacturing operations. As a result, FDA may begin to see non-traditional entities, including health care providers and suppliers (or any person who owns a 3D printer and the design file of a device), becoming "manufacturers" of medical devices. Complicated, regulatory problems are associated with this possibility. If manufacturing occurs in a non-traditional "manufacturing" site, such as a hospital, clinic or academic center that is not under control of the device sponsor (e.g., 510(k) or PMA owner), how will or should FDA regulate that site? Should the site be subject to all of FDA's Quality System Regulation (QS) / Good Manufacturing Practices (GMP) requirements and standards, such as QS/GMP requirements related to the facilities themselves, and controls for, and methods used in, purchasing, manufacturing, packaging, labeling, storing, and installing medical devices?[70] Will FDA take enforcement action because a 3D printed medical device is technically adulterated when it is not manufactured under QS-compliant conditions?

A few of the many other unanswered regulatory issues associated with 3D printing include:

- Will the FDA regulate the 3D printer or just the end product?
- Will the FDA view shared design files as the unauthorized promotion of the device if the device's benefits and risks are not disclosed?
- Will the design files of FDA Premarket-Approved devices be available through the open source community, such that anyone can modify the design file to 3D print non-approved devices?
- To what extent might FDA exercise its enforcement discretion for 3D products?
- When would a 3D printed device be considered a "custom device" that is exempt from premarket approval requirements and mandatory performance standards?[71] The



custom device exemption is traditionally very limited in scope.

- What effect, if any, will any of these issues have on FDA's programs of inspection to ensure assurance with QS and GMP requirements and standards?

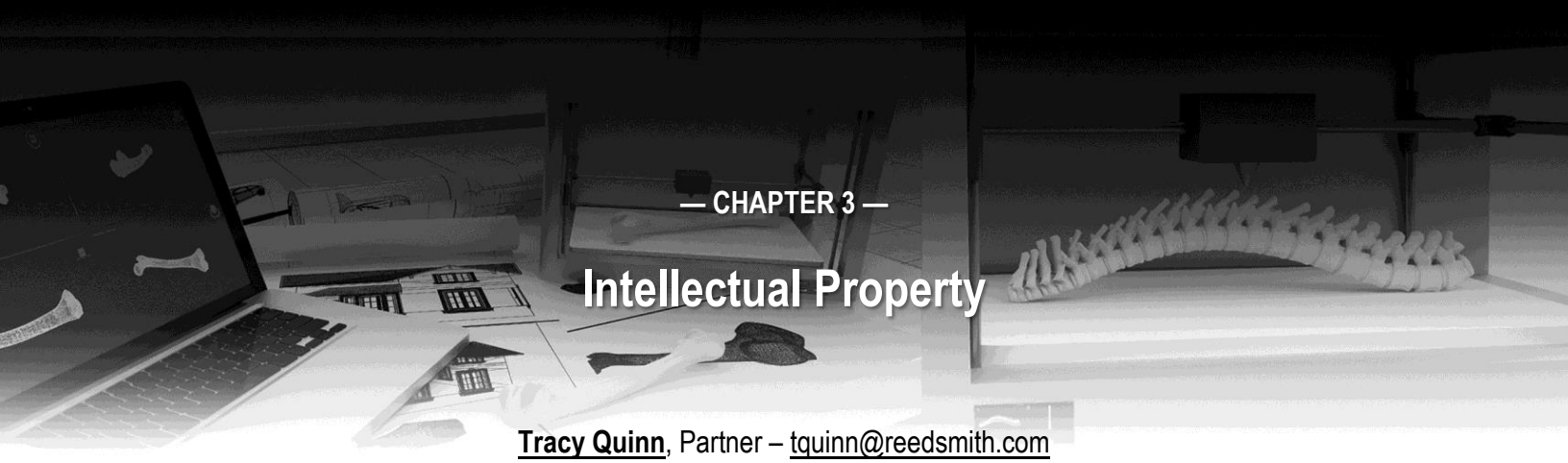
To resolve these and other issues, FDA may need to modify its regulations, and in the short term issue a few guidance documents and exercise its enforcement discretion for some FDA rules and regulations.

On October 8 and 9, 2014, FDA held a workshop on at its White Oak Campus in Silver Spring, Maryland, to obtain information and input about 3D printing issues.[72] FDA brought together technical 3D printing expertise from various industries spanning medical to aviation application, to help the agency understand the technical assessments that should be considered for 3D printed devices as part of a transparent evaluation process for future submissions of novel and unique medical devices resulting from additive manufacturing techniques.[73] Workshop attendees included medical device manufacturers, additive manufacturing companies, academia, and researchers, scientists, and engineers involved with the research and development of 3D printed products. Topics explored at the workshop were: (1) preprinting considerations (i.e., material chemistry, physical properties, recyclability, and part reproducibility and process validation); (2) printing considerations (i.e., printing process characterization, process software and post-processing steps and additional machining), and, (3) post-printing considerations (i.e., cleaning/excess material removal, sterilization and biocompatibility, final device mechanics, and design envelope, and verification).

During the workshop, FDA discussed some of its concerns with the safety and efficacy of 3D printed devices. FDA has concerns about how the porosity of a 3D printed medical device product will affect its function and mechanical performance.[74] FDA also has concerns regarding cleanliness because the 3D printing process requires the removal of support material from the 3D printed objects, manually or chemically. If excess material is not removed properly, FDA believes it may be introduced into a patient and lead to an adverse reaction.[75] Further, if a device has a porous coating, FDA is concerned this may serve to trap excess printing materials absent proper sterilization.[76] FDA is also unsure about how best to validate the sterility of internal surfaces and the porous-to-non-porous surfaces.[77]

Notably, following the October 2014 workshop, FDA indicated that it would use the information obtained from the workshop to drive the development of two guidance documents related to 3D printing.[78] The first guidance, which the agency intends to publish in 2015 (if resources permit), will focus on providing and describing the types of questions that manufacturers of 3D printed medical devices can expect from the FDA.[79] The second guidance will cover the FDA's thoughts on who the manufacturer is and where manufacturing occurs when 3D printing is used, though the FDA has not announced a timeframe for this guidance.[80]

FDA's decision to hold the October 2014 workshop and the agency's desire to issue guidance documents in 2015 about 3D printing are encouraging. Although at the time this White Paper was drafted the FDA had not published any guidance document on 3D printing, the October 2014 workshop shows that FDA has taken its first few steps in what has been (and will continue to be) a very long process within the agency to establish a framework for regulating additive manufacturing, provide guidance to the industry, and find a way to adapt to emerging 3D technologies.



— CHAPTER 3 —

Intellectual Property

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As 3D printing of medical devices becomes more commercially viable, its IP implications will become increasingly important for medical device manufacturers. For example, counterfeiting may become a pressing concern because 3D printing will simplify the manufacture of counterfeit goods. And while health care providers and patients may be unlikely to 3D-print complex medical equipment themselves, they may use 3D printing to generate replacement parts for such equipment or to replicate simpler devices.

Current laws governing IP rights pre-date the advent of 3D printing and therefore do not directly address the unique issues 3D printing raises. Nevertheless, existing laws protecting copyrighted material, patented inventions, trademarks and trade dress, and trade secrets should afford some protection to medical device manufacturers. Moreover, manufacturers can take steps now to help protect their IP rights against the risks 3D printing is likely to pose as it becomes more of a commercial reality. This chapter reviews the applicability of existing IP laws to 3D printing, and identifies some options medical device manufacturers may consider as the 3D printing industry evolves.

Copyright

To qualify for copyright protection, a work must be original and non-functional.[81] "Original works of authorship," including literary, pictorial and sculptural works, are protected by federal copyright law automatically upon their creation in a fixed form.[82] Medical devices typically are utilitarian rather than artistic objects, and thus do not often qualify for copyright protection. However, copyright implications may still be associated with their replication through 3D printing.

3D printing uses a "digital blueprint" of the object to be printed.[83] The blueprint may come from an existing CAD design file or be created with a modeling program from a 3D scanner-generated image of the object.[84] CAD files generally receive some copyright protection under current law, such that they cannot be used without the file author's (or assigned owner's) permission.[85] Thus, one who uses or copies an existing CAD file to generate a digital blueprint for 3D printing may be liable to the file owner for copyright infringement. One who uses a 3D scanner to create an image of the object to be printed and then creates a blueprint from that image, however, may escape liability for copyright infringement if (s)he copies only unprotected functional features of the object and not aesthetic or artistic elements.[86]

Patent

Patent law may provide medical device manufacturers greater protection against unauthorized 3D printing of their products. The owner of a utility patent claiming a new and novel product or process has the right to exclude others from making, using, selling, offering for sale and/or importing into the United States any products and/or processes covered by the patent.[87] A patent may be infringed directly (by one who makes, uses, sells, etc., the claimed invention); indirectly (by one who knowingly and

actively induces others to infringe); or contributorily (by one who knowingly makes, uses, sells, offers to sell or imports components of a patented product, or materials for use in a patented process, that have no other substantial non-infringing use).[88] Thus, a medical device manufacturer who has patented its device and/or methods of using that device may invoke the patent laws to: (i) enjoin the manufacture, sale and importation of 3D printed copies of its product; (ii) enjoin the use of 3D printed copies of its product; and (iii) enjoin deliberate attempts by third parties to encourage others to use 3D printed copies of its product. Importantly, although one who creates a blueprint for 3D printing from a scanned image of a product may avoid copyright infringement liability, (s)he will not escape liability for patent infringement associated with the subsequent manufacture, use, sale, offer to sell or importation of that product if the product and/or its methods of use are protected by patent.[89]

That said, 3D printing presents a number of challenges when it comes to enforcement of patent rights. For example, identifying individual health care providers (or their patients) who are printing and/or using unauthorized 3D printed devices may be a challenge in itself. Identifying the source of infringing 3D printed products may also prove difficult. Enforcing patent rights against individuals who create and/or use 3D printed products can also be expensive and inefficient.

Separately, the question of what, exactly, has been 3D-printed, and the purpose for which it has been used, may create close legal questions under the patent law. For example, repairing a patented device using a 3D printed replacement of a non-patented component may not constitute patent infringement. On the other hand, replicating a patented device by using a 3D printer to create all of its components may well constitute patent infringement.[90]

Trademark, Trade Dress and Counterfeiting

Trademark law is intended both to protect brand owners against misappropriation of the goodwill they have built in their trademarks (e.g., brand names and logos) and trade dress (i.e., the distinctive packaging or design of a product), and to protect consumers from misperception caused by the use of confusingly similar marks and trade dress.[91] Generally, 3D printing of medical devices may not implicate trademark and trade dress concerns to the extent that (i) what is printed is the device itself, exclusive of any company or brand names, patterns or designs, and (ii) the design of the device is functional rather than aesthetic.

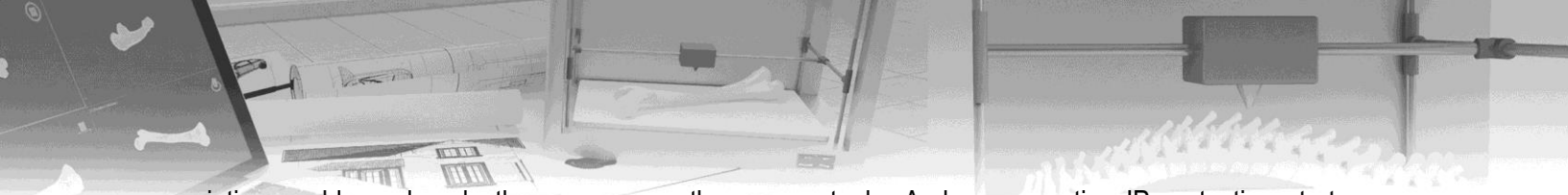
Trademarks do, however, help a device manufacturer guard against counterfeiting of its products. For products that bear a manufacturer's brand, a 3D printer who includes the manufacturer's mark on its 3D printed products will run afoul of federal trademark law and anti-counterfeiting law.[92] 3D printed products that do not include the manufacturer's trademarks, on the other hand, may be easier to spot as unauthorized copies.

Trade Secrets

If access to a particular medical device is all that is needed to derive a suitable digital blueprint of it, then 3D printing the device is not likely to be deemed a misuse of the manufacturer's trade secrets. On the other hand, someone who obtains and makes unauthorized use of a manufacturer's confidential and proprietary technical information (e.g., manufacturing tolerances) in creating a 3D printed copy of a device may be liable for misappropriation of the manufacturer's trade secrets.[93]

Planning Ahead: Strategic Considerations

Barring any changes in the law to specifically address 3D printing, the legal issues associated with protecting a manufacturer's IP rights in a 3D

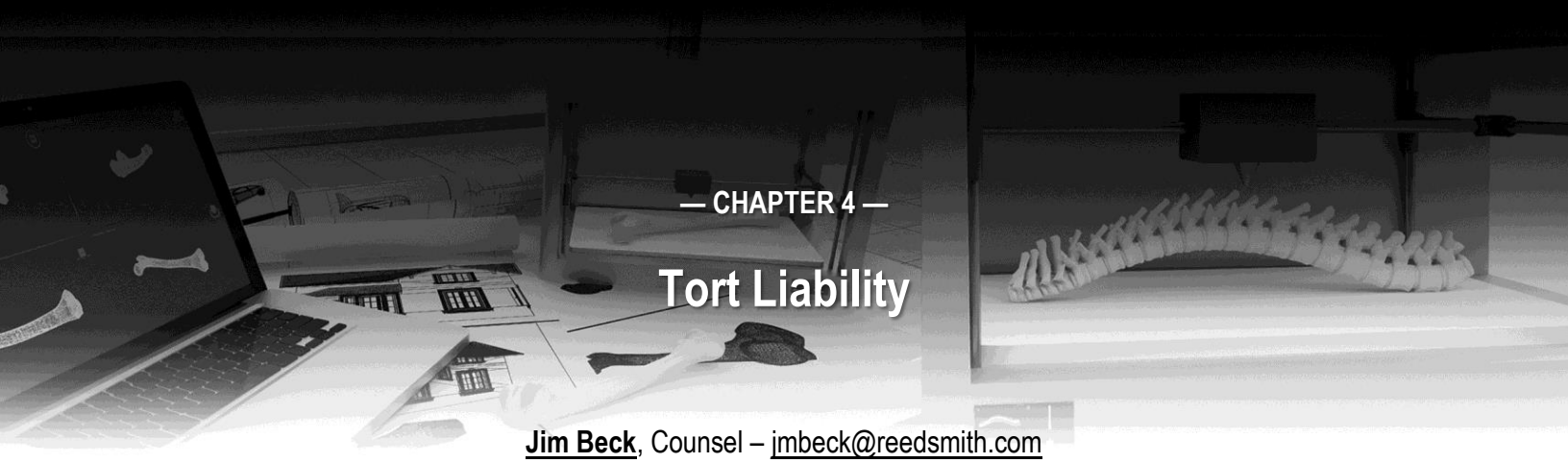


printing world are largely the same ones they face in dealing with other threats to those rights. The differences will come from the increasing ease with which IP-protected products may now be copied, and the corresponding difficulty that IP owners may have in identifying and stopping infringers.

Device manufacturers can take steps to protect their IP position against this coming reality. An anti-counterfeiting protocol, for example, including the use of proprietary product markings (some known only to the manufacturer) to distinguish genuine products and their component parts from counterfeit, can help manufacturers more readily spot unauthorized 3D printed goods in the marketplace. Seizure proceedings and actions before the International Trade Commission ("ITC") to enjoin the importation of counterfeit goods may help keep infringing goods out of the marketplace even when enforcement against individual users, printers and/or distributors of 3D printed goods might be difficult. A protocol for policing websites that allow sharing of CAD files, and for seeking the prompt take-down of copies of a manufacturer's design files, may also be a useful tool. And a preemptive IP protection strategy, which evaluates whether to seek patent protection not just for a medical device as a whole, but also for its component parts and methods of use, as well as possible opportunities for trademark and/or trade dress protection, may help manufacturers develop a portfolio of IP rights more specifically suited to protecting against encroachment from 3D printing.

Medical device manufacturers should also consider the benefits of 3D printing, not just its risks. A licensing program that allows health care providers and patients to 3D-print replacement parts for their medical devices, for example, or to print products that are relatively simple to make and frequently used, could be a source of both revenue and customer goodwill.

Commentators are already debating what changes, if any, should be made to existing IP laws to address the growing 3D printing industry.[94] Pending any such changes, manufacturers still have a number of options available under current law to both protect against unauthorized 3D printing of their devices, and take advantage of the opportunities that 3D printing may offer.



— CHAPTER 4 —

Tort Liability

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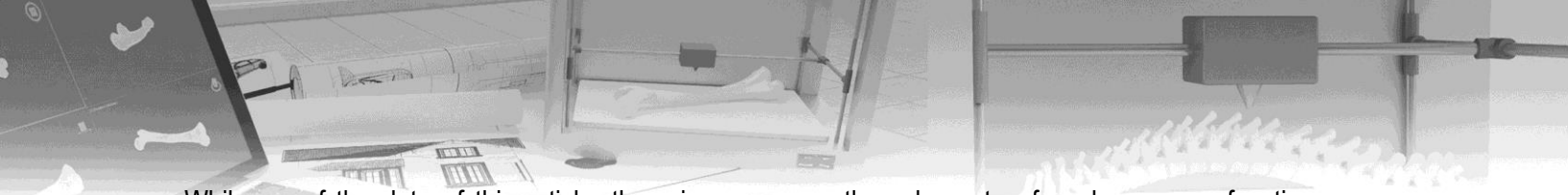
For products generally, 3D printing presents challenges with regard to potential tort liability. The overlay and interplay of FDA regulation of significant parts of the 3D printing process for medical devices further complicates the legal environment.

Product liability itself is relatively new to the law, designed to reapportion common-law liability in ways that account for the rise of mass-produced items. Product liability law originally arose from contract law, with many decisions through the early 1960s favoring manufacturers, because the general rule prohibited product users from suing manufacturers, unless they were in privity of contract.[95] The first breach of the privity doctrine came when Justice Benjamin Cardozo opined in *Macpherson v. Buick Motor Co.*, 217 N.Y. 382 (1916), that manufacturers could be liable for negligence absent privity between the manufacturer and injured consumer. In the 1960s, privity and certain other defenses were swept away by the doctrine of strict liability, introduced in *Greenman v. Yuba Power Products*, 59 Cal. 2d 57 (1963), which held that manufacturers could be liable without fault (negligence) for injuries caused by defective products. Strict liability doctrine was included in the second Restatement of Torts (Second),[96] and thereafter was widely adopted.

The advent of 3D printing has multiplied the number of possible "products" and scrambled the traditional "manufacturer"-based chain-of-sale concept on which strict liability has been based. The scenarios made possible by 3D printing include (1) defective original product used to create the digital design; (2) defective original digital design; (3) defective digital file; (4) corrupted copy of downloaded digital file; (5) defective 3D printer; (6) defective bulk printing material used in 3D printer; (7) human error in implementing the digital design; and (8) human error in using the 3D printer and/or materials.[97] The parameters of tort liability may need to be redefined once again to account for new technologies and new supply chains, where traditional "manufacturing" processes are carried out by entities elsewhere in the chain of sale – such as hospitals and treating physicians. What counts as a "product" when it comes to 3D printing? Certainly a medical device produced through 3D printing seems to fit within traditional concepts of "product." But then who is the "manufacturer"? 3D printing requires CAD models and code to operate the printer. Are these "products" as well? Many 3D-printed medical devices are, and will be, customized for individual patients using electronically inputted information from data from computed tomography or magnetic resonance imaging scans. Can such anatomical scans also become products? It can be argued that purely electronic data, such as code, does not constitute a product, at least under the Restatement (Third) of Torts, which defines a product as "tangible personal property distributed commercially for use or consumption."[98] Does 3D printing render parts of the Third Restatement obsolete?



While, as of the date of this article, there is no case law addressing whether the code for 3D printing designs constitutes a "product," courts – for purposes of strict liability or negligence – already have held that computer code does not constitute a "product" in other contexts. In *U.S. v. Aleynikov*, 676 F.3d 71 (2d Cir. Apr. 11, 2012), a criminal case construing the National Stolen Property Act ("NSPA"), 18 U.S.C. § 2314, the court reversed a conviction and held that the proprietary computer source code was not a stolen "good" within the meaning of the statute.[99] The NSPA makes it a crime to transport, transmit, or transfer, in interstate or foreign commerce, any goods, wares, merchandise, securities or money, with a value of $5,000 or more, with the knowledge that it has been stolen, converted or taken by fraud. The would-be "good" consisted of more than 500,000 lines of source code allegedly illegally uploaded by the defendant and transported across state lines on a flash drive and a laptop.[100] The Second Circuit held that source code did not qualify as "goods," "wares," or "merchandise" under the statute, "[b]ased on the substantial weight of the case law, as well as the ordinary meaning of the words."[101] NSPA precedent involving theft of intellectual property required that "some tangible property must be taken from the owner for there to be deemed a 'good' that is 'stolen' for purposes of the NSPA."[102]

Similarly, courts could consider that electronic StereoLithography "STL" files—the standard file type used by most additive manufacturing systems—would not constitute a product under the Restatement (Third) of Torts,[103] which defines products as "tangible property," potentially barring strict liability claims. If STL files are not considered products because of their intangibility, injured parties will not be able to pursue strict liability claims, which require proof of a manufacturing defect, design defect, or failure to warn with respect to a product, plus causation and injury.[104] Such definitions of "product," of course, would not preclude negligence or warranty liability, assuming that the other elements of such causes of action were present.

On the other hand, whether or not something is tangible does not necessarily dictate whether it qualifies as a product for strict liability purposes. For example, courts have held that certain non-tangible items, such as electricity, qualify as products for purposes of imposing strict liability.[105] Aeronautical maps and charts have also been held to be products.[106] On the other hand, information in books generally has not been held to be a product.[107] In addition, courts across the country have held that publishers may not be held liable for "informational defects" in published material pursuant to the First Amendment.[108]

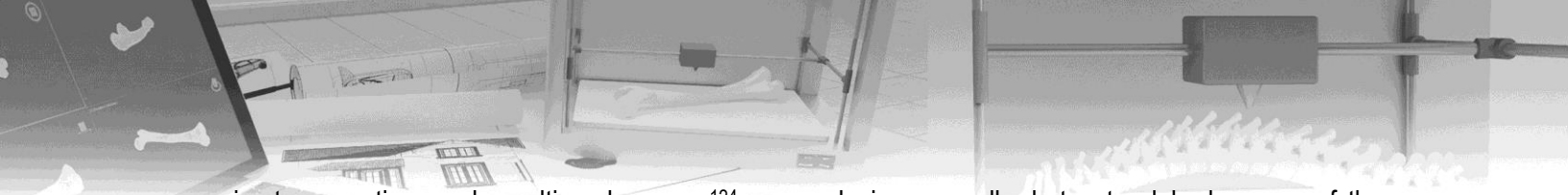
As consumers continue to turn to 3D printing services like Shapeways[109] to print their products—transactions that combine products and services—whether a plaintiff can recover for strict liability can also turn on the defendant's role.[110] The purpose of imposing strict product liability on a commercial seller, manufacturer or distributor of products is that the defendant played an "integral role in the overall production or marketing enterprise."[111] Courts often decline to impose strict liability on defendants whose primary objective is providing services—particularly doctors and hospitals, entities that will be operating medical device 3D printers. The majority of courts view hospitals as service providers, not sellers of products, as they are neither affiliated with drug or device manufacturers nor marketers in the commercial sphere.[112] The Pennsylvania Supreme Court explained that hospitals are suppliers of "services" as opposed to "products" for purposes of strict liability as follows: "The thrust of the inquiry is thus not on whether a separate consideration is charged for the physical material used in the exercise of medical skill, but what service is being performed to restore or maintain the patient's health."[113]

Although the majority rule traditionally holds that hospitals are service providers not strictly liable for personal injuries arising from product defects,[114] that could change as hospitals start to incorporate a 3D printing center on-site.[115] Hospitals, including Children's Hospital of Illinois in Peoria, and Rush University Medical Center, have already begun incorporating 3D printing labs to print 3D-printed anatomical models based on CT scans and MRIs of the patient for use in pre-surgical planning.[116] Thus, to the extent that 3D printing is considered a service, or as producing products incident to the provision of medical services, consumers may not be able to recover under a strict liability theory against 3D printing services.

Product users seeking to recover for injuries resulting from a 3D printed product, under a strict liability theory, face an additional hurdle—proving that the product was placed *on the market* by a commercial manufacturer or seller. In order to prevail on a product liability claim, a plaintiff must show that the product, which allegedly caused the injuries, was placed on the market, with knowledge that the product would be used without inspection for defect, and that the product was defective, and caused harm.[117] Whether an end-user can recover for injuries under a strict liability theory will depend on a number of factors, including whether the "seller is engaged in the business of selling" the product.[118] As set forth in comment f of section 402A of the Restatement (Second) of Torts, while section 402A "applies to any person engaged in the business of selling products for use or consumption," such as product manufacturers, retailers, and distributors, it does not apply to the "occasional seller" of products "who is not engaged in that activity as a part of his business." In *Racer v. Utterman*, 629 S.W.2d 387, 398 (Mo. Ct. App. 1981), where the plaintiffs sued the defendant hospital for strict liability arising from injuries allegedly caused by surgical drapes, which caught fire, the court held that the hospital was not strictly liable for the patient's injuries because there was "no evidence that the drape was sold by the hospital to plaintiffs or that the hospital was in the business of selling disposable drapes. . . . [T]he hospital is in no different position than any other business which purchases goods for its own use in conducting its business." A hobbyist who occasionally uses 3D printing to make, for example, a hard-to-obtain spare part, which then injures a consumer, is less likely to be subjected to strict liability than an entity that regularly makes, markets, distributes and sells 3D printed products as part of its ongoing business activities.[119] It remains to be seen whether in-house 3D printing brings hospitals one step closer to being in the business of selling medical devices, and thus potentially becoming a "manufacturer" for purposes of either strict liability or negligence.[120]

Even overcoming these obstacles, a plaintiff, to recover under a strict liability theory, would have to show that the product was defective when it left the defendant's control.[121] However, with the open source movement, where 3D designs are shared with a community of users who are encouraged to share and improve upon existing designs, plaintiffs may find it virtually impossible to trace the design to its original owner or show that it left the defendant's control without substantial change by the time it reached the consumer. Where 3D modeling and animation software is offered for free, rather than "sold," another basic strict liability prerequisite is eliminated.[122] Open source software also is generally distributed subject to terms of use that preclude recovery under product liability theories, although the applicability of such exculpatory language to injuries suffered by third persons is dubious.[123]

Given the challenges associated with asserting a strict liability claim in the context of 3D printing, plaintiffs seeking to recover for personal injuries caused by 3D printing may be left having to pursue negligence claims. To prevail on a negligence theory, a plaintiff must prove the existence of a duty of care, breach of that duty,



proximate causation, and resulting damages.[124] But who owes a duty of care to the plaintiff?

For example, does the designer of the STL file for the 3D printed product owe a duty of care to unknown third persons? Whether a designer has a duty may depend on whether the plaintiff suffered personal or economic injuries. Courts applying the economic loss rule have held that software developers do not have a duty of care to avoid intangible economic loss or emotional distress, and thus cannot be liable for negligence unless their software caused physical damages.[125]

Assuming that the manufacturer or seller of the 3D printed product has such a duty of care, what does the duty entail with respect to a 3D printed product? Generally, a manufacturer or seller has a legal duty to use reasonable care in response to a foreseeable risk of injury to others.[126] When a manufacturer or seller knows or should know of unreasonable dangers associated with the use of the product, and such dangers are not obvious to the user, there is a duty to warn of the dangers.[127] Applying these principles, STL files, without more, may not present unreasonable and unknown dangers triggering a duty to warn. On the other hand, if a designer or seller distributes STL files on ***how*** to 3D print a firearm, presumably a duty to warn of the dangers of the gun arises. Whether a duty to warn exists is likely to be a fact-driven inquiry and will depend on the type of product being 3D printed.

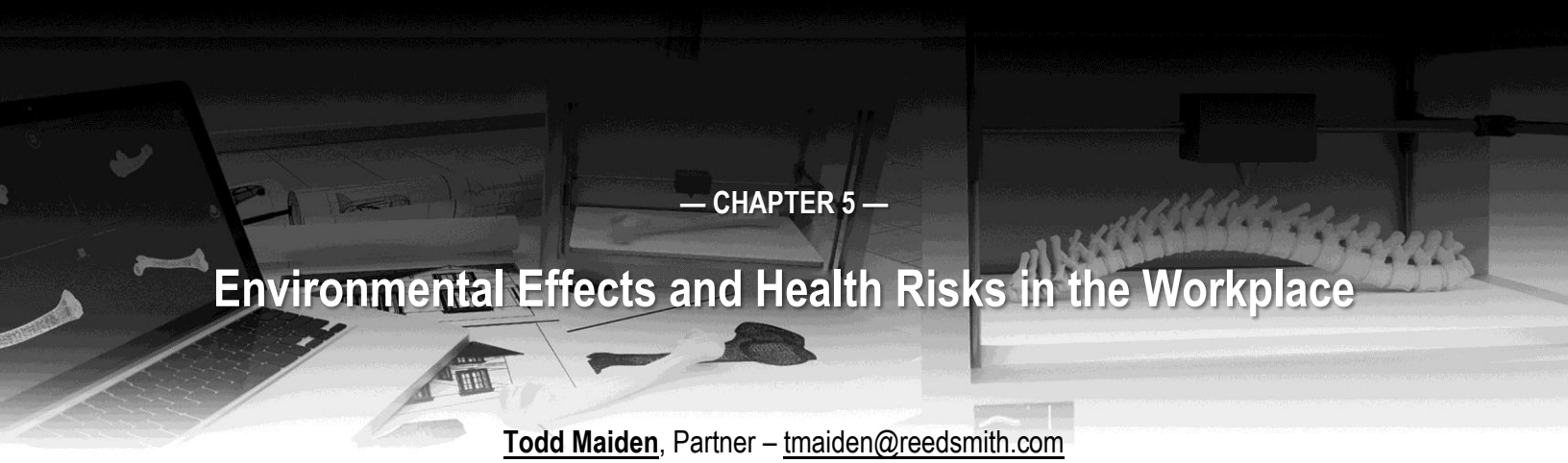
These general duty considerations are of equal importance in the health care arena, where 3D printed and patient-matched medical devices are being implanted in patients to save lives and improve health care. For example, in the event a patient is injured by a medical device that is 3D printed by a hospital (or by a separately incorporated, hospital-affiliated entity), who is the manufacturer or supplier for liability purposes? The common-law majority rule in the United States is that hospitals are not strictly liable for damages caused by prescription medical devices, usually, but not solely, because of the service/sale distinction already discussed.[128] Query whether hospital ownership of the 3D printer that printed the injury-causing device, could change the legal calculus of whether the hospital should be considered the manufacturer, particularly if no better candidate for "manufacturer" status exists.[129]

Assuming, however, that the hospital is not the manufacturer, another candidate for this role is the software designer.[130] However, product designers or inventors who were not also manufacturers of the product have historically not been held strictly liable.[131] Claims against non-manufacturers frequently occur in the context of litigation arising from the use of generic drugs, where plaintiffs seek recovery from the manufacturers of the original, or "innovator," drug who initially prepared the labeling.[132] Most courts have declined to hold that the innovator drug manufacturers owe duties of care to consumers of a generic drug manufactured by a different company.[133] Like product designers, other inventors, patents holders, and similar entities that gave input into design, but not manufacturing, may be liable, if at all, solely in negligence.[134] A final possibility, the manufacturer of the 3D printer itself, is unlikely to be held strictly liable because it only made a tool, and did not sell the actual injurious product, or its design software, to the plaintiff.[135]

Under a negligence theory, the duty to warn of the reasonably foreseeable dangers is critical given the inherent risks presented by medical devices, particularly Class III medical devices, which sustain or support human life.[136] Where the medical device is available by prescription, in the vast majority of jurisdictions that have adopted the learned intermediary doctrine, the duty to warn is satisfied where the manufacturer adequately warns the patient's physician.[137] Because physicians are typically warned about medical devices through medical literature such as product brochures, user guides, and product manuals that are created by a medical device

manufacturer, 3D printed medical devices will need to be accompanied by adequate warnings directed to physicians, if not consumers. As with other medical device warnings, these should disclose the reasonably foreseeable risks of the finished medical device (e.g., adverse reactions). In the 3D printing context, if no traditional product "manufacturer" exists, it is likely that, through the give and take of tort litigation, a duty to warn (perhaps only in negligence) will ultimately be imposed on some other entity involved in the creation of such products.

As 3D printing continues to disrupt traditional manufacturing, products liability law will likely evolve to accommodate the new technology.



— CHAPTER 5 —

Environmental Effects and Health Risks in the Workplace

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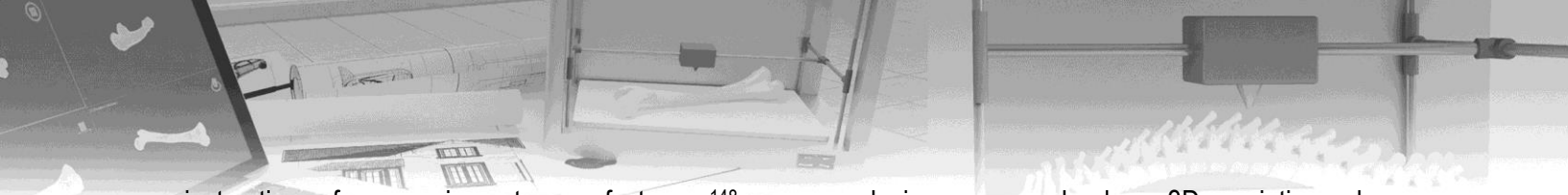
3D printing provides significant environmental benefits over traditional manufacturing techniques by reducing waste and cutting down on the raw materials used to manufacture products (as discussed *supra*, pages 2–3). That said, potential environmental hazards must be closely monitored as 3D printing technology evolves, especially in the workplace. In December 2014, the Environmental Health and Safety Department of Carnegie Mellon University published a 3D Printer Safety Fact Sheet[138] on the various hazards of 3D printer use as a result of the highly combustible powders, flammable thermoplastics and high temperatures involved in the process of 3D printing. Employers are responsible for ensuring safe work environments for the health and safety of their employees, under the Occupational Safety and Health Act of 1970, as well as other federal, state and local regulations. As such, it is important that employers understand the risks posed by 3D printing in the workplace and, where appropriate, offer employee training and implement preventive and mitigating measures.

Rather than traditional "ink," 3D printers generally use plastic filaments (as discussed *supra*, pages 2-3) comprising acrylonitrile butadiene styrene (ABS) or polylactic acid (PLA), which are heated and passed through a fine nozzle, layer by layer, to print a solid object. The heated thermoplastic extruders have been shown to release significant aerosol emissions into the environment[139], which may cause serious harm to one's health, absent adequate ventilation. Scientists in the Illinois Institute of Technology (ITT) and France's National Institute of Applied Sciences found that commercially available desktop 3D printers emitted between 20 billion and 300 billion ultrafine particles (UFPs) per minute.[140] When these UFPs are inhaled, they can end up in the lungs and, in high concentrations, cause inflammation in the respiratory system.[141] Indoor emissions, such as in the workplace, present an increased risk for health issues because 3D printers are often sold as stand-alone devices without ventilation or filtration accessories.[142] 3D printing businesses may use the U.S. Department of Labor's Occupational Safety and Health Administration (OSHA)'s ventilation standards as a guideline for reducing such risks and protecting the health and safety of employees.[143]

Another potential hazard in the 3D printing industry is combustible dust explosions.[144] Dust explosions may pose a risk where there is (1) combustible dust, (2) an ignition source, (3) oxygen in the air, (4) the dispersion of dust particles in sufficient quantity and concentration, and (5) confinement of the dust cloud.[145] In May 2014, OSHA cited a 3D printing company, Powderpart Inc., for 10 violations of workplace safety standards, and fined the company $64,400.[146] Following an investigation of an explosion and fire, which inflicted third-degree burns on a company employee, the company was cited for failing to prevent and protect its workforce from the fire and explosion hazards of reactive, combustible metal powders, such as titanium and aluminum alloys, which are used in the company's 3D printing process.[147] The company also failed to eliminate known sources of potential ignition and follow pertinent



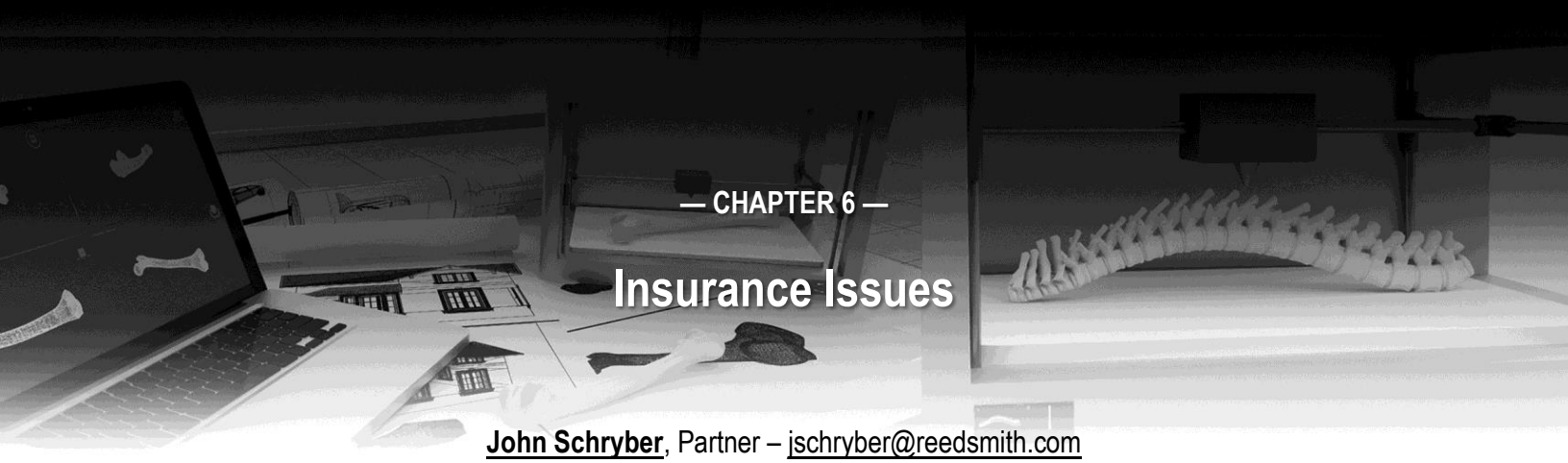
instructions from equipment manufacturers.[148] Additionally, the company placed an employee workstation and flammable powders next to an area with explosion potential.[149] In addition to the fire and explosion dangers, other serious hazards included the use of unapproved electrical equipment; electrical equipment and wiring that were unsuitable for a hazardous location; failure to train employees on chemical hazards and safeguards; failure to supply employees with all necessary protective clothing, equipment and training; no written respiratory protection program; and failure to post danger tags in potentially explosive areas.[150]

OSHA has published advisory guidelines on combustible dust hazards and safeguards in the workplace for employers.[151] According to OSHA's Safety and Health Information Bulletin, *Combustible Dust in Industry: Preventing and Mitigating the Effects of Fire and Explosions*, the primary factors for assessing the potential for dust explosions are determining whether the dust is combustible, and identifying areas that require special electrical equipment classification as a result of the presence of combustible dust.[152] Once the hazards are identified, employers may implement preventive and mitigation methods to safeguard the workplace.

National Fire Protection Association standard NFPA 654, *Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids*, also provides guidance on the prevention of fire and dust explosions from the manufacturing, processing, and handling of combustible materials. 3D printing businesses can safeguard against the potential for dust explosions caused by 3D printing by (1) minimizing the escape of dust from process equipment or ventilation systems, (2) using dust collection systems and filters, (3) utilizing surfaces that minimize dust accumulation and facilitate cleaning, (4) cleaning dust residues regularly, (5) using cleaning methods that do not generate dust clouds if ignition sources are in the vicinity, and (6) developing a hazardous dust inspection and control program.[153] Employers can also protect against potential fire and explosion hazards by controlling ignition sources by using appropriate electrical equipment and wiring methods; controlling smoking, open flames, and sparks; and keeping heated surfaces away from dust.[154] In addition, 3D printing businesses should clean and maintain workplaces, including by removing dust accumulations.[155]

Further, employers that use hazardous chemicals or combustible dust in their workplaces are required to implement comprehensive hazard communication programs (including container labeling, warnings, safety data sheets, and employee training) to ensure that safety information regarding chemical hazards is properly transmitted to employees.[156] One of the keys to providing a safe workplace in the 3D printing environment is training employees on how to identify potential hazards, maintain clean and well-ventilated workspaces, and control dust and ignition sources to prevent explosions.

Given the risks associated with 3D printing, it is also imperative for businesses to obtain appropriate insurance to protect against potential liabilities arising from 3D printing.



— CHAPTER 6 —

Insurance Issues

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As 3D printing becomes more prevalent, liability risks to individuals and businesses will likely climb in similar fashion—and with it, the need to explore whether existing insurance provides adequate coverage or whether additional coverage is needed. In addition to design and intellectual infringements, discussed *supra*, 3D printing presents many types of risks, including product liability risks and environmental liability risks, to name a few.

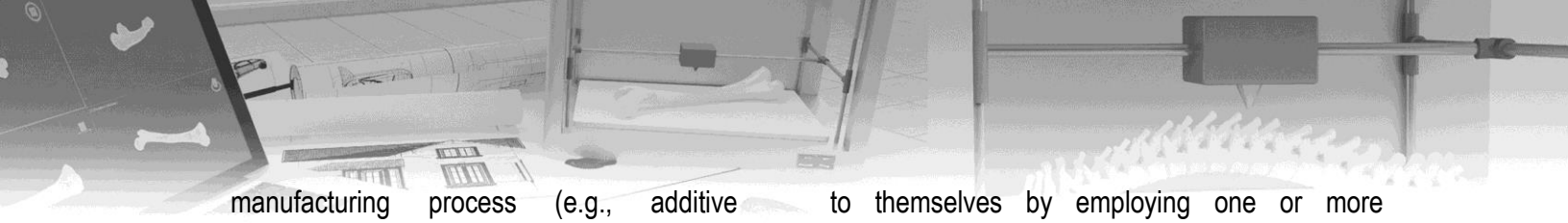
Because 3D printing will blur the line between manufacturers and end-users, it will create challenges in apportioning liabilities and pose accountability and traceability issues.[157] The number of persons potentially liable for injuries caused by a defective product is an issue plaguing insurance companies.[158] Because 3D printers are becoming more accessible—individuals can purchase the printers, use an online 3D printing service like Sculpteo[159], or use the 3D printers in a brick-and-mortar communal workspace (or "hackerspace") to print objects using designs and materials that may have been created or manufactured by a third party. As this type of 3D printing activity takes place, it will become increasingly difficult for insurers to identify the liable party.

Whether the injury will be covered by an insurer is a separate issue. Consider for example, a hobbyist who sells an object that was printed in his garage, which causes injuries to a customer. An issue will exist as to whether there will be coverage under the individual's homeowners insurance policy, which typically contains a business exclusion, which bars coverage for activities carried out for financial gain.[160] As one insurer stated regarding claims arising from 3D printed devices, "we are aware of no claims having been reported yet so we don't know exactly what will happen. We have no precedent."[161]

Not only does the finished 3D printed object present risks requiring insurance, but the 3D printing process itself also calls for environmental liability insurance because of the potential for raw materials being used to print 3D objects to release fine toxic particles into the atmosphere,[162] as discussed *supra*, Chapter 5. Injuries arising from the release of toxic particles from a 3D printer, however, may implicate the pollution exclusion.[163] Courts that have addressed this issue are split on whether the pollution exclusion applies to indoor contaminants.[164] The circuit courts are split on the meaning of the terms "discharge, dispersal, seepage, migration, release or escape," and whether the pollution exclusion bars coverage for all injuries caused by the release of pollutants where the pollutant is dispersed into a confined area.[165] Thus, whether a policyholder receives coverage for claims for bodily injuries caused by a 3D printer's release of pollutants, may depend on the particular jurisdiction's interpretation of these terms.

Against the backdrop of 3D printing, insurers will likely evaluate some or all of the following in evaluating coverage for policyholders:

- Whether there are any increases in the risk to the insured as a result of the

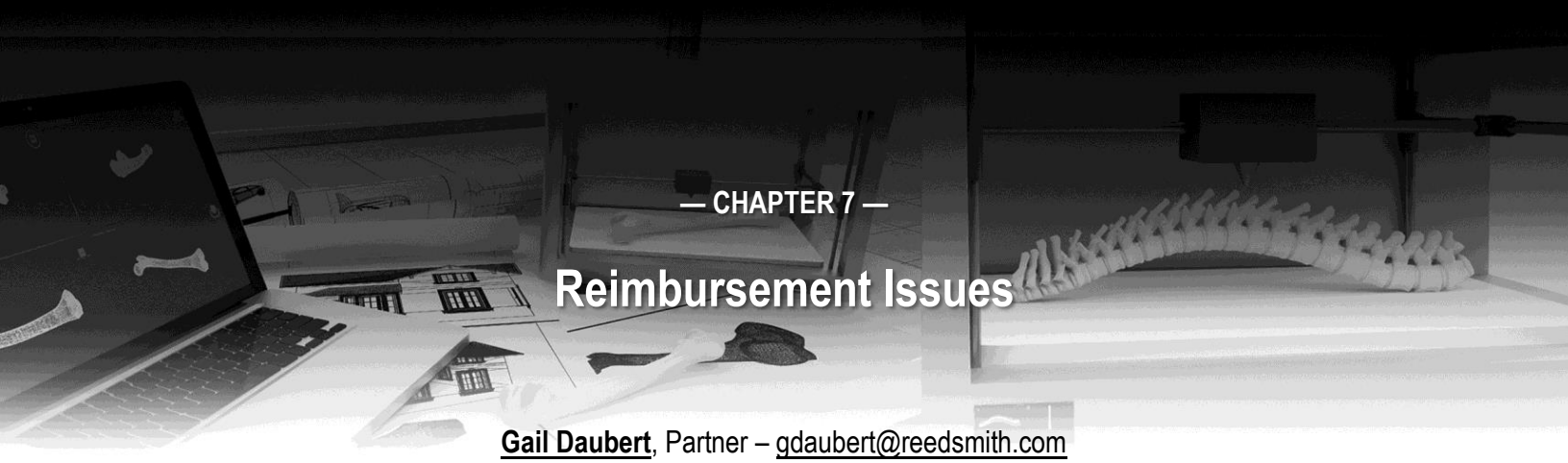


manufacturing process (e.g., additive manufacturing is not heavily regulated and poses the risk of counterfeit goods being printed and sold, arguably more so than traditional manufacturing)

- Any supply chain issues
- Complexities associated with the ability to trace the parties responsible for the defects in manufacturing and its potential impact on subrogation/recovery rights
- The number of jurisdictions in which the insured operates and their regulators
- Discussions with product developers that the policyholder uses
- The risks at each stage, from manufacturing the product to testing and distributing to the end user, including the risks associated with the quality of the raw materials being used and potentially new combinations of materials, which may not have been properly tested[166]

Whether applying for insurance or renewing one's insurance, businesses can reduce the risk to themselves by employing one or more strategies:

- Develop strategies for managing the product risks through greater traceability of designs, raw materials and components (including physical identifiers on products)
- Have an open dialogue with the insurer's risk manager to implement a risk-management solution
- Consider the need for product recall insurance
- Consider the need for worldwide coverage where products are sold globally
- Take mitigating actions and have contingency plans in place
- Implement negotiated (as vendor or buyer) disclaimers, non-liability clauses, or caps to limit one's liability
- Review risk-management processes and show underwriters that key issues, such as maintaining quality control, have been addressed[167]



— CHAPTER 7 —

Reimbursement Issues

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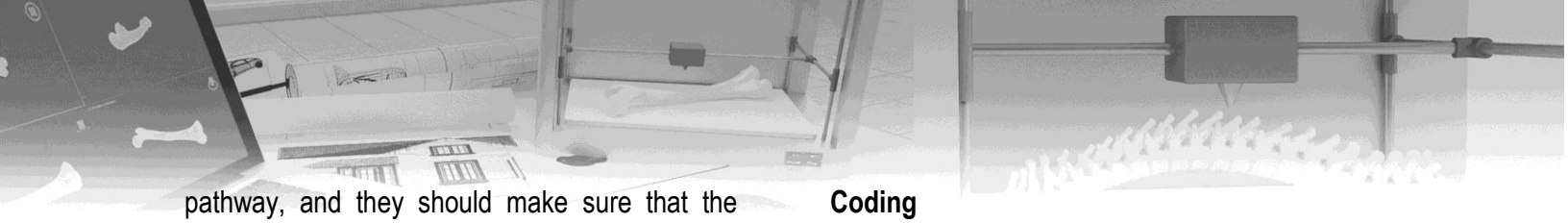
3D printing has the potential to revolutionize the medical device industry, whether through the manufacture of customizable devices (both implantable and non-implantable), or through the use of surgery models. While regulatory concerns may be the primary focus of 3D printing medical device manufacturers, these companies should also be planning ahead for reimbursement.[168] Whether 3D printed medical device implants, models, and related health care services will be eligible for reimbursement by the government or private insurance companies will depend largely on whether these 3D printed products are determined to be medically necessary, and whether they provide a substantial clinical benefit.

Public and private third-party payors represent any medical device manufacturer's largest market opportunity for most products, and therefore, it is crucial that manufacturers align their strategies with that of the payors.[169] By understanding the reimbursement process, as well as demands of payors, 3D printed medical device companies can organize clinical trials and take regulatory pathways that will support reimbursement, and in turn, help grow this new technology.

This chapter will focus on a brief overview of the reimbursement issues that companies that manufacture 3D printed implantable medical devices may face, so that they can properly plan for reimbursement.[170] While the technology may be novel, the reimbursement issues these companies face are, in many ways, commonplace for traditionally manufactured medical device companies.

Coverage

Coverage is the first step to determine whether any payment will be provided for the product.[171] Although regulatory approval is necessary for coverage, it does not guarantee coverage. The FDA ensures that products are safe and effective, while payors focus on the product being reasonable, necessary, and superior to other products on the market.[172] This difference makes it complicated for manufacturers to achieve both regulatory clearance and reimbursement. In other words, with respect to 3D printed medical devices, the key to reimbursement is to impress upon the payors that the 3D printed device is distinguishable or novel from other devices on the market, and that the 3D printed device will last at least as long or perhaps longer than the current devices. Currently, however, 3D printed medical devices entering the market are using the 510(k) process (see *supra* Chapter 4: Regulatory Issues), which in essence means that 3D printed devices are "substantially equivalent"[173] (i.e., not distinguishable or novel) to other devices already on the market. So while a manufacturer may be able to obtain FDA approval, it may not be able to obtain reimbursement for the 510(k) cleared 3D printed medical devices and/or payment will be the same as the already approved product, unless the manufacturer has clinical data demonstrating clinical efficacy and long-term outcomes. 3D printed medical device companies should look for alternatives to the 510(k)



pathway, and they should make sure that the regulatory pathway aligns with their strategy for reimbursement, as well as their marketing messages.

Another coverage issue facing 3D printed medical device companies is lack of clinical data. While 3D printed implants may theoretically reduce the overall costs associated with implant surgeries by decreasing the operating time, recovery time, and chance for medical complications, there remains a lack of clinical evidence suggesting the actual superiority and cost-effectiveness of 3D printed devices in peer-reviewed scientific/ clinical literature. For public payors, such as the Centers for Medicare & Medicaid Services ("CMS"), coverage via a national coverage decision or local coverage decision will likely be required for new medical technologies, such as 3D printed devices. Public (as well as private) payors will demand peer-reviewed clinical data in order to make a coverage determination. Payors in general also prefer data from prospective randomized clinical trials.[174] Private insurance companies also will require long-term clinical data that demonstrate the clinical value of the 3D printed device.[175] Therefore, 3D printed medical device companies will need to invest in clinical studies, with the data being disseminated though peer-reviewed journals, which provide a level of credibility that CMS, private payors, hospitals, and physicians can rely upon.[176]

Not only is long-term clinical data necessary for the reimbursement of 3D printed medical devices, but postmarket surveillance (or so-called real world data) will also likely be necessary.[177] Payors will want to understand the cost, benefits, and patient outcomes of the 3D printed devices. Registries or longitudinal studies to collect post-clearance/approval data will likely be created so that payors (and the FDA) can track the outcomes of 3D printed devices in real-world patient populations.

Coding

Coding is a short-hand system that describes diseases, procedures, or products.[178] 3D printed medical device companies will need to determine how their products fit into the coding landscape, which requires a thorough analysis. If current codes are not appropriate for the 3D printed devices and services, creating new codes may be an option; however, in order to do so, extensive clinical data demonstrating clinical efficacy and widespread adoption (or program need) is required.

Without proper coding for 3D printed medical devices, physicians may be discouraged from using such devices, as they will not be properly paid for their efforts. For example, the lack of insurance coverage and inadequate payment[179] for complex, reconstructive surgeries has been shown to deter surgeons from undergoing medical training to use 3D printed implants and 3D printed models for pre-surgical planning.[180] In order for 3D printing to become sustainable within the orthopedic industry and elsewhere, surgeons must be paid appropriately for planning (such as scanning the patient in order to create a customizable implant) needed to develop 3D printed implants. This means that new Current Procedural Terminology ("CPT")[181] codes will need to be created to describe these services, in order for the physician to be paid. The American Medical Association ("AMA") is responsible for establishing new CPT codes, and the criteria for Category I CPT codes[182] includes, among other things, widespread adoption of the procedure, and that the clinical efficacy of the procedure is well-documented in peer-reviewed clinical literature. Assuming all the criteria can be met, obtaining a new CPT code may take 18-24 months. Without a new CPT code, a physician is less likely to use 3D printed devices over traditionally manufactured devices, especially if extra work including planning is required. However, if the physician does not need to do any extra work, whether he uses a 3D printed device or a traditional manufactured device, then

existing CPT codes may work and a physician may be more likely to use a 3D printed device.[183]

Payment

Assuming, 3D printed devices are able to obtain coverage and either can use existing CPT codes or new CPT codes are created, then hospitals and physicians can be paid for using 3D printed medical devices. Medicare payment to the facility will vary based on the site of service.[184]

Hospital Inpatient	Medicare Severity Diagnosis-Related Group (MS-DRG) – assigned when patient is discharged. Additional payment for new technology may be made if technology qualifies for New Technology DRG Add-on
Hospital Outpatient	APC – Ambulatory Payment Classification
Ambulatory Surgery Center	Percent of APC payment

Medicare payment to the physician for his or her professional services is based on a fee schedule.[185] The fee schedule payment is based on the time, skill, complexity of the procedure as well as where the service is furnished.

Even outside of the regulatory context, acceptance of the medical device within the medical community is necessary for sales.[186] Acceptance from physicians will come as more and more data supports the use of 3D printed devices over traditionally manufactured counterparts. The data will also clear the pathway for reimbursement, which will in turn create even more support from physicians.

Conclusion

Regarding reimbursement, 3D printed medical device companies do not face any new challenges that traditional manufactures face when releasing new products. Understanding reimbursement and creating a successful reimbursement strategy in the product development phase is necessary to ensure that 3D-printed medical devices are not only innovative, but are also actually used by the patients who need them.

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John's success for one of his Fortune 500 clients was chronicled in October 2013 in a nationally televised investigative report on the Scripps-Howard network of stations. John has represented a number of private equity firms and their portfolio companies in coverage litigation.

In addition, John has prosecuted the rights of policyholders and beneficiaries of private indemnity agreements in connection with virtually every kind of coverage dispute. He has handled coverage cases for claims involving trademark infringement, CERCLA liability, breach of corporate fiduciary duty, violations of securities laws, Ponzi-scheme conversion, predatory subprime mortgage lending, forgery, defective building construction, race discrimination, and products liability.

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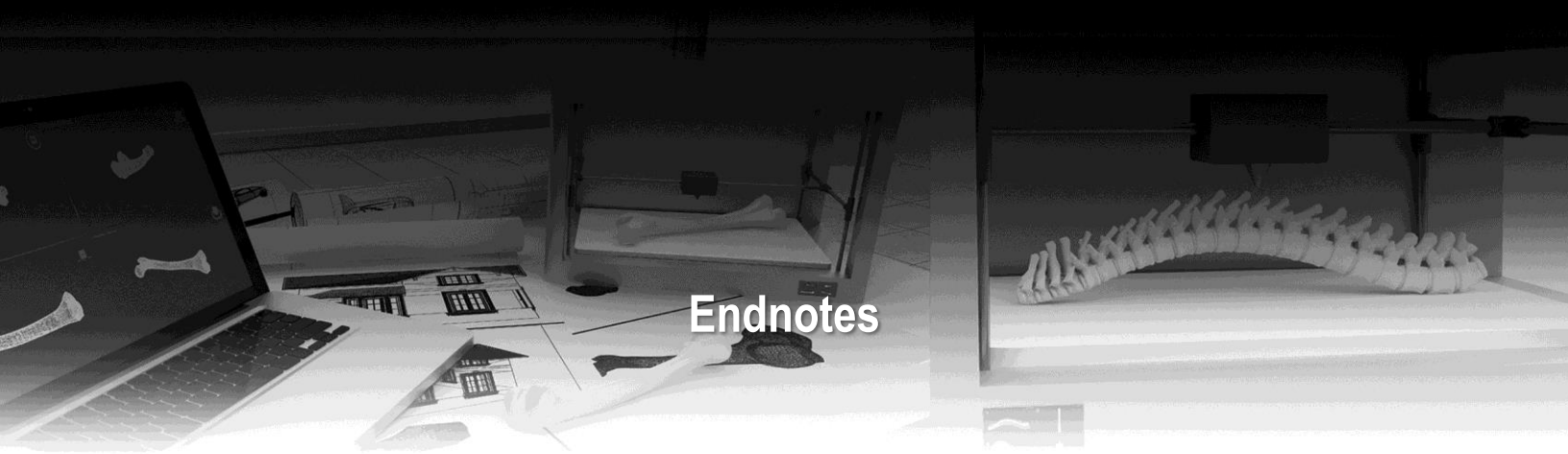

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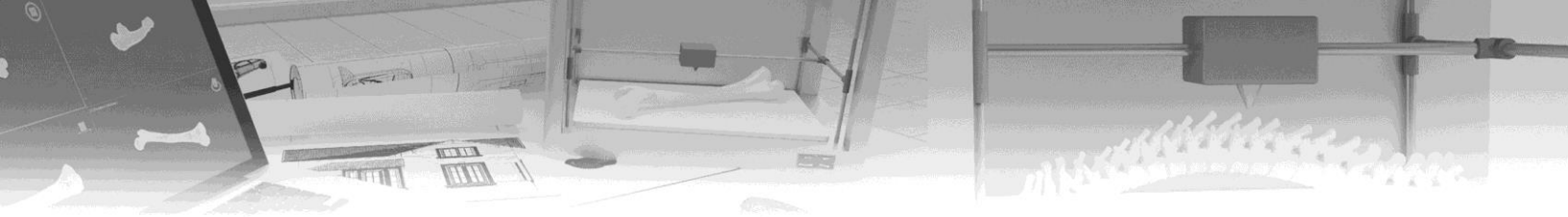

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[33] Renovis Surgical Porous Acetabular Cup System, 510(K) Number K141676, cleared Nov. 4, 2014, summary available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K141676

[34] Renovis S141 Lumbar Interbody Cage System, 510(k) Number K143126, cleared Feb. 06, 2015, summary available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K143126

[35] Renovis A200 Cruciate Retaining Knee System, 510(k) Number K120038, cleared Feb. 14, 2013, summary available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K120038

[36] Oxford Performance Materials, Osteofab Patient Specific Facial Device, 510(k) Number K133809, cleared July 28, 2014, summary available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K133809

[37] Renovis S100 Pedicle Screw System, 510(K) Number K111940, cleared May 15, 2012, summary available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K111940 Renovis T700 Cannulated Screw System (510(K) clearance)

[38] Materialise N.V., Orthopaedic Surgical Planning And Instrument Guides, 510(k) Number K132290, cleared Apr. 10, 2014, summary available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K132290

[39] C. Lee Ventola, MS, Medical Applications for 3D Printing: Current and Projected Uses, 39 P T. 10, 704, 708 (Oct. 2014).

[40] 3D Printing Revolutionizing Healthcare, eHealth (Jan. 14, 2015), http://ehealth.eletsonline.com/2015/01/3d-printing-revolutionizing-healthcare/

[41] http://www.oxfordpm.com/news/article/2014-08-19_oxford_performance_materials_receives_fda_clearance_for_3d_printed_osteofab_patient-specific_facial_device.php (last visited June 1, 2015); *see also* http://3dprintingindustry.com/2013/02/22/the-first-3d-printed-polymer-implant-to-receive-fda-approval/ (last visited June 1, 2015).

[42] http://www.renovis-surgical.com/2013/10/renovis-surgical-received-fda-clearance-of-porous-titanium-spinal-implant/ (last visited June 2, 2015).

[43] *See* SPRITAM (levetiracetam) Tablets, Full Prescribing Information ("SPRITAM tablets are unitary porous structures produced by a three-dimensional printing process that binds the powders without compression."), http://www.spritam.com/pdfs/full-pi.pdf.

[44] *See* Aprecia Pharmaceuticals Press Release (Aug. 3, 2015), https://aprecia.com/pdf/2015_08_03_Spritam_FDA_Approval_Press_Release.pdf.

[45] Steven K. Pollack & James Coburn, *FDA Goes 3D*, FDA Voice, (Aug. 15, 2013), http://blogs.fda.gov/fdavoice/index.php/tag/osel/ (last visited July 30, 2015).

[46] *Id.*

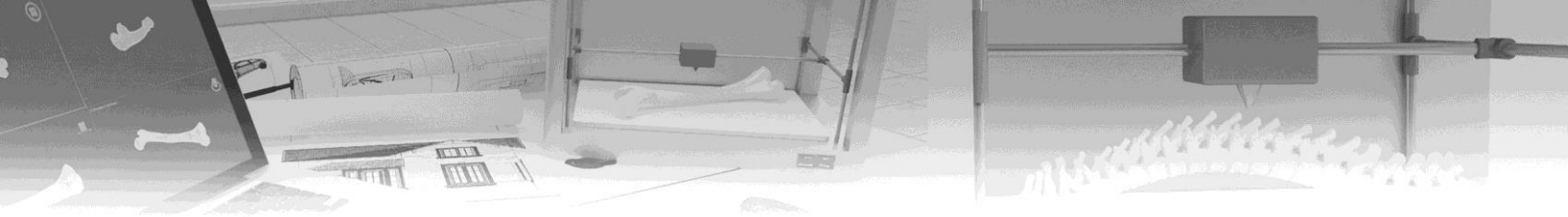
[47] Pollack & Coburn, *supra* note 1.

[48] *Id.*

[49] *Id.*

[50] *Id.*

[51] Transcript of FDA Public Workshop: Additive Manufacturing of Medical Devices at 82, Oct. 8, 2014, available at http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM425399.pdf.



[52] *See* Jamie Hartford, *FDA's View on 3-D Printing Medical Devices*, MDDI (Feb. 11, 2015), http://www.mddionline.com/article/fdas-view-3-d-printing-medical-devices (discussing FDA's director of the Office of Science and Engineering Laboratories, Stephen Pollack's, speech to his audience at the medical device conference at MD&M West).

[53] *Id.*

[54] *Id.*

[55] *See Classify Your Medical Device*, FDA.gov, http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/default.htm (last visited July 10, 2015). *Compare* Class II devices with Class I devices that are low risk and subject to very minimal regulatory controls, *and* Class III devices that are devices with the highest risk and are subject to the highest level of regulatory control.

[56] *See* 21 C.F.R. § 807.92(a)(3)).

[57] Hartford, *supra* note 8.

[58] Hartford, *supra* note 8.

[59] *See* FDA Information Sheet Guidance for IRBs, Clinical Investigators and Sponsors – Frequently Asked Questions About Medical Devices (Jan. 2006), pg. 10. *See also* 21 C.F.R. § 812.35.

[60] *See* Food and Drug Administration Safety and Innovation Act of 2012 § 520(b).

[61] *See* 21 U.S.C. § 360bbb-3(b)(1)(C). FDA considers "life-threatening condition" to include situations involving risk of irreversible morbidity or other serious disease conditions.

[62] Pollack & Coburn, *supra* note 1.

[63] Todd Halterman, Robohand, the FDA and 3D Printing, 3D Printer World, Aug. 30, 2013, http://www.3dprinterworld.com/article/robohand-fda-and-3d-printing.

[64] *Id.*

[65] *Id.*

[66] *Id.*

[67] Patient-specific devices (also referred to as patient-matched devices) are, in general, ones in which ranges of different specifications have been approved or cleared to treat patient populations that can be studied clinically. Premarket submissions for such devices are sometimes referred to as "envelope" submissions because their approval or clearance covers the entire range of specifications data they contain to support. The final manufacturing of these devices can be delayed until physicians provide imaging data or other information to the manufacturer to finalize device specifications within cleared or approved ranges. As a result, such devices are specifically tailored to patients.

[68] For traditional medical device manufacturers, demand-based manufacturing through 3D printing technology offers immense potential by, among other things, eliminating the need for excess inventory and significantly reducing (or at least changing) costs associated with supply chain logistics. For providers, demand-based manufacturing offers immense potential for product offerings and capabilities. *See* Chapter 1 ("3D Printing And Its Impact On Medical Device And Health Care"), *supra*.

[69] 21 C.F.R. § 820.3(o).

[70] 21 C.F.R. § 820.

[71] 21 C.F.R. § 812.3(b) (defining a "custom device" as a device that, among other things, is "intended for use by an individual patient named in the order form of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice"). Custom devices are not exempt from any other requirements, including, but not limited to, FDA's Quality System Regulation, particularly Design Controls (21 C.F.R. Part 820); Medical Device Reporting (21 C.F.R. Part 803); Labeling (21 C.F.R. Part 801); Corrections and Removals (21 C.F.R. Part 806); and Registration and Listing (21 C.F.R. Part 807).

[72] FDA Workshop, "Public Workshop - Additive Manufacturing of Medical Devices: An Interactive Discussion on the Technical Considerations of 3D Printing" (October 8-9, 2014), available at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm397324.htm.

[73] FDA, Public Workshop - Additive Manufacturing of Medical Devices: An Interactive Discussion on the Technical Considerations of 3D Printing, Oct. 8-9, 2014, http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm397324.htm.

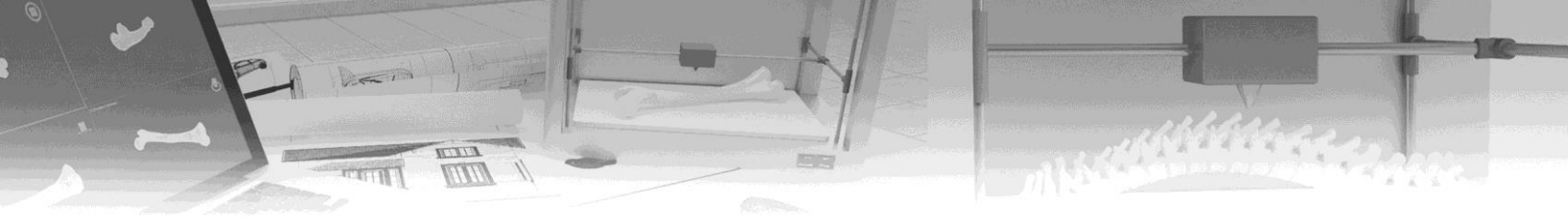
[74] Transcript of FDA Public Workshop: Additive Manufacturing of Medical Devices at 84-86, Oct. 8, 2014, available at http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM425399.pdf.

[75] *Id.*

[76] *Id.*

[77] *Id.*

[78] *Id.*; *see also* FDA, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/ucm321367.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery (last visited May 8, 2015); Transcript of FDA Public Workshop: Additive



Manufacturing of Medical Devices at 82, Oct. 8, 2014, available at http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM425399.pdf.

79 Hartford, *supra* note 8.

80 *Id*.

81 *See generally* 1 Melville B. Nimmer & David Nimmer, Nimmer on Copyright ("Nimmer") § 2.18 (Matthew Bender, Rev. Ed. 2015).

82 17 U.S.C. §§ 101 et seq. *See generally, e.g.*, 1 Nimmer § 2.03.

83 *See, e.g.*, Sarah Swanson, 3D Printing: A Lesson in History: How to Mold the World of Copyright, 43 Sw. L. Rev. 483, 484 (2014) ("Swanson").

84 *Ibid*.

85 *See* 1 Nimmer § 2.18[D][2]; *see also, e.g.*, Swanson, *supra*, at 486-88; Perry J. Viscounty, *et al.*, 3D Printing: A New Technology Challenges the Existing Intellectual Property Framework, 56-OCT Orange County Law. 16, 18 (Oct. 2014) ("Viscounty").

86 *Ibid*.

87 35 U.S.C. §§ 101, 271. *See generally* 1-1 Donald S. Chisum, Chisum on Patents ("Chisum") §§ 1.01(Matthew Bender Rev. Ed. 2015); 5-16 Chisum §16.01. Design patents may also be used to protect ornamental, non-functional product design elements. 35 U.S.C. § 171. Given the limited applicability of design patents to the medical device industry, however, this chapter will focus on issues involving utility patents and 3D printing.

88 *See* 5-16 Chisum § 16.01; 5-17 Chisum §17.01.

89 *See generally*, e.g., Davis Doherty, Downloading Infringement: Patent Law as a Roadblock to the 3D Printing Revolution, 26 Harv. J. Law & Tech. 353,359-61 (Vol. 26 No. 1) (2012) ("Doherty").

90 *See*, e.g., Doherty, at 361 and n 49.

91 *See, e.g.*, J. Thomas McCarthy, 1 McCarthy on Trademarks and Unfair Competition § 2.1 (4th Ed.)

92 *See* 15 U.S.C. § 1114(a).

93 *See, e.g.*, Roger M. Milgrim and Eric E. Bensen, 1-1 Milgrim on Trade Secrets § 1.05 (Matthew Bender Rev. Ed. 2015).

94 *See generally, e.g.*, Doherty and Swanson, *supra*.

95 *See generally Winterbottom v. Wright*, 152 Eng. Rep. 402 (1842).

96 Restatement (Second) of Torts § 402A (1965).

97 Karishma Paroha, June 2, 2014, 3-D *Printed Products, Product Liability And Insurance Implications*, http://www.kennedyslaw.com/article/3dprintedproducts/.

98 Restatement (Third) of Torts: Prods. Liab. § 19 (2015).

99 *U.S. v. Aleynikov*, 676 F.3d 71, 73 (2d Cir. Apr. 11, 2012).

100 *Id.* at 74.

101 *Id.*

102 *Id*. at 77 (citing *United States v. Bottone*, 365 F.2d 389, 393 (2d Cir. 1966)).

103 Restatement (Third) of Torts: Prods. Liab. § 19 (2015).

104 *See County of Santa Clara v. Atlantic Richfield Co.*, 137 Cal. App. 4th 292, 318 (2006) (citing *Soule v. General Motors Corp.*, 8 Cal. 4th 548, 560 (1994)).

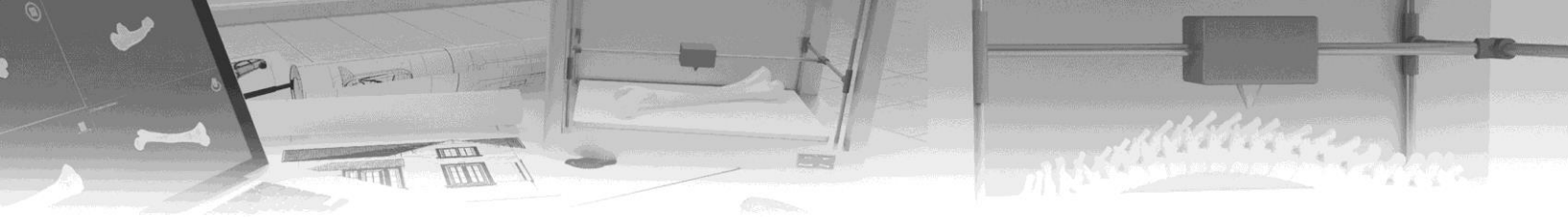
105 *See, e.g.*, *Smith v. Home Light and Power Company*, 695 P.2d 788, 789 (Colo. 1984) (holding "electricity itself is a product"); *Schriner v. Pennsylvania Power & Light Co.*, 501 A.2d 1128, 1133 (1985) (holding that "electricity can be a 'product,' within the meaning of § 402A"); *Stein v. Southern California Edison Co.*, 7 Cal. App. 4th 565, 571 (1992).

106 *See Brockelsby v. U.S.*, 767 F.2d 1288, 1295 (9th Cir. 1985) (holding that an aeronautical chart "was a defective product for purposes of analysis under section 402A"); *Saloomey v. Jeppesen & Co.*, 707 F.2d 671, 676-77 (2d Cir. 1983) (holding that navigational charts were products under section 402A, and that mass production and marketing of charts required that the defendant bear the costs of accidents proximately caused by the charts).

107 *e.g.*, *Winter v. G.P. Putnam's Sons*, 938 F.2d 1033, 1039 (9th Cir. 1991); *Lewin v. McCreight*, 655 F. Supp. 282, 284 (E.D. Mich. 1987) (applying Michigan law and holding that publisher did not have duty to warn of "defective ideas" supplied by third-party authors); *Way v. Boy Scouts of America*, 856 S.W.2d 230, 239 (Tex. App. 1993) (holding that the information conveyed by magazine and supplement were not products within the meaning of the Restatement (Second) of Torts).

108 *See* Drug and Device Law, Apr. 7, 2011, http://druganddevicelaw.blogspot.com/2011/04/on-suing-publishers.html (last visited July 28, 2015).

109 *See, e.g.*, Shapeways – 3D Printing Service and Marketplace, http://www.shapeways.com/ (last visited July 29, 2015).



[110] Simon, *Should You Buy a 3D Printer or Use a 3D Printing Service?* 3Ders.org, June 28, 2015, http://www.3ders.org/articles/20150628-should-you-buy-a-3d-printer-or-use-a-3d-printing-service-sculpteo-releases-2015-edition.html.

[111] *See Hector v. Cedars-Sinai Medical Center*, 180 Cal. App. 3d 493, 500 (1986) (quoting *Vandermark v. Ford Motor Co.*, 61 Cal. 2d 256, 262 (1964)).

[112] James M. Beck & Anthony Vale, Drug and Medical Device Product Liability Deskbook, § 8.05[1] (2015).

[113] *Cafazzo v. Central Medical Health Services, Inc.*, 668 A.2d 521, 532 (1995); *see also Hollander v. Sandoz Pharmaceuticals Corp.*, 289 F.3d 1193, 1217, n.22 (10th Cir. 2002) (applying Oklahoma law and following "majority of jurisdictions" in declining to hold hospital liable for strict product liability); *Vergott v. Deseret Pharmaceutical Co.*, 463 F.2d 12, 16, n.5 (5th Cir. 1972) (applying Texas law and holding that a "hospital is not a seller engaged in the business of selling the product" under section 402A); *Wages v. Johnson Regional Medical Center*, 916 F. Supp. 2d 900, 904 (W.D. Ark. 2013) (holding that hospitals cannot be considered product suppliers under the Arkansas Products Liability Act merely because the hospital uses the product during a medical procedure); *Samuels v. Health & Hospital Corp. of City of New York*, 432 F. Supp. 1283, 1284-85 (D.C.N.Y. 1977) (applying New York law and holding that "the doctrine of strict liability in tort is inapplicable to the service by the hospital of providing blood transfusions). *But see Cunningham v. MacNeal Memorial Hosp.*, 266 N.E. 2d 897, 902 (1970) (finding hospital, which provided blood transfusions to patients, was liable for strict liability).

[114] *See, e.g.*, *Pierson v. Sharp Memorial Hospital, Inc.*, 216 Cal. App. 3d 340, 346-47 (1989).

[115] In June 2015, Materialise, a Belgian provider of high-end 3D printed products, announced that it partnered with Fuwai Hospital in Beijing, China, to open a medical 3D printing center at the hospital. *See* 3Ders.org., *Materialise & Fuwai Hospital Collaborate on China's First Cardiovascular 3D Printing Center*, June 25, 2015, http://www.3ders.org/articles/20150625-materialise-fu-wai-hospital-collaborate-on-china-first-cardiovascular-3d-printing-center.html (last visited July 28, 2015).

[116] *See* Meribah Knight, *3-D Printing is Revolutionizing Surgery, Crain's Chicago Business*, Mar. 22, 2014, http://www.chicagobusiness.com/article/20140322/ISSUE01/140229904/3-d-printing-is-revolutionizing-surgery (last visited July 28, 2015).

[117] *See Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal. 3d 987, 994 (1991).

[118] *See* Restatement (Second) of Torts § 402A(1)(a) (1964); *see also* Restatement (Third) of Torts § 402A (1998); Drug and Device Law, Feb. 5, 2015, http://druganddevicelaw.blogspot.com/2015/02/some-ideas-about-3d-printing.html (last visited May 8, 2015).

[119] Heidi Nielson, *Manufacturing Consumer Protection for 3-D Printed Products*, 57 Ariz. L. Rev. 609, 617 (2015); Nora Freeman Engstrom, *3-D Printing And Product Liability: Identifying The Obstacles*, 162 Univ. of Penn. Law Review Online 35, 37 (2013). Generally, under existing product liability principles, so-called "occasional sellers" of products are not subject to strict liability. *See Garcia v. Becker Bros. Steel Co.*, 194 Cal. App. 4th 474, 482 (2011).

[120] *See Netherland v. Ethicon, Inc.*, 813 So. 2d 1254, 1259-60 (La. Ct. App. 2002) (finding plaintiff had a viable cause of action for negligence against hospital that knowingly and negligently distributed contaminated sutures).

[121] *See, e.g.*, *Gaumer v. Rossville Truck & Tractor Co.*, 292 Kan. 749, 761 (2011).

[122] *See List of 3D Software*, http://www.3ders.org/3d-software/3d-software-list.html, 3ders.org. (last visited July 28, 2015); *see also* 3DPrintingforBeginners.com, *Software & Tools for 3D printing*, http://3dprintingforbeginners.com/software-tools/ (last visited July 28, 2015).

[123] *See* George L. Graff, *The Enforceability Of Open Source Licenses*, 7 No. 2 E-Commerce L. Rep. 4 (2005).

[124] *Gartin v. S&M NuTec LLC*, 245 F.R.D. 429, 439 (C.D. Cal. Apr. 4, 2007).

[125] *See Gus' Catering, Inc. v. Menusoft Sys.*, 171 Vt. 556, 559 (2000); *Hayes v. Spectorsoft Corp.*, No. 1:08-cv-187, 2009 BL 238025, *13-14 (E.D. Tenn. Nov. 3, 2009).

[126] 63 Am Jur. 2d Products Liability § 212 (2015).

[127] 63A Am Jur. 2d Products Liability § 1030 (2015).

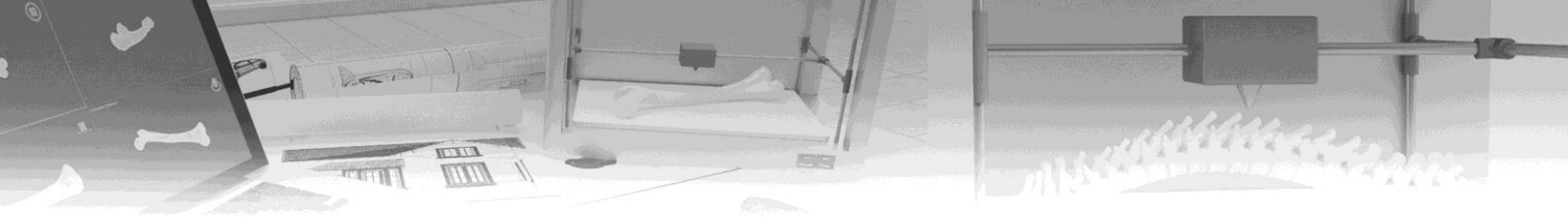
[128] James M. Beck & Anthony Vale, Drug and Medical Device Product Liability Deskbook, § 8.05[1] (2015).

[129] *Id*. A number of states, however, have addressed this issue statutorily, and in such jurisdictions, evolution of the law could be restrained by statutory definitions.

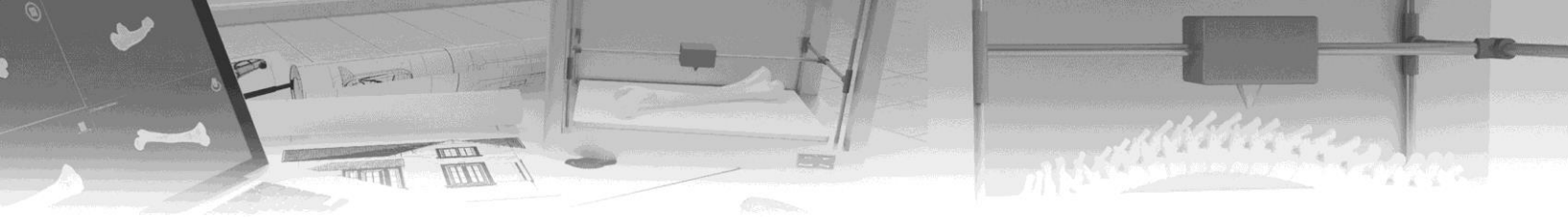
[130] Drug and Device Law, Feb. 5, 2015, http://druganddevicelaw.blogspot.com/2015/02/some-ideas-about-3d-printing.html (last visited May 8, 2015).

[131] *See, e.g.*, *In re Minnesota Breast Implant Litig.*, 36 F. Supp. 2d 863, 872 (D. Minn. 1998) (applying Arizona law and holding that "if 3M played no role in the manufacture or sale of Plaintiffs' breast implants, 3M cannot be strictly liable"); *Christian v. Minnesota Mining & Manufacturing Co.*, 126 F. Supp. 2d 951, 958 (D. Md. 2001) (same); *Parker v. St. Vincent Hosp.*, 919 P.2d 1104, 1113 (N.M. Ct. App. 1996) (affirming summary judgment in favor of hospital on strict products liability claim).

[132] *See* James M. Beck & Anthony Vale, Drug and Medical Device Product Liability Deskbook, § 8.09 (2015).



[133] *Id.*; *see, e.g.*, *Foster v. American Home Products Corp.*, 29 F.3d 165, 171 (4th Cir. 1994) (applying Maryland law and refusing to find non-manufacturer was liable for negligent misrepresentation).
[134] *See* James M. Beck & Anthony Vale, Drug and Medical Device Product Liability Deskbook, § 8.09 (2015).
[135] *Heidi Nielson, Manufacturing Consumer Protection for 3-D Printed Products*, 57 Ariz. L. Rev. 609, 618 (2015); *see also* Drug and Device Law, Feb. 5, 2015, http://druganddevicelaw.blogspot.com/2015/02/some-ideas-about-3d-printing.html (last visited May 8, 2015).
[136] Preemption by reason of FDA premarket approval of Class III medical devices is beyond the scope of this article.
[137] *See, e.g.*, *Talley v. Danek Medical, Inc.*, 179 F.3d 154, 162 (4th Cir. 1999).
[138] Carnegie Mellon University, 3D Printer Safety Fact Sheet, http://www.cmu.edu/ehs/fact-sheets/3D-Printing-Safety.pdf (last visited July 23, 2015).
[139] 3ders.org, *3D Printers Emit Potentially Hazardous Ultrafine Particles*, July 21, 2013, http://www.3ders.org/articles/20130721-3d-printers-emit-potentially-hazardous-ultrafine-particles.html (last visited on May 8, 2015).
[140] Dexter Johnson, July 29, 2013, *Nanoparticles Emitted from 3D Printers Could Pose a Risk*, http://spectrum.ieee.org/nanoclast/semiconductors/nanotechnology/nanoparticles-emitted-from-3d-printers-could-pose-a-risk (last visited June 12, 2015).
[141] Sam Shead, July 26, 2013, *Scientists Warn of 3D Printing Health Effects as Tech Hits High Street*, http://www.techworld.com/news/personal-tech/scientists-warn-of-3d-printing-health-effects-as-tech-hits-high-street-3460992/ (last visited July 26, 2013).
[142] Brent Stephens, et al., *Ultrafine Particle Emissions From Desktop 3D Printers*, in Atmospheric Environment (Elsevier 2013).
[143] *See* 29 CFR 1910.94.
[144] OSHA, *Compatible Dust: An Explosion Hazard*, https://www.osha.gov/dsg/combustibledust/guidance.html \ (last visited July 23, 2015).
[145] *Id.*
[146] OSHA, May 20, 2014, *After Explosion, US Department Of Labor's OSHA Cites 3-D Printing Firm For Exposing Workers To Combustible Metal Powder, Electrical Hazards*, https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEWS_RELEASES&p_id=26019 (last visited July 23, 2015).
[147] *Id.*
[148] *Id.*
[149] *Id.*
[150] *Id.*
[151] *Id.*
[152] OSHA, November 12, 2014, C*ombustible Dust in Industry: Preventing and Mitigating the Effects of Fire and Explosions*, https://www.osha.gov/dts/shib/shib073105.html (last visited July 23, 2015); *see also* 21 CFR Part 1910 Subpart S (general requirements for electrical installations in hazardous areas).
[153] *Id.*
[154] *Id.*
[155] *See* 29 CFR 1910.22(a)(1).
[156] 29 CFR 1910.1200.
[157] Swiss Re, *3D Printing: Implications For The Re/Insurance Industry*, http://www.swissre.com/reinsurance/insurers/casualty/3D_printing_implications_for_the_reinsurance_industry.html (last visited May 8, 2015).
[158] Julie Sammarco, August 24, 2014, 3-*D Printing: Who is Responsible?* http://www.zurichna.com/zna/knowledgecenter/rr_3dprintingresponsible.htm (last visited June 12, 2015).
[159] http://www.sculpteo.com/en/.
[160] Charlie Kingdollar, March 11, 2013, *3D Printers – A New Exposure for Personal Lines Carriers*, http://www.genre.com/knowledge/blog/3D-Printers---A-New-Exposure-for-Personal-Lines-Carriers.html (last visited June 12, 2015).
[161] Julie Sammarco, August 24, 2014, *3-D Printing: Who is Responsible?* http://www.zurichna.com/zna/knowledgecenter/rr_3dprintingresponsible.htm (last visited June 12, 2015).
[162] *See* Phys.Org, 3D printers shown to emit potentially harmful nano-sized particles, July 24, 2013, http://phys.org/news/2013-07-3d-printers-shown-emit-potentially.html (last visited May 8, 2015).
[163] William F. Knowles and Kathleen M. Grohman, May 22, 2014, *Thorns of 3D Printing*, http://claims-management.theclm.org/home/article/Thorns-of-3D-Printing (last visited June 12, 2015).



[164] *Id.*

[165] *Firemen's Ins. Co. of Washington, D.C. v. Kline & Son Cement Repair, Inc.*, 474 F. Supp. 2d 779, 792-94 (E.D. Va. 2007).

[166] Karishma Paroha, June 2, 2014, 3-*D Printed Products, Product Liability And Insurance Implications*, http://www.kennedyslaw.com/article/3dprintedproducts/.

[167] Stuart Collins, Allianz, The universe in 3D, http://www.agcs.allianz.com/insights/expert-risk-articles/the-universe-in-3d/

[168] Reimbursement refers to coding, coverage, and payment – all three components are needed for reimbursement.

[169] Michael Sanchez, M.A., Medical Device Reimbursement presented at St. Thomas University, Design and Manufacturing in the Medical Device Industry Course, December 3, 2012.

[170] CMS, private insurers, analysts, and venture capitalists should also be part of these early discussions, so that all parties are on the same page for this new and increasingly growing technology.

[171] Gail L. Daubert, et al., Food and Drug Law and Regulation 944 (David Adams, et al., eds. 3d ed.)

[172] *Id*. Payors will ask, for example, is the 3D printed device better than a traditionally manufactured device and will the 3D printed device have the same longevity as its traditionally manufactured counterpart? If the answer is no to either of these questions, then the payor will not understand the benefit derived from the 3D printed device, as opposed to a traditionally manufactured device, which likely has a long-standing clinical history.

[173] *See* section 510(k) of the Food, Drug and Cosmetic Act (21 U.S. Code § 360)

[174] Tiffini Diage, MPH, Planning for Successful Medical Device Reimbursement: So Your Device is Cleared, Now What? NAMSA

[175] *See* Aetna Stereolithography Policy Decision No. 0613, located at: http://www.aetna.com/cpb/medical/data/600_699/0613.html

[176] Tiffini Diage, MPH, Planning for Successful Medical Device Reimbursement: So Your Device is Cleared, Now What? NAMSA

[177] *See id*.

[178] Gail L. Daubert, et al., Food and Drug Law and Regulation 944 (David Adams, et al., eds. 3d ed.)

[179] *See* Prospective Payment Systems ("PPS"), located at cms.gov/Medicare/Medicare-fee-for-service-Payment ("Medicare payment to facilities is based on prospective payment systems in which payment is made based on a predetermined, fixed amount."). Payment for a particular service is then derived based on the code reported on the claim form and the classification system of that service (for example, diagnosis-related groups for inpatient services; ambulatory payment classification for hospital outpatient services). Thus, if a new service is billed with an existing code and the new service and technology (e.g., 3D printed implant) is more expensive, the payment to the hospital will not reflect added costs. On the other hand, if the 3D printed implant is less expensive than the current implant, and surgery and other care is similar and an existing code is reported, the hospital may be satisfied with the PPS payment.

[180] Medicare payment to physicians is based on a fee schedule that looks at the (1) physician work, (2) practice expense and (3) professional liability insurance costs associated with furnishing a service. Each of these three components is assigned relative value units ("RVUs") and then adjusted for geographical cost differences and site of service. The total adjusted RVUs are multiplied by the annual conversion factor, which is a dollar amount to determine the Medicare-allowed payment to a particular physician for a specific service. Gail L. Daubert, et al., Food and Drug Law and Regulation 960-61 (David Adams, et al., eds. 3d ed.)

[181] Although there are several major coding systems, CPT codes are the system most likely to play a role with 3D printed medical devices.

[182] There are three categories of CPT codes:

- Category I: procedures that are consistent with contemporary medical practice and are widely performed
- Category II: supplementary tracking codes that can be used for performance measures
- Category III: temporary codes for emerging technology, services and procedures

See http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/applying-cpt-codes.page

[183] If existing CPT codes are used, payors may still not approve 3D printed devices if they are more costly, over traditional manufactured devices, without any proven benefit.

[184] Gail L. Daubert, et al., Food and Drug Law and Regulation 955-56 (David Adams, et al., eds. 3d ed.)

[185] Gail L. Daubert, et al., Food and Drug Law and Regulation 960-61 (David Adams, et al., eds. 3d ed.). *See generally* Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014, 78 Fed. Reg. 74,229 (Dec. 10, 2013) (final update to the 2014 Medicare physician fee schedule).

[186] *See* Tiffini Diage, MPH, Planning for Successful Medical Device Reimbursement: So Your Device is Cleared, Now What? NAMSA