How Will 3D Printing Alter the Products-Liability Landscape?

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Bold statements have been made that 3D printing (also known as additive manufacturing) will change virtually every aspect of our lives in the next three to five years. News articles suggest that everything from children's toys to replacement auto parts to prescription medicines[1] will be 3D printed in the near future. Some have argued that 3D printing will impact manufacturing on the same scale that the personal computer affected the office environment. One open question, however, that companies must begin to evaluate is how corporate exposure and liability issues will evolve as products-liability lawsuits begin to surface involving 3D-printed products. This manuscript will explore the underpinnings of traditional products-liability law, describe what additive manufacturing is and how it disrupts the traditional paradigm, and then examine how the new technology could impact products-liability litigation.

Traditional Manufacturing and the Applicable Legal Paradigm

Products-liability law developed to address individuals who were injured by defects in (tangible)[2] products that were manufactured by a commercial[3] seller. The legal framework evolved at a time when product manufacturers tended to be large commercial enterprises, which were primarily responsible for the design and development of their products as well as their sale and distribution. This centralization of this activity supported an underlying premise of products-liability law: that a "manufacturer" is most knowledgeable about the products that it sells and is in the best position

[1] The FDA has now approved a 3D printed prescription medicine, Spritam®, which is manufactured by Aprecia Pharmaceuticals and indicated to treat epilepsy. The manufacturer touts its use of a proprietary "ZipDose" 3D printing technology, which "prints" the medicine layer-by-layer and results in a pill that is more porous than traditional pills, allowing it to disintegrate more quickly in a patient's mouth.

[2] *See* Restatement (Third) of Torts: Prod. Liab. §19(a).

[3] *See* Restatement (Third) of Torts: Prod. Liab. §1 (indicating that to be subject to a products liability theory of recovery that a person or entity must be "engaged in the business of selling or otherwise distributing products." *But see id.*, at cmt. c. (providing that the liability does not apply to "noncommercial seller[s] or distributor[s]" nor to an "occasional or causal" sale).

to ensure that safe products reach the marketplace. Under such a paradigm, the imposition of strict liability theories on such manufacturers was deemed appropriate.

Mass production is the second characteristic of traditional manufacturing upon which products-liability law is based. Historically, products were uniform, mass-produced, and based upon a single (or small set of) design(s) as captured in the manufacturing specifications. Liability theories evolved out of this paradigm. For example, the Restatement (Third) of Torts describes theories of recovery based upon whether a product deviates from a manufacturing specification (manufacturing defect), whether the risks associated with the product's design specifications exceed the benefits (design defect), and whether the product (as designed) requires a specific warning to be used in a safe manner (inadequate warning).

Additive manufacturing, however, has the potential to unmoor both of these underlying principles. The proliferation of 3D printing technology is likely to dispense with the historic, *de facto* requirement that a "manufacturer" be a large commercial entity that is also responsible for design and distribution activities. Likewise, the "mass production" paradigm will, in time, likely be replaced with the "mass customization" of products, given the lower costs and manufacturing flexibility that 3D-printing technology provides over traditional manufacturing. Inevitably, these fundamental changes will exert pressure on existing products-liability theories, but to better understand how the legal framework may change, it is first important to explore the new technology at issue.

What is Additive Manufacturing?

Additive Manufacturing (AM), also known as 3D printing or rapid prototyping, is defined by ASTM International (formerly known as the American Society for Testing and Materials) as the "process of joining materials to make parts from 3D model data, usually layer upon layer, as opposed to traditional subtractive manufacturing and formative manufacturing methodologies."[4] The technology dates back to 1984, when Charles Hull, who later founded 3D Systems, Inc., patented a process described as "stereolithography" (solid imaging) using fluids and digital blueprints.

Additive manufacturing differs from the traditional manufacturing methods of subtractive manufacturing (e.g. milling, drilling or turning) and formative manufacturing (e.g. pressing, forging or stamping) as the part is "printed" in a machine from a digital model of the part layer by layer. The material that the part is manufactured from is built up, layer by layer, from the raw

[4]ASTM International / The International Organization for Standardization, *52900:2015(E) Standard Terminology for Additive Manufacturing – General Principles – Terminology*, available at https://www.iso.org/obp/ui/#iso:std:iso-astm:52900:ed-1:v1:en.

material by the printer, rather than starting the production process with a solid block of material which is cut and shaped to produce the final part.

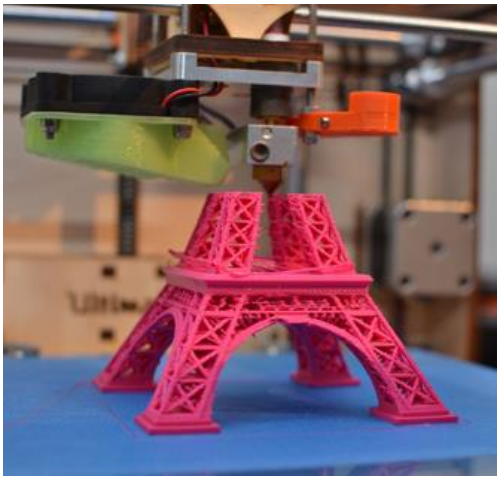

Figure 1 – Half-complete 3D printout of Eiffel Tower model

The technology offers everybody the chance to become a "manufacturer," using either their own home 3D printer or one of many commercial entities offering 3D-printing services, such as UPS.[5] Parts can be printed from digital models created by the individual or from models downloaded from the internet. Some futurists predict that every house will soon have a 3D printer, displacing traditional factories and mass production entirely. Others have described the huge potential offered by this technology as "the next industrial revolution."

What Are the Benefits and Limitations?

There are many potential advantages to additive manufacturing. For example, it allows designers to produce easily customizable parts, or parts that cannot be manufactured by other production methods. Additionally, additive manufacturing has the potential to produce finished products, with multiple materials and moving pieces, and it allows production with no upfront cost due to manufacturing tooling. It also offers cost and time savings for prototype parts or smaller production runs. In terms of the potential, imagination is the limit!

Additive manufacturing does, however, have some disadvantages compared to traditional manufacturing methods. Currently, additive manufacturing processes may have slower build rates and are more expensive for mass production parts. Parts produced by additive manufacturing may have inferior or variable mechanical properties and are limited by the size of the available printer. Parts may require post-processing (cleaning, for example), further procedures to improve material

[5] *See* The UPS Store, *3d Printing: Custom solutions to meet your unique business needs, Let your ideas take shape with 3D printing*, available at https://www.theupsstore.com/print/3d-printing.

properties, improvements to surface finish or further machining. Additionally, in some industries, the regulatory approval pathways are currently undefined.

How Does Additive Manufacturing Work?

The world of additive manufacturing is currently bogged down in a lexical quagmire. For legal and marketing reasons, individual manufacturers frequently use different terms for nearly identical processes. The standardization bodies, ASTM International and ISO (the International Organization for Standardization) have classified all additive manufacturing technologies into seven generic categories.[6,7] The basic principles, advantages and disadvantages of these seven categories are summarized in Appendix A.

Some basic, common steps apply to all additive manufacturing technologies. All 3D printers require a digital model (i.e., a digital blueprint) of the part to be produced. And this model can be generated by reverse engineering, a process where an existing part can be 3D scanned to produce a digital model of the physical object.

Figure 2: Demonstrative of Commercially Available 3D Scanner[8]

The digital model created by the 3D scan can then be used to 3D print a duplicate part with the same dimensions as the original part (though not necessarily the same mechanical properties). Alternatively, websites exist with libraries of digital models of 3D parts that are available for free

[6] ASTM International / The International Organization for Standardization, *52900:2015(E) Standard Terminology for Additive Manufacturing – General Principles – Terminology*, available at https://www.iso.org/obp/ui/#iso:std:iso-astm:52900:ed-1:v1:en.
[7] ASTM International / The International Organization for Standardization, *17296-2:2015 Additive manufacturing -- General principles -- Part 2: Overview of process categories and feedstock*
[8] *See* Donald Melanson, *Z Corporation debuts "world's most affordable" portable 3D scanner, still more expensive than your car*, available at http://www.engadget.com/2009/09/17/z-corporation-debuts-worlds-most-affordable-portable-3d-scann/.

or paid download. The source of these models may be unknown individuals designing untried and untested parts, reverse engineered parts, or potentially pirated designs from OEMs (Original Equipment Manufacturer).[9] Digital models also can be generated using the traditional engineering design tools or free software that allows unskilled individuals to design particular custom components or parts, for example children's toys.[10]

The digital model is then uploaded to the 3D printer, which typically builds up the finished part in successive layers until the whole part is completed. Printer feedstocks include powders, filaments, sheets, pastes, liquid photopolymers[11], or other liquids. Feedstock materials include metals, plastics, ceramics or even concrete. Today, it is possible with adequate processing and controls to print metal or plastic parts with comparable mechanical properties to similar parts made via traditional manufacturing processes.[12] It is even possible to print tissue, cells or whole organs in a process known as "bioprinting."

Challenges of Additive Manufacturing

In some applications and industries, additive manufacturing offers significant advantages over traditional manufacturing processes. It is likely that the use of additive manufacturing techniques will only become more widespread in the future. However, additive manufacturing does come with a specific set of challenges and potential problems that do not exist with traditional manufacturing processes.

3D printers have hundreds of variables that may potentially affect the mechanical and geometrical properties of the finished part. While many of these variables are controlled by the printer software and established by the printer manufacturer, there are still many quality-critical factors under the control of the user.

For example, in the case of powder-bed fusion printing (one specific type of additive manufacturing that uses powder as the feed material which is then fused together layer by layer by a high-powered laser beam), powder management is an important factor. Powder that is not consumed during the printing process is typically recycled and used for the next print. However, the powder has been reported to degrade over subsequent uses. More specifically, the morphology of the particles may change or the oxygen content may increase, either of which can alter mechanical properties over subsequent builds.[13] Further, if the 3D printer is used to print different

[9] An OEM (Original Equipment Manufacturer) is a company that makes a part or subsystem that is used in another company's end product.
[10] The design and sale of such digital models raises unique products-liability questions that will be addressed later in this manuscript.
[11] In this context, a photopolymer is a liquid that changes to a solid when exposed to light.
[12] However, in many instances, the mechanical properties remain inferior.
[13] LPW Technology, Case Study 05: Powder Degradation, available at http://www.lpwtechnology.com/cms/lpw-content/uploads/2016/02/LPW-Case-Study-05-E.pdf.

materials, then care must be taken to prevent cross contamination of the powders. If all traces of the previous powder are not cleaned out of the printer, even a small amount of contamination can cause structural defects in the subsequent parts.[14] Likewise, the mechanical properties of parts produced by powder bed fusion printing can vary depending on the precise location of the part in the 3D printer, the orientation of the part in the 3D printer, and even within the same part at different locations. This variation must be understood by the printer user, and allowed for in the design, specification and build plan of the parts. These material factors are far more important in additive manufacturing (where the bulk material is laid down layer by layer in the printer) than in traditional manufacturing processes (where certified material can be bought in bulk form from an external supplier).

Standardization

The development of consensus standards to support the additive manufacturing industry has been spearheaded by ASTM International and ISO. ASTM International committee F42, formed in 2009, aims to address the requirements and issues across a wide range of additive manufacturing processes and applications by establishing a top level set of fundamental standards. To date, the committee has prepared more than 11 standards, with an additional 20 standards currently under development. In the future, the committee plans to disseminate specialized standards that will address a specific additive manufacturing process or technology. A list of the relevant ASTM standards can be found at the ASTM website[15]. Currently, ASTM standards cover areas such as the specifications for powder-bed fusion additive manufacturing with a range of materials and test methods for evaluating material properties of metal parts made via additive manufacturing.

Since 2011, ASTM has cooperated with ISO in the development of additive manufacturing standards to eliminate the duplication of efforts between the two organizations. Several joint standards have been developed, including "ISO/ASTM 52900, Standard Terminology for Additive Manufacturing Technologies." ISO technical committee ISO/TC 261 Additive Manufacturing has published 6 standards to date and has several more in development. ISO standards cover areas such as an overview of additive manufacturing process categories as well as main characteristics and testing requirements. ISO is currently developing standards including requirements for purchased additive manufacturing parts and a guide for design for additive manufacturing. A list of the standards developed by ISO/TC261 can be found on the ISO website.[16]

[14] LPW Technology, Case Study 01: Root Cause Analysis, available at http://www.lpwtechnology.com/cms/lpw-content/uploads/2016/02/LPW-Case-Study-01-E.pdf

[15] *See* ASTM International, *Additive Manufacturing Technology Standards*, available at http://www.astm.org/Standards/additive-manufacturing-technology-standards.html.

[16] *See* ISO, *Standards Catalogue: ISO/TC 261 – Additive Manufacturing*, available at www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_tc_browse.htm?commid=629086.

Other organizations are working to develop industry specific standards outside the medical product industry. For example SAE International (formerly known as the Society of Automotive Engineers) is working to develop and maintain Aerospace Material Specifications (AMS) and Aerospace Standards (AS) relating to areas such as materials, processes, post processing, inspection, testing and quality assurance.[17]

Standards organizations focused on medical products also are examining the issue of additive manufacturing. For instance, the ASTM Committee on Medical and Surgical Materials and Devices (F04) held a work shop in May 2016 on Additive Manufacturing for Medical Applications.[18] The objective of the workshop was to discuss the applications of additive manufacturing in the medical device arena and to consider if medical-device-specific standards are needed. Presentations during the workshop included topics such as cleaning and sterilization of additive manufactured parts for use in medical devices, powder management in 3D printers, and examples of additive manufacture uses in medical devices.[19] Members of the FDA gave presentations on variability in custom cutting guides for total knee arthroplasty and the effects of build orientation on the fatigue life of laser sintered Ti-6Al-4V. The philosophy of the standardization strategy of the ASTM Committee F42 on Additive Manufacturing Technologies was presented, and the integration of future standards into the existing framework of standards was discussed. In the group discussion, the requirements for specific standards related to additive manufacturing and medical devices were addressed. It seems probable that the committee may draft medical-device-specific standards in the future, which should be monitored by in-house counsel and outside counsel representing manufacturers that have implemented the technology into their products.

Additive Manufacturing and the FDA

The FDA has formed an Additive Manufacturing Working Group in response to the increase in utilization of additive manufacturing and uncertainties relating to how additive manufacturing can affect the safety and effectiveness of the products.[20] In October 2014, the Working Group organized a workshop, Additive Manufacturing of Medical Devices: An Interactive Discussion on

[17] SAE AMS-AM Additive Manufacturing Standards Committee, available at: www.sae.org/works/upcomingmeetingResources.do?eventGenNum=30001
[18] ASTM International, *F04 Medical and Surgical Materials and Devices*, available at: www.astm.org/SYMPOSIA/filtrexx40.cgi?+-P+MAINCOMM+F04+-P+EVENT_ID+3044+P+MEETING_ID+107020+sympotherinfo.frm
[19] ASTM International, *Workshop on Additive Manufacturing for Medical Applications*, available at: https://www.astm.org/MEETINGS/SYMPOSIAPROGRAMS/F04ID3044.pdf
[20] Di Prima, Coburn, Hwang, Kelly, Khairuzzaman, & Ricles, *Additively manufactured medical products–the FDA perspective."* 3D PRINTING IN MEDICINE 2, no. 1 (2015): 1-6.

the Technical Considerations of 3D Printing, to obtain input from additive manufacturing stakeholders, including device manufacturers, medical device companies and academia.[21]

The FDA is also actively investigating how additive manufacturing may affect the manufacturing of medical devices in the future in two laboratories of the Office of Science and Engineering Laboratories (OSEL).[22] This work to aid the FDA in the review of future submissions and will help the FDA to "develop standards and set parameters for scale, materials, and other critical aspects that contribute to product safety and innovation." The Laboratory for Solid Mechanics is investigating how different printing processes and techniques affect the strength and durability of materials used in medical devices, and the Functional Performance and Device Use Laboratory is investigating the effect of design changes on the performance of medical devices when used in different populations. The FDA will use this research to further refine their evaluation of patient fitted products.

FDA Guidance Document: "Technical Considerations for Additive Manufactured Devices"

In May 2016, the FDA issued a draft guidance document entitled "Technical Considerations for Additive Manufactured Devices."[23] The draft FDA guidance is considered a "leap frog" guidance regarding an emerging technology that is likely to be of public health importance during the early stages in product development. The purpose of the guidance is not to set forth specific requirements, but to describe the issues to be considered and addressed during product development and premarket submission. The deadline for comments on this document closed in August 2016.

This guidance focuses on two primary topics surrounding additive manufacturing: 1) Device and Manufacturing Considerations, and 2) Device Testing Considerations. Overall, these two topics cover aspects involving the various stages during the additive manufacturing process (i.e. design, software workflow, material control, build, post-processing, and testing), as well as process validation and acceptance activities and considerations for testing that would impact the information to be included in a regulatory submission. The draft guidance does not cover point-of-care applications or use of additive manufacturing for biologic, cellular, or tissue based products. The FDA's recommendations may change as information becomes available.

[21] US Food & Drug Administration, *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.
[22] US Food & Drug Administration, *FDA Goes 3D*, available at: http://blogs.fda.gov/fdavoice/index.php/2013/08/fda-goes-3-d/.
[23] *See* US Food & Drug Administration, *Technical Considerations for Additive Manufactured Devices: Draft Guidance for Industry and Food and Drug Administration Staff*, available at: http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm499809.pdf.

FDA Regulatory Considerations

As of December 2015, more than 85 medical devices manufactured using additive manufacturing technology had been cleared for sale by the FDA.[24] Examples of cleared devices include surgical instruments, dental restorations (e.g. crowns), external prosthetics, spine implants, [25] cranial implants and orthopaedic devices. However, there are specific considerations in this industry related to the regulatory framework which are elaborated upon in Appendix B.

In 2016, the FDA published an editorial which detailed its current perspective on additive manufacturing of medical products.[26] The editorial included the perspectives of Center for Devices and Radiological Health (CDRH), the Center for Drug Evaluation and Research (CDER), and the Center for Biologics Evaluation and Research (CBER) with an overview of additive manufacturing products in their respective areas and the specific concerns about the use of additive manufacturing. In the regulation of medical devices using additive manufacturing technology, the editorial reported that:

> *"The FDA has been able to review and regulate these devices under existing regulations, by proactively identifying similarities with existing technologies and key differences that needed to be evaluated."*

Current Applications of Additive Manufacturing in Pharmaceuticals

In August 2015, the FDA approved the first 3D printed drug – Spritam, a drug used for treating epileptic seizures.[27,28] The use of 3D printing allows the manufacturer to produce a tablet with a highly porous structure that will rapidly dissolve in the mouth with a sip of liquid. The tablet is produced using a binder jet additive manufacturing technique through which a powdered pharmaceutical blend is deposited layer-by-layer and bound with a binder liquid.[29] The porous structure, composed of powder bound with the jetting binder liquid produced by the 3D printing method, allows the tablet to rapidly dissolve in the mouth. This offers the advantages for patients

[24] US Food & Drug Administration, *3D Printing of Medical Devices*, available at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/3DPrintingofMedicalDevices/default.htm
[25] *See* Oxford Performance Materials, Inc., *SpineFab® VBR implant system*, available at http://www.oxfordpm.com/oxford-performance-materials-receives-fda-clearance-spinefab-vbr-implant-system.
[26] Di Prima, Coburn, Hwang, Kelly, Khairuzzaman, & Ricles. "Additively manufactured medical products–the FDA perspective." 3D PRINTING IN MEDICINE 2, no. 1 (2015): 1-6.
[27] The American Society of Mechanical Engineers, *3D-Printed Drugs: What Does the Future Hold?*, available at https://www.asme.org/engineering-topics/articles/manufacturing-design/3dprinted-drugs-does-future-hold.
[28] Aprecia Pharmaceuticals, *First FDA-Approved Medicine Manufactured Using 3D Printing Technology Now Available*, available at https://www.aprecia.com/pdf/ApreciaSPRITAMLaunchPressRelease__FINAL.PDF.
[29] Aprecia Pharmaceuticals, *Harnessing the power of 3DP to develop innovative medicines*, available at https://www.aprecia.com/zipdose-platform/3d-printing.php.

who have difficulty swallowing tablets and allows a much larger dose of medication to be delivered in a form that will rapidly dissolve in the mouth compared to existing "fast melt" tablets.[30]

In the future, researchers have speculated that it may be possible to "print your own medicine" on a home 3D printer.[31] Using a printer loaded with a universal set of chemical inks, it may become possible to download a "chemical blue print" and carry out "on the fly molecular assembly." The proposed advantages include the ability to print drugs at the point of need or rapidly distribute a particular drug.

However, this also represents a significant departure from the traditional supply chain for pharmaceutical products. It also raises questions about whether the sale or license of an ***intangible,*** digital blueprint for a medicine would expose the designer or distributor of that blueprint to strict products liability.[32] While not in the context of 3D-printed products, existing jurisprudence reflects a hesitancy of courts to label digital files, software, and/or intangible thoughts and ideas as "products" for purposes of products liability law.[33] However, even the Restatement itself recognizes that there may be exceptions to the traditional requirement that "products" be tangible items. *See* Restatement (Third) of Torts: Prod. Liab. § 19(a) ("[o]ther items . . . are products when the context of their distribution and use is sufficiently analogous to the distribution and use of tangible personal property . . . ."). And this exception may ultimately swallow the rule if additive manufacturing results in this sort of supply-chain reconfiguration.

Current Applications of Additive Manufacturing in Medical Devices

The medical industry is also exploring the use of additive manufacturing technologies. While medical devices that have received regulatory clearance to date have been made using a variety of additive technologies covering a number of device types, they can generally be separated into implantable and non-implantable devices and devices that are patient-matched or non-patient-matched.[34]

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[30] The American Society of Mechanical Engineers, *3D-Printed Drugs: What Does the Future Hold?*, available at https://www.asme.org/engineering-topics/articles/manufacturing-design/3dprinted-drugs-does-future-hold.

[31] Ted Global, *Lee Cronin: Print Your Own Medicine*, available at: http://www.ted.com/talks/lee_cronin_print_your_own_medicine.

[32] *See* Restatement (Third) of Torts: Prod. Liab. §19(a) (defining a "product" as "tangible personal property distributed commercially for use of consumption.")

[33] *See, e.g., U.S. v. Aleynikov*, 767 F.3d 71, 76-79 (2d. Cir. 2012) (concluding that computer source code was not a "product" within the meaning of the Economic Espionage Act but rather "purely intangible property embodied in a purely intangible format."); *Sanders v. Acclaim Entertainment, Inc.*, 188 F. Supp. 2d 1264, 1279 (D. Colo. 2002) (finding intangible content contained in video games are not "products" for purposes of strict products liability); *Gorran v. Atkins Nutritionals, Inc.*, 464 F. Supp. 2d 315, 324, aff'd 279 Fed. Appx. 40 (2d Cir. 2008) (same with respect to intangible ideas in books).

[34] Di Prima, Coburn, Hwang, Kelly, Khairuzzaman, &Ricles, *Additively manufactured medical products – the FDA perspective*, 3D PRINTING IN MEDICINE, 2 (2016) 1-6.

Non-Implantable Products

Patient-matched devices are usually customized using either medical imaging data or laser scans of an individual patient's anatomy to modify the geometry of the resulting device. Patient-matched custom cutting guides and drill templates are non-implantable products that are widely used in the orthopaedic industry. These are disposable products, which are used by surgeons during arthroplasty procedures to aid the surgeon in positioning bone cuts and are derived by the manufacturer from computed tomography or magnetic resonance imaging scans of the patient. Their use can decrease surgical time, replace trays of reusable instruments, and are thought to reduce surgical errors during arthroplasty. However, opportunity for more widespread use of such customized surgical aids (particularly when provided by a medical device manufacturer), also will increase the opportunities for plaintiffs' attorneys to argue that the manufacturer is now an active participant in the surgical procedure, a role traditionally limited to the surgeon and his or her surgical team. This is another example of how the adoption of additive manufacturing technologies could conceivably impact the scope of legal exposure for product manufacturers.

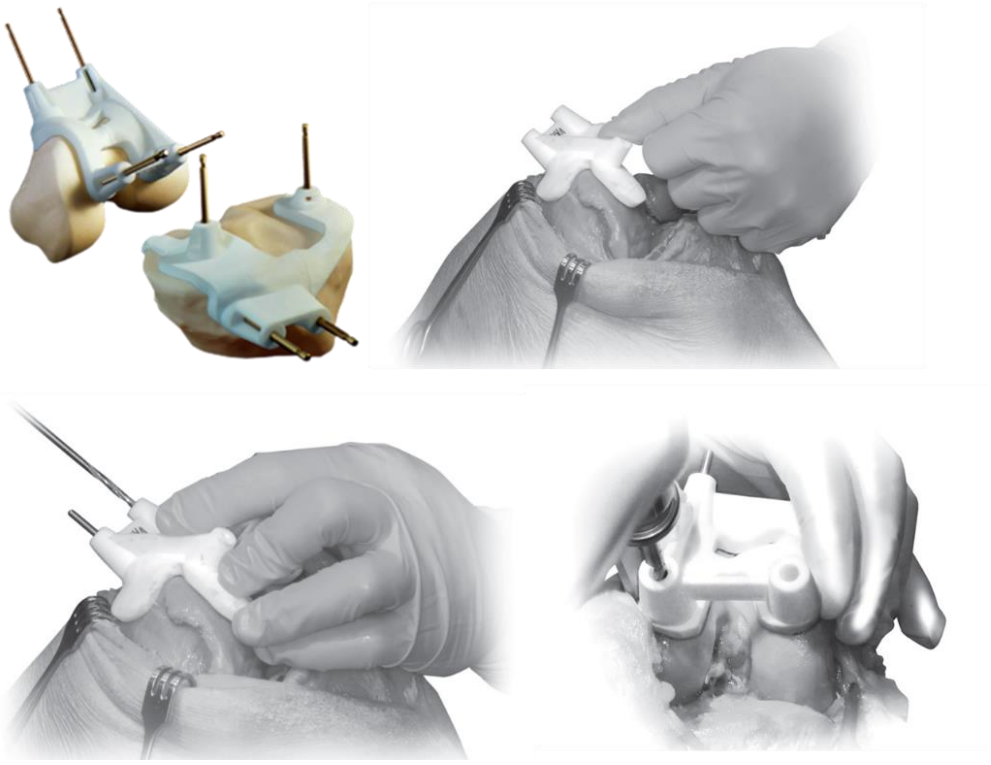

Figure 3 – Zimmer patient specific instrumentation[35]

[35] *See* Zimmer, *Zimmer® PSI Knee Surgical Technique*, available at: http://www.zimmer.com/content/dam/zimmer-web/documents/en-US/pdf/surgical-techniques/knee/zimmer-psi-surgical-technique.pdf.

Implantable Products

Standard-Sized Device Designs

Additive manufacturing is being used by device manufacturers to make standard-sized, or a range of discrete-sized, medical devices. The use of additive manufacturing allows manufacturers to make devices with features that would be either expensive or complex to manufacture using other methods.

An example of the use of additive manufacturing to manufacture standard-sized devices is the Zimmer Biomet Unite3D Bridge Fixation System, which is used in joint and ankle joint fusion surgery.[36] It is reported that the porous structure, "directly mimics the architecture of human cancellous bone."[37] Additive manufacture allows the solid and porous regions of the implant to be printed simultaneously.[38]

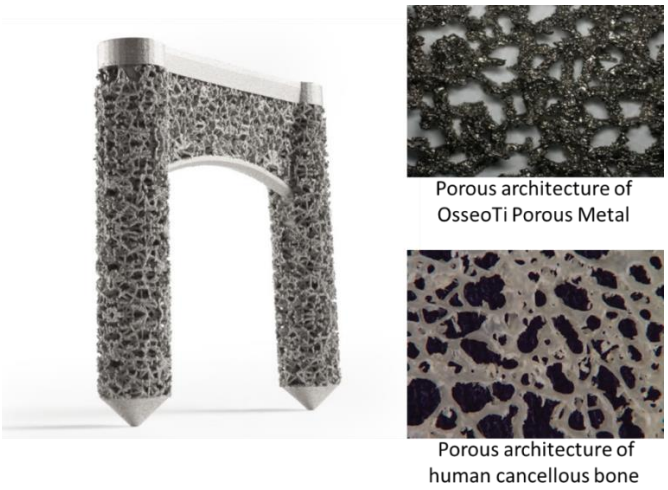

Figure 4 – Picture of Zimmer Biomet Unite3D™ Bridge Fixation System[39] and the structure of the porous structure of OsseoTi Porous Metal and human cancellous bone.[40]

[36] Additive Manufacturing Today, *Zimmer Biomet Announces FDA Clearance for Metal 3D Printed Bridge Fixation System*, available at https://additivemanufacturingtoday.com/zimmer-biomet-announces-fda-clearance-for-metal-3d-printed-bridge-fixation-system.
[37] Zimmer Biomet, *OsseoTi® Porous Metal Technology*, available at http://www.zimmerbiomet.com/medical-professionals/foot-and-ankle/product/osseoti-porous-metal.html.
[38] 3Printer, *Zimmer Biomet Receives FDA Clearance for 3D Printed Unite3D Ankle Fusion Systems*, available at https://www.3printr.com/zimmer-biomet-receives-fda-clearance-for-3d-printed-unite3d-ankle-fusion-systems-3335468/.
[39] Additive Manufacturing Today, *Zimmer Biomet Announces FDA Clearance for Metal 3D Printed Bridge Fixation System*, available at https://additivemanufacturingtoday.com/zimmer-biomet-announces-fda-clearance-for-metal-3d-printed-bridge-fixation-system.
[40] Gautam Gupta, Ph. D., *OsseoTi Porous Metal for Enhanced Bone Integration* an Animal Study, available at http://www.zimmerbiomet.com/content/dam/zimmer-biomet/medical-professionals/foot-and-ankle/osseoti-porous-metal/osseoti-porous-metal-for-enhanced-bone-integration-an-animal-study.pdf.

The Renovis acetabular cup, with its integral porous coating, is another example of the technology. The porous bone ingrowth surface on the back of the cup is produced using additive manufacturing.[41,42] In a presentation at the FDA Additive Manufacturing Workshop, Renovis showed a process flow comparison between a traditionally manufactured and additive manufactured acetabular cup. Renovis highlighted that it was possible to reduce the number of manufacturing steps by using additive manufacturing to print the porous coating and the cup structure simultaneously.[43]

Patient-Matched Device Designs

Additive manufacturing also is being used in the manufacture of patient-matched devices. Patient-matched devices may be based on a standard template that can be modified to match the patient's anatomy either by scaling the device, matching to specific anatomical landmarks or using a model of the patient-specific anatomy from imaging. The design of a patient-specific device may be carried out either by clinical staff, the device manufacturer or a third party.

An example of the trend to mass customization can be found in total knee replacements. ConforMIS currently offers patient-matched orthopaedic implants based on medical imaging data.[44] In this process, a CT scan of the knee is converted to a 3D model by mapping the articular surface of the joint. Additive manufacturing technology then is used to form an implant from cobalt-chromium alloy based on a patient's own CT scan.[45,46] See Figure 5, below.

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[41] Renovis, *Renovis Surgical Receives FDA Clearance for Tesera Trabecular Technology™ Acetabular Devices*, available at: http://www.renovis-surgical.com/2014/04/renovis-surgical-receives-fda-clearance-for-tesera-trabecular-technology-acetabular-devices/.

[42] Renovis, *Tesera Trabecular Technology™ Acetabular System*, available at: http://www.renovis-surgical.com/2014/10/tesera-trabecular-technology-acetabular-system/

[43] US Food & Drug Administration, *FDA Public Workshop: Additive Manufacturing of Medical Devices*, available at http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM418397.pdf.

[44] *See* ConforMIS, *Total Knee Replacement*, available at http://www.conformis.com.

[45] Although each implant is matched to an individual patient, this device was cleared for use under the 510(k) regulatory pathway. US Food and Drug Administration (FDA) has indicated that patient-matched medical devices are not considered to be "custom" devices as defined by section 520(b)(2)(B) of the FD&C Act and therefore do not qualify for a custom device exemption from premarket notification. *See* M. Di Prima, J. Coburn, D. Hwang, J. Kelly, A. Khairuzzaman, L. Ricles, *Additively manufactured medical products – the FDA perspective*, 3D PRINTING IN MEDICINE, 2 (2016) 1-6.

[46] As stated in the draft FDA guidance *(see Appendix B)*, "Patient-specific 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." *See* M. Di Prima, J. Coburn, D. Hwang, J. Kelly, A. Khairuzzaman, L. Ricles, *Additively manufactured medical products – the FDA perspective*, 3D PRINTING IN MEDICINE, 2 (2016) 1-6.

Figure 5 – iTotal kit of pre-sterilized and disposable custom instruments and ConforMIS knee components[47]

Another example of the use of additive manufacturing in a patient-specific medical device is the bronchial splint.[48,49] Tracheobronchomalacia (TBM) is a pediatric condition where the airways may collapse during respiration. A multidisciplinary team from the University of Michigan developed a tracheobronchial splint (TBS) to treat this condition. A 3D CT scan of the patient's airway is obtained and a 3D model of the airway generated using Mimics software. Measurements are taken from airway model and used as design inputs for the splint design. The splint design is converted into an input file for the printer and the design is verified using finite element analysis and by virtually fitting the splint design onto the CT model. The device is approved using a Humanitarian Use Device Program, intended for devices used to treat life-threatening diseases or conditions that affect less than 4000 patients per year.

[47] *See* Scott J Grunewald, *3D Printed Knee Replacement Manufacturer ConforMIS (CFMS) Raises $135M As The Company Goes Public*, available at https://3dprint.com/78272/conformis-3d-printed-knee/.
[48] R.J. Morrison, K.N. Kashlan, C.L. Flanangan, JK Wright, GE Green, SJ Hollister, KJ Weatherwax, *Regulatory Considerations in the Design and Manufacturing of Implantable 3D-Printed Medical Devices*, CLIN TRANSL SCI., 2015 Oct; 8(5):594-600.
[49] S.J. Hollister, C.L. Flanagan, D.A. Zopf, R.J. Morrison, R.G. Ohye, G.E. Green, *Laser Sintered Resorbable PCL Splints for Treating Tracheobronchalmalacia (TBM)*, available at http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM418398.pdf.

Legal Implications

Mass customization of medical implants raises a host of unanswered legal queries. As mentioned, products-liability law is predicated on a mass-production environment. In that setting, manufacturing specifications typically are uniform, and thus, it is relatively straightforward to evaluate whether a product complies with its manufacturing specifications in the context of a manufacturing-defect claim. Likewise, a risk/benefit analysis of an overarching design (as defined by product specifications) is possible among a broad population of users to determine whether a particular design is "defective." But this sort of legal inquiry is complicated in the context of customized products.

For example, if a person that has received a customized implant ultimately requires a revision procedure, the implant manufacturer could face significant challenges if a design defect claim is asserted. The alternative-design/risk-utility test employed in most jurisdictions becomes weighted in the plaintiff's favor because:

(1) There are an infinite number of alterative designs available to the manufacturer using 3D printing technology;
(2) There is a reduced feasibility hurdle that weighs against the alternative design (because all designs may be possible to print using additive manufacturing);
(3) There is not a broader population of implant recipients available to demonstrate the principle that widespread benefits of the implant outweigh the particular risks that occurred for the plaintiff.

Moreover, Plaintiffs' lawyers will surely argue that the manufacturer failed to appropriately test their customized products. But it is impossible, practically speaking, for a manufacturer to test each of the theoretically unlimited product designs that are now available via additive manufacturing in the same manner in which a single design traditionally would have been tested during research and development.[50]

Conclusions

In theory, 3D printing has the potential to reduce an entire manufacturing facility into a single 3D printer that might range in size from a desk to a desktop. "Manufacturing" then becomes as easy

[50] Similar complications exist when analyzing a "manufacturing defect" claim involving a customized, 3D-printed product. To begin, the manufacturing specifications themselves become murky. Are the "specifications" the digital model generated by the scanning software or perhaps the digital instructions to the 3D printer concerning how to actually print the implant? Likewise, evidentiary and spoliation issues begin to arise regarding whether a customized product manufacturer should have a duty to preserve files and software related to every customized product that it makes so that an injured party can evaluate whether a deviation from a manufacturing specification (whatever that is) actually occurred.

as hitting a button from within computer-aided-design (CAD) software once the product has been digitally designed.

Ultimately, two aspects of additive manufacturing are likely to have the most significant impact on products-liability law: (1) the mass customization of products; and (2) the inevitable dissociation of product design, manufacturing, and sales.

As previously noted, products-liability law was formulated to address injuries to individuals resulting from ***mass-produced*** products. As such, the products-liability law framework that developed does not immediately lend itself to the analysis of injuries from custom-made items. Moreover, the fracture or dissociation of product design, manufacturing, and sales, which is now more likely with the adoption of additive manufacturing, will require a reanalysis of fundamental products-liability questions, such as: what is a product? (e.g., tangible item or digital model) and who is a manufacturer? (e.g., designer of digital model or owner of 3D printer that prints the item).

Unfortunately, the law lags technology, and the preceding issues have yet to be addressed by our courts. Our research reveals only one decision addressing liability for a 3D-printed product, the Invisalign orthodontic system. But the case focused on allegations of misrepresentations regarding the effectiveness of the system, as opposed to more product-oriented allegations of the sort that we have raised here. *See Buckley v. Align Technology, Inc.*, No. 5:13-CV-02812-EJD, 2015 WL 5698751, (N.D. Cal. Sept. 29, 2015).

Thus, while there is dearth of legal authority on the subject, there are nonetheless common-sense steps that corporate manufacturers and their outside legal counsel should keep in mind when venturing into these untested waters:

1. Consider the potential ramifications of new business ventures employing additive manufacturing, and evaluate whether the new venture could subject the company to a new type of exposure, such as strict product liability.

2. Reevaluate hold-harmless and indemnity agreements with vendors and component-part suppliers when additive manufacturing is being used by any entity in the supply chain.

3. Examine all types of corporate insurance to determine whether additive manufacturing is the subject of any exclusions or special treatment.

4. Ensure that company employees and engineers are monitoring regulatory and trade organization activities on the subject – and updating company practices and protocols accordingly.[51]

[51] As discussed, the FDA recently issued a guidance on the use of additive manufacturing with prescription medical devices entitled "Technical Considerations for Additive Manufactured Devices." Likewise, the American Society of

Additive manufacturing technology is exciting and likely to have an impact on industry and the associated legal landscape, but corporate manufacturers should monitor developments closely to ensure that potential legal implications are understood and exposure is minimized.

Testing and Materials (ASTMi) held a symposium on the subject of additive manufacturing in May of 2016. ASTMi is actively exploring how to implement standards in the area, which will undoubtedly appear in litigation once disseminated.

Appendix A – Summary of Additive Manufacturing Processes

AM Process	Description	Advantages	Disadvantages	Typical Feedstock and Materials	Synonyms
Material Extrusion	A filament is melted as it passes through the heated print nozzle and is then deposited layer by layer onto the work piece.	• Filament can be standard engineering plastics. • Printers may be purchases for a few hundred dollars for small business / home use.	• Mechanical properties are anisotropic (i.e. parts are weaker in some directions than others). • Support structures required for some geometries. • Part surface will have a "stepped profile."	Filament or paste • Thermoplastics (e.g. ABS or PLA). • Structural ceramics • Concrete.	FDM – Fused Deposition Modelling PJP – Plastic Jet Printing FFM – Fused Filament Modelling MEM – Melted and Extruded Modelling FFF – Fused Filament Fabrication FDM – Fused Deposition Modelling
Vat Photo-polymerization	Computer controlled laser beam (or light source) selectively cures photopolymer in vat of liquid. The laser traces out each layer, then the build platform lowers and the object is built up layer by layer.	• Parts can be printed with good accuracy and good surface finish • Wide range of build materials are available	• Cost of resins higher than other build materials for other methods. • Feedstock is UV-active photopolymers and not standard materials. • Parts may not be durable over time. • Support structures required for some geometries.	Liquid photopolymer. • Compounds that simulate properties of ABS, PC, or rubber.	SL – Stereolithography SLA – StereoLithographic Apparatus
Material Jetting	Photopolymer is sprayed from print head and set with UV light from print head. Support structures are printed at the same time. The 3D shape is built up from successive layers.	• Good accuracy and surface finish • Multiple materials can be printed at the same time. • Multi-material and multi-colored parts can be printed.	• Feedstock is UV-active photopolymers and not standard materials. • Parts may not be durable over time. • Support structures required for some geometries.	Liquid photopolymer. • Compounds that simulate properties of ABS, PE, PC, or rubber. • Molten wax	MJP – Multijet Printing Polyjet modeling Multijet modeling, polyjetting Multijetting Jetted photopolymer DOD – Drop on demand
Binder Jetting	Thin layer of powder spread onto build platform and then print head selectively sprays liquid binding agent onto thin layer of powder particles. Platform is then lowered and the process repeated.	• Parts can be printed in full color • Technology is relatively fast and cheap • Parts can be post processed to improve mechanical properties • Often used to make casting patterns and molds • No support structures required	• Parts straight from the machine have limited mechanical properties and may be fragile • Excess powder must be removed during post processing for some applications	Powders and liquid adhesive / bonding agent • Ceramics, composites, metals, plastics or sand	

AM Process	Description	Advantages	Disadvantages	Typical Feedstock and Materials	Synonyms
Powder Bed Fusion	A layer thin layer of powder is spread over the build platform and is then melted or fused together by a laser or other high energy source. A new layer of powder is spread across the previous layer using a roller or scraper.	• Metal parts can be manufactured with high density and good mechanical properties • Plastic parts can be manufactured with good mechanical properties, but do not have the same mechanical and surface finish properties as injection molded parts • No support structures required	• Technology is slow and expensive compared to other technologies • Tolerances and surfaces finished are limited • Mechanical properties are not the same as their injection molded counterparts	Power • Thermoplastic polymers, metals, ceramics	LS – Laser Sintering LBM – Laser Beam Melting DLMS – Direct Metal Laser Sintering DMP - Direct Metal Printing SLM – Selective Laser Melting EBM – Electron Beam Melting EBAM - Electron Beam Additive Manufacturing SHS – Selective Heat Sintering SLS – Selective Laser Sintering
Directed Energy Deposition	Metal powder or wire is melted in a high power laser bean and deposited as molten build material. The process does not have to take place on a flat powder bed.	• Metal powder fed into print head can be continuously altered during the build, and can therefore fabricate objects with properties that cannot be obtained using traditional production methods • Parts can be used directly after printing as fully dense metal parts Method can be used to repair old parts as well as fabricating new parts	• Parts may require surface finishing	Wire or powder • Metals	LENS – Laser Engineered Net Printing
Sheet lamination	Object is built up from layers (sheets) of material bonded to the previous layer by adhesive backing or sprayed adhesive. The sheets of material are advanced onto the build platform and outline of layer cut with laser or blade.	• Cheap feedstock	• Large amounts of waste	Sheet Material • Paper, metal foil, polymers or composite sheets	LOM – Laminated Object Manufacturing UAM – Ultrasonic additive manufacturing

Appendix B - Special Considerations for Medical Devices

As a regulated industry, the potential uses of additive manufacturing raise many questions when applied to medical devices. Additive manufacturing has been used historically both as a design tool for rapid prototyping of new designs and to create physical models of unique patient anatomy to aid in surgical planning. With improvements in the ability to print structural materials from both polymeric and metallic materials, additive manufacturing has been rapidly adopted by the medical device industry for use in surgical instruments, surgical guides, dental implants, orthopaedic implants, prosthetics, hearing aids and porous tissue engineering scaffolds. However, as regulatory law lags the development of this technology, there is increasing regulatory uncertainty regarding the traditional role of a medical device manufacturer. This uncertainty may also result in new risks in products-liability litigation as compliance with FDA regulations and conformance with recognized consensus standards are often used to aid in the technical defense of FDA-regulated products.

A medical device is defined under Section 201(h) of the Food, Drug & Cosmetic Act as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

Therefore, the determination of whether a device is FDA regulated is often driven by the intended use via claims in the labelling and promotional materials.

The degree of regulatory scrutiny that a manufacturer or distributor faces by the FDA is determined based on the regulatory classification of the device. Devices are classified as Class I, II or III according to a risk assessment, which is based on the intended use of the device and the indication for use. Class I devices are considered lowest risk while Class III devices are considered greatest risk. And while most Class I and a few Class II devices are exempt from premarket regulatory oversight by FDA, most Class II devices require a review process called Premarket Notification or 510(k) to demonstrate to the FDA that the devices are substantially equivalent to a legally marketed predicate device. Novel or high-risk devices must seek FDA approval through a more burdensome approach known as the Premarket Approval (PMA) process. Other, less common regulatory pathways include:

- *De Novo* for low risk devices for which there is no direct precedent
- *Humanitarian Device Exemption (HDE)* for devices intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect (or are manifested in) fewer than 4000 individuals in the US per year
- *Investigation Device Exemption (IDE)* for devices that are the object of a clinical investigation
- *Product Development Protocol (PDP)* for Class III devices using well established technology
- *Custom Device Exemption (CDE)* for devices created or modified in order to comply with the order of an individual physician or dentist, subject to certain restrictions

Although many Class I and a few Class II devices are exempt from premarket notification [510(k)] requirements, these devices are not exempt from other general controls. With the exception of a few exemptions, all medical devices must be manufactured under a quality assurance program, be suitable for the intended use, be adequately packaged and properly labeled, and have establishment registration and device listing forms on file with the FDA. The Quality System Regulation's current good manufacturing practice requirements are intended to ensure that finished medical devices are safe and effective and compliance with the Food, Drug & Cosmetic Act. Moving manufacturing away from established manufacturing sites and into the clinical setting will require consideration of these regulatory factors in order to maintain compliance with the existing Quality System Regulation.

The use of additive manufacturing for medical devices and the associated uncertainty of how the technology can affect the safety and effectiveness of products led to the creation of the Additive Manufacturing Working Group by FDA.[52] This workgroup held a public workshop in October of 2014 entitled "Additive Manufacturing of Medical Devices: An Interactive Discussion on the Technical Considerations of 3D Printing," to obtain input from stakeholders. Topics discussed included best practices for validation and verification, technical challenges, future use of bioprinting (3D printed tissue engineered biologics), and printing of pharmaceuticals. Details of this meeting, including minutes are available on the FDA website.[53] Following this meeting, an FDA draft guidance document was released entitled "Technical Considerations for Additive Manufactured Devices."[54] This draft guidance document represents the FDA's initial thinking on technical considerations specific to devices using additive manufacturing and broadly covers

[52] M. Di Prima, J. Coburn, D. Hwang, J. Kelly, A. Khairuzzaman, L. Ricles, *Additively manufactured medical products – the FDA perspective*, 3D PRINTING IN MEDICINE, 2 (2016) 1-6.
[53] US Food & Drug Administration, *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.
[54] *See* US Food & Drug Administration, *Technical Considerations for Additive Manufactured Devices: Draft Guidance for Industry and Food and Drug Administration Staff*, available athttp://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm499809.pdf.

design and manufacturing and device testing considerations. This guidance document does not address point-of-care manufacturing or bioprinting. A separate guidance document is expected that will cover the agency's thinking on who the manufacturer is and where manufacture occurs when 3-D printing is used. It is noteworthy that the FDA guidance acknowledges the specific technical challenges associated with additive manufacturing, and considers additive manufacturing as an enabling technology, like CNC (computer numerical control) machining.

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