NOTE

REGULATING THE THREE-DIMENSIONAL FUTURE: HOW THE FDA SHOULD STRUCTURE A REGULATORY MECHANISM FOR ADDITIVE MANUFACTURING (3D PRINTING)

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INTRODUCTION

Additive manufacturing, or 3D printing as it is called colloquially, is by no means a new technology. Most of the foundational 3D printing technology was established in the 1980s.[1] The early technology was large, expensive, and thus often inaccessible for individuals or small businesses. In the last decade, however, many new companies have entered the 3D printing market with smaller, cheaper, higher quality machines. Increased availability has led to extensive use in emerging industries, which has produced a variety of interesting legal implications. Additive manufacturing technology affects all aspects of intellectual property law,[2] muddies the proximity of cause and chain-of-sale of product liability,[3] and disrupts the typical course of FDA regulation,[4] on which this paper focuses.

Despite the suggestive moniker – additive manufacturing – 3D printing has not yet become a standard manufacturing process. However, the technology is seductive and many industries are eager to tap into the vast potential promised by 3D printing.[5] This potential includes greater freedom of design, simple

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[1] U.S. Patent No. 4,575,330 (filed Aug. 8 1984) (patent granted in 1986 covering the first 3D printing technology); *History of 3D Printing: The Free Beginner's Guide,* 3DPRINTINGINDUSTRY, http://3dprintingindustry.com/3d-printing-basics-free-beginners-guide/history/ [https://perma.cc/JTR9-UUQP].

[2] *See* Mark A. Lemley, *IP in a World Without Scarcity*, 90 N.Y.U. L. REV. 460, 482-83, 508 (2015) (stating 3D printers make it simpler to violate patents, trademarks, and copyrights at the consumer level; this makes enforcement difficult and less worthwhile to pursue).

[3] *See* Heidi Nielson, *Manufacturing Consumer Protection for 3-D Printed Products*, 57 ARIZ. L. REV. 609, 614-15, 617-19 (2015) (stating 3D printers can be integrated into the manufacturing chain at many distinct points and through a variety of avenues, including consumer home printing, causing the product liability chain to be difficult to trace).

[4] Q1 Conferences, *3D Printing and Innovative Medical Devices: Clarifying FDA Regulations & Identifying Strategies for Success, Medical Device and Diagnostic IP/Patent Strategy Conference*, http://www.wileyrein.com/newsroom-events-2283.html [https://perma.cc/2CDF-GMN6].

[5] Lee Hibbert, *Adding Beats Subtraction*, PROFESSIONAL ENGINEERING 43, 43 (Aug. 2014). Lockheed Martin and GE, among others, have already invested heavily in 3D printing as a

customization, and novel material properties. Additive manufacturing is uniquely positioned to provide both mass production and customizable, single-run production.[6] Unlike traditional manufacturing processes, with 3D printing, single-run or one-off productions can be made without incurring an increased cost.

As 3D printers become more accessible, they are being integrated into the work-flow of many industries, including the healthcare industry. From doctors creating models for surgical planning, to dentists making fixtures for fitting and direct implantation, to companies offering custom implants, 3D printers are fast becoming key tools in the healthcare industry.[7] Many top 3D printing companies are already pushing the boundaries of targeted marketing that could give rise to regulatory concerns regarding intended use.[8] Further, 3D printers are becoming more and more common among consumers with community websites like Thingiverse and Shapeways hosting individually designed products with medical applications.[9]

The Food and Drug Administration (FDA) is currently working to develop a plan for regulating not only 3D printed devices and drugs, but also how to treat the 3D printers themselves.[10] The FDA has already indicated that it may not consider 3D printing to be akin to traditional manufacturing methods such as molding techniques and CNC milling, which the FDA typically does not regulate.[11] It is possible that the FDA will consider 3D printers to be stand-alone

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full scale manufacturing process. These companies are particularly investing in the 3D printing of metals. As this technology grows, the impact on the medical device industry will grow with it. *Id.*

[6] Q1 Conferences, *supra* note 4.

[7] *See infra* notes 71-77.

[8] *Objet30 OrthoDesk*, STRATASYS, http://www.stratasys.com/industries/dental/objet30-orthodesk [https://perma.cc/7G8A-PXZW] (describing the printer as "The Future of Orthodontics" and "specially designed for small to medium-sized orthodontic labs and clinics.").

[9] *See* Chris Wiltz, *If You Can 3-D Print a Gun, Why Not a Medical Device?,* MDDIONLINE (Apr. 2, 2013), http://www.mddionline.com/blog/devicetalk/if-you-can-3-d-print-gun-why-not-medical-device [https://perma.cc/Z545-LEYE] ("Just a cursory search of ThingiVerse – a Web site for sharing and distributing designs for 3-D printing - uncovers, among various items - a knee and joint protractor, a syringe adaptor head, forceps, a hemostat, and a 'logically working model of a human hip replacement,' all available to download and print using a commercially available 3-D printer."). Shapeways currently hosts a file for a print-your-own Intrauterine Device. Ronen, *Bearina-Open Design IUD (concept)*, SHAPEWAYS, http://shpws.me/CdE7 [https://perma.cc/7N4K-KKMK].

[10] COLLEEN T. DAVIES ET AL., 3D PRINTING OF MEDICAL DEVICES: WHEN A NOVEL TECHNOLOGY MEETS TRADITIONAL LEGAL PRINCIPLES, 10-11 (1st ed. 2015), http://www.reedsmith.com/files/Publication/130448b9-7565-4295-a697-5c5d7c6eb516/Presentation/PublicationAttachment/9ba9b53c-2009-488d-ba91-5cc5a19a38f7/3d-printing-white-paper_79444049.pdf [https://perma.cc/WS2V-K8C5].

[11] 3D printed medical devices may be required to provide further manufacturing information regarding what printing technology and which printer model was used in

medical devices. Otherwise, the FDA could develop a new category of quality regulations for this manufacturing tool. Regardless, the FDA should reevaluate the regulatory structure to better suit modern production.

The field of additive manufacturing is becoming more diverse as smaller players enter the market every year. This is good for innovation as a whole; however, the uncertainty of FDA compliance limits how those companies are able to gain market share in medical industries. As the technology continues to develop and 3D printed products begin to move from inert implantables to functional tissues, the FDA needs to develop a comprehensive plan or guidance for the 3D printing industry to maintain a relevant regulatory structure going forward.

This paper endeavors to understand and explain the intricacies and complications associated with the 3D printing industry as it continues to impact the medical industry. In Part I, the paper will explore the background of the 3D printing industry: how it works; how it is being integrated into medical applications; and what concerns it raises as a manufacturing process. In Part II, the paper will examine the current trends of the FDA with respect to additive manufacturing. Part III will discuss the benefits and detriments of regulating the 3D printing industry and Part IV concludes by proposing a solution going forward.

I. BACKGROUND

Additive manufacturing technologies build an object one layer at a time. This layer-by-layer construction potentially reduces material waste and cuts production costs up to 90%.[12] Because 3D printers add material instead of removing it, they use only the material necessary to produce the part.[13] With expensive medical grade materials, the savings could be immense.

Additive manufacturing grants a greater freedom of design over other manufacturing methods through the ability to create complex internal structures, modulate material properties through design, and quickly create customized pieces.[14] Unlike conventional manufacturing techniques, if you can model a design on a computer, it can almost always be manufactured through 3D printing.[15] Further, because 3D printers are able to create intricate internal

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production when seeking FDA approval. Michael H. Park, Note, *For A New Heart, Just Click Print: The Effect on Medical and Products Liability from 3-D Printed Organs*, 2015 U. ILL. J.L. TECH. & POL'Y 187, 199.

[12] *Additive Manufacturing Summit: Medical, Bioprinting, and Drug Discovery*, IQPC [hereinafter *AM Summit*], http://www.additivemanufacturingmedical.com/ [https://perma.cc/MX7R-DL4H]; Terry Wohlers, *Making Products By Using Additive Manufacturing*, 146 MANUFACTURING ENGINEERING 4 70, 76 (Apr. 2011) (noting a reduction of scrap material up to 95%).

[13] Mathew Varkey & Anthony Atala, *Organ Bioprinting: A Closer Look at Ethics and Policies*, 5 WAKE FOREST J.L. & POL'Y 275, 277 (June 2015).

[14] *See* Hibbert, *supra* note 5, at 45; Lemley, *supra*, note 2, at 471-73.

[15] Wohlers, *supra* note 12, at 72.

structures, they are able to create designs that optimize strength while reducing the overall weight of the device.[16]

As a manufacturing technique, 3D printing combines hardware, software, and material science. Most additive manufacturing materials require a chemical reaction or polymerization to transform the raw materials into a final product.[17] A traditional subtractive manufacturing technique would include hardware, software, and a material; but the material would not undergo a phase change, and the quality of the raw material could easily be inspected.[18] Additionally, the more traditional manufacturing techniques are trusted, despite their well-known limitations. For the purposes of this paper, the term 3D printer will include both the hardware and software components of the product.

A. Overview of 3D Printing

3D printers may one day become common household appliances, with one in nearly every home, similar to dishwashers.[19] While that vision is already technically achievable, 3D printers still have a few barriers to market entry. Most 3D printers are known to be quite finicky, requiring time and care to ensure quality and consistency.[20] This fussy nature exists not just between printer models, but individual printers of the same type as well. This means that users must spend a good deal of time learning quirks and working with their machines to achieve acceptable outcomes.

While 3D printers can be purchased for under a thousand dollars. However, machines capable of producing end-products range in price from a couple thousand dollars to a couple hundred thousand dollars.[21] This range in prices

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[16] Hibbert, *supra* note 5, at 43, 45 (stating GE is using 3D printers to manufacture a fuel nozzle that is up to 25% lighter, with a higher complexity and improved performance than nozzles made with traditional manufacturing methods).

[17] *3D Printing Materials: Choosing the Right Material For Your Application*, STRATASYS 3 (2015), https://www.stratasysdirect.com/content/white_papers/STR_7463_15_SDM_WP_3D_MATERIALS.PDF [https://perma.cc/US8H-XG3H].

[18] *See Additive vs Subtractive Manufacturing: Which is Right for You*, AMERICAN PRECISION PROTOTYPING (June 9, 2014), http://www.approto.com/Media-Center/Additive-vs-Subtractive-Manufacturing—Which-is-Ri.aspx [https://perma.cc/YLX5-X43E] [hereinafter *Additive vs Subtractive*].

[19] Jasper L. Tran, *The Law and 3D Printing*, 31 J. MARSHALL J. INFO. TECH. & PRIVACY L., 505, 508 (2015).

[20] *See* Dave Johnson, *3D printing: Don't believe the hype*, CBS NEWS, MONEYWATCH (June 21, 2013, 3:28 PM), http://www.cbsnews.com/news/3d-printing-dont-believe-the-hype/ [https://perma.cc/66LM-5SHF].

[21] Nick Allen, *Why 3D Printing Is Overhyped (I Should Know, I Do It For a Living)*, GIZMODO (May 17, 2013, 9:11 AM), http://gizmodo.com/why-3d-printing-is-overhyped-i-should-know-i-do-it-fo-508176750 [https://perma.cc/DNH5-JTXE]; Vishesh Thakur, *Everything you need to know about 3D printing*, LINKEDIN (Dec. 28, 2015), https://www.linkedin.com/pulse/everything-you-need-know-3d-printing-vishesh-thakur [https://perma.cc/57UZ-L58G].

indicates a range in quality as well as several other factors that one should consider before purchasing a machine; such as, size, post-processing steps needed, and technology type.[22] Additionally, the materials used both in the printing as well as in the post-processing can be extremely messy, sticky, and sometimes malodorous.[23] All of these factors tend to impede the adoption of 3D printing as a manufacturing tool, especially in smaller offices and labs. However, 3D printing has many positive contributions for manufacturing that justify the above complications.

A 3D printer operates in a similar manner to a conventional printer with one key difference. Conventional printers only make one layer of an overall design, while 3D printers stack layer-by-layer.[24] Both printers translate information from a digital source into a tangible product.[25] Printers know where and how to dispense material because of a computer "blueprint."[26] This blueprint can be a digital file[27] or a 3D scan of a physical object.[28]

The capabilities and overall quality of 3D printers vary greatly between different printing technologies and within the same printing technology. Some technologies require extensive post-processing to clear excess material or fully solidify the object.[29] Many require support structures for printing that must later be removed, often manually.[30] Every post-processing step could have an effect on the final product, such as: altering material properties, changing shape by shrinking or warping, or introducing defects. Especially with smaller or cheaper printers, the post-processing steps are manual rather than automated, which creates a further risk of inconsistency and error.

With traditional manufacturing techniques, the more of a single object you need to make, the lower the per-object cost.[31] This is because many traditional manufacturing techniques require a hefty front-end investment to create special tools or molds that can be used repeatedly to make the same structure.[32]

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[22] Thakur, *supra* note 21.

[23] *See* Allen, *supra* note 21.

[24] *Id.*

[25] Lemley, *supra* note 2, at 471.

[26] Park, *supra* note 11, at 190.

[27] *See id.* The digital file can be created in a variety of ways. Users can design a file on one of a variety of computer programs for three-dimensional modeling, such as AutoCAD or SolidWorks. Other users may download open source design files. *Id.*

[28] *See* Varkey, *supra* note 13, at 278; 3D Printing Ninja, *3D Printing from MRI data in 5 steps*, INSTRUCTABLES, http://www.instructables.com/id/3D-Printing-from-MRI-data-in-5-steps/?ALLSTEPS [https://perma.cc/7SCS-PM4B] (with the right software, it only takes five steps to turn an MRI scan into a tangible, 3D printed model).

[29] *See* Park, *supra* note 11, at 190 (quoting Elizabeth Palermo, *What is Stereolithography?,* LIVESCIENCE (July 16, 2013, 2:39 AM), http://www.livescience.com/38190-stereolithography.html [https://perma.cc/LYA7-SJYH].

[30] Thakur, *supra* note 21.

[31] *Additive vs Subtractive, supra* note 18; *see also* Hibbert, *supra* note 5, at 43-45.

[32] *Additive vs Subtractive*, *supra* note 18.

However, additive manufacturing does not require such tooling. The creation of each part requires exactly the same resources and has the same risks of failure or error. While 3D printing could be integrated into mass production manufacturing, its real value lies in creating "low-volume, high-value, and highly complex" devices.[33] Without 3D printing, these customized or small-run devices would be prohibitively expensive.[34]

As mentioned above, different additive technology types use different materials and have different overall properties, but, for the purposes of this paper, those differences are mostly unimportant with one exception─printers using living tissue or cells. Devices that work with tissue or cells are more commonly referred to as bioprinters.[35] Bioprinters are likely at least a decade away from being commercially useful for printing complex tissues ready for implantation.[36] Biotechnology creates a strong impetus for FDA regulation because it utilizes living cells to create implantable tissues, bringing the technology squarely within the agency's regulatory jurisdiction over human tissues.[37] Because FDA regulation is more certain, bioprinting will not be addressed in depth in the present paper. However, this looming technological capability is relevant because it poses a risk of becoming available before the FDA has established an appropriate regulatory structure.[38] Putting time and resources towards better understanding 3D printing as a whole, and its potential impact on the medical market, could help prepare the FDA as bioprinters enter the market or as novel applications are developed.[39]

B. Quality Control

One aspect that complicates the consideration of 3D printing as a manufacturing tool is the sheer number of variables that must be considered.[40]

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[33] Wohlers, *supra* note 12, at 70.

[34] *Id.* at 72.

[35] *See* Jasper L. Tran, *To Bioprint or Not to Bioprint*, 17 N.C. J.L. & TECH. 123, 128 (2015).

[36] Varkey & Atala, *supra* note 13, at 284.

[37] *Tissue & Tissue Products*, FDA, http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/ [https://perma.cc/LB6F-PEYE].

[38] Varkey & Atala, *supra* note 13, at 28.

[39] DAVIES, *supra* note 10, at 7. *See* Bonnie Scott, *3-D Printing Guidance Only a B-List Priority for FDA*, PHARMA MEDTECH INSIGHTS (Mar. 10, 2015), http://pharmamedtechinsights.com/2015/03/3-d-printing-guidance-only-a-b-list-priority-for-fda/ [https://perma.cc/R25X-G568] ("it seems like there are still regulatory challenges and uncertainties to address, which will likely only multiply as 3-D printed devices are developed for a greater variety of (and more complicated) uses," for now, the FDA is not rushing to provide regulatory guidance specific to 3D printing).

[40] Hibbert, *supra* note 5, at 43-45; Robert J. Morrison et al., *Regulatory Consideration in the Design and Manufacturing of Implantable 3D-Printed Medical Devices*, 8 CLINICAL & TRANSLATIONAL SCI. 594, 596 (2015).

Those variables are inherent in the machines themselves, but also in the custom devices they are capable of producing. Additive manufacturing is an overarching term that actually encompasses seven distinct 3D printing technologies.[41] Each of those technology segments has numerous companies producing different printer models. Different methods have advantages and drawbacks that make them suited for distinct applications. These differences do not just pertain to areas such as what types of material can be used, but also affect speed, cost, quality, and what sort of post processing is required.[42]

As the industry stands, 3D printing technology has no simple or consistent method of measuring or advertising accuracy, precision, and material strength.[43] 3D printers are commonly advertised based on a layer height; this measurement represents the thickness of material for each layer of the finished part.[44] Layer height tells you something about the resolution of the end product, but is not the only factor that matters. Resolution is also affected by laser diameter, material properties, and printing process.[45] Therefore, regardless of the layer height, the actual resolution of each printer will vary. A more accurate characterization of printer quality might be the minimum feature size.[46]

Besides differences between printing technologies, variations can occur within the same type or even the same printer. Each printing parameter, such as the minimum feature size, may be further dependent on part orientation, the material being used, location on the building plane, temperature of the surrounding environment (and the material itself), post processing techniques, and many other factors.[47]

Because 3D printers build objects layer by layer, objects produced are anisotropic, meaning their material properties are directionally dependent.[48]

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[41] DAVIES, *supra* note 10, at 2 (material extrusion, material jetting, binder jetting, sheet lamination, vat photopolymerization, powder bed fusion, and directed energy deposition).

[42] *See generally* H. Bikas, P. Stavropoulos & G. Chryssolouris, *Additive Manufacturing Methods and Modeling Approaches: A Critical Review*, 83 INT. J. ADVANCED MFG. TECH. 389 (2016) (providing a good overview of the basic mechanism behind the current primary 3D printing technologies).

[43] *Frequently Asked Questions "What is the Resolution of the Printer?*, FORMLABS, http://formlabs.com/support/faq/ [https://perma.cc/HJE9-B8CG].

[44] *Id.*

[45] *See* Demetris Zavorotnitzienko, *Understanding 3D Printer Quality & Resolution*, ILIOS 3D, http://www.ilios3d.com/en/product-documentation/ilios-documentation-3dprint-quality [https://perma.cc/K7E6-G6S9].

[46] *See generally Formlabs Design Guide*, FORMLABS, http://formlabs.com/media/upload/formlabs-design-guide.pdf [https://perma.cc/T973-8CSZ] (providing various minimum or maximum feature sizes based on a particular material with specific printer settings).

[47] *See* Hibbert, *supra* note 5, at 45; Erin Durkin, *FDA Gathers Stakeholder Input For 3-D Printing Standards, Guidances*, INSIDEHEALTHPOLICY (Oct. 17, 2014), http://insidehealthpolicy.com/fda-gathers-stakeholder-input-3-d-printing-standards-guidances-0 [https://perma.cc/8MPR-E6GB].

[48] Morrison, *supra* note 40, at 598.

Anisotropy can reduce the material strength to as low as 15% of the typical or stated material strength.[49] These properties depend on the material and the technology, but also how the part is oriented within the printer.[50] Material strength is an important factor for most medical devices, but particularly devices that will be load bearing. This is an area that should continue to improve as 3D printing technology develops.

Beyond improving print quality, growth and development of the 3D printing industry will no doubt improve the metrics for defining accuracy and precision. With this development, the consistency and reliability of different techniques will also improve. However, because of all of these variables, simply stating that a device is produced through additive manufacturing may not be enough to ensure the safety and efficacy of that device. Traditional manufacturing techniques have more established protocols and avoid many of the complex variables discussed above. Therefore, the FDA may be more willing to ignore the method of manufacture when considering a more conventional device.[51]

3D printers are useful additions to the manufacturing world for their ability to create complex structures unavailable through traditional manufacturing techniques.[52] Additionally, 3D printers give users the ability to easily create custom or one off products.[53] In the age of personalized medicine, custom is a huge buzzword. Personalized medicine uses treatments or devices that are specifically tailored to individual patients, or groups of patients based on unique characteristics.[54] The use of custom implants allows for accommodation of unique anatomical features to improve the performance of devices. In many cases, patients consider personalized or custom as synonymous with better.[55]

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[49] *Id.*

[50] *Id.*

[51] Bonnie Scott, *3-D Printing Guidance Only a B-List Priority for FDA*, PHARMA MEDTECH INSIGHTS (Mar. 10, 2015), http://pharmamedtechinsights.com/2015/03/3-d-printing-guidance-only-a-b-list-priority-for-fda/ [https://perma.cc/R25X-G568].

[52] Dominic Basulto, *Why it Matters That the FDA Just Approved the First 3D-Printed Drug*, WASH. POST (Aug. 11, 2015), https://www.washingtonpost.com/news/innovations/wp/2015/08/11/why-it-matters-that-the-fda-just-approved-the-first-3d-printed-drug/ [https://perma.cc/UM4T-6F7K] (stating 3D printed drugs can allow for the manufacture of a pill that is more porous and therefore readily dissolvable).

[53] Several companies have long relied on additive manufacturing for custom medical devices. *See, e.g.*, *Biomedical Manufacturing,* OXFORD PERFORMANCE MATERIALS (2016), http://www.oxfordpm.com/biomedical-manufacturing [https://perma.cc/6WEG-ALUU]; *Software & Services for Biomedical Engineering*, MATERIALISE, http://www.materialise.com/products-and-services/products-and-services-for-medical-professionals-0 [https://perma.cc/3Q8G-KAN9].

[54] Steven K. Pollack and James Coburn, *FDA Goes 3-D*, FDA VOICE (Aug. 15, 2013), http://blogs.fda.gov/fdavoice/index.php/2013/08/fda-goes-3-d/ [https:// perma.cc/ZV38-35UY].

[55] IMAGE-TO-IMPLANT SOLUTION FOR PERSONALIZED MEDICAL DEVICE, SIEMENS 3 (2014), https://m.plm.automation.siemens.com/en_us/Images/Siemens-PLM-Image-to-Implant-

The FDA recognizes the difficulty of regulating personalized medicine, and is actively engaging the industry and using in-house task forces to create regulatory best practices.[56] The FDA generally considers 3D printing to fall under this personalized medicine umbrella.[57] This means that, for some purposes, it may be useful to monitor the way the FDA regulates personalized medical applications and evaluate how those regulations may apply to other 3D printing technologies.

With all the variables discussed above, quality control may be a more difficult matter for 3D printing than it is for traditional methods of manufacturing. Further, additive manufacturing allows for manufacturing in a variety of spaces with smaller vendors or even individuals.[58] Manufacturing no longer requires a significant investment in space, equipment, and development of good manufacturing practices. Additionally, because there could potentially be many more manufacturing vendors, ensuring adherence with quality standards and good manufacturing practices would be substantially more difficult.

II. CURRENT TRENDS IN FDA REGULATION

Despite being a complicated and somewhat difficult manufacturing technology, "3D printing['s] . . . potential for transformation is clear."[59] That clarity is particularly evident in the medical industry where customization, material property modulation, and complex internal structures can add immense value.[60] With 3D printing already very much involved in the medical industry, it is time for the FDA to provide more substantial guidelines and standards to address the concerns raised above. So far, the FDA has raised many questions but has produced few concrete answers regarding additive manufacturing and the devices produced through this process. Without structure or some measure of certainty, manufacturers may still be hesitant to put resources towards developing new medical devices made by additive manufacturing.

Solution-for-Personalized-Medical-Devices-wp_tcm1224-219009.pdf [https://perma.cc/9UKZ-5PMV] ("Patient-matched implants and surgical instruments result in better alignment of implants during surgery and reduced incidence of subsequent corrective surgeries.").

[56] Leena H. Karttunen Contarino, *Personalized Medicine Providers, FDA Has Your Back*, LAW360 (Nov. 8, 2013), https://www.law360.com/articles/487146/personalized-medicine-providers-fda-has-your-back [https://perma.cc/JAQ6-KPV3].

[57] *Id.*

[58] Ashok Khanna et al., 3D PRINTING: NEW OPPORTUNITIES FOR THE MEDICAL DEVICES INDUSTRY, TATA CONSULTING SERVICES 7 (2015), http://www.tcs.com/SiteCollectionDocuments/White%20Papers/3D-Printing-New-Opportunities-for-Medical-Device-Industry_0315-1.pdf [https://perma.cc/2T4L-VMSB].

[59] Lemley, *supra* note 2, at 471.

[60] *See* Jerome Groopman, *PRINT THYSELF: How 3-D Printing is Revolutionizing Medicine*, THE NEW YORKER (Nov. 24, 2014), http://www.newyorker.com/magazine/2014/11/24/print-thyself [https://perma.cc/LNT9-6PWU].

The FDA, as well as professional organizations within the 3D printing industry, held several events in the past few years to gather feedback and information to support the construction of a regulatory regime.[61] The FDA has been thinking over how to deal with both 3D printed medical devices, as well as the unique challenges the 3D printers and their materials create. The intention has been to create regulatory guidelines for the field of additive manufacturing and devices created from these manufacturing processes.[62] Initially the FDA was eager to publish guidelines in mid-2015 after two events in 2014.[63] However, these guidelines were delayed until late 2015, and as of the date of this paper have still not been released in 2016.[64] These events discussed the many issues surrounding regulation of the 3D printing industry.[65] The meetings demonstrate that the FDA is grappling with how to handle this new manufacturing method effectively. Generally, the FDA does not consider manufacturing processes in its review. However, with the 3D printed medical devices that have sought approval so far, the FDA required more information, in part because of the uncertainty surrounding the printing process for the products produced by the medical community.[66] This uncertainty extends to both mass produced items and patient customized devices,[67] because the same variables impacting 3D printing are at play regardless of whether the machine is producing one item, or mass-producing the same item. That is, unlike some traditional manufacturing processes, 3D printing does not become more reliable as the production count increases.

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[61] Alexander Gaffney, *FDA Plans Meeting to Explore Regulation, Medical Uses of 3D Printing Technology*, REG. AFF. PROF. SOC'Y (May 16, 2014), http://www.raps.org/regulatory-focus/news/2014/05/19000/FDA-3D-Printing-Guidance-and-Meeting/ [https://perma.cc/C8RQ-H4G4]; *AM Summit*, *supra* note 12.

[62] *Id.* (stating the agency intended to release guidelines before the second 3D printing event in October 2014, guidelines still have not been released).

[63] *Public Workshop - Additive Manufacturing of Medical Devices: An Interactive Discussion on the Technical Considerations of 3D Printing,* FDA, http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm397324.htm [https://perma.cc/R3GE-NC4W].

[64] Michelle Bonn, *Bio-Printing & 3D Printed Medical Devices – Navigating Today's Regulatory Challenges & Opportunities*, GUIDELINE MEDICAL, http://nybiomedreport.com/member-spotlights/guideline-medical [https://perma.cc/SFT2-WQKV]; *see also* DAVIES, *supra* note 10, at 11 (stating guidelines would be published in 2015, if resources permit).

[65] Such topics include: FDA technical knowledge of initial designs, 3D printing, and post-processing; how to standardize and verify 3D printed devices; what design considerations are necessary for both implantable and non-implantable medical devices; what challenges and metrics are required to verify and validate 3D printed devices; and ensuring material properties remain as advertised through the process. *AM Summit*, *supra* note 12.

[66] Tanya Lewis, *3D-Printed Medical Devices Spark FDA Evaluation*, LIVESCIENCE (Aug. 30, 2013, 4:13 PM), http://www.livescience.com/39339-how-fda-regulates-3d-printed-devices.html [https://perma.cc/KXB4-R62F]; *see also* Park, *supra* note 11, at 189.

[67] Q1 Conferences, *supra* note 4.

The FDA's move away from a strict timeline for the guidance publication[68] shows a downgrade in priority and indicates that while the FDA recognizes 3D printing poses unique issues to medical device regulation, immediate guidance is not required. Therefore, the agency will continue to process regulatory submissions for 3D printed devices without new procedures in place.[69]

In part, the FDA defines a medical device as "an instrument, apparatus, implement, machine, [or] contrivance . . . which is . . . 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 . . . ."[70] 3D printers are already being used in all sorts of medical applications. Doctors are integrating them into surgical planning by printing out anatomical models based on patient scans for ease of visualization, measurement, and patient communication.[71] Dentists use 3D printers extensively to create custom dental implants, bridges, and other products either directly or by casting and molding.[72] Individuals (even non-medically trained users) can print customized prosthetics for people with amputations or other deformations based on open-source design files.[73] Additionally, the FDA recently approved a 3D printed drug to treat epilepsy.[74] Novel implantable medical devices are being used in investigational and emergent cases.[75] Moreover, the FDA has approved numerous 3D printed

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[68] Scott, *supra* note 51.

[69] *Id.*

[70] *Is The Product A Medical Device?*, FDA, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm [https://perma.cc/2UNJ-N9NQ].

[71] Larry Hardesty, *Personalized Heart Models for Surgical Planning: System Can Convert MRI Scans into 3D-Printed, Physical Models in a Few Hours*, MIT NEWS OFFICE (Sept. 17, 2015), http://news.mit.edu/2015/3-d-printed-heart-models-surgery-0917 [https://perma.cc/UH7U-G3LV].

[72] Wohlers, *supra* note 12 (estimating that 6000 dental copings (portions of a crown or bridge) are created every day using an additive manufacturing technique called direct metal laser sintering).

[73] *Prosthetics*, BIOPRINTING WORLD, http://bioprintingworld.com/category/prosthetics/ [https://perma.cc/2PCP-7LHG].

[74] Basulto, *supra* note 52.

[75] *See* Marissa Fessenden, *3-D Printed Windpipe Gives Infant Breath of Life*, NATURE (May 28, 2013), http://www.nature.com/news/3-d-printed-windpipe-gives-infant-breath-of-life-1.13085 [https://perma.cc/BN7R-Q8GY] (reviewing a 3D printed device that aids with infants' collapsing airways); Jeremy Hsu, *3D-Printed Skull Implant Ready for Operation*, TECHNEWS DAILY (Mar. 6, 2013, 12:25 PM), http://www.technewsdaily.com/17191-3d-printed-skull-implant.html [https://perma.cc/ZY3V-C5GX] (using a 3D printed plate to replace part of a patient's skull); Brooke Kaelin, *First 3D Printed Titanium Jaw Implant Successful*, 3D PRINTER WORLD (Aug. 16, 2013), http://www.3dprinterworld.com/article/first-3d-printed-titanium-jaw-implant-sucessful [https://perma.cc/5PJY-VL5C] (introducing 3D printed titanium jaw implant for a woman whose jaw bone could not be saved).

devices through the 510(k) process.[76] While printing functional organs for transplant into humans may be far off from a regulatory standpoint, proof of the scientific concept came in 2011 when Anthony Atala used a 3D printer to make a functional human kidney.[77] The above are just a smattering of the 3D printing applications currently being explored by the medical industry. These are all examples of 3D printers being used to create medical devices. Whether 3D printers themselves may be "an instrument intended for use" in a medical device type application is possibly an open question.

A. Emergency Use Devices

The FDA Emergency Use Exemptions allow for treatment with unapproved medical devices under certain circumstances involving: (1) a life-threatening condition; (2) no acceptable alternative treatment; and (3) due to the nature of the emergency, FDA review is unobtainable.[78] Several devices have been granted an Emergency Use Exemption in the past few years.[79] With the Emergency Use Exemption, FDA approval is fast-tracked and can be granted within weeks of the request.[80]

In 2012, the FDA granted approval for the emergency-use of a 3D printed trachea on a six-week old infant.[81] The device was made of the same material used in sutures, and therefore did not involve any new biocompatibility concerns.[82] Printing with a bio-resorbable material allows a device to dissolve overtime, and in the case of the trachea, dissolves as the infant's own cells produce a cartilage matrix.[83] The trachea implantation was successful and by now could be fully resorbed. Research has continued and has led to the development of a device currently in the process of FDA consideration as a Humanitarian Use Device.[84]

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[76] DAVIES, *supra* note 10, at 4–5 ("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.").

[77] Anthony Atala, *Printing A Human Kidney*, TED (Mar. 2011), http://ed.ted.com/lessons/printing-a-human-kidney-anthony-atala [https://perma.cc/D6CE-WTQ7] (demonstrating the creation of a functional and transplantable kidney by 3D printing living cells).

[78] *IDE Early/Expanded Access*, FDA http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm [https://perma.cc/CN5Q-GRCR].

[79] Park, *supra* note 11, at 198; DAVIES, *supra* note 10, at 12.

[80] Park, *supra* note 11, at 198.

[81] Fessenden, *supra* note 75.

[82] *Id.*

[83] Bob Grajewski, *3-D Printing: Changing the Landscape of Medical Device Manufacture*, MEDICAL DESIGN NEWS (Mar. 31, 2014), http://medicaldesign.com/design-engineering/3-d-printing-changing-landscape-medical-device-manufacture [https://perma.cc/8VU8-3TUD].

[84] Morrison, *supra* note 40, at 595.

In 2013, a man received 3D printed plates to replace 75% of his skull.[85] Printed parts are well suited to replicate the complex contours of a structure, such as the skull, and surface detail that promotes cell growth and attachment.[86] The company that conducted this implantation, Oxford Performance Materials (OPM), had already been selling their devices abroad.[87] OPM now has three customized, implantable, medical devices approved by the FDA through the 510(k) process.[88] As the FDA continues to approve devices through 510(k), it is likely that more devices pushing the boundaries of substantial equivalence will look for opportunities for Emergency Use or Humanitarian Use approval.

B. Approved 3D Printed Products

The Emergency Use Exemption allows devices to be used in specific, one-off cases. Devices on the open market undergo a different regulatory scheme. The FDA divides devices into three classes depending on the associated risk.[89] These device classifications, along with any exemptions, dictate the FDA's approval process that, in most cases, requires premarket notification with a 510(k) or Pre-Market Approval (PMA).[90] PMAs are used for high-risk devices that are not similar to any devices currently on the market.[91] For many devices, filing with a 510(k) requires demonstrating substantial equivalence with a currently marketed device.[92] The primary concern of the FDA is whether devices are safe and effective.

In the past few years, the FDA has approved eighty-five 3D printed medical

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[85] Carol Kuruvilla, *Doctors Replace 75 Percent of Patient's Skull with 3-D-Printed Polymer Implant*, NY DAILY NEWS (Mar. 9, 2013, 5:38 PM), http://www.nydailynews.com/news/national/doctors-replace-75-percent-patient-skull-3-d-printed-implant-article-1.1284049 [https://perma.cc/RCV9-4LRX].

[86] *Id.*

[87] *Id.*

[88] Oxford Performance Materials Named One of Fast Company's Most Innovative Companies of 2016, OXFORD PERFORMANCE MATERIALS (Mar. 8, 2016), http://www.oxfordpm.com/oxford-performance-materials-named-one-fast-companys-most-innovative-companies-2016 [https://perma.cc/T2TL-CEYV].

[89] Class I devices represent little to no risk and therefore have loose FDA controls, typically without a premarket notification requirement. Class II devices represent a moderate risk, so generally a premarket notification 510(k) is filed. Class III devices represent a high risk and may require Pre-Market Approval (PMA) which is a substantially more stringent review process. However, Class III devices may be able to avoid the PMA process by demonstrating substantial equivalence to a currently marketed device. These substantially equivalent devices can seek clearance through premarket notification with the 510(k). *What Does it Mean for FDA to "Classify" a Medical Device?*, FDA [hereinafter *FDA "Classify"*], http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194438.htm [https://perma.cc/4TH9-HF3C].

[90] *See id.*

[91] *See id.*

[92] *See id*.

devices almost entirely through the 510(k) process.[93] While eighty-five devices would seem to be significant, it appears that only fifteen of those devices expressly claim the use of 3D printing.[94] The rest can be shown to incorporate 3D printing only through examining press releases and journal articles.[95] The first additively manufactured implant made of a polymeric material was approved in 2013.[96]

So far, the FDA has cleared custom implants, orthopedic devices, dental devices, and custom surgical guides.[97] By using the 510(k) pathway, the FDA has been evaluating and treating 3D printed devices as at least substantially equivalent to conventionally manufactured devices.[98] That is to say, evaluating for safety and effectiveness without a full consideration of the manufacturing technique and associated risks.[99] The FDA has required some additional data on these products, such as what printer is being used, but the approval process so far has not been based on this information.[100] While this approval rate seems high, it is likely that the healthcare industry has been reticent to fully adopt additive manufacturing technology due to the uncertainty within the FDA.[101] Early adopters face an ambiguous and potentially expensive process of approval.[102]

3D printers are being used to create products in all three regulatory classifications.[103] As mentioned above, the FDA has approved many devices so

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[93] DAVIES, *supra* note 10, at 8.

[94] *Id.*

[95] *Id.*

[96] *OsteoFab™ Patient Specific Cranial Device Receives 510(k) Approval - Implants Ready for US Market and Beyond*, OXFORD PERFORMANCE MATERIALS (Feb. 18, 2013) [hereinafter *OsteoFab Cranial Device*], http://www.oxfordpm.com/news/article/2013-02-18_osteofab_patient_specific_cranial_device_receives_510k_approval_-_osteofab_implants_ready_for_us_market_and_beyond.php [https://perma.cc/2DQ6-QQEM].

[97] STEVE POLLACK, U.S. FOOD AND DRUG ADMIN., 3D PRINTING: WHAT WE KNOW AND WHAT WE DON'T 18 (2014), http://www.abiakron.org/sites/default/files/assets/docs/Steve%20Pollack%2010-22-2014%20Event%20Presentation.pdf [https://perma.cc/63Z6-SVC2] (listing: custom implants (skull plates, orthopedic implants, and customized emergency devices); orthopedic devices (acetabular cups for hip replacements, spinal cages, and knee trays); and dental devices (temporary bridges and reconstructive implants)).

[98] Lewis, *supra* note 66.

[99] *Id.*

[100] *Id.*

[101] Michelle Bonn, *Guideline Medical: Bio-Printing & 3D Printed Medical Devices – Navigating Todays Regulatory Challenges & Opportunities*, BIO/MED BREAKTHROUGHS, http://nybiomedreport.com/member-spotlights/guideline-medical [https://perma.cc/6D9Y-UXLJ].

[102] *See id.*

[103] One company in particular has spanned all three regulatory Classes. They have Class I flexible cardiovascular models, Class II surgical guides for knee implants, and not yet

far, and more approvals in both "traditional and patient-matched devices" are coming.[104] One factor shared by devices currently approved through the Emergency Use Exemption and the 510(k) pathway is that they are common or established devices.[105] Companies have not started pushing the boundaries of what is possible through the use of additive manufacturing.[106] Those devices would potentially be subject to substantially more FDA scrutiny as Pre-Market Approval (PMA) submissions are required.[107] The PMA process will represent a substantially higher investment in time and expense for device developers, but will also provide a more rigorous review of devices for safety and efficacy. This review could include an appraisal of the manufacturing process. This increased review will also clarify the regulatory scheme for future companies looking to pursue the broader capabilities of additive manufacturing for novel medical devices.

The FDA's current recommendation is that parties seeking FDA approval for "3D printed devices should participate in pre-submission meetings."[108] These meetings are helpful in ensuring the FDA understands the technology and the potential manufacturing, but the meetings also add time, expense, and uncertainty to the regulatory process.[109] Additionally, as of May 10, 2016 the FDA has released new draft guidelines for devices manufactured by 3D printing.[110] These guidelines discuss specific considerations that have made additive manufacturing a greater concern for the FDA than traditional manufacturing techniques, including the factors discussed in this paper.[111]

C. Material Considerations

Similar to medical devices, specialty materials used for implantation also undergo FDA clearance.[112] The approval of these materials requires review of

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approved custom implants that would likely be Class III devices. Rebecca Rudolph, *Future of Using 3D Printing in ORs is Defined by Materials*, SURGICAL PRODUCTS (May 15, 2015), http://www.surgicalproductsmag.com/article/2015/05/future-using-3d-printing-ors-defined-materials [https://perma.cc/MSG9-K7UP].

[104] Gaffney, *supra* note 61.

[105] Jamie Hartford, *FDA's View on 3-D Printing Medical Devices*, MED. DEVICE DIAGNOSTIC INDUSTRY (Feb. 11, 2015), http://www.mddionline.com/article/fdas-view-3-d-printing-medical-devices [https://perma.cc/6Q52-TKN8].

[106] *Id.*

[107] *Id.*

[108] DAVIES, *supra* note 10, at 10.

[109] *Id.*

[110] Technical Considerations for Additive Manufactured Devices Draft Guidance for Industry and Food and Drug Administration Staff, FDA (May 10, 2016) http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm499809.pdf [https://perma.cc/HWA7-9BUW].

[111] *See id.*

[112] Varun Saxena, *In a First, FDA Clears a Material Enabling 3-D Printing of Dentures*, FIERCE MEDICAL DEVICES (Aug. 12, 2015), http://www.fiercemedicaldevices.com/story/first-

the entire fabrication process to ensure the materials meet requirements.[113] However, particular 3D printer's software and hardware components are not part of the material approval, so once a material is approved it may be used with any applicable 3D printer.

These new materials represent novel material combinations requiring transition or polymerization. Some medical devices that received approval use materials that—in their final stage—have already gone through FDA clearance. Other materials have been developed specifically for the additive manufacturing processes and have undergone the FDA regulatory processes independently. In all six companies that have developed materials for 3D printing, the materials have undergone biocompatibility screening.[114] The number of companies that have approved materials promises to continue increasing in the coming years.

III. THE CASE FOR (OR AGAINST) REGULATION

With increased accessibility to 3D printing, it is not difficult to imagine a time when every hospital and doctor will have access to 3D printers.[115] Medical television shows already feature 3D printers as life-saving interventions.[116] As patients push for more personalized care—and as doctors and hospitals use patient specific models to map out surgical plans and better connect with patients—3D printers are only just beginning to impact the healthcare market.[117] The FDA needs to decide how to handle this burgeoning manufacturing industry and catch up with technological developments.

The FDA is currently studying additive manufacturing techniques, materials, and devices in three distinct process segments: pre-processing (input), print processing (process), and post-processing (output). Pre-processing includes the selection of material and printing technique appropriate for the application at hand. Print processing includes the function of the actual printer hardware and software to create a product. Post-processing includes all cleaning steps, quality assurance, and sterilization for appropriate medical devices. Each step affects the part produced, but the material, equipment, and process used are central to all three segments.[118] Because the 3D printer used in manufacturing has the

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fda-clears-material-enabling-3-d-printing-dentures/2015-08-12 [https://perma.cc/5TKH-88EP].

[113] The FDA recently approved the first additive manufacture photopolymer resin for use in denture repair and fabrication. *Id.*

[114] Crystal Morrison, *Materials, Medicine & Manufacturing: Materials Awareness and Selection,* Event Presentation, Slide 15 (Oct. 22, 2014), http://www.abiakron.org/sites/default/files/assets/docs/Crystal%20Morrison%2010-22-2014%20Event%20Presentation.pdf [https://perma.cc/3836-V88X].

[115] *See* Lemley, *supra* note 2, at 474-75.

[116] *See* Te Halterman, *"Grey's Anatomy" Prominently Features Medical 3D Printing Technology*, 3D PRINTING (Feb. 9, 2015), http://3dprint.com/43211/greys-anatomy-3d-print-heart/ [https://perma.cc/ZR3T-PHTG].

[117] *See id.*

[118] Durkin, *supra* note 47.

potential to impact the final medical device, some question exists as to whether the FDA should have a hand in ensuring the safety and efficacy of these printers. Additionally, if the definition of a medical device above applies to 3D printers, the FDA would have the ability to regulate the 3D printers as medical devices themselves. 3D printers are certainly instruments or machines. Therefore, the real question hinges on their *intended* use. The FDA could regulate 3D printers under existing procedures, or could modify and create new procedures to handle this burgeoning technology.

Two different FDA laboratories have spent at least the last two years studying 3D printing techniques to determine what sort of considerations and risks additive manufacturing poses.[119] One group, the Functional Performance and Device Use Laboratory, is focused on considerations inherent to patient specific or customized devices and how those "tweaks" impact safety and efficacy of a device.[120] The other group, the Laboratory for Solid Mechanics, focuses on how different printing technologies can affect material properties.[121] The FDA is working to build a strong base of knowledge regarding additive manufacturing. A strong foundation will support proper analysis and technical assessment of medical device submissions.[122] Understanding the additive manufacturing technologies is essential to understanding the safety and efficacy of a device.[123]

Developing regulations for additive manufacturing techniques will be an undertaking nearly as complex as the technology itself. A regulatory structure or guidelines would provide a level of certainty for device manufacturers and additive manufacturing companies. However, that certainty could come at an unacceptable cost.

A. Regulating Specific Devices and Manufacturing Facilities May Be More Efficient

Additive manufacturing technologies involve numerous complex variables. Some of these variables are directly relevant to the 3D printer; however, many variables are dependent on extrinsic factors. Rather than regulating 3D printers, the FDA may be better able to ensure patient safety and efficacy through controlling extrinsic factors, such as manufacturing facilities, device design, and materials.

Device designers and manufacturers can and should be properly aware of the risks and complexities of their chosen 3D printing technique.[124] Device manufacturers are the parties most likely to have the expertise and motivation to

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[119] Pollack & Coburn, *supra* note 54.

[120] *Id.*

[121] *Id.*

[122] *See* Renee Eaton, *FDA Considers Approach to Additive Manufacturing of Medical Devices*, RAPIDMADE (Oct. 10, 2014), http://www.rapidmade.com/rapidmade-blog/2014/10/10/fda-considers-regulations-for-additive-manufacturing-of-medical-devices [https://perma.cc/DAX7-38E3].

[123] Pollack & Coburn, *supra* note 54.

[124] *See* DAVIES, *supra* note 10, at 18-19.

ensure proper verification and validation in device production. Additionally, doctors will have a much greater proximity to patients receiving the devices for purposes of tracking and monitoring success.

One concern with passing regulatory responsibility entirely to manufacturers and designers of devices is that the manufacturing facility is less easily discernible than it has been in the past. Having FDA approved 3D printers would provide a level of certainty in the manufacturing process. This has been an issue in products liability law.[125] As this shows, 3D printing introduces the potential for error or liability in many ways,[126] but only two or three are directly under the control of the 3D printers and their manufacturers. Additionally, scholars of products liability have noted that the manufacturers of 3D printers are unlikely to face strict liability based on products produced through their printer because the printer is merely a tool.[127] This same principle applies to medical device regulations; 3D printers enable medical device manufacturers, but are likely not stand-alone medical devices. Because regulation of 3D printers would be highly complex, the FDA could look into other areas for more straightforward methods of addressing additive manufacturing.

1. Device manufacturers should be responsible for verification and validation of manufacturing methods

For device approval, the FDA requires a showing of safety and efficacy.[128] In some cases safety and efficacy are shown through substantial equivalence to a currently approved device.[129] In other cases, devices will have to go through a more extensive review process to prove safety and efficacy of the particular device. In both of these approval structures, it is possible and recommended that the FDA take into account, material, manufacturing process, and the type of device.[130] In this way, the FDA could ensure the manufacturing process is appropriate.

Modifying FDA regulation per device by requiring more extensive testing or validation will be far more effective at ensuring safety and efficacy than ensuring

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[125] *See* Clifton B. Parker, *3-D printing creates murky product liability issues*, *Stanford scholar says*, STANFORD REPORT (Dec. 12, 2013), http://news.stanford.edu/news/2013/december/3d-legal-issues-121213.html [https://perma.cc/4TH9-HF3C] (stating difficulty showing a Printer Manufacturer should be subject to strict liability for home-printed objects).

[126] Products liability is based on the chain-of-sale or control. 3D Printing introduces at least eight possible scenarios for liability (1) defective software or scanner for the creation of an original design, (2) defective digital design, (3) defective file, (4) corrupted file from a download, (5) defective 3D printer, (6) defective material in the 3D printer, (7) human error in the digital design, (8) human error in operation and post processing of printer and materials. DAVIES, *supra* note 10, at 15.

[127] *Id.* at 18.

[128] *FDA "Classify," supra* note 89.

[129] *See id.*

[130] *See* Durkin, *supra* note 47.

a specific printer meets FDA determined quality guidelines. Each printer has different capabilities and most limitations are only relevant to specific applications. Because devices vary so widely, if the FDA were to regulate 3D printers directly, there may need to be a complicated multi-tiered system. This system would need to certify printers on a per application basis, but it still may not sufficiently capture the concerns of the FDA. Further, because 3D printers do not have standardized terminology regarding quality, the FDA would need to develop an entire lexicon for an industry that is still evolving. Placing the burden of showing safety and efficacy on the device designer would simplify the regulatory process. Additionally, this would allow device designers to take advantage of the full gamut of 3D printing technologies, not just the technologies that have the resources and expertise to pursue an ambiguous FDA regulatory structure.

Device designers or manufacturers are also the parties directly in control of the 3D printers and can therefore be charged with ensuring proper quality control measures are taken. As with all manufacturing techniques, 3D printers require quality control and maintenance.[131] These measures may be more complicated than those for traditional manufacturing, but it is still possible to minimize the impact of variables and ensure a level of consistency by choosing the right technology and utilizing it appropriately. For example, to minimize the impact of anisotropy and material differences, parts should be printed at standardized and optimized orientations.[132] Additionally, manufacturers could ensure machines and software function properly by printing a control piece of a standard shape and size with every part.[133] With new technologies, new quality control measures can be created. These measures should be tailored to devices and applications rather than 3D printers themselves. The FDA can exert control over additive manufacturing through more stringent regulation of medical devices. This assertion is especially true for customizable devices.

2. Discomfort with manufacturing techniques could be attributed to uncertainty in the regulation of customizable devices

Additive manufacturing has made customization accessible in a way that traditional manufacturing techniques are not readily able to achieve.[134] 3D printers have substantially lowered the cost of creating one-off or single run devices.[135] Further, the manufacturing cost is not dependent on complexity of a device, as it would be with traditional manufacturing.[136] Many concerns

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[131] *See* Morrison, *supra* note 40.

[132] *Id.*

[133] *See e.g.*, *id.* (discussing using a "standardized porous cylindrical construct" as a control test to detect variations among printers).

[134] Rudolph, *supra* note 103.

[135] Additive *vs Subtractive, supra* note 18.

[136] *See Oxford Performance Materials Receives FDA Clearance For 3D Printed Facial Device*, SURGICAL PRODUCTS (Sept. 3, 2014), http://www.dev.surgicalproductsmag.com.690elmp01.blackmesh.com/product-

regarding additive manufacturing of medical devices could be more properly classified as concerns over the implications of regulating ever-changing designs.[137] In fact, one of the laboratories examining additive manufacturing for the FDA is focused directly on design verification for customized devices.[138]

Validation and verification systems are particularly important when considering custom designs, which add further potential for error or weakness.[139] Standardizing a process with so many variables, including the customized device itself, is an insurmountable task, but minimizing the potential for error is vital.[140] Verification and validation steps can be incorporated throughout the production process with manual measurements, visual inspection, or various virtual analysis tools.[141]

Many of the 3D printed medical devices currently approved through the 510(k) pathway are customizable versions of earlier approved devices.[142] Based on the currently approved customizable devices, the FDA seems to accept virtual design verification and validation using Finite Element Analysis to analyze different potential design issues for each customized product.[143] Regardless of the technology or verification method chosen, having standard operating procedures in the design and manufacturing process will improve the devices' reliability.[144]

Because personalized medical devices are often crafted using additive manufacturing techniques, the complex issues regarding FDA regulation of medical devices and additive manufacturing have become somewhat intertwined.[145] As with traditional devices, FDA regulation of specific, customized devices is more likely to achieve the desired outcome of ensuring a safe and effective device than regulation of individual printers.

3. Although Quality Systems Regulations would ensure manufacturing facilities of end use devices adhere to good manufacturing practices, 3D printers complicate the definition of "manufacturer"

The FDA does have a system for regulating device manufacturers called quality systems regulations.[146] Quality systems regulations only apply to end and

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release/2014/09/oxford-performance-materials-receives-fda-clearance-3d-printed-facial-device [https://perma.cc/ADX2-WBB2].

[137] *See* DAVIES, *supra* note 10, at 9.

[138] Morrison, *supra* note 40, at 595.

[139] *Id*. In fact, this is a primary concern of one of the two labs evaluating FDA regulation of additive manufacturing, the Functional Performance and Device Use Laboratory. Pollack & Coburn, *supra* note 54.

[140] Morrison, *supra* note 40, at 595.

[141] *Id.*

[142] *See* DAVIES, *supra* note 10, at 9.

[143] Morrison, *supra* note 40, at 596.

[144] *Id.*

[145] Contarino, *supra* note 56.

[146] *Quality System (QS) Regulation/Medical Device Good Manufacturing Practices*,

complete device manufacturers currently.[147] The FDA defines "manufacturers" broadly as "any person who designs, manufactures, fabricates, assembles, or processes a finished device."[148] Rather than providing strict requirements for manufacturers, quality system regulations provide a loose framework in order to accommodate the diverse range of medical devices. This framework is detailed in 21 CFR § 820 and provides several methods for complying with Good Manufacturing Procedures (GMP).[149] Manufacturers are able to construct their own standardized procedures for compliance. Those procedures may be reviewed periodically and the FDA may conduct visits to ensure manufacturing facilities are complying with GMPs.

While traditional manufacturing facilities are controlled through quality systems regulations, additive manufacturing may pose some unique difficulties based on the accessibility of the technology. Smaller, cleaner, and lower cost machines are now being used, on-site, in hospitals and dental offices creating a unique issue the quality systems regulations do not currently address.[150] Being a manufacturer no longer has to involve a substantial investment in space and equipment, but can be accomplished by anyone able to afford a 3D printer and a digital file.[151] One manufacturer can use the same 3D printer to make many different medical devices at the same time. With stand-alone medical devices being produced in common areas of hospitals or dental offices, ensuring GMPs are followed at every site can be a more complicated matter.

Beyond the potential for non-conforming manufacturing facilities, the uncertainty of manufacturing structure affects the chain of liability.[152] Because 3D printers can be located in various parts of the supply chain, it is more difficult to determine in advance which parties might be liable for damage caused by different devices.[153] Because the chain of liability is so uncertain, the FDA may

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FDA, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/ [https://perma.cc/9YWG-75CV].

147 *Id.*

148 21 C.F.R. § 820.3(o) (2016).

149 *Quality System (QS) Regulation/Medical Device Good Manufacturing Practices*, FDA, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/ [https://perma.cc/9YWG-75CV].

150 Aviva Lev-Ari, *FDA's "510(k)" Given to 85 Medical Devices Manufactured Through 3D Printing Technology*, PHARMACEUTICAL INTELLIGENCE (Sept. 24, 2015), http://pharmaceuticalintelligence.com/2015/09/24/fdas-510k-given-to-85-medical-devices-manufactured-through-3d-printing-technology/ [https://perma.cc/4CUF-QRMT]; Shana Leonard, *FDA Grapples with Future Regulation of 3-D Printed Medical Devices,* MED. DEVICE DIAGNOSTIC INDUSTRY (June 13, 2014), http://www.mddionline.com/article/fda-grapples-future-regulation-3-d-printed-medical-devices-140613 [https://perma.cc/Y9X9-2U8C].

151 DAVIES, *supra* note 10, at 10.

152 *See* Park, *supra* note 11, at 188-89.

153 Nielson, *supra* note 3, at 616.

be inclined to exercise control at an earlier point in the process, potentially through 3D printer manufacturers themselves.

At least one medical device manufacturer has undergone quality systems regulations certification for its additive manufacturing facility.[154] The oversight available through quality system regulation and device design controls should be enough to ensure safety and efficacy of 3D printers in large manufacturing facilities. The issue becomes complicated when the use of 3D printers diverges from that of traditional manufacturing facilities. Large manufacturing firms are in favor of stringent quality systems regulations which would somewhat alleviate the need for FDA regulation of the 3D printers themselves.[155] Predictably, smaller manufacturers are opposed to these requirements because their facilities would have a more difficult time conforming to FDA regulations.[156]

Quality systems regulations would be a good regulatory regime for additive manufacturing in cases where its use is comparable to traditional manufacturing. These sorts of GMPs would also be useful to guide less traditional manufacturing arrangements, but some adjustments need to be made from how the system is currently structured. For example, the FDA could proffer a more structured framework than currently provided in order to exert more control over small manufacturers. While it might seem attractive to regulate the individual 3D printers, it is possible that other factors against regulation outweigh the benefit here. FDA regulation and oversight should be as close to the final medical device as possible.

4. Enhanced regulation on materials would be more helpful than regulating individual printers

The FDA is also in charge of ensuring safety and biocompatibility of different materials. Generally this is done by ensuring materials comply with standards created by entities, such as the International Organization for Standardization (ISO).[157] Companies currently selling biocompatible materials for additive manufacturing tout compliance with these ISO standards.[158] Because the 3D printing materials undergo polymerization or phase change depending on the 3D printing technique, they may pose some unique regulatory issues.[159] Even though a raw material may meet the ISO standards, the 3D printing process may raise questions as to the biocompatibility and other material properties of the

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[154] *OsteoFab Cranial Device*, *supra* note 96.

[155] *See* DAVIES, *supra* note 10, at 10.

[156] *Id.* at 10-11.

[157] *Use of International Standard ISO- 2 10993, "Biological Evaluation of 3 Medical Devices Part 1: Evaluation and Testing"*, Draft Guidance, FDA (Apr. 23, 2013), http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm348890.pdf [https://perma.cc/ML29-66VW].

[158] *Quality*, OXFORD PERFORMANCE MATERIALS, http://www.oxfordpm.com/quality-0 [https://perma.cc/M4YM-KU9E].

[159] DAVIES, *supra,* note 10, at 10.

finished product.[160] The companies selling 3D printers do not always control what materials are usable in their product. In fact, 3D printing companies often feel pressure from consumers to keep their printers open to third-party materials.[161]

With any material, one concern is ensuring the 3D printer does not adulterate the material and the finished product conforms to the proffered standards.[162] This means, in order to analyze a material for FDA approval, the FDA should focus not only on raw materials, but also materials that have been printed and post-processed. Approving materials for certain printers or printing technologies would be an appropriate measure of control for the FDA.

B. Other forms of quality control are available

The FDA itself mentions that one goal of their industry events is to collaborate on best practices and solutions to the technical challenges posed by 3D printing.[163] Having best practices or industry wide standards in terminology and measurements would be a real benefit to the additive manufacturing industry. However, these standards do not need to come from the FDA itself. The FDA is just starting to get up to speed with the technology.[164] The FDA's understanding is important for evaluating devices and custom device regulation, but it is not necessary for the FDA to exert control over the 3D printing industry. Other parties are able to — and more importantly, incentivized to — follow industry wide standards without a need for FDA oversight.

1. Industry quality standards and terminology outside of the FDA can ensure quality of 3D printers

Regulation of the 3D printing industry would work to ensure patient safety and product efficacy; however, the social value of 3D printers goes far beyond the medical industry and excessively broad regulation could greatly hinder the technologies' potential.[165] One route to ensuring efficacy and consistency, while limiting potential strain on the 3D printing industry, would be to support uniform standards created by professional organizations.

Industry standards are set by various professional groups in an effort to foster consistency between companies.[166] These industry standards lay out uniform

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[160] *Id.*

[161] *Form 2*, FORMLABS, http://formlabs.com/products/3d-printers/form-2/ [https://perma.cc/ZG7X-FTCA] (stating that although Formlabs created this printer to have an automated material dispensing system, an "Open Mode" was included to allow users to experiment with 3rd party resins).

[162] *See* Morrison, *supra* note 40 (stating that cross-linking or melting that occurs during the print process potentially alters many material properties).

[163] Durkin, *supra* note 47.

[164] Pollack and Coburn, *supra* note 54.

[165] *See* Lemley, *supra* note 2, at 503.

[166] *About Us*, IEEE STANDARDS ASSOCIATION, http://standards.ieee.org/about/ieeesa.html [https://perma.cc/PXE4-NSU9].

terminology and metrics of quality. The Institute of Electrical and Electronics Engineers Standards Association (IEEE-SA) recently published guidelines regarding 3D printers and other electronic devices for use in medical applications.[167] The IEEE-SA standards under development address terminology and file formats related to 3D printing.[168] These standards are often collaboratively created, allowing for input from industry representatives, as well as consumers and manufacturers, regardless of their membership status.[169]

Standards created by a professional organization, such as the IEEE-SA, incentivize industry participation and broad adoption.[170] Standards would allow 3D printing companies to advertise their compliance and utilize the consistent quality metrics so purchasers are better informed regarding the capabilities of the 3D printing technology they buy. Industry standards may further reduce the impetus for regulating 3D printers themselves because device manufacturers would be able to use standard conforming printers as part of their manufacturing line and the FDA could wield oversight by adopting these standards as part of their quality systems regulations.

2. Device manufacturers have a strong incentive to invest in quality machines; therefore, machines that do not produce sound devices will not be utilized.

Because parties manufacturing medical devices will be held accountable for issues with their devices, they have a strong incentive to ensure the manufacturing techniques chosen are appropriate. The same motivation works to ensure the verification and validation of devices and manufacturing processes are stringent. In the competitive 3D printing industry, machines that are not reliable or do not maintain the necessary material properties will not continue to be used. Device manufacturers will choose to pursue 3D printers that conform with industry standards in order to ensure quality production.

C. FDA Regulations Would Unduly Burden 3D Printer Manufacturers

Putting additional regulatory burden on 3D printing companies would go against the current goal of fostering innovation.[171] This additional burden would not result in much gain relating to the safety and efficacy of medical devices.

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[167] Clare Scott, *IEEE Introduces New Regulations to Standardize 3D Printing Software Used in Medical Settings*, 3D PRINT (Nov. 11, 2015), http://3dprint.com/104846/ieee-3d-printing-standards/ [https://perma.cc/52H2-MMFM] (stating the standard is currently being drafted under IEEE P3333.2.5 Draft Standard For Bio-CAD File Format for Medical Three-Dimensional (3D) Printing).

[168] *Id.*

[169] IEEE STANDARDS ASSOCIATION, *supra* note 166.

[170] *Id.*

[171] The FDA and the President have recognized the importance of developing 3D printing technology. President Obama even established the National Additive Manufacturing Innovation Institute in 2012 to foster collaboration supporting 3D printing and products developed through such. DAVIES, *supra* note 10, at 2.

1. Post market surveillance is particularly difficult for the manufacturers of 3D printers

One requirement for products regulated as medical devices is that any adverse events must be recorded and reported to the FDA.[172] The FDA recognizes that a passive medical device reporting system has limitations, including inaccurate or missing reports of adverse events.[173] Because 3D printers would be sold to all sorts of device manufacturers, with little control over what devices are produced or where they end up, 3D printer manufacturers would have very little ability to monitor and report adverse events. Additionally, it would be nearly impossible to prove a device failure was due to an issue with the manufacturing technique independent from the device design, material, or some other step between the 3D printer and the use of the medical device. Other device and drug manufacturers may have difficulties monitoring adverse events, but they at least are aware of the range of intended uses for their products.

3D printers may be incorporated in any variety of medical device applications. Generally, companies selling 3D printers have no vetting systems in place to monitor what users are manufacturing. The groups selling 3D printers are more interested in delivering their machinery than having an in-depth knowledge of its application. Further, the medical device designers are often focused on maintaining a level of confidentiality, and are not likely to divulge that information.

2. Advertising targets healthcare markets, not individual consumers

Some 3D printing companies are aggressively targeting specific medical device applications;[174] however, most printers are advertised as useful to entire, broad markets. That is, companies market 3D printers as a useful tool for creating generally, rather than as a useful tool for creating medical devices specifically. Even if companies target the creation of medical devices, it is difficult to believe 3D printers themselves are medical devices. No companies hold out 3D printers as an instrument for direct use in the diagnosis, cure, mitigation, treatment, or prevention of disease. While asserting that a 3D printer is not in itself a medical device might seem like parsing language, it is a valid point. 3D printers do not accomplish diagnosis, treatment, cure, or mitigation. 3D printers are more like an instrument or machine intended for use on another "instrument, apparatus, implement, machine . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease."[175] 3D printers will continue to be once removed from the actual medical devices.

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[172] *Current Postmarket Surveillance Efforts*, FDA, http://www.fda.gov/MedicalDevices/Safety/CDRHPostmarketSurveillance/ucm348738.htm [https://perma.cc/L2JW-N5PC].

[173] *Id.*

[174] STRATASYS, *supra* note 8.

[175] *Is The Product A Medical Device?*, *supra* note 70.

Advertisements are intended to convince doctors, dentists, and device manufacturers that 3D printing is a useful tool, but the advertising is not directed toward medical device consumers. The FDA only has authority over advertisements when they pertain to "restricted medical devices."[176] If 3D printers are not medical devices, they cannot fall under restricted medical devices. Additionally, the purpose of the FDA monitoring advertisements is to ensure advertisements are truthful and not misleading.[177] Even with the most aggressive advertising campaign of the Objet 30 Orthodesk, the FDA would have a difficult time showing that the advertising material was either false or misleading. This direct advertising strategy may not be recommended for 3D printing companies looking to minimize regulatory requirements, but their printer does use approved material and has been incorporated into dental labs around the country.[178]

3. Controlling what users print is nearly impossible and would be highly detrimental

One potential motivation for regulating 3D printers directly is that even unsophisticated users can create medical devices with a printer.[179] While this kind of consumer intervention is not ideal, it would be very difficult for 3D printing manufacturers to control, as has been evidenced by companies trying to limit the manufacture of guns on 3D printers. One company claims to have made a software add-on that can detect firearm components and prevent a 3D printer from creating those parts.[180] While the software may work, it is likely cumbersome, causing printing programs to take longer, and ineffective as it would not be too difficult to get around with minor design alterations. This sort of solution would be unworkable in the healthcare industry. Medical applications vary broadly. Additionally, it would directly limit prototyping, a main use of 3D printers.

4. The FDA does not regulate traditional manufacturing techniques; 3D printing should be no different

At a basic level, additive manufacturing is the exact opposite of subtractive manufacturing.[181] Both use software and a digital model to create a final

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[176] Daniel Schultz, *FDA Oversight of Direct-to-Consumer Advertising of Medical Devices*, FDA (Sept. 17, 2008)), http://www.fda.gov/NewsEvents/Testimony/ucm096272.htm [https://perma.cc/94AN-9TS9].

[177] *Id.*

[178] STRATASYS, *supra* note 8.

[179] *See* Ronen, *supra* note 9; *Prosthetics*, *supra* note 73.

[180] Grace Wyler, New Software Will Prevent You From Accidentally Printing a Gun, Motherboard (July 13, 2013, 10:15 AM), http://motherboard.vice.com/blog/new-software-will-prevent-you-from-accidentally-printing-a-gun [https://perma.cc/3NKH-D7KN].

[181] DAVIES, *supra* note 10, at 2, 3.

product.[182] Additive manufacturing techniques are less established and are capable of forming significantly more complex structures using a wide variety of materials.[183] These differences trigger hesitancy where regulators are concerned.

Like the manufacturers of most other traditional manufacturing tools, 3D printing companies have little to no experience creating medical devices. They are generally not savvy to the world of medical device regulation. Requiring 3D printer companies to make a substantial investment of time and capital just to be able to compete in the additive manufacturing healthcare market would unduly burden emerging companies. These regulations would limit options for medical device manufacturers to access the machines best suited for their applications. This burden seems unwarranted when the FDA has not imposed a similar burden on other manufacturing techniques and has other options for ensuring safety and efficacy of devices themselves.

D. "How it's Made" is not the Relevant Concern

The FDA is currently approving 3D printed medical devices through the 510(k) regulatory process.[184] Because the 510(k) process requires a showing of substantial equivalence, the FDA's approval indicates that it generally views 3D printing as equivalent to other forms of manufacturing. Later requiring 3D printers to undergo another form of regulation would take away from these early determinations of substantial equivalence.

The official FDA presentations on 3D printing focus on the various areas where concerns could arise.[185] As has been discussed throughout this paper, concerns may be warranted due to the sheer number of variables involved in additive manufacturing. However, the three principle concerns – mechanical properties, biocompatibility, and design[186] – are not directly, or at least not solely, under the control of the 3D printer. Design is clearly controlled by a third party. Biocompatibility would principally be a material consideration. However, it is possible for the 3D printing process to affect the design or biocompatibility in some way, either through under curing or otherwise affecting the material properties. While it is possible for a printer to affect these properties, it would be more effective for material and device manufacturers to create settings and protocols to ensure proper production. Mechanical properties would seemingly be relevant to the 3D printer itself, but the broad properties are also tied to the design and material.

It is relevant to consider that 3D printers as a manufacturing tool are relatively new. The development of surrounding infrastructure and quality control

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[182] *Id.* at 2.

[183] *Id.* at 3.

[184] Lev-Ari, *supra* note 150.

[185] *See* Steve Pollack, *3D Printing: What We Know and What We Don't*, FDA (Oct. 22, 2014), http://www.abiakron.org/sites/default/files/assets/docs/Steve%20Pollack%2010-22-2014%20Event%20Presentation.pdf [https://perma.cc/BZV2-2B84].

[186] *Id.*

mechanisms is ongoing.[187] However, just because a technology is new, or presents issues and complications not present in more traditional manufacturing, does not mean that the technology requires FDA intervention in the form of regulation. Patients are generally not concerned with the manufacturing origins of their devices; they want to know devices work effectively and safely.[188] The FDA should be, and currently is, taking the time to learn about the different additive manufacturing technologies and their potential impacts on medical devices.[189] This knowledge should be used to create appropriate analyses and inquiries for devices manufactured by 3D printing. Safety and efficacy should be controlled at a per-device level, not at the production level.

IV. CONCLUSION

While it might be favorable to provide some form of oversight or regulation for the 3D printing industry as it relates to the medical field, direct regulation of 3D printers is not the most efficient or effective solution. Most 3D printing companies are not focused solely on the medical industry and are not structured to comply with FDA oversight requirements, such as post-market surveillance. Further, some 3D printing companies may not even be aware that their product might create FDA regulatory implications.

The FDA has mechanisms of oversight through device regulatory pathways and quality systems regulations for device manufacturers. The FDA should exert regulatory control in the manner most likely to result in safe and effective medical devices. In this case, device manufacturers that choose to use 3D printers should be the focus of any FDA regulatory scrutiny. These are the parties most capable of ensuring verification and validation in device production.

Ultimately, 3D printers are one of numerous manufacturing tools that each offer advantages for different applications and different materials.[190] Other manufacturing tools have avoided FDA scrutiny; 3D printers should not face additional regulatory measures. The FDA has impliedly agreed to this assertion by approving devices and drugs manufactured through 3D printing.[191]

In any case, the FDA should continue to pursue guidelines for additive manufacturing because the technology will only continue to develop. The knowledge and understanding gained from these guidelines would serve as a basis for regulating bioprinting.[192] A regulatory structure or guidelines would provide a level of certainty for device manufacturers and additive manufacturing companies.

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[187] *See generally* Morrison, *supra* note 40, at 594; *supra* Part I.

[188] Rudolph, *supra* note 103.

[189] *See supra* note 63 and accompanying text.

[190] Hibbert, *supra* note 5, at 43, 45 (stating that in an interview, a representative from GKN said "[y]ou investment cast, diecast, and sand cast for different applications. And it's the same with additive manufacturing.").

[191] Basulto, *supra* note 52.

[192] DAVIES, *supra* note 10, at 8.

Because current quality systems regulations may not be well-tailored for new additive manufacturing facilities, the FDA could proffer a more structured framework than currently provided. Having best practices or industry-wide standards in terminology and measurements would be a benefit to the additive manufacturing industry. These standards are already beginning to be developed by the industry. The FDA should support these standards and adopt them as they become applicable. However, as the FDA is really just learning the 3D printing technology, the agency should not be in charge of developing standards.

3D printers are at least a step removed from medical devices. They are tools used to make medical devices, but are not in themselves an "instrument, apparatus, implement, machine . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease."[193] Just because additive manufacturing presents issues and complications not present in more traditional manufacturing, does not mean that the technology requires FDA intervention in the form of regulation. The FDA already regulates medical devices; it does not need additional oversight just because a device is 3D printed.

Ultimately, the FDA will need to continue to monitor medical devices produced through additive manufacturing. As the market for additive manufacturing continues to develop it is likely that the terminology and standards will develop as well. The FDA should take an active role in encouraging device manufacturers to carefully consider the numerous variables associated with additive manufacturing. These manufacturers should also have careful verification and validation measures in place.

Additive manufacturing has a lot to offer the healthcare industry. Overly stringent regulations should not hinder the adoption of this manufacturing tool.

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[193] *Is the Product a Medical Device?*, *supra* note 70.