COMMENT

PRINTING FOR THE PERFECT FIT: BALANCING FDA REGULATION OF 3D PRINTED MEDICAL DEVICES

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The world of 3D printing is making its debut on the cutting edge of healthcare. The industry, once traditionally focused on manufacturing, modeling, and small businesses consumerism, now includes vital healthcare objectives. Patient care is not only enhanced by 3D printing of models, but also through the custom design, manufacture, and implementation of patient-specific medical devices. Now, patients can receive implantable devices custom created for their specific anatomy and doctors can tailor prosthetics to a growing child heavy financial. In other words, 3D printing has opened the door to a reduced cost, highly innovative implementation of medical devices. That innovation is crucial to deft and nimble care and addressing patient needs in an increasingly customized world.

How do patients know the devices are safe? The current Food and Drug Administration approach to regulating 3D printed medical devices for safety has come a long way in its approach to the industry, but still has important steps to overcome. The regulatory scheme's shortfalls are primarily due to the drastically different manufacturing processes of 3D printed devices versus traditionally manufactured devices. The Food and Drug Administration's regulation of medical devices is focused on that traditional device manufacturing process, with no separate or distinct regulations regarding 3D printed medical devices. While manufacturers can look to guidance for direction on device approval, the scheme can go further to address continuing ambiguities surrounding the technology. This Comment attempts to address the current Food and Drug Administration's regulatory scheme and identify its weaknesses for the 3D printing world. In addition, this Comment proposes a new idea—the regulation of 3D printed medical devices in a separate regulatory category.

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INTRODUCTION

Perfectly customized care, specific to each individual patient, seems like a doctor's dream come true—especially before medical technology could easily accommodate individualized patient needs. But that dream is becoming a reality as 3D printing, otherwise known as additive manufacturing, is taking off in the medical field. Previously relegated to innovative and disruptive startups, 3D printing is gaining significant momentum in clinical care,[1] accomplishing a range of small to extremely complex tasks.[2] In short, applications for 3D printing in patient care are exploding; hospitals, doctors, and other medical organizations and professionals are creatively implementing 3D printing to enhance patient care. Currently in the medical field, a major use of 3D printing is for custom, patient-specific, medical devices, implants,

1. 3D printing in the medical field is growing at a Compound Annual Growth Rate of 30.46%. *3D Printing Medical Devices Market – Segmented by Product Type, Product Type Material Type, Technology, and Region – Global Growth, Trends, and Forecast to 2024*, MARKET DATA FORECAST (Oct. 2018), http://www.marketdataforecast.com/market-reports/global-medical-device-three-dimension-printing-market-330/ [https://perma.cc/99NA-MFAH].

2. *A Brief History of 3D Printing*, T. ROWE PRICE ASSOCIATES, INC., https://individual.troweprice.com/staticFiles/Retail/Shared/PDFs/3D_Printing_Infographic_FINAL.pdf [https://perma.cc/VF4N-BHLD].

and biological machines. There are many obvious benefits to this application of the technology, not least of which is access to care that matches patients' individualized medical needs. However, as it currently stands, the Food and Drug Administration's (FDA) regulatory scheme for 3D printed devices is inadequate to certify to patients that the 3D printed devices are safe. As 3D printing in the medical industry grows, it is increasingly crucial that the regulatory scheme properly address the unique circumstances and processes surrounding additive printing. In recent years the FDA has expanded its approach to 3D printed medical devices, but as the technology grows, the need for a separate regulatory category is increasingly important. Such a regulatory scheme would allow the FDA to change binding standards, create less uncertainty for manufacturers, and continue to refine important quality and patient safety processes.

A separate regulatory category would also help to clear up important distinctions for device manufacturers, such as when a 3D printed, patient specific medical device crosses from iterative to sufficiently custom to qualify for an exemption to pre-market approval standards. While the custom device exemption ("CDE")[3] seems to encompass 3D printed medical devices, the FDA has noted in guidance documents that the fact that a device is specifically designed for an individual patient is not enough to qualify for the exemption.[4] Instead, the FDA requires that the device independently reach the requirements of the CDE.[5] However, it is not clear when a device becomes so custom as to be exempt from the pre-market approval standards.[6] The major benefit of 3D printed devices is that they can be customized for the individual patient—but how much customization is enough to qualify as a CDE? Creating patient-specific 3D printed devices helps improve patient care because there are some specific patient needs that may not otherwise be addressed by a standardized product.[7] As they are

3. U.S. FOOD & DRUG ADMIN., CUSTOM DEVICE EXEMPTION: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2014); *see also infra* Section I.C.

4. U.S. FOOD & DRUG ADMIN., TECHNICAL CONSIDERATIONS FOR ADDITIVE MANUFACTURED MEDICAL DEVICES: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 8 (2017); *see also* Rachael E. Hunt & Allyson B. Mullen, *FDA Issues Final Guidance on Additive Manufactured ("3D-Printed") Devices*, FDA L. BLOG (Jan. 3, 2018), http://www.fdalawblog.net/2018/01/fda-issues-final-guidance-on-additive-manufactured-3d-printed-devices/ [https://perma.cc/N7HZ-SHV5].

5. U.S. FOOD & DRUG ADMIN., *supra* note 4.

6. *See* Hunt & Mullen, *supra* note 4.

7. For example, one study assessed the use of 3D printing to create a customized implant for a patient's missing mandible bone, with the final design "provid[ing] an excellent fit" with the patient. MAZHER MOHAMMED ET AL., CUSTOMIZED DESIGN AND DEVELOPMENT OF PATIENT SPECIFIC 3D PRINTED WHOLE MANDIBLE IMPLANT (Aug. 8–10, 2016).

customized, the scans and final product are designed to work with that particular patient's anatomy.[8] At some point, the customization goes beyond an iterative design and becomes sufficiently custom, but the FDA has not provided guidance on when that line is crossed.[9]

Neither, however, does the traditional FDA pre-market approval process adequately address the needs of the additive printing world of the medical industry. The pre-market approval process is cumbersome and extensive,[10] often asking for data items and tests that are simply impractical for the flexible and individualized use of 3D printing for custom patient-specific devices.[11] The pre-market approval process which introduces heavy constraints and requirements for new medical devices does so because the impact of those devices is far reaching on large patient populations.[12] While 3D printing has a large scope in terms of medical devices, no one specific 3D printed medical device *itself* has the same reach as a mass-manufactured device going out to thousands of patients—even though the design might. The pre-market approval process has extensive requirements designed to protect patient safety regardless of scope, but the requirements were designed with traditional manufacturing in mind.[13] While the pre-market approval process is not specific to 3D printed devices, the benefits associated with it are still relevant to patient specific 3D printed medical devices.[14] As the regulations currently stands, there is no guidance for designers of 3D printed devices as to when they should even consider getting pre-market approval.[15]

Because of the current scheme's focus on traditionally manufactured devices, patient specific medical devices created through 3D printing could get lost in the regulatory shuffle. With the uncertainty surrounding the CDE, along with the pre-market approval standard's tailoring to traditionally manufactured devices, the industry

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8. *Id*. at 1710.

9. *See* Hunt & Mullen, *supra* note 4.

10. Stephen Barlas, *Critics Assail FDA Medical Device Approval Process*, 36 PHARMACY & THERAPEUTICS 395, 395, 409 (2011).

11. Michael Drues, *3D-Printed Medical Devices: Which Regulatory Strategy is Appropriate? (And Why)*, MED DEVICE ONLINE (Nov. 20, 2015), https://www.meddeviceonline.com/doc/3d-printed-medical-devices-which-regulatory-strategy-is-appropriate-and-why-0001 [https://perma.cc/P4LM-SET6].

12. When our intended patient population for a new medical device is thousands . . . it makes sense to do a clinical trial . . . to make sure the product is safe and effective. But when our intended patient population is only one person—as is the case with personalized medicine—is it even possible?

Id.

13. *See id.*

14. *See id.*

15. Hunt & Mullen, *supra* note 4.

of 3D printing is still in limbo.[16] To address these issues, the FDA should regulate patient specific 3D printed devices with rigor combined with flexibility. In other words, 3D printed devices, even when they are patient specific, should be regulated in their own category, bringing flexibility for the FDA to respond to changes in an adaptive and innovative industry.

Part I of this Comment explores the background of 3D printing and the regulatory scheme currently in place at the FDA. This background covers the manufacturing process of 3D printing, uses for 3D printing in the medical field, as well as the traditional FDA pre-market approval process for medical devices as it stands today including a discussion of the CDE to the typical rigorous approval process. Part II of this Comment discusses changes to the regulatory system for 3D printed medical devices. In particular, Part II asserts that these changes can be beneficial to patients, providers, and growth and innovation. Part II also proposes where the FDA should consider changing the regulatory scheme and makes substantive recommendations for new regulatory rules. Finally, this Comment concludes with an overview of the proposed regulatory scheme, its benefits, and the potential future of 3D printing regulation.

I. 3D PRINTING: APPLICATIONS AND REGULATIONS

3D printing as an industry has grown dramatically over the past 20 years, in both consumer and commercial uses.[17] The ease of printing 3D objects has bolstered the technology's popularity amongst consumer enthusiasts and small businesses. The industry is also picking up speed in larger and historically less flexible industries, such as oil and gas.[18] Creative uses for additive manufacturing are growing, with some scholars pointing to 3D printing as one of the new driving forces in

16. Maya M. Eckstein & Kyle Sampson, *How Will the FDA Regulate 3D Printing?*, HUNTON & WILLIAMS (Mar. 9, 2016), https://www.huntonak.com/images/content/3/6/v2/3606/How_will_the_FDA_regulate_3D_printing.pdf [https://perma.cc/BQ7P-6NHD] ("Despite the increased usage of 3D printing in drug and device manufacturing, many manufacturers are holding back due to regulatory uncertainty.").

17. *See 3D Printing Medical Devices Market – Segmented by Product Type, Product Type Material Type, Technology, and Region – Global Growth, Trends, and Forecast to 2024*, *supra* note 1.

18. For example, the oil and gas industry, generally considered to be inflexible, is exploring options for 3D printing some of their high complexity, low quantity parts, particularly used in the drilling process itself. Harshit Sharma, *Lucrative Use for 3-D Printing in Oil and Gas Industry*, HART ENERGY (Mar. 1, 2017), https://www.hartenergy.com/exclusives/lucrative-use-3-d-printing-oil-and-gas-industry-176387#p=2 [https://perma.cc/YU49-YBK7].

manufacturing today.[19] The flexibility for "mass customization, enables firms to economically build custom products in small quantities."[20] In the healthcare world, 3D printing is growing in both its instructive and constructive applications.[21] Not only are healthcare organizations and professionals using it to teach and inform providers, but they are also using it in preparation for surgery and in creation of implantable and external medical devices, just to name a few applications.[22]

The application of 3D printing in medical devices poses a challenge for FDA regulation, as current medical device regulation, as written, is focused primarily on traditionally manufactured devices. Pre-market approval, the FDA's current approval process, includes many steps with quality checks throughout the development, research, and implementation of the device in question.[23] 3D printing's production cycle tends to have drastically different steps in design, manufacturing, and implementation of the device itself. The FDA's current analysis of 3D printing in the medical industry has grown dramatically since the technology caught on in the healthcare industry, but there are still unanswered questions, which this Comment aims to address.

A. 3D Printing, Origins, Processes, and Uses

3D printing, or additive manufacturing, is a type of manufacturing that creates objects by taking complex digital representations of an object and printing it, layer by layer, until the object is completed.[24] To begin the process, solids (most typically plastics) are added to the printer where they are converted into a liquid-like material.[25] The flexibility of the material in the printer itself allows each slice to be

19. Barry Berman, *3-D Printing: The New Industrial Revolution*, 55 BUS. HORIZONS 155, 160–61 (2012).

20. *Id.* at 156.

21. Helena Dodziuk, *Applications of 3D Printing in Healthcare*, 13 POLISH J. THORACIC CARDIOVASCULAR SURGERY 283, 283 (2016).

22. Applications for 3D printing in healthcare "include customized implants and prosthetics, medical models, and medical devices that revolutionize healthcare and may even disrupt many areas of traditional medicine." *Id.* at 283 (citation omitted).

23. *See PMA Approval Process*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm047991.htm [https://perma.cc/7Q46-7TEV].

24. Andrew Walker, *3D Printing For Dummies: How do 3D Printers Work?*, INDEP. (June 21, 2013, 5:10 PM), http://www.independent.co.uk/life-style/gadgets-and-tech/features/3d-printing-for-dummies-how-do-3d-printers-work-8668937.html [https://perma.cc/398F-9EVA].

25. *Id.*

added to the design with extreme detail.[26] While 3D printing has been around since the early 1980s, the cost and access to 3D printing technology generally made it difficult to use in practical settings.[27] Now, the technology in 3D printers has gotten much cheaper and more accessible, even to the every-day consumer.[28] Currently, your average citizen can buy a 3D printer for under $500.[29] 3D printing allows consumers, small business users, and commercial users to design, fabricate, and iterate without having to use traditional manufacturing techniques. Its accessibility and low cost has caused the technology to explode in many industries where the technology had not previously been considered.

In many ways, the popularity of 3D printing is attributable to the low cost of entering the business. Unlike traditional manufacturing, 3D printing does not require quantity to keep costs low. In traditional manufacturing, such as injection mold manufacturing (where a mold of an object is created, filled, and produced), the higher the quantity of the item, the cheaper it is to produce. In contrast, 3D printing can produce an individual design at relatively low cost. 3D printing reduces cost by reducing waste—that is, in some 3D printing processes, over 98% of the material is utilized in the final product.[30] This efficiency is markedly different from traditional manufacturing techniques that require extensive processes for melting down and re-using material that was wasted in the original injection mold process. The processes used in 3D printing reduce this waste because the process builds an object from the ground up.

3D printing makes an object by slowly adding material at each level of the object itself.[31] This process is done with micro-slices of the object placed on top of one another until the object takes form, and is ultimately complete.[32] For example, if a user wanted to print a pencil, the process might begin with printing the eraser, slowly adding material until the eraser is the proper size before moving on to the actual wood, lead, and exterior lacquer of the pencil. In the end, the user would have

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26. *Id.*

27. Alicia Miller, *The Evolution of 3D Printing, Past, Present, and Future*, 3D PRINTING INDUSTRY (Aug. 1, 2016, 11:56 AM), https://3dprintingindustry.com/news/evolution-3d-printing-past-present-future-90605/ [https://perma.cc/L5ZG-WDPZ].

28. *Id.*

29. Dong Ngo, *3D Printing in Brief and a Few Printers for Your Consideration*, CNET (Jan 13, 2016, 11:47 AM), https://www.cnet.com/news/3d-printing-in-brief-here-are-a-few-printers-for-your-consideration/.

30. *How 3D Printers Work*, U.S. DEP'T ENERGY (June 19, 2014), https://energy.gov/articles/how-3d-printers-work [https://perma.cc/AST4-A42G].

31. *Id.*

32. Walker, *supra* note 24.

a pencil created from the printer rather than through an assembly line or injection mold manufacturing system.

The first step in the process is taking highly detailed scans of an object which are then uploaded to a computer.[33] Then, using Computer-aided Design (CAD) programs, those scans are turned into three dimensional designs.[34] The design is usually broken down into micro-slices, or cross-sections, stacked on top of one another. Once this design is ready to go, most 3D printers use the material extrusion method.[35] The materials must be added to the 3D printer.[36] Many different materials are used in 3D printing, such as metal, polymers, and plastics.[37] These materials are usually reduced to a liquid-like material that is then ejected from the printer.[38] In many ways, 3D printing is like using a large glue gun to build an object.[39]

Currently, 3D printing has many varied uses, including as a way to prototype new designs,[40] print custom devices,[41] and bring educational materials to classrooms.[42] In the healthcare world, 3D printing is becoming increasingly important. The uses in the healthcare world are varied, with physicians thinking of new ways to use 3D printers to assist in patient care. For example, surgeons can use 3D printing to build accurate models of their patient's mechanical

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33. *How 3D Printers Work*, *supra* note 30.

34. *Id.*

35. Nikhil A, *3D Printing Processes- Material Extrusion (Part 2/8)*, ENGINEER'S GARAGE, https://www.engineersgarage.com/articles/3d-printing-processes-material-extrusion [https://perma.cc/2ZCK-H2KH]; There are at least 10 types of 3D printing that are available in 2019 including Material Extrusion, Fused Deposition Modeling (heated material pushed through a nozzle to build the design layer by layer), Vat Polymerization (where a vat of material is "selectively cured by a light source"), Stereolithography (where a vat of material is selective cured by a laser), and Powder Bed Fusion (where "thermal energy will selective induce fusion between powder particles . . . to create a solid object"), just to name a few. All3DP, *All 10 Types of 3D Printing Technology in 2019*, ALL3DP (January 15, 2019), https://all3dp.com/1/types-of-3d-printers-3d-printing-technology/ [https://perma.cc/6X4U-AA97].

36. *See How 3D Printers Work*, *supra* note 30.

37. *Id.*

38. *Id.*

39. *Id.*

40. Amit Chowdhry, *What Can 3D Printing Do? Here Are 6 Creative Examples*, FORBES (Oct. 8, 2013, 11:25 AM), https://www.forbes.com/sites/amitchowdhry/2013/10/08/what-can-3d-printing-do-here-are-6-creative-examples/#21b04e325491 [https://perma.cc/5P23-ESYR].

41. *See id.*

42. For example, the Smithsonian Institution's National Portrait Gallery has made scans of President Abraham Lincoln's death mask available to schools around the country so they can 3D print their own replica of the mask for use in the classroom. Educators, SMITHSONIAN 3D DIGITIZATION, https://3d.si.edu/article/educators [https://perma.cc/28DR-58YH].

systems.[43] By seeing and feeling a model of a patient's malformed bone, the surgeon can have a much better idea of what they will be working with before the surgery actually begins.[44] Similarly, in the pharmaceutical world, 3D printed drugs customized to a patient's individual chemical needs are picking up speed, with the first 3D printed drug approved by the FDA as recently as 2015.[45] 3D printing is also important in the creation of true customized patient prosthetics, that can be crafted to match the bone structure, height, or weight of the individual patient. The possibilities do not stop there; 3D printing is now being contemplated for use in replacing the actual tissues in a patient's body. This technology is referred to as bioprinting.

Bioprinting is in development for replacing certain soft tissues and organic structures within the body.[46] Proponents of bioprinting believe that in the future the process will produce printed tissues as complex as hearts and other organs.[47] Bioprinting, for now, is relatively limited, and includes only simple biological tissues.[48] Bioprinting has many exciting potential uses, including potentially reducing or eliminating completely the shortage of organs available for transplant.[49] It also raises troubling ethical questions about ownership of the biological material, who has the right to create the bioprinted objects in the first place, and if bioprinted objects should be created at a profit.[50]

As an emerging industry in terms of scope and accessibility, 3D printing poses interesting questions about regulatory schemes. For

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43. *The 3Rs of 3D Printing: FDA's Role*, U.S. FOOD & DRUG ADMIN. (Dec. 2016), https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm533992.htm [https://perma.cc/A43C-EDNJ].

44. *See id.*

45. Assraa H. Jassim-Jaboori & Moses O. Oyewumi, *3D Printing Technology in Pharmaceutical Drug Delivery: Prospects and Challenges*, 4 J. BIOMOLECULAR RES. THERAPEUTICS 1, 1 (2015).

46. *3D Bioprinting of Living Tissues*, WYSS INST., https://wyss.harvard.edu/technology/3d-bioprinting/ [https://perma.cc/6PVL-B5NN].

47. *Id.*

48. *Id.*

49. Dave Fornell, *The Future of 3-D Printing in Medicine*, DIAGNOSTIC & INTERVENTIONAL CARDIOLOGY (May 17, 2016), https://www.dicardiology.com/article/future-3-d-printing-medicine [https://perma.cc/HJ84-PMN8].

50. Niki Vermeulen et al., *3D Bioprint Me: A Socioethical View of Bioprinting Human Organs and Tissues*, J. MED. ETHICS 1, 5 (2017), http://jme.bmj.com/content/medethics/early/2017/03/20/medethics-2015-103347.full.pdf [https://perma.cc/5KAB-DJMR]. It should be noted that the FDA has declined to address bioprinting at this time, as "Biological, cellular or tissue-based products manufactured using [Additive Manufacturing (AM)] technology may necessitate additional regulatory and manufacturing process considerations and/or different regulatory pathways. Therefore, AM questions pertaining to biologics, cells or tissue products should be directed to the Center for Biologics Evaluation and Research (CBER). US. FOOD & DRUG ADMIN., supra note 4, at 2.

example, who should report on quality outcomes for devices: the manufacturer, the hospital, the physician, someone else? Similarly, how do you normalize reporting data to account for the individualized nature of 3D printed medical devices, especially in light of patient transparency and increasing access to informed patient decision making? These questions are important to keep in mind when assessing the FDA regulatory scheme for 3D printing the medical field, as the FDA's role is, in part, to hold manufacturers accountable for their manufactured medical device products.[51]

B. Medical Device Regulation—An Overview

Relevant to a discussion of 3D printing in the healthcare industry is how the FDA regulates medical devices in general.[52] The FDA is careful to regulate medical device manufacturing and final product from start to finish.[53] A typical medical device takes an average of around six months to get from the beginning to the end of the FDA approval process.[54] Generally medical devices go through a sequence of approval steps, with different classes of devices subject to different approval processes.[55] The FDA's process includes registration and listing.[56] Similarly, depending on the type of medical device, it may also have to go through pre-market notification or pre-market approval.[57] Other FDA processes include Investigational Device Exemption (or clinical studies), Quality Systems or Good Manufacturing Processes, labeling, and Medical Device Reporting.[58] This extensive process vets medical devices at many different stages to check for quality and safety standards.[59] In addition to these steps, there are also three classes of

51. *See What We Do: FDA Mission*, U.S. FOOD & DRUG ADMIN. (April 4, 2017), https://www.fda.gov/AboutFDA/WhatWeDo/#mission [https://perma.cc/YYT2-QGDH].

52. *Overview of Device Regulation*, U.S. FOOD & DRUG ADMIN. (Feb. 21, 2018), https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm [https://perma.cc/6YQ4-EA94].

53. *Id.*

54. EMERGO GROUP, HOW LONG IT TAKES THE US FDA TO CLEAR MEDICAL DEVICES VIA THE 510(K) PROCESS (2017), https://www.emergogroup.com/sites/default/files/emergo-fda-510k-data-analysis-2017.pdf [https://perma.cc/4VZZ-98M7].

55. *Overview of Device Regulation*, *supra* note 52.

56. *Id.*

57. *Id.*

58. *Id.*

59. U.S. FOOD & DRUG ADMIN., INFORMATION SHEET GUIDANCE FOR IRBS, CLINICAL INVESTIGATORS, AND SPONSORS: FREQUENTLY ASKED QUESTIONS ABOUT MEDICAL DEVICES 1–2 (Jan. 2006),

medical devices. Class I devices are devices that are relatively low risk that the FDA has approved and do not need pre-market approval.[60] Class I devices are usually simple devices like bandages and tongue depressors.[61] Class II devices are more complex and require more process before they are approved.[62] Finally, Class III devices are devices of which the FDA is more suspicious and believe pose a higher risk.[63]

Registration is when the manufacturer of the device registers its establishments with the FDA,[64] informing the FDA that it is a manufacturer of medical devices. Next is listing, or essentially filing notice with the FDA that the device is up for FDA approval.[65] Specification developers are included on this list, which would include the developers of 3D printed designs.[66] Class II devices go through additional steps. After the device has been listed, Class II devices move on to apply for pre-market notification.[67] When the application is reviewed and returned, it is the first official notification from the FDA authorizing the manufacturer to distribute the device.[68] This application must show that the device is substantially equivalent to one legally in commercial distribution in the United States.

Class III devices, or devices that "support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury," must go through pre-market approval.[69] Pre-market approval involves the manufacturer submitting to the FDA clinical data and support for the claims they made about the device itself.[70] Pre-market approval is an extensive process that requires substantiation on the part of the manufacturer itself.[71] Another, similar process is often referred to as the "510(k) process" and represents several steps that must be

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https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm127067.pdf [https://perma.cc/869A-BQNJ].

60. *See Overview of Device Regulation*, *supra* note 52.

61. *See Product Classification*, U.S. FOOD & DRUG ADMIN. (Mar. 11, 2019), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm [https://perma.cc/S6QZ-DUQN].

62. *See Overview of Device Regulation*, *supra* note 52.

63. *Id.*

64. 21 C.F.R. § 807.20(a) (2018).

65. *Id.*

66. *Id.*

67. 21 C.F.R. § 807.81 (2018).

68. *Id.*

69. *Premarket Approval (PMA)*, U.S. FOOD & DRUG ADMIN. (April 5, 2019), https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketapprovalpma/ [https://perma.cc/469Z-UJ5D].

70. 21 C.F.R. 814.20 (2018).

71. *Id.*

completed before the device is approved for distribution.[72] In all, the process is a culmination primarily consisting of clinical trials to test for adequate characteristics in biocompatibility, physical characteristics, efficacy, and patient risk.[73] In a win for manufacturers, if a device is substantially similar in risk and application to a device already available on the market, the pre-market approval process may be sped up or bypassed completely.[74]

This pre-market FDA approval for devices also includes quality system regulation (QS) or Good Manufacturing Practices (GMP) assurances. This section of the FDA medical device regulation focuses on the actual manufacturing of the devices, including methods for design, purchase, and packaging. The FDA uses these requirements to ensure that the devices have adequate controls before they reach the consumer.[75] Finally, medical device manufacturers must report any incident where the device malfunctioned or contributed to significant injury. This regulation is designed to address and react to problems in the devices quickly.[76]

C. Exemptions from Traditional Medical Device Regulation

Realizing that in some cases the FDA approval process can potentially limit access to patient care, the FDA included an exemption for custom medical devices.[77] The custom medical device exemption is rooted in a rationale that it would be generally unreasonable to have each extremely individualized class III device submit applications for pre-market approval. In order to qualify for the CDE, the device must meet several requirements, including:

1. The device is created or modified in compliance with an order of a physician or dentist.
2. It deviates from performance standards of other similar devices.
3. It is not generally available in its finished form.
4. It is specific to an individualized pathology that no other device is domestically available to treat.
5. It is intended to meet the needs of an individual patient.
6. It is assembled from components or manufactured and finished on a case-by-case basis.

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72. *Premarket Notification 510(k)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketnotification510k/default.htm [https://perma.cc/V6A9-JYGK].

73. *Id.*

74. *Id.*

75. 21 C.F.R. § 807.81 (2018).

76. 21 C.F.R. § 803 (2018).

77. U.S. FOOD & DRUG ADMIN., *supra* note 3, at 1–2.

7. It may have common or standardized design characteristics.
8. It is for the purpose of treating a sufficiently rare condition, such that conducting clinical investigation would be impractical.
9. The device may be manufactured at a rate of no more than 5 units per year.[78]

These requirements center around an idea of customization. The CDE has been the focus of significant uncertainty in the medical device industry,[79] and the FDA has released guidance to help medical device manufacturers know if they qualify.[80] One of the most significant parts of that guidance is the definition of five units per year. Essentially, the five units per year should be interpreted as fewer than 5 *patients* per year. That is, if one patient needs more than five different units of a device per year, then the device may still fall under the custom medical device exemption. To be clear, the CDE is relatively narrow.[81]

For more traditional medical devices, the CDE has primarily focused on devices such as prosthetics. Since many prosthetics are necessarily custom to the patient they are used for, the custom medical device exemption may seem like a logical next step for those manufacturers. The FDA has not shied away from litigating this particular issue. In 2009, the Eleventh Circuit handed down a famous decision interpreting the FDA's CDE and who is *not* included in it.[82] In *United States v. Endotec*,[83] the Eleventh Circuit found that if a doctor testifies that a commercially available device does not meet the patient's needs based on a clinical diagnosis, then that is enough to show that the device is not available to other physicians or providers.[84]

The FDA, in recently issued 3D printing guidance, is clear that unless a 3D printed medical device otherwise meets the standards for a CDE, then they do not fall under that category. The "commercially unavailable" holding is particularly relevant to 3D printing, as a clinical diagnosis may be all that is necessary to prove that a custom printed

78. Dave Fornell, *FDA Changes Rules for Custom Medical Device Exemption*, DIAGNOSTIC & INTERVENTIONAL CARDIOLOGY (Oct. 13, 2016), https://www.dicardiology.com/article/fda-changes-rules-custom-medical-device-exemptions [https://perma.cc/RQS3-VQZZ]; *see also* U.S. FOOD & DRUG ADMIN., *supra* note 3, at 3–4.

79. Lindsey Adams-Hess & Kim Schmid, *Law and Regulation of 3D Printed Medical Devices*, BOWMAN & BROOKE LLP (Mar. 21, 2016, 11:58 AM), https://www.bowmanandbrooke.com/insights/law-and-regulation-of-3d-printed-med-device.

80. U.S. FOOD & DRUG ADMIN., *supra* note 3, at 1–2.

81. Adams-Hess & Schmid, *supra* note 79.

82. *United States v. Endotec, Inc.*, 563 F.3d 1187, 1196–200 (11th Cir. 2009).

83. 563 F.3d 1187 (11th Cir. 2009).

84. *Id.* at 1204.

medical device is commercially unavailable,[85] and seemingly increases the reach of the exemption to potentially cover clinically ordered custom devices. To be clear, this does not include all patient specific designs. Instead, it would include designs that are *brand new*, rather than modified from a stock design to match a patient's anatomy. What is unclear is how much modification may occur before a device is considered sufficiently "custom" to qualify for the CDE. The *Endotec* decision makes this distinction even less clear as it shows that a doctor may be able to help qualify a device for the CDE by a clinical diagnosis. Nevertheless, in other parts of the decision, the court sided with the FDA, concluding the CDE is a relatively high standard to meet.[86] The Eleventh Circuit's holdings in *Endotec* are both friendly to the FDA's flexibility around the CDE, as well as friendly to the ultimate scope of the exemption, especially as it relates to 3D printing.

D. 3D Printing as the FDA Sees It Now

3D printing and additive manufacturing has been in the mind of the FDA for several years now, with the agency looking for appropriate ways to regulate the industry.[87] Currently, the FDA views its role in 3D printing as three-fold: it researches, regulates, and provides a resource for the industry.[88] That role also includes issuing guidance for 3D printed devices—the FDA released final, non-binding guidance on the topic in the CDE, however, appears to include 3D printed devices that are created specifically for patients. In 2014, the FDA released additional guidance on what qualified as a CDE[89]—and 3D printed devices must meet these additional guidelines in order to avoid the pre-market approval that is so difficult to overcome.[90]

The FDA is also concerned about the quality system issues that arise when the 3D printed devices are necessarily individualized. The FDA's quality system requirements for non-CDE devices are stringent, and have been harmonized with international standards for medical devices.[91] It is less clear, however, how stringent those requirements

85. *Id.*

86. *Id.* at 1196–200.

87. *3D Printing of Medical Devices*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/3DPrintingofMedicalDevices/default.htm [https://perma.cc/M9H2-NEJE].

88. *The 3Rs of 3D Printing*, *supra* note 43.

89. U.S. FOOD & DRUG ADMIN., *supra* note 3, at 1–2.

90. TECHNICAL CONSIDERATIONS FOR ADDITIVE MANUFACTURED MEDICAL DEVICES, *supra* note 4, at 19, 21–22.

91. The FDA has "harmonize[d] its quality system regulation with [International Organization Standardization] standards." *What is the Relationship between FDA's Quality System Regulation for Devices, Part 820 and ISO 9001: 2000?*

are for the CDE devices themselves. Similarly, 3D printing's major component, the digital scans and representations, are recommended to comply with certain technical considerations from the FDA. In the guidance document, the FDA submits extremely specific technical considerations for the industry to consider.[92] The draft guidance outlines that patient-matched designs will generally not meet the CDE unless they meet all the specific guidelines of section 520(b).[93] In those patient-matched designs, the effects of the imaging as well as the interactive models should be considered by the manufacturer.[94] To be clear, this guidance is not binding but does provide crucial, if not incomplete, direction for 3D printed device manufacturers.[95]

II. OVER AND UNDER INCLUSIVE: HOW THE CURRENT REGULATORY SCHEME FALLS SHORT

Despite issuing guidance specific to 3D printing, the FDA's current regulatory scheme including the CDE, leaves the 3D printing technology with regulatory uncertainty. As the technology grows and evolves, clarity in the regulations will make it easier for 3D printed devices to help to deliver patient care. Because the industry is so unique, a specific regulatory scheme would help the FDA effectively respond to the new technology by getting in line with the innovative industry. 3D printed devices need their own category for medical device regulation, outlining requirements for specifications, materials, and adequate clinical trials for 3D printed devices that are considered Class III medical devices. The need for an independent regulatory scheme is especially important as the uncertainty surrounding 3D printed devices leaves questions that increase risks for manufacturers that want to enter the market.

Compounding the conundrum of non-specific regulation are the expanded new uses and research into 3D printed devices. As these new uses evolve, new patient safety considerations will likely evolve as well, introducing a competing goal with flexible and innovative uses of the technology. It is a tall order to balance both growth and innovation with patient safety, further showing the FDA should consider a

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U.S. FOOD & DRUG ADMIN., https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/UCM134625.pdf [https://perma.cc/QD5S-UHRC].

92. TECHNICAL CONSIDERATIONS FOR ADDITIVE MANUFACTURED MEDICAL DEVICES, *supra* note 4, at 1–2.

93. *Id.* at 8–9.

94. *Id.*

95. *Id.* at 1–2.

regulatory scheme specifically tailored to the medical applications of 3D printing.

Similarly, 3D printing is not only used in the medical industry for printing medical devices. 3D printing is also used in a variety of other medical contexts, such as customizable pharmaceuticals, modelling surgery, and potentially printing human tissue and organs.[96] The FDA's work in the 3D printed medical device sector can help inform changes to the regulatory schemes down the line for the less developed areas of 3D printing in the medical context. Doing this work up front, beyond non-binding guidance to identify manufacturing, materials, specifications, and reporting best practices in regulatory rules will not only help the FDA create an efficient and balanced regulatory scheme for 3D printed medical devices, but it will also lay important ground work for regulating 3D printing in the future for other applications in the medical world. The first part of this analysis argues that an adjusted or completely new regulatory scheme for 3D printed devices is beneficial to patients and manufacturers alike. The analysis also proposes solutions for an adjusted regulatory framework to reflect the ideals of innovation and patient safety.

A. Change Is Good—How Adjustments to 3D Printed Device Regulation Is Beneficial

The medical device industry and the 3D printing industry are important for increasing access to patient care, reducing cost per patient, and addressing individualized patient needs. By increasing patient access to safe, custom devices, the FDA can help decrease the risk associated with mass produced medical devices. With mass produced medical devices, the patients face the risk of the medical device, implants in particular, not fitting perfectly in their body.[97] The body may reject the device.[98] In contrast, custom 3D printed devices are designed with the patient's body in mind, vastly reducing the risk by decreasing surgery time and healing while also reducing pain.[99]

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96. *Id.* at 2, 9–10.

97. Implantable medical devices tend to be more invasive and smaller than other, non-implantable devices. For example, implanting a device in the heart is considered more difficult because the heart is considered a "hostile environment" since it is always moving. These are risks associated with implantable medical devices. Shawn H.E. Harmon, Gill Haddow & Leah Gilman, *New Risks Inadequately Managed: The Case of Smart Implants and Medical Device Regulation,* 7 LAW INNOV. TECH. 231, 234 (2015).

98. The body may reject the device in a process known as bio-fouling that causes more difficulties than the "original condition that necessitated the device." *Id.* at 235.

99. Juliet Van Wagenen, *Is Healthcare on the Cusp of a 3D Medical Printing Revolution?*, HEALTH TECH (Aug. 21, 2017)

Because of these benefits, 3D printing is an important and growing part of the healthcare industry,[100] and the FDA should regulate the process to ensure the benefits still outweigh the risks. The FDA's regulatory scheme is important to protect consumer health and safety by ensuring that these patient-specific devices are up to high quality standards, are safe, and prove effective before they are ever used in a patient's care.

1. INCREASED FDA REGULATIONS FOR 3D PRINTING BENEFITS PATIENTS

While critics of the FDA's relatively extensive regulatory scheme claim that federal regulation of the medical device industry slows down care to patients,[101] this position overlooks many benefits to patients that come from FDA oversight. For example, the FDA's approval process increases patient trust in the devices and drugs that they are prescribed during their medical treatment and care. Patients generally trust the FDA and its choices in regulations.[102] Similarly, the approval process increases transparency when the medical device fails or malfunctions. Transparency in the FDA's approval process arguably increases patient access to information that could aid in their care decisions.[103] The FDA approval process also sets industry standards for quality and safety at a threshold that keeps patients, not profits, as the highest priority.[104] A properly tailored regulatory scheme could bring these benefits to the 3D printed medical device industry.

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https://healthtechmagazine.net/article/2017/08/healthcare-cusp-3d-medical-printing-revolution [https://perma.cc/QV2N-MAS2].

100. 3D printing forecasted to show the most growth in the healthcare services segment. Allied Market Research, Press Release, *3D Printing Healthcare Market Is Expected to Reach $2.3 Billion, Globally, by 2020*, https://www.alliedmarketresearch.com/press-release/3d-printing-healthcare-market.html [https://perma.cc/8TM4-JXRU].

101. "Medical device companies say that if the FDA doesn't speed up the process, foreign competitors will win the innovation race and hospitals in the U.S. will see patients go overseas for cutting-edge treatments that domestic hospitals can't offer." Barlas, *supra* note 10, at 409.

102. Sarah D. Kowitt, et al., *Awareness and Trust of the FDA and CDC: Results from a National Sample of U.S. Adults and Adolescents*, PLOS ONE (May 16, 2017), https://doi.org/10.1371/journal.pone.0177546 [https://perma.cc/MSX4-GQDJ].

103. Marta Pagán-Ortiz, *Researchers Make Recommendations to Improve FDA Transparency*, MAD AM. (Mar. 28, 2017), https://www.madinamerica.com/2017/03/researchers-make-recommendations-improve-fda-transparency/ [https://perma.cc/5VHX-WRLV].

104. *Id.*

2. TRUST IN THE PRODUCTS

Not only do FDA regulations build quality standards and safety measures for medical device companies, they also build trust with patients who receive and use the medical devices. One illustration of this proposition is Americans' perceptions of the generic drug approval process.[105] This process puts the FDA stamp of approval on generic drugs before they are available to American consumers for their medical ailments.[106] According to a recent study, Americans trust products that have FDA approval more than products that do not.[107] Despite lacking knowledge of the mechanics of the approval process, the study's respondents expressed "support for the safety and effectiveness of generic drugs."[108] This conclusion "suggest[ed] trust in the regulator's decision making" and illustrated that the FDA approval process increases confidence in the safety of a product.[109]

Sometimes, Americans even want the FDA to regulate areas in the health industry where no regulations currently exist.[110] For example, a majority of surveyed users of dietary supplements wanted a requirement of FDA approval before the supplements could be sold.[111] The respondents agreed the FDA should have power to ensure products would be "remove[d] . . . from the market if they proved unsafe."[112] These examples illustrate how FDA approval and regulation bolsters public trust in those regulated products. Patient-specific, 3D printed devices will also benefit from more specified FDA regulation. It will show patients that 3D printed devices are more than innovative technology and are also safe and effective.

3. INFORMING THE PUBLIC

The FDA approval process also keeps the public informed about the pertinent risks associated with different medical devices. The reporting requirements help to inform patient choice and increase patient autonomy in their medical treatment. With FDA approval,

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105. Aaron S. Kesselheim et al., *Do Patients Trust the FDA?: A Survey Assessing How Patients View the Generic Drug Approval Process*, 26 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 694, 695, 699 (2017).

106. *Id.*

107. *Id.*

108. *Id.* at 699.

109. *Id.*

110. Robert J. Blendon et al., *Americans' Views on the Use and Regulation of Dietary Supplements*, 161 ARCHIVES INTERNAL MED. 805, 805 (2001).

111. The majority of respondents wanted FDA regulation to ensure purity and consistent dosage, and no harmful effects. *Id.* at 809.

112. *Id.* at 808–09.

products gain new exposure to the market.[113] Similarly, patients can make informed choices about their medical care. The FDA's process fleshes out and sets minimum standards for the safety and efficacy of medical devices.[114] A specific regulatory category for 3D printed devices would make it easier for the public to know when something goes wrong, especially since failures would be explicitly reported as a result of adherence to quality reporting rules.

Other medical devices are subject to stringent reporting standards,[115] including reporting when the medical device malfunctions or fails.[116] Often, reporting requirements of regulatory schemes are the only reliable source of consumer information available to patients and providers.[117] Reporting requirements allow patients to know exactly what risks they encounter when using a particular product, in addition to the standard risks that come along with any medical procedure. Reporting makes it easier for patients, as well as doctors and healthcare organizations, to make better choices about which products, designs, and scans to use when printing 3D devices.[118]

4. FDA PRE-MARKET APPROVAL SETS INDUSTRY STANDARDS FOR QUALITY

The FDA approval process also enhances safety and quality in the medical industry by setting industry standards. The approval process necessarily sets a standard to which products must conform if they want approval. In a 2011 campaign to increase quality standards in their medical devices, the FDA noted "increased product quality also benefits hospitals, payers, health care providers, and patients by generating confidence among them that the devices they rely on will

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113. For example, the FDA publishes a list each year of approved medical devices that is accessible to patients. *See 2019 Device Approvals*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm630196.htm [https://perma.cc/4KGS-MGX3]. Further, the FDA also works to engage patients in the regulatory processes, and has created patient engagement initiatives to keep patients informed. *See, e.g.*, *Learn About FDA Patient Engagement*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/ForPatients/PatientEngagement/default.htm [https://perma.cc/7W9W-FM27].

114. Linda Baird & Matthew Jacobson, *3D Printing and Its Impact on Medical Device and Health Care*, *in* 3D PRINTING OF MEDICAL DEVICES: WHEN A NOVEL TECHNOLOGY MEETS TRADITIONAL LEGAL PRINCIPLES (1st ed.).

115. 21 C.F.R. § 803.50 (2018).

116. *Id.*

117. TED FUHR, KATY GEORGE & JANICE PAI, MCKINSEY CTR. FOR GOV'T, THE BUSINESS CASE FOR MEDICAL DEVICE QUALITY 7 (2013).

118. *Id.*

perform as intended."[119] Without the FDA, the standard for quality, manufacturing, and safety would be set by the industry itself, as well as by market forces.[120] In fact, "[r]egulatory approval sets a baseline and is often the only objective measure of product quality."[121] These industry standards are important across the medical industry, with insurance companies paying close attention. In fact, they even help to define how insurance companies will cover patients' care. Many insurance companies use FDA approval as a requirement for coverage.[122] This reliance on FDA approval is an indication that the FDA standards and guidelines provide important litmus tests for devices and drugs across the medical industry.

Similarly, the FDA's process continually checks quality standards and makes it visible for patients.[123] These visibility efforts are important for patients as many medical device companies experience difficulties in increasing transparency for patients.[124] The FDA's efforts to increase medical device quality can help combat these transparency issues.[125] For example, Theranos, a medical device company, was recently audited and punished by the FDA for poor quality standards.[126] By exposing and punishing poor quality standards, the FDA ensures that

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119. *Case for Quality*, FOOD & DRUG ADMIN. (Last updated Dec. 27, 2017), https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm378185.htm [https://perma.cc/FTF7-ATHL].

120. *See* FUHR, GEORGE & PAI, *supra* note 117 at 7.

121. *Id.* at 6.

122. *See, e.g.*, Independence, Provider News Center *Coverage of Non-FDA Approved Drugs* (Dec. 1, 2015), http://provcomm.ibx.com/provcomm/provcomm.nsf/1f6044fcdb96fdcc8525791f00604004/403cb2df9960d64f85257f08005df92e!OpenDocument; Horizon Blue Cross Blue Shield of New Jersey, *Change in Coverage for non-FDA approved products*, (May 4, 2016), https://www.horizonblue.com/providers/news/news-legal-notices/change-coverage-for-non-fda-approved-products [https://perma.cc/3G7L-SSL8]; Aetna Better Health, *Off-Label Use of FDA-Approved Drugs Policy* (Dec. 2016) (noting stringent requirements for non-FDA approved, or "off label" drugs and devices: "Coverage will not be provided for off-label usage, unless as outlined"), https://www.aetnabetterhealth.com/pennsylvania/assets/pdf/pharmacy/Penn%20Off-Label_Use_Guideline.pdf [https://perma.cc/S7V2-64Q3].

123. Elizabeth Lopatto & Arielle Duhaime-Ross, *FDA Inspector Slams Theranos for Poor Quality Management,* THE VERGE (Oct. 27, 2015), https://www.theverge.com/2015/10/27/9621026/fda-theranos-lab-inspection-elizabeth-holmes [https://perma.cc/RWE3-MVSF].

124. One of the "key challenges related to improving quality" in medical devices is "low quality transparency, driven by a lack of information for consumers and decision-makers around comparative quality . . . time to market competition, and cost pressures, limit significant quality upgrades." U.S. FOOD & DRUG ADMIN., UNDERSTANDING BARRIERS TO MEDICAL DEVICE QUALITY 4 (Oct. 31, 2011).

125. The FDA "focus[es] regulatory efforts to address industry quality gaps." *Id.*

126. Lopatto & Duhaime-Ross, *supra* note 123.

company's products are safer for patients. These industry standards are important to ensure patient safety and keep the industry free of unnecessary errors.

Institutions who use additive manufacturing can innovate while continuing to provide for adequate controls on patient care.[127] Healthcare organizations and medical device manufacturers have a tremendous opportunity to shape the regulatory environment surrounding 3D printed medical devices simply by buying into and contributing to the rules early on.[128] Early buy in will help the medical community stay at the cutting edge of the 3D printing technology without compromise to patient safety.[129] In the end, "the ultimate goal is to introduce a truly beneficial medical device to the market."[130] FDA approval and regulation can help ensure that goal is accomplished.[131]

B. The Current Regulatory Scheme for 3D Printed Devices Is Inadequate

Though the FDA has come a long way in regulating 3D printed medical devices, several important issues remain unsolved. For example, while the FDA has explicitly noted that most patient specific medical devices that are produced via additive manufacturing are not covered by the CDE, it is unclear what products would be covered. The CDE, like other rules built off of the foundation of traditional manufacturing, is not clear when a patient specific device moves from regular printing and into the custom device realm. The FDA created the CDE to accommodate patients who have medical devices that are truly custom and therefore going through the approval process would both be burdensome for the manufacturer and as well as overly costly for the FDA.[132] By definition, 3D printed devices are *patient specific*, but patient specificity does not always mean that a device will qualify for the CDE. Instead, a device must independently meet the requirements of the CDE—but for 3D printed devices the line is fuzzy. Specific

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127. "Agency guidelines are not meant to be a barrier to innovation. Rather, by taking advantage of FDA's recommendations when submitting [additive manufactured] products, innovative devices not only get to market quicker but also provide increased treatment options to those with specialized physiologies." MUTHAR SHAMSI ET AL., DELOITTE INSIGHTS, 3D OPPORTUNITY FOR HEALTH CARE: DEMYSTIFYING FDA REGULATIONS FOR MEDICAL DEVICES 12 (Feb. 21, 2017).

128. *See* Drues, *supra* note 11 (suggesting that companies "figure out . . . [what] is necessary from an engineering perspective and from a medical perspective, and then go work with FDA to make it happen").

129. *Id.*

130. *See* Shamsi, *supra* note 127.

131. *Id.*

132. *See id.*

discussion and rules would help manufacturers on the cutting edge of 3D printed medical devices to thread the needle between patient matched design and the CDE.

Further, the current regulatory scheme does not help a party decide when they should file a Pre-Market Approval application.[133] Just as in the ambiguities surrounding the line of demarcation between custom devices and patient matched devices, manufacturers are not given additional guidance by the FDA on when a device should be sent in for Pre-Market Approval. This problem is compounded when hospitals and other healthcare providers (who may or may not be manufacturers)[134] are printing patient specific devices that perhaps are not custom, but could also fall under premarket approval. The need for regulatory clarity in this area will help manufacturers respond more quickly and surely to patient needs.

C. A Proposed Regulatory Scheme

As discussed earlier, the FDA's approval process and regulatory schemes are beneficial to most medical devices and increase consumer protection. The additive printing industry will also benefit from tailored FDA regulations to match the growing use of custom 3D printed devices in patient care across the country. The FDA should alter its current regulatory scheme and add specific regulatory categories for 3D printed devices. The new scheme should include elements designed specifically to address the unique nature of additive printing as a manufacturing process, particularly in the area of premarket approval. The advantages of the regulatory approval process in terms of patient safety, trust, and care, are important for medical devices and should be a part of the regulatory scheme for 3D printed medical devices. This way, the FDA can keep up with current technological advances without endangering patient safety and choice.

1. FOR FLEXIBILITY'S SAKE: THE FDA SHOULD CREATE A SEPARATE REGULATORY CATEGORY FOR 3D PRINTED DEVICES

3D printing should retain a separate status under FDA regulations to account for the unique nature of the manufacturing process and its growing use in the medical field. These regulations specific to 3D printing should include specifications for the process of creating the

133. Hunt & Mullen, *supra* note 4.

134. *See infra* Section II.C.4.

device[135] as well as the process for what happens after the device is complete.[136] It will mirror the current regulatory scheme in terms of structure, but will also include important deviations where the regulatory scheme is inadequate to address the unique needs of 3D printing for medical devices.[137] To be clear, this new regulatory category would still fall under the medical device classifications already set in place by the FDA, but include elaborations and exceptions for additive printed devices. A separate regulatory category from the FDA would increase the certainty surrounding 3D printed medical devices, bring the benefits associated with appropriate regulatory schemes to both the patients and the manufacturers, and enforce action against bad actors.

2. 3D PRINTED DEVICES SHOULD BE ADDRESSED EXPLICITLY IN THE CUSTOM DEVICE EXEMPTION

Because most 3D printed devices are made from a similar[138] design and manufacturing process, with similar materials, the FDA considers them as not "custom" for the purposes of the CDE. However, there are nevertheless 3D printed designs that could be included under the Device

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135. The easiest way to ensure that the device is quality is to focus quality specifications on the front end, especially since the devices may vary significantly once they are already in place.

> Indeed, unlocking the full potential of [additive manufacturing] may necessitate a reversal of the qualification process to which engineers are accustomed: the development of a means to certify [additive manufacturing] parts based on design, as well as observations and corrections made during the build process, rather than verifying performance *after* fabrication.

Ian Wing, Rob Gorham & Brenna Sniderman, *3D Opportunity for Quality Assurance and Parts Qualification*, DELOITTE INSIGHTS, https://www2.deloitte.com/insights/us/en/focus/3d-opportunity/3d-printing-quality-assurance-in-manufacturing.html [https://perma.cc/BTL6-RVMR].

136. Of course, focusing only on pre-manufacturing quality controls is also incomplete. 3D printing regulations will still need post-manufacturing quality checks, especially in the healthcare world where the device created through 3D printing will directly affect patient care—a much higher risk than simple customer satisfaction in other, lower risk fields.

137. Because technology evolves fairly quickly, some may assume that guidance instead of regulatory rules is the more flexible route for the FDA. However, while guidance is nimbler, importantly for patient safety, it is also non-binding. A set of regulatory rules should provide the basis for general principles that can then be explained by guidance, allowing the FDA to directly regulate on areas that are so important for patient safety and outcomes.

138. Similar, but not identical. In contrast, identical products are common in traditional manufacturing techniques, with large start-up costs associated with changes in design. Felix Nadin, *When Is 3D Printing the Best Solution for Production?*, SCULPTEO (May 25, 2016), https://www.sculpteo.com/blog/2016/05/25/when-is-3d-printing-the-best-solution-for-production/ [https://perma.cc/L94R-B4LT].

Exemption but do not have specific guidance on how the CDE applies. While most patient specific designs will be modified from a stock design or program, there are circumstances where a truly custom design is necessary.[139]

3. THE FDA SHOULD CLASSIFY 3D PRINTED DESIGNS AS THE EQUIVALENT OF CLASS III MEDICAL DEVICES

If the FDA were to continue along the traditional path of classifying medical devices, then the FDA should create a new, unique category of regulatory classifications for 3D printed medical devices. In this category, most new 3D printed patient-matched designs should be considered the equivalent of Class III medical devices, using the existing Class III standards as a guide while incorporating concerns that are specific to 3D printing as a manufacturing process.[140] 3D and bioprinted medical devices should have specific regulatory schemes that govern their unique manufacturing and specification needs. These needs are especially urgent as 3D medical materials are likely to become more common as the price of 3D printing lowers even further, increasing access to patient care due to reduced cost.[141]

This separate classification would focus on the quality of the 3D printing software, the specific materials used in the creation of the patient-specific medical device, the process through which the device is created, and appropriate internal controls for handling when patient specific devices are not successful. The FDA has addressed several of these areas in the recent 3D printed device guidance,[142] but specific regulatory (and binding) rules surrounding those devices would allow the FDA to respond to changing technical considerations for the industry. Included in the focus for 3D printed devices should be an emphasis on QS requirements. The FDA could draw inspiration from some of the other 3D printing industries for beginning guidance on those requirements in terms of technical specifications.[143] This

139. Take, for example, a case where a patient needs a 3D printed device made from a material that isn't normally used in that particular design and where the design addresses a medical need that is particularly unique. Under a circumstance like this, a CDE would be appropriate for that very specific individualized need.

140. Class III medical devices provide for the most regulatory requirements for medical devices, ensuring that the devices are subject to rigorous approval methods before even making it to the market. *See* 21 C.F.R. § 807.87 (2018).

141. C. Lee Ventola, *Medical Applications for 3D Printing: Current and Projected Uses*, 39 PHARMACY & THERAPEUTICS 704 (2014).

142. TECHNICAL CONSIDERATIONS FOR ADDITIVE MANUFACTURED MEDICAL DEVICES, *supra* note 4.

143. 3D printed devices are moving towards a standard of data and information that could provide the backbone for such a regulatory category. *What is the*

technically focused approach, however, should only be the initial step, as medical devices and software need to be held to a higher standard than other industries. Much more is at stake when data is incorrect or faulty when the resulting product will eventually be used in a patient's medical care.[144]

Additional guidance could be found in other medical software that calculates and reports highly complex data for use in a patient's care. One example, Medical Administration Records (MARs) have extremely high quality standards.[145] These higher standards in areas of high risk keeps patients safe and makes it easier for healthcare organizations to respond to failures in the system.[146] 3D printing would benefit from a robust quality standard and technical specification regime to make sure the devices that were produced from the 3D printing software were safe and effective, particularly given the needs of the scanning and imaging design process. Similar to a MAR or other electronically focused medical device, 3D printed devices rely heavily on the technical specifications of software. In particular, the quality of the 3D imaging used to create the blueprint for the actual device manufacturing is crucial to the end quality of the medical device itself. The FDA has already begun to address healthcare software and imaging, just like the MAR, which may provide further guidance for regulating patient specific 3D printed devices.[147]

Reporting would also be enhanced by a new regulatory category. 3D printed medical devices required to meet Medical Device Reporting Requirements maintain the benefits of increased transparency and patient trust in the FDA's approval process and in the device itself. The current Medical Device Reporting requirements are designed for devices that are created through a standardized design and traditional

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Relationship Between FDA's Quality System Regulation for Devices, Part 820 and ISO 9001: 2000? U.S. FOOD & DRUG ADMIN., *supra* note 91.

144. In fact, quality assurance testing in the healthcare industry has increased quality assurance testing in other areas of industry as well. This is primarily because the industry has "a higher need for quality given the adverse implications . . . on human life if something were to go wrong." *Can Quality Assurance and Testing Transform Global Healthcare?*, QA INFO TECH (Aug. 4, 2017), https://qainfotech.com/can-quality-assurance-and-testing-transform-global-healthcare/ [https://perma.cc/KMW7-E2EM].

145. *See, e.g.*, THE OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY, *Test Procedure for §170.314(a)(16) Electronic Medication Administration Record – Inpatient Setting Only* (Sept. 21, 2012).

146. *See Can Quality Assurance and Testing Transform Global Healthcare?*, *supra* note 144.

147. *See* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF – COMPUTER ASSISTED DETECTION DEVICES APPLIED TO RADIOLOGY IMAGES AND RADIOLOGY DEVICE DATA – PREMARKET NOTIFICATION [510(K)] SUBMISSIONS (July 3, 2012), https://www.fda.gov/MedicalDevices/ucm187249.htm [https://perma.cc/63Y8-EFRF].

manufacturing process. In the case of patient specific 3D printed design, issues with the processes or design controls are a lot harder to detect; purely by being customizable, designs may have hundreds or thousands of variations leading to differences in the final product.[148] Therefore, more stringent and fact-specific requirements should be explored by the FDA in order for patient safety to be adequately protected.

4. REGULATIONS FOR THE MANUFACTURING PROCESS

The FDA has thought about the manufacturing process for 3D printed devices carefully and has issued guidance on the important considerations for materials, cleanliness, type of printing process, and data conversion.[149] This information has been tailored to meet the needs of 3D printing as it stands today, but it is not mandatory. One of the major challenges of making classifications for such an innovative technology is making sure that the standards are up to date with the technology. Since technology standards change frequently,[150] any regulatory category for 3D printed devices would have to be updated regularly. However, by creating a separate category with general rules and information for manufacturers to use when determining if they need to follow any particular regulatory step, then guidance can be the source that manufacturers can turn to when creating their quality specifications. These guidelines have already emerged from the FDA, in detail that make it much clearer what types of technical considerations manufacturers should be implementing. This guidance, however, still simply documents the FDA's initial thinking, and particularly for patient matched devices, represents the floor of what can be done.

Before the printing process for a patient matched device even begins, healthcare practitioners and 3D printing manufacturers must create patient-specific designs. These designs need robust standards to make sure they are safe—this includes verification, user needs, system needs, and specifications for the devices. Since the core of the

148. Matthew Jacobson, *Lessons for Medical Device Manufacturers Using 3D Printing* MED DEVICE ONLINE (July 18, 2018), https://www.meddeviceonline.com/doc/lessons-for-medical-device-manufacturers-using-d-printing-0001 [https://perma.cc/39GK-SUHF].

149. TECHNICAL CONSIDERATIONS FOR ADDITIVE MANUFACTURED MEDICAL DEVICES: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF, *supra* note 4, at 3.

150. Alison E. Berman & Jason Dorrier, *Technology Feels Like Its Accelerating—Because It Actually Is*, SINGULARITY HUB (March 22, 2016), https://singularityhub.com/2016/03/22/technology-feels-like-its-accelerating-because-it-actually-is/#sm.0000yvrmqzsjjd9mr7m25wyqosqs3 [https://perma.cc/8QT4-UEX8].

customization, efficacy, and safety of any product begins with its design, rules, and standards, outlining best practices are crucial to ensure a quality, safe product.[151] In traditional manufacturing, and even in non-patient matched 3D printing manufacturing, design requirements are much easier to prescribe since they apply to each and every device created from that design. 3D printing of patient matched devices, on the other hand, needs a different approach since each device can be customized to fit individual patient needs. This individualization can result in an "infinite number of design variants."[152] Therefore, the FDA's regulatory scheme, in order to account for this unique manufacturing process, should "incorporate design verification and design validation steps into the overall design and manufacturing process for personalized 3D printed devices."[153] Again, the guidance issued by the FDA acknowledges the specific concerns surrounding patient matched devices, noting that, especially for the design phase, the quality of the conversion of the patient's data can lead to vulnerabilities in the end product. Further regulation should focus on how to address those vulnerabilities beyond the requirements for other non-patient specific devices.

One of the uncertainties surrounding the current regulatory scheme is who is considered a 3D printing manufacturer.[154] Unlike traditional manufacturing, the manufacturer of a specific device is no longer clear.[155] Some hospitals are now printing their own medical devices in house rather than ordering from an off-site printer.[156] However, since the CDE does not apply to most patient specific devices, considering the hospital as the manufacturer can add additional burdens that may get in the way of patient care. Therefore, in order to be successful and safe for patients, the FDA should consider how design specifications

151. Kishu Manghani, *Quality Assurance: Importance of Systems and Standard Operating Procedures*, 2 PERSP. CLINICAL RES. 34–36 (2011).

152. Robert J. Morrison et al., *Regulatory Considerations in the Design and Manufacturing of Implantable 3D-Printed Medical Devices*, 8 CLINICAL & TRANSLATIONAL SCI. 594, 595 (2015).

153. *Id*.

154. Hunt & Mullen, *supra* note 4.

155. The FDA intends "to explore the role of nontraditional manufacturing facilities like a hospital operating room or university laboratory" in the future. U.S. FOOD & DRUG ADMIN., *Statement by FDA Commissioner Scott Gottlieb, M.D., on FDA Ushering in New Era of 3D Printing of Medical Products; Provides Guidance to Manufacturers of Medical Devices* (Dec. 4, 2017), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm587547.htm [https://perma.cc/GKV3-RXCU].

156. Marion Munley, *The Liability of Hospitals and Doctors Printing 3D Medical Devices*, LEGAL INTELLIGENCER (Apr. 11, 2017), https://www.law.com/thelegalintelligencer/almID/1202783349691/The-Liability-of-Hospitals-and-Doctors-Printing-3D-Medical-Devices/?slreturn=20180306120239 [https://perma.cc/FGJ2-E43L].

are translated and sent to different printers used by technicians that aren't necessarily a part of the original design process. This could be accomplished perhaps by new definitional phrases that are specific to a 3D printed device. If a manufacturer is the party *actually performing the printing process*, then perhaps the original designer has a different classification. Because the designer for a mass-produced 3D printed device will have a different role than the manufacturer, then the FDA will be able to more concretely outline the responsibilities of each party. As an example, a designer may have stringent technical specifications for the beginning stages, whereas the manufacturer would have more post-manufacturing requirements for cleanliness and testing. In some cases, the manufacturer and the designer could be the same party.

Quality specifications are an essential element of quality in a device, and FDA regulations help to ensure that the specifications in devices are up to par with the ideal final product.[157] In fact, by making specific rules for 3D printed medical devices in the realm of quality standards and technical specifications, the FDA can ensure the baseline quality for 3D printed devices is at an appropriate level to accommodate patient safety. Similarly, quality and technical specifications are traditionally designed by the FDA to ensure flexibility from manufacturer to manufacturer to avoid prescribing a specific method while still maintaining high quality.[158]

5. REGULATIONS FOR POST-MANUFACTURING

Perhaps even harder to pin down for 3D printed devices is data and outcome reporting. Pre-market approval standards for data and outcome reporting are geared towards more traditionally created medical devices. Patient specific devices may find it more difficult to keep up with a regulatory scheme that requires clinical data for each specific medical device.[159] Similarly, keeping the data straight is a difficult problem in terms of reporting patient outcome trends for

157. *Quality System (QS) Regulation/Medical Device Good Manufacturing Practices,* U.S. FOOD & DRUG ADMIN., https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/default.htm [https://perma.cc/6BS7-SS89].

158. *Id.*

159. 3D printed medical devices have encountered difficulties in verifying the clinical benefits through evidence medicine too. Studies have shown "insufficient statistical power, lack of homogeneity and a high risk of bias in published studies as major limitations to the current evidence for 3D printing in the scientific literature" as major hurdles for creating evidence-based methods with 3D printing. The FDA can help decrease these issues by introducing a robust regulatory scheme. Jos Vander Sloten et. al., *Building Evidence for 3D Printing Applications in Medicine*, *in* MEDICAL MANUFACTURING INNOVATIONS SERIES (Aug. 25, 2017).

patient specific devices.[160] It is difficult to measure patient specific devices against one another and come up with meaningful data for outcomes, primarily because, by definition, each patient will have a different set of parameters.[161]

The FDA should include in any 3D printed device-specific regulation, a scheme for reporting quality and patient outcomes in a meaningful way. This reporting scheme could include how many patients had a better experience with a 3D printed device than a mass-manufactured device, which devices had to be replaced, and what devices proved most effective in terms of material, design, and implementation. The FDA could also include categories of similar devices (e.g. pacemakers) as a way to meaningfully organize the data. Still, there will be challenges to identify when the device malfunctioned due to bad individualized design, and when it failed due to poor base design.

CONCLUSION

Medical devices that have been personally customized for the patient have the potential to drastically increase access to care by lowering out-of-pocket costs and by decreasing risks normally associated with mass produced medical devices. The benefits of 3D printed medical devices are obvious. The regulatory scheme as it now stands is insufficient to promote the benefits of additive printing in the medical industry while also promoting the important values of patient safety and efficacy. Ultimately, these devices should be considered in their own, separate regulatory category with their own scheme. Not only will this increase patient awareness and trust in the medical industry, but it will also allow the necessary flexibility to allow for continued innovation and growth of the applications of 3D printing in the medical industry.

The perfect solution for 3D printing is unclear, but the main elements of a drastic improvement of the regulatory scheme that this comment proposes include a separate regulatory category for 3D printed medical, an explicit explanation of the CDE's application to patient-matched devices, definitional clarity on what party performs what responsibilities in the manufacturing process, and a reporting scheme for patient outcomes with proper controls for individuality. For all these proposals, the FDA should consider the unique nature of 3D printing, including the challenges surrounding standardizing data and requirements for devices that are inherently unique and designed for individual patients.

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160. *Id.*
161. *Id.*