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3D PRINTED MEDICAL DEVICES: SAVING LIVES BUT DO WE NEED MORE REGULATION?

CHERIE-LYNN DINGMAN

ABSTRACT

3D printing applications have evolved rapidly over the years, and are making their mark in the Medical Device Industry. In February of 2013, because of 3D printing, an Ohio family was given hope that their 6-week old baby, Kaiba, would make it out of the hospital alive. Kaiba was suffering from Tracheobronchomalacia, a respiratory condition that was causing his central airways to collapse. The doctors obtained emergency clearance from the Food and Drug Administration to create and implant a custom-made tracheal splint. They were able to take a CT scan of Kaiba’s lungs and create the splint using a 3D printer. Kaiba has not had a single breathing emergency since.

There are two pathways a medical device can take to market, the 510(k) premarket submission or the Premarket Approval process. Currently, 3D printed devices are receiving clearance through the 510(k) process. To receive 510(k) clearance, a medical device manufacturer must provide evidence that the new device is “substantially equivalent” (at least as safe and effective) to another legally U.S. marketed device. There are concerns with clearing these 3D printed devices through the current 510(k) process, as they have different technical considerations than standard medical devices. Therefore, to ensure patient and product safety, the FDA must implement new regulations or alter the existing framework to account for these customizable devices.

This Article will walk through the history of 3D printing and how the technology is currently being utilized in the medical device industry. It will then lay out the existing regulatory pathway for medical devices and demonstrate the concerns of clearing and approving 3D printed devices through this framework. Finally, the Article offers recommendations on the framework that should be put in place to regulate this remarkable scientific application.

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I. INTRODUCTION

3D printing in the medical context is saving lives, quite literally. Day after day, the Gionfriddo family watched their 6-week old baby, Kaiba, stop breathing and have to be resuscitated over and over again.¹ Kaiba was suffering from Tracheobronchomalacia, a rare respiratory condition resulting from weak cartilage in the walls of the trachea and bronchi, ultimately causing his central airways to collapse.² The family was told by their doctors that there was a pretty high chance that Kaiba would not be leaving the hospital alive, and if it were not for 3-D printing, those doctors would have been right.³ The family traveled to a University of Michigan affiliated hospital, where the physicians were developing a bioresorbable tracheal

¹ David A. Zopf et al., *Baby's Life Saved with Groundbreaking 3D Printed Device from University of Michigan that Restored His Breathing*, May 22, 2013, <http://www.uofmhealth.org/news/archive/201305/baby%E2%80%99s-life-saved-groundbreaking-3d-printed-device>.

² Id.

³ Id.

splint that could be implanted in Kaiba to treat his condition.⁴ The Hospital was able to obtain emergency clearance from the FDA to create and implant this splint for Kaiba.⁵ Using a detailed CT scan of Kaiba's lungs, the doctors were able to make a custom-designed device out of a biopolymer, polycaprolactone.⁶ The splint was then sewn around Kaiba's airway to expand the bronchus and provide a skeletal framework to allow for proper growth.⁷ Since the splint was made out of bioresorbable plastics, it will dissolve within three years, after the airway has grown back with greater strength. Since the implantation of the splint, Kaiba has not had a single breathing emergency.⁸

3D printing, also known as "additive manufacturing," was first invented in the early 1980s.⁹ At first this technology was solely being utilized in the industrial sector, specifically rapid prototyping and specialized manufacturing, however, slowly, it started working its way into consumer and education sectors as well.¹⁰ Most recently, and for purposes of this Article, the technology is being applied to all areas of science and medicine. Specifically, scientists are increasingly being able to use 3D printing to engineer human tissue, organs, and medical devices.¹¹

This Article seeks to demonstrate that the current regulatory pathway, the 510(k) and Premarket Approval processes, under which 3D printed medical devices obtain clearance or approval, is insufficient to render reasonable assurance of safety and effectiveness of these new

⁴ Id.

⁵ Id.

⁶ Id.

⁷ Id.

⁸ Id.

⁹ Carl Schubert et al., *Innovations in 3D Printing: A 3D Overview from Optics to Organs*, 98 BRIT. J. OF OPHTHALMOLOGY 159 (2014).

¹⁰ Id.

¹¹ Sean V. Murphy & Anthony Atala, *3D Bioprinting of Tissues and Organs*, 32 NATURE BIOTECHNOLOGY 773 (2014).

devices. Part II of this Article lays out the current state of 3D printing, specifically addressing the processes and methods behind 3D printing as well as current medical applications using the technology. Part III addresses the FDA's role in regulating medical devices, how the existing regulatory pathway is implemented, and concerns with that regulatory pathway pertaining to 3D printing applications. Lastly, Part IV of this article enumerates regulatory concerns specific to 3D printing in the medical device industry.

Ultimately, this Article makes two recommendations. First, 3D printed medical devices are so different and unique from traditional medical devices that these applications need to be addressed by the FDA on a case-by-case basis. And because these applications are still in their infancy, it would be feasible for the FDA to follow this recommendation. Second, more controls pertaining to inputs, such as the materials used, and outputs, meaning post-market implications need to be assessed and regulated extensively. Currently, with how the 510(k) and Premarket Approval processes are written, the FDA is not tasked with evaluating these factors, and as a result, it is highly unlikely that the FDA has a reasonable assurance of safety and effectiveness of these devices.

II. CURRENT STATE OF 3-D PRINTING

A. What is 3D Printing?

To provide a simplistic definition, 3D printing is a “manufacturing method in which objects are made by fusing or depositing materials – such as plastic, metal, ceramics, powders, liquids, or even living cells – in layers to produce a 3D object.”¹² At this point in time, there are close to two- dozen 3D printing processes, all which use different methods and materials, making

¹² C. Lee Ventola, *Medical Applications for 3D Printing: Current and Projected Uses*, 39 PHARMACY AND THERAPEUTICS 704 (2014).

the information on the web describing the technology variable.¹³ To provide a generalization, the processes are able to construct a 3D object in any form, as defined in a computer-aided design (CAD) file.¹⁴

The user first must create a 3D printable-model using a 3D scanner and then convert the model into a CAD file using specific computer software.¹⁵ In the device industry, professionals are using radiographic images (x-rays, MRIs, and CT scans) as 3D printable models and converting them into the CAD file.¹⁶ The 3D printer will then follow the instructions in the CAD file to build the foundation of the object, and continually print successive layers of the material to build the 3D object.¹⁷ Finally, these layers will be joined and fused together to create the final 3D printed product.¹⁸

Charles W. Hull first invented the 3D printing method in 1984, labeling the method as Stereolithography (STL).¹⁹ When the technology was first developed, it was used in product development, data visualization, rapid prototyping, and specialized manufacturing.²⁰ However, the technology has evolved rapidly since then, making the 3D printing industry worth approximately \$700 million.²¹ While the possibilities are endless, current applications include, but are not limited to, the following: apparel, automobiles, construction, firearms, medicine, art, education, and environmental use.²²

¹³ Id.

¹⁴ Id.

¹⁵ Id.

¹⁶ Id.

¹⁷ Id.

¹⁸ Id.

¹⁹ Id.

²⁰ Schubert, *supra* note 9.

²¹ Ventola, *supra* note 12.

²² Ventola, *supra* note 12.

B. Medical and Health Aspects of 3D Printing

3D printing applications are not a new concept to medicine; they have been used to manufacture both dental implants and prosthetics since the early 2000s.²³ However as of lately, current applications in the medical field have increased and are categorized into the following: “tissue and organ fabrication, creation of customized prosthetics, implants and anatomical models, and pharmaceutical research involving drug dosage forms, delivery, and discovery.”²⁴ The increase in applications is due to the many benefits of the technology as opposed to traditional manufacturing: customization, personalization, cost-effectiveness, and enhanced productivity.²⁵ However, with those benefits, also come concerns. The FDA has expressed numerous apprehensions regarding the technology such as mechanical properties, biocompatibility, and interactive design.²⁶

There have been two instances in the U.S., where 3D printed medical devices have been cleared for commercial distribution.²⁷ Oxford Performance Materials (OPM), a company specializing in 3D printing, has received 510(k) clearance for two of its 3D printed devices.²⁸ In February 2013, OPM received 510(k) clearance for the OsteoFab Patient Specific Cranial Device.²⁹ This was a noteworthy moment, as this product was the first 3D printed, non-metal implant to receive clearance from the FDA and it allows physicians to treat the highly complex

²³ Ventola, *supra* note 12, at 706.

²⁴ Ventola, *supra* note 12, at 705-06.

²⁵ Ventola, *supra* note 12, at 705-06.

²⁶ Shana Leonard, *FDA Grapples with Future Regulation of 3-D Printed Medical Devices*, MEDICAL DEVICE AND DIAGNOSTIC INDUSTRY, June 13, 2014, <http://www.mddionline.com/article/fda-grapples-future-regulation-3-d-printed-medical-devices-140613>.

²⁷ Chris Wiltz, *The First FDA-Cleared, 3-D Printed Facial Implant*, MEDICAL DEVICE AND DIAGNOSTIC INDUSTRY, Aug. 21, 2014, <http://www.mddionline.com/article/first-fda-approved-3-d-printed-facial-implant-140821>.

²⁸ Id.

²⁹ Id.

anatomy of the brain and personalize a device for their specific patient.³⁰ In another triumphant success, on August 19, 2014, OPM received 510(k) clearance for its OsteoFab Patient-Specific Facial Device.³¹ OPM has made a remarkable contribution with this device as well, as it is the first and only cleared 3D polymeric implant for facial indications.³²

While those two products are the only 3D printed devices that have obtained clearance through the 510(k) process, the FDA has approved others by “emergency clearance” for a specific, individual patient.³³ In addition to the Gionfriddo family’s case in the Part I of this Article, C.S. Mott Children’s Hospital was able to save another child’s life with 3D printing. Garrett Peterson, an 18-month old baby, had spent his entire life in a hospital hooked up to ventilators, and there was no improvement being made.³⁴ Garrett was suffering from a condition called tetralogy of Fallot with absent pulmonary valve, which puts a tremendous amount of pressure on the airways.³⁵ As a result of this condition, he developed severe tracheobronchomalacia, which as stated previously, is a condition resulting from weak cartilage in the walls of the trachea and bronchi, ultimately causing his central airways to collapse.³⁶ Sadly, the Petersons were unable to hold their own child due to the fear of compromising his breathing.³⁷ They watched their baby turn blue in the face sometimes four to five times a day and

³⁰ Id.

³¹ Id.

³² Cory Ziskind, *Oxford Performance Materials Receives FDA Clearance for 3D Printed OsteoFab Patient-Specific Facial Device*, Aug. 19, 2014, http://www.oxfordpm.com/news/article/2014-08-19_oxford_performance_materials_receives_fda_clearance_for_3d_printed_osteofab_patient-specific_facial_device.php.

³³ See Zopf, *supra* note 1.

³⁴ Mary Masson, *Baby’s life saved after 3D printed devices were implanted at U-M to restore his breathing*, Mar. 17, 2014, <http://www.mottchildren.org/news/archive/201403/babys-life-saved-after-3d-printed-devices-were-implanted-u>.

³⁵ Id.

³⁶ Id.

³⁷ Id.

be resuscitated with heavy medications.³⁸ “It’s really hard to watch your child basically suffocate and pass out before you could revive him and bring him back, over and over,” sad Jake Peterson, Garrett’s father.³⁹

The doctors at C.S. Mott Children’s Hospital obtained emergency clearance from the FDA to create and implant a tracheal splint created from a biopolymer called polycaprolactone.⁴⁰ The doctors created a 3D model of Garrett’s airway using a CT scan of the trachea and bronchi and then created the splint for a customizable fit to Garrett’s bronchi.⁴¹ From there, Richard G. Ohye, M.D., head of pediatric cardiovascular surgery, sewed two splints around the right and left bronchi to expand the airways and give it skeletal support to aid proper growth.⁴² The body will reabsorb the splint, made out of a bioresorbable polymer, in three years, after proper airway growth is achieved.⁴³

There have also been numerous successes surrounding 3D printed medical devices in Europe and Asia. I will touch on a few of the cases occurring in Europe to provide a better illustration of existing applications, however, for purposes of this paper, I solely focus on the regulatory framework surrounding medical devices in the United States.

In the UK, a patient had been diagnosed with a rare bone tumor called chondrosarcoma, which required the doctors to remove half of his pelvis.⁴⁴ Traditional implant device methods could have been used, replacing the patient’s pelvis with a hand-made device; however, these never fit perfectly, ultimately causing discomfort and medical issues for the patient down the

³⁸ Id.

³⁹ Id.

⁴⁰ Id.

⁴¹ Id.

⁴² Id.

⁴³ Id.

⁴⁴ *British surgeon uses 3D printing to create pelvis for a cancer patient*, 3DERS.ORG, Feb. 10, 2014, <http://www.3ders.org/articles/20140210-british-surgeon-uses-3d-printing-to-create-pelvis-for-a-cancer-patient.html>.

road.⁴⁵ The orthopedic surgeon, Craig Gerrard, scanned the patient's pelvis to create a 3-D model, and a British medical device company was able to use this model to produce the half-pelvis.⁴⁶ This 3-D printed implant was made out of titanium powder and was coated with a mineral that allowed the remaining bone to grow into the pores, ultimately enhancing the strength of the implant.⁴⁷ Because of the material used and the precision of the 3D model, this technology is able to create devices more customizable to the patient.⁴⁸

Similarly, a Dutch woman was suffering from an unfortunate condition known as Acromegaly, which results in the thickening of the skull and ultimately loss of essential brain functions.⁴⁹ Before 3D printing came into the mix, the woman was experiencing severe headaches, loss of vision, and motor skill depletion.⁵⁰ It is common procedure in patients with Acromegaly to remove part of the skull temporarily to reduce pressure on the brain and then replace later with an implant that was made out of cement.⁵¹ Unfortunately, these cement implants did not fit very well on the patients, which result in sub-par brain function for the patient.⁵² The doctors at University Medical Center Utrecht were able to manufacture a skull replacement made out of plastic with the help of an Australian medical device company.⁵³ Three months post-surgery, the woman has no ruminants of pain and she has fully regained her vision.⁵⁴

⁴⁵ Id.

⁴⁶ Id.

⁴⁷ Id.

⁴⁸ Id.

⁴⁹ James Eng, *Medical First: 3-D Printed Skull Successfully Implanted in Woman*, NBC NEWS, Mar. 27, 2014, <http://www.nbcnews.com/science/science-news/medical-first-3-d-printed-skull-successfully-implanted-woman-n65576>.

⁵⁰ Id.

⁵¹ Id.

⁵² Id.

⁵³ Id.

⁵⁴ Id.

III. EXISTING REGULATORY PATHWAY

A. Role of FDA

The Food and Drug Administration (“FDA”) “is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation.”⁵⁵ To carry out that responsibility, under the Food Drug and Cosmetic Act (“FDCA”), the FDA is tasked with ensuring that there is a “reasonable assurance of the safety and effectiveness of devices intended for human use.”⁵⁶ The term “medical device” is defined in the FDCA as:

An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is: (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.⁵⁷

For purposes of this Article, the salient aspects of this definition are *intended for use in cure, mitigation, or treatment of the disease* and *intended to affect the structure or any function of the body*.⁵⁸ 3D printed devices fall into the definition of “devices,” as they are similar to traditional devices. The devices are being used in the treatment of disease and/or are intended to affect the structure of the body. For instance, the tracheal splint mentioned in Part II of this

⁵⁵ Food & Drug Admin., *What We Do*, <http://www.fda.gov/aboutfda/whatwedo/> (last updated Aug. 5, 2014).

⁵⁶ Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§393(b)(2)(C) (2006).

⁵⁷ *Id.* at §§321(h) (2006).

⁵⁸ *Id.*

Article was used in the treatment of tracheobronchomalacia to strengthen the bronchi and expand the airways, allowing for proper growth.⁵⁹

Also worth noting, the last aspect of the definition, “which does not achieve its primary intended purposes through chemical action within or on the body and which is not dependent upon being metabolized for the achievement of its primary intended purposes,” is meant to separate devices from drugs.⁶⁰ The FDA adopts the following definition of “chemical action” in their interpretation: “the formation or breaking of covalent or ionic bonds, and intermolecular forces are electrostatic interactions or forces resulting from the interaction of localized, short-range electrical fields among atoms and/or molecules.”⁶¹ For purposes of medical devices, the Agency has determined that a device will achieve its purpose through a “chemical action” if the device either “(1) mediates a bodily response at the cellular or molecular level or (2) combines with or modifies an entity so as to alter that entity’s interaction with the body.”⁶² That being said, 3D printed devices are *not* undergoing a chemical action within the body to achieve their intended uses. The 3D printing software and printer are producing a solid device that will be entering the body (similar to a standard medical device).

B. Background of Device Regulation

In 1906, when the Pure Food and Drug Act was passed, medical devices did not pose a risk to the public since they were manufactured using obvious and simple mechanical

⁵⁹ See Zopf, *supra* note 1.

⁶⁰ Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§321(h) (2006).

⁶¹ Food & Drug Admin., *Interpretation of the Term “Chemical Action” in the Definition of Device Under Section 201(h) of the Federal Food, Drug and Cosmetic Act*, June 2011 <http://www.fda.gov/RegulatoryInformation/Guidances/ucm259059.htm#what>.

⁶² Id.

processes.⁶³ However, beginning in the 1960s, medical devices began to receive a lot more attention from regulators as well as consumers.⁶⁴ As a result of such attention, the Cooper Commission (“the Commission”) was created in the late 60s and was responsible for “advising policy makers about improvements to the device regulatory system.”⁶⁵ The Commission proposed a risk-based approach to device regulation, which was adopted by the Medical Device Amendments of 1976 and is still the approach used today in assessing device applications.⁶⁶ However, recognizing that this risk-based regulatory scheme would take considerable time to implement and establish, Congress created the 510(k) process (addressed in Part C of this section) to accommodate those device that were close to being approved at the time, so as not to halt innovation.⁶⁷

The FDCA has been amended by both the Medical Device Amendments (MDA) of 1976 and the Safe Medical Device Act (SDMA) of 1990. It incorporated the Commission’s risk-based approach in creating the three regulatory classes for medical devices: Class I, Class II, and Class III.⁶⁸ A device is assigned to a specific classification based on the controls necessary to assure safety and efficacy, the intended use, and the indications for use.⁶⁹ The classification will also determine the type of premarketing submission required for FDA clearance or approval.⁷⁰

⁶³ Carol Rados, *Medical Device and Radiological Health Regulations Come of Age*, FDA CONSUMER MAGAZINE, Jan. – Feb. 2006, http://permanent.access.gpo.gov/lps1609/www.fda.gov/fdac/features/2006/106_cdrh.html.

⁶⁴ Ralph F. Hall & Michelle Mercer, *Rethinking Lohr: Does “SE” Mean Safe and Effective, Substantially Equivalent, or Both?* 13 MINN. J.L. SCI. & TECH. 737, 745 (2012).

⁶⁵ Id.

⁶⁶ Id.

⁶⁷ Id.

⁶⁸ Federal Food, Drug & Cosmetic Act, 21 C.F.R. §§860.3.

⁶⁹ Alena Allen et al., *Food and Drug Law and Regulation* 491 (David G. Adams eds., (2008).

⁷⁰ Id.

Class I devices are the most simple devices and therefore are only subject to general controls.⁷¹ These devices are those that are not being used “in supporting or sustaining human life . . . or in preventing impairment of human health, and does not present a potential unreasonable risk of illness or injury.”⁷² Because of this low-risk level, the FDA has expressed that general controls are sufficient to assure the safety and efficacy of this Class.⁷³ General controls may include provisions that relate to establishment registration and device listing, premarket notification, records and reports, and good manufacturing practices.⁷⁴ Most Class I devices are exempt from Premarket Notification 510(k), however the manufacturers are still required to register and list the classification name of the device.⁷⁵ An example of a Class I device is an examination glove, elastic bandage, and in the case of 3D printing, external hearing aids have been placed in this Class since they are for external use.⁷⁶

Next, Class II devices are medium-risk devices. The FDA has determined that general controls are insufficient to provide reasonable assurance of safety and effectiveness; therefore this Class is subject to both general and special controls.⁷⁷ Special controls may include postmarket surveillance, patient registries, development and dissemination of guidelines, and other appropriate actions, as FDA deems necessary to ensure safety and effectiveness.⁷⁸ An example of a Class II device is an infusion pump or a powered wheelchair.⁷⁹

⁷¹ Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§360c(a)(1)(A).

⁷² Id.

⁷³ Id.; See also Hall, *supra* note 64, at 747.

⁷⁴ Food & Drug Admin., *General Controls for Medical Devices*, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm055910.htm> (last updated June 26, 2014).

⁷⁵ David S. Antzis et al., *Bringing Your Medical Device to Market* 140 (John B. Reiss eds., 2d ed. 2006).

⁷⁶ Hall, *supra* note 64, at 747.

⁷⁷ Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§360c(a)(1)(B).

⁷⁸ Id.; See also Antzis, *supra* note 75.

⁷⁹ Antzis, *supra* note 75.

Most Class II devices require Premarket Notification 510(k), in which the manufacturer must demonstrate that the new device is substantially equivalent to a legally marketed device (also known as “predicate device”).⁸⁰ The FDA will make a determination that the new device is substantially equivalent if the new device has the same intended use and (1) the same technological characteristics as the predicate device, or (2) has different technological characteristics, however does not raise different questions of safety and effectiveness than the predicate device.⁸¹

Lastly, Class III devices pose the most risk to patients and therefore are subject to the strictest regulatory requirements.⁸² These devices are those that are either: “(1) are used in supporting or sustaining human life or (2) are for a use which is of substantial importance in preventing impairment of human health or (3) present a potential unreasonable risk of illness or injury.”⁸³ These devices cannot be classified as Class I or Class II because the FDA believes that there is insufficient information to suggest that general controls and special controls would provide a reasonable assurance of safety and effectiveness.⁸⁴ Most Class III devices are subject to Premarket Approval, however there are exceptions. If a Class III device is able to show that it is “substantially equivalent” to a legally marketed device, it may follow the 510(k) process until the FDA decides that that specific device category must submit a Premarket Approval application.⁸⁵

⁸⁰ Food & Drug Admin., *Overview of Device Regulation*, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/> (last updated June 26, 2014).

⁸¹ Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§360c(i).

⁸² Antzis, *supra* note 75, at 141.

⁸³ Allen, *supra* note 69, at 492.

⁸⁴ Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§360c(a)(1)(C).

⁸⁵ Allen, *supra* note 69, at 492-93.

As discussed above in Section II, Part B, the two instances in which the University of Michigan affiliated hospital created and implanted the tracheal splints; they obtained “emergency clearance” through the FDA.⁸⁶ These devices were classified, as “custom devices,” which are not available for widespread distribution, and therefore are not subject to the device regulatory framework. A “custom device” is defined in the FDCA as:

[A device] intended for use by an individual patient named in [an] order by such physician, dentist (or other specially qualified person so designated) and is to be made in a specific form for such patient, or . . . intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of [his] professional practice . . .⁸⁷

Devices fall into this definition, and are exempt from the 510(k) clearance as well as the Premarket Approval process provided they are manufactured and produced with a specific patient in mind, will be used only on that patient, and are not going to be subject to widespread distribution.⁸⁸ For purposes of this Article, it is very important to note that custom devices are different from *customized* devices.⁸⁹ A custom device is unique and manufactured for its intended use by a specific, named patient.⁹⁰ To the contrary, a *customized* device is a “specific class of devices that is manufactured and available for commercial distribution, but can vary in size, shape or material on order of a physician to meet the needs of individual patients.”⁹¹ Therefore, because customized devices are available for widespread dissemination, they are subject to the regulatory framework for medical devices.⁹²

⁸⁶ Zopf, *supra* note 1. See also Masson, *supra* note 34.

⁸⁷ Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§360j(b).

⁸⁸ Allen, *supra* note 69, at 518.

⁸⁹ Allen, *supra* note 69, at 518.

⁹⁰ Allen, *supra* note 69, at 518.

⁹¹ Allen, *supra* note 69, at 518.

⁹² Allen, *supra* note 69, at 518.

C. Getting to Market

As a result of the MDA and SMDA, there are currently two different routes devices take to be approved for commercial distribution, the 510(k) process and the Premarket Approval process. To begin, the manufacturer should check the FDA Product classification Database to determine how their device is classified and then adhere to the regulations in determining the appropriate route to market.⁹³

i. 510(k) Process

Prior to commercial distribution, the manufacturer of non-exempt Class I and Class II devices must submit a 510(k) notification to the FDA.⁹⁴ Manufacturers must adhere to the regulations for guidance on the content required in their submission.⁹⁵ Specifically, the regulations state that the manufacturer must include the classification status of the device, proposed labeling, and information that demonstrates that the device is “substantially equivalent” to a pre-1976 marketed device, known as the “predicate device.”⁹⁶

A predicate device is a device: (1) that was approved prior to May 28, 1976, the passage of the MDA, and for which a Premarket Approval is not required; (2) that has been reclassified from Class III to Class II or Class I; or (3) that has been found to be “substantially equivalent” through the 510(k) process.⁹⁷ The FDA is flexible when making a determination that a device is “substantially equivalent” to a predicate device, in order to promote innovation and evolving

⁹³ Food & Drug Admin., *Product Classification*, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm> (last visited Dec. 7, 2014).

⁹⁴ Federal Food, Drug & Cosmetic Act, 21 C.F.R. §§807(e).

⁹⁵ Id.

⁹⁶ Id.

⁹⁷ Id. at §§807.92(a)(3).

technology.⁹⁸ That being said, it is possible for the new device to have certain characteristics that are substantially equivalent to one predicate device and others that are substantially equivalent to a different predicate device.⁹⁹

If a manufacturer submits a 510(k) application for a 3D printed device, which will come into direct contact with the patient (almost always the case with 3D printed devices), the manufacturer must report the exact materials that will come into contact with the patient and if they are materially different from what the predicate device is comprised of.¹⁰⁰ If the materials are identical to the predicate device, the process ends there. However, if the materials, processes, or intended uses are not identical, biocompatibility testing (commonly known as “biological evaluation”) must be completed.¹⁰¹ Biological evaluation is required to address potential toxicities that would occur as a result of contact with body.¹⁰² To complete the testing successfully, the device must prove that the comprised materials do not: (1) produce adverse effects; (ii) produce carcinogenic effects; or (iii) produce adverse reproductive/developmental effects.¹⁰³ If any risks from the materials are found during this testing, the manufacturer must demonstrate that the benefits will greatly outweigh the potential risks.¹⁰⁴ For our purposes, 3D printed devices will have different materials and processes than predicate devices, so

⁹⁸ Food & Drug Admin., *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*, <http://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf> (last updated July 28, 2014).

⁹⁹ Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§360(c)(1)(1)(a).

¹⁰⁰ Food & Drug Admin., *Special Considerations: Biocompatibility*, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134578.htm#bio> (last updated Sept. 11, 2014).

¹⁰¹ Id.

¹⁰² Id.

¹⁰³ Id.

¹⁰⁴ Id.

manufacturers will have to undergo biological evaluation to ensure the new device is safe and effective for its intended use.

Once the 510(k) notification has been completed and submitted, the FDA will issue an order within 90 days on whether the new device is “substantially equivalent” or “not substantially equivalent” to the predicate device.¹⁰⁵ If the device is found to be “substantially equivalent” the device is cleared for commercial distribution.¹⁰⁶ The new device is then classified into the same class and subject to the same requirements and controls as the predicate device.¹⁰⁷ The manufacturer must not to commercially distribute the device until the order is received. If the device is found to be “not substantially equivalent” to the predicate device, the new device is classified into Class III as a default, and must submit a pre-market approval (“PMA”) application.¹⁰⁸

ii. Premarket Approval Process

Typically, Class III devices, as well as some Class II devices, require a Premarket Approval (PMA) submission because there is not sufficient information to assure safety and effectiveness solely through general and special controls.¹⁰⁹ The PMA process is the most rigorous process for a medical device, both in terms of time and money. The submission must

¹⁰⁵ Federal Food, Drug & Cosmetic Act, 21 C.F.R. §§807.100.

¹⁰⁶ Food & Drug Admin., *Premarket Notification 510(k)*, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm>. (last updated Aug. 8, 2014).

¹⁰⁷ *Id.*

¹⁰⁸ Food & Drug Admin., *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*, <http://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf> (last updated July 28, 2014).

¹⁰⁹ Antzis, *supra* note 75, at 141.

contain valid and robust scientific evidence to provide reasonable assurances to the FDA that the device is safe and effective for its intended use.¹¹⁰

First, the manufacturer must submit the PMA application, which is very specific and extensive, outlined in the statute and regulations.¹¹¹ The application must include: (1) Name and address of the applicant; (2) A table of contents; (3) A summary of the data and information supplied in the application; (4) A complete description of the device, including ingredients, properties, principles of operation, and facilities used; (5) Reference to any performance standard under the FDCA or the Radiation Control for Health and Safety Act of 1968 that is relevant to the safety and effectiveness of the device; (6) Data and information regarding nonclinical and clinical studies; (7) Any other information relevant to safety and effectiveness of the device; (8) Samples of the device, if requested; (9) Proposed labeling; (10) An environmental assessment; (11) A financial statement and/or disclosure statement; and (12) Any other information deemed necessary by the FDA.¹¹²

Specifically and most importantly, the information provided regarding nonclinical laboratory studies and clinical trials will play a significant role in whether the FDA chooses to approve or deny the application.¹¹³ Nonclinical studies include “microbiological, toxicological, immunological, biocompatibility, stress, wear, shelf life, and other laboratory or animal tests as appropriate.”¹¹⁴ Pursuant to these studies, the manufacturer must submit certification they were conducted in compliance part 58 of the regulations.¹¹⁵

¹¹⁰ Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§360e.

¹¹¹ Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§814.20.

¹¹² *Id.*

¹¹³ Antzis, *supra* note 75, at 164.

¹¹⁴ Antzis, *supra* note 75, at 164.

¹¹⁵ Antzis, *supra* note 75, at 164.

Next, the section pertaining to clinical trials must include, among other things, clinical protocols, number of investigators and subjects per investigators, subject selection, safety and effectiveness data, adverse events, etc.¹¹⁶ The manufacturer is also responsible for submitting certification that this study was conducted in compliance with IRB regulations or if not subject to those regulations, that it was conducted in compliance with informed consent regulations.¹¹⁷ The main difference between the 510(k) and PMA processes is the requirement for clinical trials to prove safety and efficacy. In order to engage in clinical evaluation of devices, an investigational plan must be approved by an IRB and the IDE must be approved by the FDA.¹¹⁸ “An investigational device exemption (IDE) allows the investigational device to be used in a clinical evaluation in order to collect safety and effectiveness data” required in a PMA application.¹¹⁹ The manufacturer must also obtain informed consent from all patients, submit labeling stating that the device is for investigation use only, monitor the study and maintain records and reports.¹²⁰

Once the FDA receives the application, they will review the contents to ensure completeness and conformity with the formal requirements explained above.¹²¹ Within forty-five (45) days of receipt, the FDA will notify the manufacturer whether the application has been “filed,” meaning it has met the threshold of completeness.¹²² From there, the FDA has 180 days from the date of the filing to approve or deny the application, however, in practice this timeframe

¹¹⁶ Antzis, *supra* note 75, at 164.

¹¹⁷ Antzis, *supra* note 75, at 164.

¹¹⁸ Federal Food, Drug & Cosmetic Act, 21 C.F.R. §§812.

¹¹⁹ Food & Drug Admin., *Device Advice: Investigational Device Exemption (IDE)*, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm> (last updated June 19, 2014).

¹²⁰ *Id.*

¹²¹ Antzis, *supra* note 75, at 166.

¹²² Antzis, *supra* note 75, at 166.

is considerably longer.¹²³ It is important to note, the manufacturer's responsibilities do not end here. During this waiting period, PMA applicants have an affirmative duty to periodically update their pending application with new safety and effectiveness information learned about the device, in order to allow the FDA to make an informed decision regarding their device.¹²⁴ As shown, the PMA process takes a considerable amount of time compared to other methods of pre-approval, such as the 510(k) process. To illustrate, on average it will take several hundred days for the FDA to respond to a PMA, where the 510(k) process usually takes about 90-100.¹²⁵

D. Criticisms of the 510(k) process

The 510(k) process was initially developed in the late 1960s and revised in 1990 as a result of the SMDA of 1990.¹²⁶ While the SMDA made worthy additions to the process, medical device innovation has evolved tremendously since the 1990s. Technological innovation and corroboration between medical institutions and manufacturers has changed greatly over the years, warranting a new and improved system of premarket approval and postmarket checks. As a result of the increasing innovation, the 510(k) process has been intensely criticized as not ensuring safety and effectiveness among medical devices.

i. Institute of Medicine Review

Among one of those criticisms is a consumer study showing that devices cleared through the 510(k) process make up a large share of serious recalls on medical devices, as opposed to

¹²³ Antzis, *supra* note 75, at 166.

¹²⁴ Antzis, *supra* note 75, at 166.

¹²⁵ Hall, *supra* note 64, at 754.

¹²⁶ Food & Drug Admin., *The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications*, Mar. 20, 1998, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080187.htm>.

devices approved through the PMA process.¹²⁷ In 2011, in response to that study, the FDA requested the Institute of Medicine (IOM), an independent organization which provides advice to decision makers, to review the 510(k) process to determine if it was allowing the FDA to accomplish its goal of ensuring safety and effectiveness.¹²⁸ The IOM was asked to answer two questions: (1) Does the current 510(k) process protect patients and promote innovation in support of public health? And (2) If not, what legislative, regulatory, or administrative changes are recommended to achieve the goals of the 510(k) process optimally?¹²⁹

In their analysis, the IOM looked at numerous factors such as the legislative history of the 510(k) process, the resulting framework, how the process is currently implemented, postmarket information on safety and effectiveness, and many more.¹³⁰ After reviewing such factors, the committee drew two conclusions: (1) the current 510(k) program lacks the statutory basis to make it a reliable premarket screen for safety and effectiveness of Class II devices and (2) it is unclear whether the 510(k) clearance process is facilitating or inhibiting innovation.¹³¹

Regarding the first conclusion, the committee found that the 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices, and therefore, the process cannot be adequately transformed into a “premarket evaluation of safety and effectiveness” so long as the standard of “substantial equivalence” still exists.¹³² The committee explicitly states they are “not suggesting that all, many, or even any medical devices cleared

¹²⁷ Jeffrey K. Shapiro, *Substantial Equivalence Premarket Review: the Right Approach for Most Medical Devices*, 69 FOOD DRUG L.J. 365 (Citing Alicia Mundy & Jon Kamp, *Device Review Process Faulted: Most Recalled Medical Products Were Cleared in an Abbreviated Manner, Study Says*, WALL STREET J., Feb 15, 2011) (2014).

¹²⁸ Institute of Medicine (IOM), *Medical Devices and the Public’s Health: The FDA 510(k) Clearance Process at 35 Years*, at 189 (2011) [hereinafter “IOM Report”].

¹²⁹ Id.

¹³⁰ Id.

¹³¹ Id. at 193-95.

¹³² Id. at 193.

through the 510(k) clearance process and currently on the market are unsafe or ineffective,” however there is insufficient information to support highly confident conclusions regarding safety and effectiveness.¹³³

The Center for Devices and Radiological Health (CDRH) and the FDA both enumerate two goals of the 510(k) clearance process: (1) to assure devices are safe and effective and (2) to promote innovation in the medical device industry.¹³⁴ However, both of these goals are inconsistent with the purpose that Congress laid out in the 510(k) program. By law, the 510(k) process focuses solely on the determination of a device’s “substantial equivalence” to a predicate device. In that regard, it is imperative to note that devices on the market prior to the enactment of the MDA of 1976 (those devices involved in substantial equivalence comparisons) have never been systematically assessed to determine their safety and effectiveness.¹³⁵ The risk-based classification system was developed in 1976, and these predicate devices were placed in the classes, however, they were never reassessed for safety and effectiveness under the revised FDCA.¹³⁶ Therefore, because the predicate device was not itself reviewed for safety and effectiveness, the committee found that clearance of a 510(k) submission was not a determination that the cleared device was safe or effective.¹³⁷

Regarding the second conclusion, the committee found that there is no information illustrating whether the 510(k) process facilitates or inhibits innovation in the medical device industry.¹³⁸ The committee defines innovation broadly as improving the quality of, efficiency of,

¹³³ Id.

¹³⁴ Id. at 190.

¹³⁵ Id. at 191.

¹³⁶ Id.

¹³⁷ Id.

¹³⁸ Id. at 195.

or access to health care.¹³⁹ While it is found that the 510(k) is a faster and more efficient route to market, as opposed to the PMA process, the committee found that demonstrating substantial equivalence to a predicate device is not a scientific means of adapting to new technology.¹⁴⁰ Ultimately, FDA’s implementation of the process, not the process itself, has stifled innovation due to the lack of transparency and predictability, which has led to an adverse effect on investment in future medical device development.¹⁴¹ The committee believes that the FDA’s role in facilitating innovation is to create a regulatory framework that sets thresholds stringent enough to satisfy its own objective – medical devices cleared for commercial distribution will be safe and effective.¹⁴² Ultimately, the committee concluded that the FDA should move away from the 510(k) process as soon as possible and implement a framework that allows for premarket and postmarket review to assure safety and effectiveness through the device’s life cycle.¹⁴³

ii. The Predicate Creep

Another common criticism of the 510(k) process is the “Predicate Creep.”¹⁴⁴ As laid out above, devices are cleared through the 510(k) process if they are deemed “substantially equivalent” to a predicate device.¹⁴⁵ However, devices are allowed to be substantially equivalent to one predicate device for one characteristic, and to another predicate for another characteristic.¹⁴⁶ This creates the concern of the “Predicate Creep.”¹⁴⁷ This danger arises from the “repeated cycle of slight component changes from predicate device to predicate device,

¹³⁹ *Id.* at 193.

¹⁴⁰ *Id.* at 194.

¹⁴¹ *Id.*

¹⁴² *Id.* at 196.

¹⁴³ *Id.*

¹⁴⁴ Arianne Freeman, *Predicate Creep: The Danger of Multiple Predicate Devices*, 23 ANN. HEALTH L. 127 (2014).

¹⁴⁵ Federal Food, Drug & Cosmetic Act, 21 C.F.R. §§807(e).

¹⁴⁶ Freeman, *supra* note 144, at 129.

¹⁴⁷ Freeman, *supra* note 144, at 129.

which leads to uncertainty in the clinical risks and benefits of the device” and possibly putting patients in danger.¹⁴⁸ The ability to use multiple predicate devices creates significant problems because you are comparing a device piece-meal instead of comparing the entire device to a predicate.¹⁴⁹

The FDA has responded to this criticism by stating that this is not an adequate concern since the new device is simply combining the functionality of two predicates.¹⁵⁰ However, this logic fails where mixing the two predicate creates a device with uncertain risks and benefits.¹⁵¹ Put simply, because of this process, manufacturers are able to bypass significant and important clinical trials and ultimately pass the risk to the public. To illustrate the popularity of the 510(k) process, about 98% of devices obtain clearance through the 510(k) process, the remaining 2% going through the PMA process.¹⁵² The 510(k) is clearly the preferred route to market for devices, even when the appropriate route would be the PMA process.¹⁵³

IV. REGULATORY CONCERNS IN 3D PRINTING

As stated earlier, the 3D printing industry is currently worth about \$700 million, with only 2% being spent in the medical device industry.¹⁵⁴ However, the 3D industry is expected to grow into an \$8.9 billion industry in the next 10 years, and it is predicted that 21% will be spent on medical applications.¹⁵⁵ That being said, while only two 3D printed devices have been approved through the 510(k) process, it is likely that those numbers will also increase in the years to come. And while the current 510(k) process may be appropriate for traditional devices,

¹⁴⁸ Freeman, *supra* note 144, at 129.

¹⁴⁹ Freeman, *supra* note 144, at 136.

¹⁵⁰ Freeman, *supra* note 144, at 136.

¹⁵¹ Freeman, *supra* note 144, at 136.

¹⁵² Shapiro, *supra* note 127, at 378.

¹⁵³ Shapiro, *supra* note 127, at 378.

¹⁵⁴ Ventola, *supra* note 12.

¹⁵⁵ Ventola, *supra* note 12.

although this has rebutted in Section III, Part C, in *Criticisms of the 510(k) Process*, it is a very dangerous framework for regulating 3D printed devices.

As stated in Section III, Part C, non-exempt Class I as well as Class II devices must obtain clearance through the 510(k) program prior to widespread distribution of their devices.¹⁵⁶ To obtain clearance, the manufacturer must demonstrate that the new device is “substantially equivalent” to a predicate device.¹⁵⁷ A predicate device is any of the following: (1) A device that was approved prior to May 28, 1976, for which a PMA is not required; (2) A device which has been reclassified from Class III to Class II or Class I; or (3) A device which has been found to be “substantially equivalent” through the 510(k) process.¹⁵⁸ There are a couple different reasons why it is troubling that a 3D printed device could be found to be “substantially equivalent” to such predicate device through the 510(k).

First and foremost, to be categorized as “substantially equivalent” the device must have the same intended uses as the predicate device and either (1) have the same technological characteristics or (2) if there are new technological characteristics; the new device must be as safe and effective as the predicate.¹⁵⁹ Being that 3D printed devices use a completely different process, known as “additive manufacturing,” than that used to manufacture traditional devices, these device automatically fall into the second category of having different technological characteristics. Therefore, to be proven “substantially equivalent,” they would need to demonstrate that they have no new safety concerns. However, this is not possible. 3D printed devices are using raw materials, such as powder, plastic, paper, etc. that are coming into contact with the body, therefore safety concerns arise that must be tested. It is inappropriate for the FDA

¹⁵⁶ Federal Food, Drug & Cosmetic Act, 21 C.F.R. §§807(e).

¹⁵⁷ Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§360c(i).

¹⁵⁸ Federal Food, Drug & Cosmetic Act, 21 C.F.R. §§807(e).

¹⁵⁹ Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§360c(i).

to label these devices “as safe and as effective” as a traditional device just because they have the same intended use.

Second, if the manufacturer is comparing the new 3D printed device to a predicate device that was approved prior to May 28, 1976, there are low assurances that this device will be “substantially equivalent” or even worse, safe and effective. This assertion is made in reference to the IOM report in 2011.¹⁶⁰ Devices that were approved prior to May 28, 1976 (the enactment of the MDA) have not undergone assessment by the FDA to determine their safety and effectiveness, therefore the only real evidence of their safety and efficacy is the benefits and risks displayed from the public.¹⁶¹ While this would not be as grave of a concern if we were dealing with traditional devices, 3D printed devices that have different material and technical processes, which create uncertainty. It is illogical to say that a 3D printed device is substantially equivalent or “as safe and effective” as a device pre-1976 that has not been properly tested for safety and effectiveness.

Furthermore, the PMA process is also not an appropriate check of safety and effectiveness for 3D printed devices. The crutch of the PMA process is nonclinical and clinical trials in order to establish safety and effectiveness of the device.¹⁶² However, well it may seem logical at the moment to mandate 3D printed devices go through the PMA process; it will be difficult for manufacturers to complete the clinical trial requirement. The PMA application requires that the manufacturer submit a summary of the clinical investigations involving human subjects involved, selection criteria, study population, study period, adverse reactions and complications, etc.¹⁶³ It will be impossible for a 3D medical device manufacturer to satisfy these

¹⁶⁰ IOM Report at 191.

¹⁶¹ Id.

¹⁶² Antzis, *supra* note 75.

¹⁶³ Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§814.20(b)(3)(v).

regulation requirements, as the patient population of their device will most likely be one, since it is a customizable device. Therefore, while the PMA process may provide greater assurances of safety and effectiveness, due to the technological nature of manufacturing 3D printed medical devices, it is not the appropriate process for these devices.

V. RECOMMENDATIONS

While the 3D printing technologies have been around since the 80s, 3D printed medical devices are just gaining momentum. The applications offer significant benefits such as customization, personalization, cost-effectiveness, and enhanced productivity.¹⁶⁴ However, with every great technology, come concerns, that our regulatory framework must take into account. I have addressed those concerns with the 510(k) and PMA process in this Article. That being said, I have two recommendations regarding the future regulation of 3D printed medical devices. First, while the technology is still in its infancy, I would suggest that the FDA continue to address applications on a case-by-case basis. However, as the applications increase, it will not be feasible to address on a case-by-case basis, which brings me to my second recommendation. I would suggest adding controls specifically tailored to 3D printed devices, to address concerns that 3D printed devices are substantially different from standard medical devices.

A. *Case-by-Case Review*

3D printing is not a new concept to our society; it has been regulated since the 1980s. However, it is currently gaining attention in the medical sector. There are currently two medical devices, the OsteoFab Cranial Device and OsteoFab Facial Device, which have achieved FDA clearance through the 510(k) process and are currently being marketed for widespread

¹⁶⁴ Ventola, *supra* note 12, at 705-06.

distribution.¹⁶⁵ In my opinion, these devices were wrongly classified as “substantially equivalent” to devices that had the same intended use, as the 3D printing process was not taken into account during that assessment.

On the other hand, two 3D printed tracheal splints have been created and implanted at a University of Michigan affiliated hospital and were approved through emergency clearance, since they were classified as a “custom device.”¹⁶⁶ These devices are *not* approved for commercial distribution; they are solely used for the individual patient named in the order. While this Article focuses on devices that will be introduced into the commerce scheme, I would argue that the FDA should treat every 3D printed device as they did the tracheal splints during emergency clearance. These devices are reviewed on a case-by-case basis and do not bypass a “safety and effectiveness” assessment, being that there is no “substantial equivalence” standard in the emergency clearance process.

It will be feasible to address applications on a case-by-case basis right now because 3D printing in the medical device industry is still in infancy stages. The FDA is currently reaching out to stakeholders to obtain input regarding a future regulatory framework, so it seems they are not completely satisfied with using the 510(k) or PMA processes either. They held a workshop in October and received valuable input regarding the technical considerations of this application. In the years to come, there will need to be an established regulatory framework to address 3D printed devices, which will lead me to my second recommendation.

B. Specialized Controls

My second recommendation is to implement specialized controls pertaining to 3D printed devices. I agree with the IOM Report (referenced in Section III, Part C) that with the way the

¹⁶⁵ Wiltz, *supra* note 27.

¹⁶⁶ See Zopf, *supra* note 1. See also Masson, *supra* note 34.

510(k) program is written, there is no “safety and effectiveness” testing done on the new device.¹⁶⁷ However, should the FDA choose to stay with the 510(k) process for the time being, I would argue that additional controls would ease the minds of the public and industry.

3D printed devices that meet the custom device exemption, which are intended for use by a specific patient and are not being made available for commercial distribution, are not subject to the medical device regulatory framework described throughout this Article, and therefore we need not address their controls.¹⁶⁸ However, for purposes of 3D printed devices that will be subject to either the 510(k) or PMA process, there needs to be sufficient checks in place to assure safety and effectiveness.

Devices cleared under the 510(k) process are regulated by both general controls and special controls in order to ensure the safety and effectiveness of the device.¹⁶⁹ General controls include checks such as records and reports and good manufacturing practices.¹⁷⁰ And special controls may include postmarket surveillance, dissemination of guidelines, and any other appropriate actions deemed necessary by the FDA.¹⁷¹ All of these controls are relating to the process of manufacturing the device. However, in the case of 3D printed devices, we need to focus on the materials comprising the device, in addition to the process, as the materials are what is creating safety concerns in the eyes of the FDA and the public.

Devices approved through the PMA process must undergo clinical trials to demonstrate that the new device is both safe effective.¹⁷² As stated in Part IV, it is impossible for a 3D device

¹⁶⁷ IOM Report at 190-91.

¹⁶⁸ Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§360j(b).

¹⁶⁹ *Id.* at §§360c(a)(1)(A).

¹⁷⁰ Food & Drug Admin., *General Controls for Medical Devices*, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm055910.htm> (last updated June 26, 2014).

¹⁷¹ Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§360c(a)(1)(B).

¹⁷² Antzis, *supra* note 75, at 164.

manufacturer to satisfy the clinical trial requirements comprising the PMA process, since the device has a patient population of one, being that it is a customizable device. A way to maneuver around this requirement and still complete the PMA process would be to require clinical trials on the process itself, instead of the product. The manufacturer would be required to show that the manufacturing process is itself safe and repeatable throughout all manufactured devices, regardless of the patient customization. This validation in conjunction with the additional specialized controls would be an appropriate course of action to ensure safety and effectiveness of these devices.

VI. CONCLUSION

3D printing, while it may seem years off to most, is gaining momentum in the Medical Device Industry. The technology is being used right now to create non-functional replacements such as tracheal splints, skulls, hips, etc., however, scientists and healthcare professionals are also in the process of using the technology to create functional organs such as hearts and kidneys. While I assume that by the time these functional organs are viable for distribution, the FDA will have established a more robust approval process, there is no harm in implementing the process right now to allow for consistency and predictability in FDA approval.

When the Medical Device Amendments of 1976 were enacted, Congress recognized that they would take some time to implement, and thus came up with the 510(k) process so as not to stifle device innovation and penalize those manufacturers that were close to approval pre-MDA.¹⁷³ The same concern should be recognized right now. We are not far off from being able to develop functional organs using 3D printing, and yet, there is no regulatory framework robust enough to ensure the safety and effectiveness among these products. Unfortunately, if the system

¹⁷³ Hall, *supra* note 64.

is not reworked to accommodate for 3D printed device, those functional organs, which require more quality control than standard devices, will either be cleared through the relaxed 510(k) process, or those innovations, which could save lives, will be halted to ensure implementation of the new approval process. It's a lose-lose. There needs to be immediate action from the FDA to address this remarkable scientific advancement.