FOR A NEW HEART, JUST CLICK PRINT:
THE EFFECT ON MEDICAL AND
PRODUCTS LIABILITY FROM 3-D
PRINTED ORGANS

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I. INTRODUCTION

The advent of three-dimensional (3-D) printing has changed the possibilities of how everyday items are manufactured.\(^1\) From bike parts, phone covers,\(^2\) and even guns,\(^3\) these items can be made at the push of a button.\(^4\) Soon, blood vessels, tissues, and even organs are expected to be produced through 3-D printing.\(^5\) Being able to manufacture valuable resources such as livers, hearts, nerves, and blood vessels with this technology would reduce shortages and make transplant lists almost obsolete.\(^6\)

3-D printing is by no means a new technology, despite the recent exposure in the media.\(^7\) In fact, the idea of making three-dimensional solid objects with printers was first developed in the mid-1980s.\(^8\) While 3-D printers are able to create simple inanimate objects,\(^9\) biological structures are more complex.\(^10\) Doctors have begun creating prototypes of 3-D printers capable of creating complex structures, but the use of 3-D printed organs for transplantation is years from becoming a reality.\(^11\)

Concerns regarding 3-D printing and its impact on the law have been raised. One of these concerns is the issue of intellectual property rights over the items manufactured.\(^12\) Another concern that has gained some media attention is the manufacture of firearms with 3-D printers and its implications on current firearms regulations.\(^13\) A potential issue that may be raised and affect future jurisprudence is the tort liability for doctors who use or manufacturers who create 3-D printed organs and use them for transplant in


\(^{2}\) Id.


\(^{4}\) Gary, supra note 1.

\(^{5}\) Dr. Stuart Nathan, Building Body Parts With 3D Printing, ENGINEER (May 24, 2010), http://www.theengineer.co.uk/in-depth/analysis/building-body-parts-with-3d-printing/1002542.article.

\(^{6}\) Id.


\(^{8}\) Id.

\(^{9}\) Gary, supra note 1.

\(^{10}\) Jeremy Hsu, 3D Printing Aims to Deliver Organs on Demand, LIVE SC. (Sept. 24, 2013, 8:10 AM), http://www.livescience.com/39885-3d-printing-to-deliver-organs.html.

\(^{11}\) Id.


In Illinois, a doctor owes a duty to his or her patient to exercise reasonable skill and care in the treatment of his or her patient. Furthermore, the Illinois Supreme Court has held that manufacturers of medical devices and pharmaceuticals owe a duty to warn physicians of their products’ dangerous properties, who in turn owe a duty to warn their patients. The process of organ donation in Illinois is governed by the Illinois Anatomical Gift Act.

However, medical devices, such as artificial hearts, are regulated by the Food and Drug Administration (FDA). Medical devices that meet the FDA’s requirements of product approval under the Medical Device Amendment of 1975 can preempt state tort claims. Since 3-D printed biological organs are new and their use is years from occurring, the law has been caught unaware by this technological revolution.

This Note will provide an in-depth analysis of 3-D printers, the current printing and prototyping of biological, artificial organs, and current Illinois tort law. Part II will provide the background on the development of 3-D printing, how 3-D printing has been modified for printing organs, and current regulation on the procurement and transplantation of artificial and biological organs. Part III will examine the impact of current regulation and current Illinois tort law on 3-D printed organs. Part IV offers a recommendation on how tort claims may still be raised under Illinois law and reconciling whether 3-D printed organs should be classified as “artificial” or normal organs as though harvested from another person.

II. BACKGROUND

A. A Brief Introduction to 3-D Printing

Despite its recent exposure in the media, 3-D printing is not a new technology. In fact, Charles Hull, the founder of 3D Systems, Inc., patented a new and improved process for creating 3-D objects using computer blueprints and a fluid in 1984. The patented process, known as stereolithography (solid imaging), developed into today’s 3-D printing. There are different types of printers for 3-D printing, but all of them use
“additive” processes. An “additive” process involves applying a thin layer of material, such as plastic or metal, repetitively adding additional layers one on top of the other until the object is formed.

In order for this process to begin, a blueprint of the object needs to be created. The most common blueprint used is “computer aided design” files (CAD). Ready-made CAD files are made available on the Internet for purchase or download by sites such as Shapeways, Sculpteo, or Thingiverse. These CAD files are computerized models of an object that allow engineers and manufacturers to test, improve upon, and 3-D print that object. However, since the printing process is done in layers, the CAD model must similarly be broken into layers so that each layer is printed according to the model.

As each layer of the CAD file is given to the printer, it is translated into a language that the 3-D printer can understand. The most common language that 3-D printers are programmed to use is Standard Tessellation Language (STL). The printing is a multiple step process:

In the initial step of the SLA process, a thin layer of photopolymer (usually between 0.05-0.15 mm) is exposed above the perforated platform. The UV laser hits the perforated platform, "painting" the pattern of the object being printed.

The UV-curable liquid hardens instantly when the UV laser touches it, forming the first layer of the 3D-printed object.

Once the initial layer of the object has hardened, the platform is lowered, exposing a new surface layer of liquid polymer. The laser again traces a cross section of the object being printed, which instantly bonds to the hardened section beneath it.

This process is repeated again and again until the entire object has been formed and is fully submerged in the tank.

The platform is then raised to expose a three-dimensional object. After it is rinsed with a liquid solvent to free it of excess resin, the object is baked in an ultraviolet oven to further cure the plastic.

The amount of time it takes to create an object varies because large objects require large printers and longer curing times whereas smaller objects

24. Id.
29. Palermo, supra note 27.
30. Id.
31. Id.
32. Id.
33. Id.
require smaller printers and shorter curing times.\textsuperscript{34}

3-D printing is a boon to the manufacturing industry because of the efficiency it bears.\textsuperscript{35} Normal machining processes are when "a piece of raw material is cut into a desired final shape and size by a controlled material-removal process."\textsuperscript{36} This results in up to 90\% of material wasted that is cut away, in contrast to 3-D printing which only uses the amount of material necessary to form the final product.\textsuperscript{37}

However, there are limitations to the technology. One is the material that can be used with the 3-D printer.\textsuperscript{38} Only a handful of plastic and metal compounds can be used in 3-D printing, where the metals must be able to form a powder that will melt.\textsuperscript{39} These specific materials may cost more than the metals or plastics used in conventional manufacturing.\textsuperscript{40} Another limitation is the possibility of failure of the object created.\textsuperscript{41} When printing in layers, each layer has the potential to fail manufacturing standards.\textsuperscript{42} Considering that products are made up of multiple layers, the potential for flaws is multiplied by the number of layers needed to complete the product. This is in contrast to conventional manufacturing which does not require multiple layers.\textsuperscript{43}

However, it cannot be denied that 3-D printing will change how manufacturers consider making their products and with this technology, an operable firearm,\textsuperscript{44} a fully functional automobile,\textsuperscript{45} and, soon, transplantable organs\textsuperscript{46} will be capable of being printed.

\section*{B. The Advent of "Bio-Printing"}

While it's already clear that it is possible to 3-D print inanimate objects, the medical industry has turned towards 3-D printing in hopes of making human tissues and organs.\textsuperscript{47} The need for these organs is great, as an average of twenty-one people die every day waiting for transplants.\textsuperscript{48} In 2009, there

\begin{itemize}
\item \textsuperscript{34} Id.
\item \textsuperscript{35} See generally Freedman, supra note 26 (noting the lowered costs and increased efficiency with which 3-D printing is able to manufacture devices in many markets including niche markets in upcoming years).
\item \textsuperscript{36} Machining, WIKIPEDIA, http://en.wikipedia.org/wiki/Machining (last modified March 12, 2015, 6:58 AM).
\item \textsuperscript{37} Freedman, supra note 26.
\item \textsuperscript{38} Id.
\item \textsuperscript{39} Id.
\item \textsuperscript{40} Id.
\item \textsuperscript{41} Id.
\item \textsuperscript{42} Id.
\item \textsuperscript{43} Id.
\item \textsuperscript{44} See generally Chayka, supra note 13 (describing the 3-D printing of fully operable handguns).
\item \textsuperscript{45} See generally Joe Bargmann, Urbee 2, the 3D-Printed Car That Will Drive Across the Country, POPULAR MECHANICS (Nov. 4, 2013), http://www.popularmechanics.com/cars/news/industry/urbec-2-the-3d-printed-car-that-will-drive-across-the-country-16119485 (describing a 3-D printed hybrid automobile that can get hundreds of miles to the gallon).
\item \textsuperscript{46} See generally Hsu, supra note 10 (describing the ability of 3-D printing to provide patients organs made from their own cells).
\item \textsuperscript{47} Nathan, supra note 5.
\item \textsuperscript{48} The Need is Real: Data, U.S. DEP'T HEALTH & HUMAN SERVS., http://www.organdonor.gov/about/data.html (last visited Apr. 28, 2015).
\end{itemize}
were 105,567 people on the waiting list for a transplant and only 28,463 transplants occurred.\textsuperscript{49} As of December 2014, there are 123,936 people waiting for an organ transplant.\textsuperscript{50} What developed from the hope of reducing this shortage and making the availability of organs more widespread was the process of “bio-printing.”\textsuperscript{51} Similar to regular 3-D printing, bio-printing is an additive process where, instead of plastic or metal is built up in layers, cells are used.\textsuperscript{52}

At present, there are two different processes that can be used to bio-print: use of a dissolvable scaffolding or use of the cells’ natural tendency to organize themselves.\textsuperscript{53} The scaffolding process involves using a dissolvable material, such as sugar, and layering cells over the scaffold.\textsuperscript{54} This allows the cells to derive nutrients from the scaffold and to grow into structures the manufacturer intended them to, such as blood vessels, tissue, and organs.\textsuperscript{55}

The second process involves simply layering the cells upon each other without a scaffold.\textsuperscript{56} While this process leaves the cells without support, it avoids the necessary challenges of finding a suitable material to use as a scaffold.\textsuperscript{57} Instead, the process depends on the cells’ natural ability to form a structure themselves.\textsuperscript{58} As Dr. Anthony Atala, a researcher in bio-printing, explained, “[a]ll the cells in your body are already pre-programmed. There’s a genetic code within all your cells that drives them to do what they are supposed to do if you place them in the right environment.”\textsuperscript{59}

While it may seem simple to upload a blueprint of a heart onto a computer and hit print, it is the complexity of the organs themselves that makes it difficult to print them into viable transplants.\textsuperscript{60} With bio-printing, there are four levels of complexity based on the type of object to be printed.\textsuperscript{61} The first and simplest level is flat structures such as human skin.\textsuperscript{62} The second level of complexity consists of tubular structures such as blood vessels.\textsuperscript{63} The third level of complexity involves hollow organs such as the stomach, bladder, or intestines.\textsuperscript{64} The most complex organs to print are heart, liver, and kidneys because these perform multiple biological functions such as filtering toxins,
pumping blood, and regulating the chemical content of blood.65

One of the reasons the heart, liver, and kidneys are such complex structures is because of their vascularity.66 Vascularity refers to the network of blood vessels in the organ.67 This network is important to the development of bio-printed organs because it is the blood vessels that carry the nutrients and oxygen throughout the organ and carry the waste out.68 Another limitation to the creation of these organs is that even the best 3-D printers have difficulty working on the tiny scale that cell architecture requires.69 Stuart Williams, the scientific director of the Cardiovascular Innovation Institute, stated, "[w]e will be printing things on the order of tens of microns, or more like hundreds of microns, and then cells will undergo their biological developmental response in order to self-organize correctly. Printing is only going to take us partway."70

Currently there are steps being taken towards obtaining the ability to print all the levels of complexity.71 For example, prototypes of bladders, skin, and livers have been produced using 3-D printers.72 China has used a 3-D printer to print an ear.73 Even a transplantable jaw was made by a 3-D printer and fitted onto an eighty-three-year-old woman.74 However, the biggest obstacle to the advancement of this technology is funding.75 Most 3-D printers capable of bio-printing are custom made and even the currently most advanced printers are unable to print cells to match the complexities of real organs.76 However, there are hopes that in ten years, a bio-printed, fully functional heart will be available.77

C. Federal & State Regulation of Organ Donation

Currently, the federal government regulates the procurement of organ donations.78 The Division of Transplantation, a part of the Department of Health and Human Services, is the primary federal entity responsible for the oversight of the organ and blood stem cell transplant systems in the United

65. Id.
68. BBC NEWS, supra note 54.
69. Hsu, supra note 10.
70. Id.
71. Nathan, supra note 5.
76. Hsu, supra note 60.
States. Organ procurement organizations facilitate the procurement, evaluation, and matching of organ donations to patients. These organ procurement organizations were established by the Secretary of Health and Human Services under the National Organ Transplant Act (NOTA).

Under the NOTA, the Secretary of Health and Human Services was directed to establish a task force on organ procurement and transplantation that was to study, among other topics, the long-term health effects of living organ donation. The Secretary of Health and Human Services was also granted the authority to establish organ procurement organizations (OPOs). These organizations would be:

(A) nonprofit,
(B) have agreements with hospitals in its area to identify potential organ donors,
(C) arrange the “acquisition and preservation of donated organs” and provide standards for the acquiring of organs
(D) have a system to distribute donated organs “equitably among transplant patients according to established medical criteria,”
(E) and help hospitals establish and implement protocols for making inquiries about organ donations by potential donors.

In order for these OPOs to operate at a national scale, an organ procurement and transplantation network was also set up. This network was to:
(A) establish a national list of individuals who needed organs,
(B) create a medical criteria for the allocation of organs among transplant patients,
(C) and establish standards for acquiring, transporting, and evaluating donated organs.

This legislation allowed the federal government to establish the standards of how organs are procured, how they are distributed, and whether the organ is viable for donation. While the processes are established by the organ procurement organizations, they are medically based. When a person is referred to a transplant center, their physical and mental health are evaluated to

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84. Id.
86. Id.
determine if the person is suitable for donation and that they do not possess any conditions that could complicate the transplant or recovery steps. If they are accepted onto the waiting list, their information such as tissue type, blood type, length of time on the waiting list, immune status, and location are constantly updated. When a donor is identified and an organ is available, the computer system creates a ranked list of patients based on their physical and mental health information and medical urgency. All of this is to ensure that the best candidate for transplantation is selected.

The states also have their own regulations regarding organ donation. In 1968, the Uniform Anatomical Gift Act (UAGA) was created as a model statute for the states to adopt. The statute provided "the legal foundation upon which human organs and tissues can be donated for transplantation by execution of a document of gift." Illinois adopted the 1968 version of the UAGA.

It is important to note that this statute covers donations of organs, not artificial organs. Under the Illinois statute, a donor is "an individual whose body or part is the subject of an anatomical gift." An organ is "a human kidney, liver, heart, lung, pancreas, small bowel, or other transplantable vascular body part as determined by the Organ Procurement and Transplantation Network . . . ." To donate an organ, the organ must undergo an examination to assure that it would be medically acceptable for transplantation.

D. Federal & State Regulation of Medical Devices

The U.S. Food and Drug Administration (FDA) regulates the use of artificial hearts and valves. In order for a product, such as an artificial heart, to be marketed as a medical device, the FDA must review it. According to the FDA, a medical device:

is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including

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

Furthermore, these medical devices are broken into classes based on the risks of the device.  

Class I devices are low risk and as such have the least regulatory controls. Class II devices have higher risks than Class I devices, which require greater regulatory controls to provide reasonable assurance of the device’s safety and effectiveness. Class III devices have the highest risk and must go through an “approval” process before they can be marketed. 

In order to approve a medical device for marketing, it must either be “cleared” after reviewing a premarket notification or “approved” after reviewing a premarket approval. The process to have a medical device “cleared,” also known as the 510(k) process, requires the submitter to show that the medical device is “substantially equivalent” to a device that is already marketed for the same use. To have a medical device “approved,” reasonable assurance of the device’s safety and effectiveness must be shown. Typically Class I and II devices go through the 510(k) exempt process since they are such low risk. Class III devices typically go through an “approval” process since they are high risk.

E. Riegel v. Medtronic, Inc.

In 1996, Charles Riegel went through an operation called a coronary angioplasty after suffering a myocardial infarction, a heart attack.

104. Id. An example would be dental floss.
105. Id. An example of a Class II device would be condoms.
106. Id. An example given of a Class III device is a replacement heart valve.
107. FDA, supra note 101.
108. Id.
109. Id.
111. Id.; FDA, supra note 103.
113. Conditions We Treat: Myocardial Infarction (Heart Attack), JOHNS HOPKINS MED.,
procedure involved the use of an Evergreen Balloon Catheter, a Class III device approved by the FDA. It was alleged that the device was defective in design, label, and manufacture under New York common law claims. The District Court and the Court of Appeals for the Second Circuit both held that the Medical Device Amendment of 1976 preempted Riegel’s common law claims. The United States Supreme Court granted certiorari.

The Medical Device Amendment of 1976 (MDA) established the classification of medical devices depending on the level of risk each device possessed. The process of premarket approval for these devices is described as “rigorous,” where the FDA spends an average 1,200 hours reviewing each application for approval. It was held that the MDA expressly preempts state requirements “different from, or in addition to, any requirement applicable . . . to the device” under federal law. It was held that the MDA expressly preempts state requirements “different from, or in addition to, any requirement applicable . . . to the device” under federal law.

The Court also relied upon its previous holding in Medtronic, Inc. v. Lohr, where the Court held that common law claims for negligence and strict liability impose requirements that would be preempted by federal requirements specific to a medical device. State common law claims would impose requirements because successful claims would force manufacturers to make safer devices but at the cost of possibly making them less effective. Therefore, state juries would have greater power than officials and legislators in the lawmaking process that set the standards. While the MDA does not prevent a state from providing a remedy for claims based on a violation of FDA requirements, that remedy is a parallel to the FDA requirements, it does not add to them.

The Court held that common law claims of negligence, strict liability, and implied warranty against the manufacturer of the catheter were preempted by the MDA and affirmed dismissal of those claims.


114. Riegel, 552 U.S. at 320.
115. Id.
116. Id. at 321.
117. Id.
118. Id. at 316.
119. Id. at 317–19.
120. 21 U.S.C. § 360(k)(1) (2012); Riegel, 552 U.S. at 321.
123. Riegel, 552 U.S. at 325.
124. Id.
125. Id. at 330.
126. Id.
A. 3-D Printed Organs Will Be Regulated Under the FDA Instead of State Organ Procurement Organizations

The federal body that handles organ donations, the Organ Procurement and Transplantation Network (OPTN), was created to facilitate the process of matching donor organs to patients.127 This would be facilitated by the creation of organ procurement organizations (OPOs) that would establish criteria for acceptable donor organs.128 When the purpose of the organization and its policies are taken into consideration, it is clear that the OPTN and state OPOs only handle the examination and distribution of donated organs from living or deceased donors.129 Therefore the creation, use, and distribution of 3-D printed organs is likely to be regulated by the FDA.

The FDA already regulates medical implants.130 These implants can have a variety of functions, such as replacing body parts or supporting organs and tissues.131 These implants can also be made from skin, bone, or other body tissues.132 Another analogous device to 3-D printed organs is the artificial heart. The FDA regulates devices that are artificial hearts as Class III.133 Furthermore, the FDA has already received several submissions of 3-D printed medical devices.134

An experimental 3-D printed trachea was given emergency-use approval from the FDA for implantation into a six-week-old child.135 While the trachea was not made up of biological tissues, it was created from biocompatible plastic, which means that the trachea would dissolve over time.136 Another patient had seventy-five percent of his skull replaced with an implant created by a 3-D printer.137 That implant was approved by the FDA just weeks prior to the surgery.138 This plethora of examples suggests that 3-D printed organs may be considered medical devices as well.
If 3-D printed organs are considered medical devices by the FDA, they would go through the approval process before going to market. The FDA treats 3-D printed medical devices the same way it treats conventionally manufactured medical devices. However, since the 3-D printing process is different from conventional methods, additional information may be required. That information could be the specific manufacturing process used since there are multiple ways to print an organ, whether mature cells or stem cells are used, and possibly what specific printer was used.

It can be argued that the artificial organs created out of living cells could prevent them from being classified as medical devices under FDA regulations due to their organic nature. However, the FDA does regulate the use of biological products in addition to medical devices through its Center for Biologics Evaluation and Research (CBER). The FDA’s regulations cover human cells and tissues that are “intended for implantation, transplantation, infusion, or transfer into a [patient] . . . .” These cells or tissues can cover “bone, skin, corneas, ligaments, tendons, dura mater, heart valves, hematopoietic stem/progenitor cells derived from peripheral and cord blood, oocytes, and semen.”

The FDA notes that its CBER does not regulate the transplantation of vascularized human organs. That responsibility lies with the Health Resources Services Administration (HRSA). However, as stated earlier, HRSA’s responsibility is to oversee organ transplants that are from donations, not manufactured organs. Therefore, it is likely that with the combination of the FDA’s oversight of biological tissues for transplantation, medical devices for transplantation, and the similarity between artificial hearts and 3-D printed organs that the FDA will have the duty to regulate the manufacture of 3-D printed organs.

139. Lewis, supra note 134.
140. Id.
141. Id.
145. Id.
148. Tissue & Tissue Products, supra note 144.
149. Id.
150. Id.
B. The 510(k) Process Does Not Adequately Assure Safety or Effectiveness of Medical Devices for Users

The 510(k) procedure is a method of notifying the FDA that a manufacturer intends to sell a medical device. The reason why manufacturers would prefer the 510(k) procedure over the premarket approval (PMA) process is because the 510(k) process requires the manufacturer to show "that the medical device is ‘substantially equivalent’ to a device that is already legally marketed for the same use." The 510(k) process is easier than the PMA process because the PMA is "more rigorous" and requires a "reasonable assurance of its safety and effectiveness." Therefore, if a manufacturer can show that their 3-D printed organ is substantially equivalent to a medical device already on market (i.e. artificial hearts), then, after ninety days of review, the device is approved for sale on the market. However, this review process does not adequately assure the effectiveness or safety of medical devices.

On July 29, 2011, the Institute of Medicine of the National Academies released a report on the FDA’s 510(k) process. The committee formed to review the 510(k) process were asked by the FDA to answer two questions: (1) "Does the current 510(k) process protect patients optimally 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?" Ultimately, the committee concluded that the 510(k) process was flawed and suggested changes for the process.

As illustrated by the report, "it generally does not require evidence of safety or effectiveness" because when a device is found to be ‘substantially equivalent,’ it is assumed it has the same safety and effectiveness as the device it is substantially equivalent to. This is a problem for several reasons. First, as the committee’s report brief notes, some devices that are considered substantially equivalent were not subject to stricter modern standards of safety and effectiveness. Secondly, "it essentially requires regulators to approve a new product without clinic trial data . . . ." In sum, so long as manufacturers fill out 510(k) forms correctly, their 3-D printed organs could be approved for

153. FDA, supra note 101.
154. FDA, supra note 110.
157. Id.
158. Id.
159. Id.
160. Id.
sale even if they are substantially equivalent to a flawed medical device and without clinical testing.

C. Riegel Does Not Prohibit All Common Law Claims Against Manufacturers

The Supreme Court in Riegel held that the Medical Device Amendment of 1976 (MDA) preempted state common law claims challenging the safety and effectiveness of medical devices given approval by the FDA. While this may seem like all common law claims would be summarily dismissed, it does not bar all claims against manufacturers.

One avenue of redress for prospective plaintiffs is that they can bring common law claims based on a state's medical device regulations. This is possible because the state's regulations mirror, or "parallel," federal regulations so that both are virtually identical. When a common law claim is raised that is based on a regulation that "parallels" a federal regulation, it imposes no additional requirements on the manufacturer. This avenue of relief was upheld by the Seventh Circuit, which recognized that common law claims based on a state regulation that parallels federal requirements are not preempted by Riegel.

Another potential avenue for plaintiffs to claim relief is through claims against doctors who are negligent or strictly liable in the use of a medical device or against the representative of the manufacturer who provided the medical device to the physician. The District Court in Virginia held that "the FDA does not regulate interactions between corporate representatives and physicians." Since the FDA does not have specific regulations for corporate representatives advising physicians, those claims are not preempted by the MDA and can be brought forward.

However, criticism and controversy has come from the Court's decision in Riegel. One criticism is the Court's reliance on the "rigorous regime" as adequate oversight on Class III medical devices. One device that went through the FDA's Class III evaluation was approved in less than thirty days. Another criticism is that Riegel would prevent plaintiffs from

163. Id.
164. Id.
165. Id.
166. Id.
168. See McMurtrie v. Iolab Corp., 914 F.Supp. 1372, 1373 (E.D. La. 1995) (holding that plaintiff's state law claims of negligence and strict liability were not preempted by federal law).
169. See Schenebeck v. Sterling Drug, Inc., 423 F.2d 919, 922 (8th Cir. 1970) (holding that manufacturers of drugs have a duty under state law to keep abreast of developments of the manufacturer's product and warn the medical profession of those developments).
171. Id.
173. Feder, supra note 172.
obtaining access to discovery since judges will summarily dismiss complaints based on federal preemption.\(^{174}\) This would prevent plaintiffs from obtaining documents, production data, and other records that would provide proof of violation of federal regulations.\(^{175}\)

1. **Parallel State Claims**

The Court’s decision in *Riegel* has closed down one avenue of recovery for plaintiffs against medical device manufacturers.\(^{176}\) One of the effects of this is that plaintiffs have been forced to adapt their claims against medical device manufacturers.\(^{177}\) That adaption is to conform with one of the few remaining ways that *Riegel* has left open, which is to conform with *Lohr* and file claims against manufacturers for violating their common law duties to comply with parallel state requirements.\(^{178}\)

In 1996, the Supreme Court granted certiorari to a products liability case, *Medtronic, Inc. v. Lohr*, concerning a manufacturer of pacemakers, pacemakers which were classified as Class III medical devices by the FDA.\(^{179}\) At issue was whether the common law claims against the manufacturer were preempted by the MDA.\(^{180}\) While the Court recognized that the MDA preempts some states’ laws, it was not meant to preempt all common law claims.\(^{181}\) The reason being is that after examining the language of the MDA, it was clear that Congress did not intend to preempt all, or even most, common law claims.\(^{182}\) Claims brought through common law based on state requirements for medical devices were not preempted by the MDA so long as they were substantially identical or parallel to the federal requirements.\(^{183}\) In order for claims to be preempted, the state requirements “must be ‘with respect to’ medical devices and ‘different from, or in addition to,’ federal requirements.”\(^{184}\) This holding was upheld in the subsequent case of *Riegel*.\(^{185}\)

Therefore, with *Lohr* and *Riegel*, plaintiffs can still assert claims against medical device manufacturers.\(^{186}\) So long as the claim is based on a state requirement that does not subject the manufacturer to additional requirements than federal laws, they are not preempted by the MDA.\(^{187}\) The Seventh Circuit has similarly upheld this rationale by holding that state requirements are not preempted when the plaintiff can show that the state law is “genuinely

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\(^{174}\) Id.

\(^{175}\) Id.

\(^{176}\) *Riegel*, 552 U.S. at 330.


\(^{178}\) Id. at 299–300.


\(^{180}\) Id. at 481–82.

\(^{181}\) Id. at 486–87.

\(^{182}\) Id. at 491.

\(^{183}\) Id. at 496.

\(^{184}\) Id. at 500.


\(^{186}\) *Wartman*, supra note 177 at 300.

\(^{187}\) Id.
equivalent” to the federal law.\textsuperscript{188}

2. \textit{Claims Against Manufacturers Who Have Obtained Pre-Market Approval}

Another issue that has arisen through the plethora of products liability suits against medical device manufacturers is whether or not a claim can still be made when the device gains pre-market approval (PMA).\textsuperscript{189} While a product may gain PMA, the FDA still requires medical device manufacturers to follow a set of standards called the “Current Good Manufacturing Practices” (CGMP).\textsuperscript{190} So can a plaintiff file a claim against a manufacturer if the device gains PMA but violates the CGMP? For this issue, the Fifth, Sixth, and Seventh Circuits have answered yes.\textsuperscript{191}

The Seventh Circuit in \textit{Bausch v. Stryker Corp} upheld a common law claim against a medical device manufacturer for failing to comply with the CGMP.\textsuperscript{192} The Sixth Circuit also upheld common law claims when a manufacturer had failed to comply with a CGMP, even though the manufacturer had complied with the PMA.\textsuperscript{193} Both of these cases provided support to a recent case in Illinois where a federal District Court judge allowed a plaintiff’s common law claims to go forward because a hip implant manufacturer failed to comply with its CGMP.\textsuperscript{194} The Seventh Circuit found that even though Class III devices could obtain PMA, if the manufacturers violated federal law afterwards, then the civil immunity of preemption would no longer apply.\textsuperscript{195} It was the Seventh Circuit’s contention that to grant civil immunity to a manufacturer in the face of violations of federal law would be “counter-intuitive” to what Congress intended.\textsuperscript{196}

In \textit{Hughes v. Bos. Scientific Corp.}, the Fifth Circuit affirmed that several of the plaintiff’s claims were preempted by federal law.\textsuperscript{197} However, the Fifth Circuit also held that the plaintiff’s failure to warn claim, based on Mississippi law, was parallel to federal requirements and not impliedly preempted by federal law.\textsuperscript{198} Therefore, the plaintiff’s failure to warn claim could go forward because the state law did not impose additional requirements on top of the MDA and there was evidence the manufacturers had failed to comply with federal regulation.\textsuperscript{199}

\textsuperscript{188.} Bausch v. Stryker Corp., 630 F.3d 546, 552 (7th Cir. 2010).
\textsuperscript{189.} \textit{See id.} at 556 (upholding a common law claim based on the allegation that the defendant violated the Current Good Manufacturing Process requirements).
\textsuperscript{190.} 21 C.F.R. § 820.1 (2010).
\textsuperscript{192.} \textit{Bausch}, 630 F.3d at 556.
\textsuperscript{193.} \textit{Howard v. Sulzer Orthopedics, Inc.}, 382 F. App’x 436, 441 (6th Cir. 2010).
\textsuperscript{195.} \textit{Bausch}, 630 F.3d at 549.
\textsuperscript{196.} \textit{Id.}
\textsuperscript{197.} \textit{Hughes v. Bos. Scientific Corp.}, 631 F.3d 762, 768 (5th Cir. 2011).
\textsuperscript{198.} \textit{Id.} at 769.
\textsuperscript{199.} \textit{Id.}
Therefore, another potential avenue for plaintiffs to recover from manufacturers of 3-D printed organs would be if the manufacturer violated their CGMP requirements after obtaining PMA.

D. Riegel May Not Protect Manufacturers Who Withhold or Falsify Safety Data

Another question that Riegel brings up is whether preemption would apply to common law claims when the manufacturers deceived the FDA by providing false data or withholding data on safety and effectiveness. 200 Justice Ginsburg made note of this, stating, “[t]he Court’s holding does not reach an important issue outside the bounds of this case: the preemptive effect of § 360k(a) where evidence of a medical device’s defect comes to light only after the device receives premarket approval.” 201 The Seventh Circuit was also confronted with this issue after Riegel in a products liability action against a manufacturer of a Class III medical device. 202 However, the District Court did not address the issue of whether the scope of Riegel was limited to whether the device’s defect came to light during the approval process. 203 This issue was addressed pre-Riegel by the United States District Court for the Eastern District of Texas, holding that for the purposes of preemption analysis, there is no difference between the approval process and supplemental process. 204 However, since that decision was prior to the holding of Riegel, 205 it is unlikely to be upheld post-Riegel.

The Circuits have also been split on this issue, without resolution by the Supreme Court since it denied cert. 206 Specifically, the Sixth and Eighth Circuits have held that the MDA preempts claims of manufacturers violating their obligation to report safety data to the FDA, 207 whereas the Ninth and Fifth Circuits have held that those claims are not preempted by the MDA. 208 Therefore, until the Supreme Court addresses this split, the circuit where a plaintiff is injured will decide whether they can bring such claims forward.

What the Eighth Circuit specifically held was that since the plaintiff failed to provide “concrete allegations that the product sold by Medtronic was not the design approved in the PMA Supplement, these are not parallel claims.” 209 The Eighth Circuit further held that the design defect claim was an attack on the approval process that led the FDA to approve the Class III device,

200. Feder, supra note 172.
203. Id. at 923 n.5.
205. Id.
206. Petition for a Writ of Certiorari at 10, Medtronic, Inc. v. Stengel, 704 F.3d 1224 (9th Cir. 2013) (No. 12-1351).
208. Stengel v. Medtronic, Inc., 704 F.3d 1224, 1233 (9th Cir. 2013); Hughes, 631 F.3d at 775–76.
which is expressly preempted by § 360k(a). But this highlights, again, the flaws pointed out earlier when Riegel was handed down. The flaw is that unless the plaintiff is permitted access to discovery, it would be impossible to discover if there was a defect that was not brought out in the approval process. The reason this is impossible is because the FDA’s approval files are only accessible to the applicant and the FDA.

In response, the Ninth Circuit handled this issue in a way that the Riegel court did not address. It distinguished In re Medtronic, Inc. by analyzing the relief sought and the basis of the claim. The type of relief sought in the Eighth Circuit decision was that the plaintiffs wanted additional labeling and warnings added to the Class III device. This was expressly the type of relief that is contrary to federal requirements and contrary to the holding in Riegel. The plaintiffs in In re Medtronic, Inc. also based their claims on the MDA instead of state law, as opposed to Stengel where the plaintiff’s claim was grounded on a state law claim based on a state-law duty that paralleled a federal-law duty. Since it is based on a state law claim that the manufacturer had a duty to disclose risks associated with use and the MDA also required Medtronic to disclose those risks, those duties were parallel and the claim could not be preempted.

Furthermore, the Fifth Circuit reached a similar conclusion in Hughes. The court in Hughes allowed the plaintiff to go forward on its failure to warn claim that was based on the theory that the manufacturer had failed to report data as required by the FDA. However, the court also held that the plaintiff’s claim of failure to warn based on inadequate labeling was preempted because not only had the device gone through the PMA process but also because the state law that formed the basis of the claim imposed additional requirements.

This line of cases will be likely to impact the availability of relief against manufacturers of 3-D printed organs. Per Riegel, so long as the 3-D organ manufacturer follows proper approval procedure, then common law claims are likely to be preempted by the MDA and summarily dismissed. But if these organs obtain approval and that approval was obtained by withholding safety

210. Id.
211. Id. at 1206.
212. Id.
215. Id. (citing In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200, 1203 (8th Cir. 2010)).
216. Riegel, 552 U.S. at 330.
217. Stengel, 704 F.3d at 1232–33 (citing In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200, 1203 (8th Cir. 2010)).
218. Stengel, 704 F.3d at 1232.
220. Id. at 776.
221. Id. at 768–69.
222. See Riegel, 552 U.S. at 329 ("Surely this means that the MDA would pre-empt a jury determination that the FDA-approved labeling for a pacemaker violated a state common-law requirement for additional warnings.").
data, then there is a possibility for recovery through state “parallel” claims.

E. Are Physicians Who Use 3-D Printed Organs Liable?

While there is excitement about the possibilities that 3-D printing presents, much of the legal controversy surrounding 3-D printing has been around the intellectual property concerns.223 There has also been some concern about the product liability issues of 3-D printing.224 However, one question that should be asked and answered is whether a doctor that implants a 3-D organ could be held liable.

Assuming that doctors will not be the persons manufacturing 3-D printed organs, it will generally be the manufacturers that will incur liability through strict liability or negligence theories of a defective product.225 Therefore, what remains to claim relief from doctors who use 3-D organs is a negligence standard where the burden is on the plaintiff to prove the elements of a negligence medical malpractice case.226 Those elements are: 1) the proper standard of care that the physician conduct is measured against, 2) failure to comply with that standard, and 3) the injury was proximately caused by the failure to comply with the standard.227 And unless the physician’s level of care was grossly apparent, expert medical testimony is required to establish what the standard of care was and that the physician deviated from that standard.228

While any attempt here to envision what would constitute medical malpractice on the part of the physician when using 3-D printed organs would be speculative, looking at other medical device litigation could illustrate what we might expect in the future. For example, one illustrative example could be hip replacement litigation where surgeons install artificial hips.229 Some of these include: 1) failure to antiseptically prepare hip joint prostheses prior to surgery, 2) injuring arteries, veins, nerves, tendons, ligaments, or other anatomical structures during surgery, and 3) failure to monitor patient for signs of prosthesis defect or failure.230

Another medical field that could be illustrative of what to expect for physicians who use 3-D printed organs is cardiology. The reason being is that cardiologists have the option of implanting totally artificial hearts, Class III FDA approved devices.231 The duties of a cardiac surgeon can include: 1) the duty to perform only surgery which is necessary, 2) the duty to properly

228. Purtil, 489 N.E.2d at 872.
229. 98 AM. JUR. Trials 1 § 29 (2014).
230. Id.
prepare the patient for surgery, 3) the duty to properly monitor the patient during surgery, and 4) duty to recognize and treat intra-operative or post-operative complications.\(^{232}\)

One illustrative case of how a physician can be held responsible for negligently implanting a medical device is \textit{Longnecker v. Loyola University Medical Center}.\(^ {233}\) In that case, Mr. Longnecker was seen by the defendant physician who determined that he needed a heart transplant.\(^ {234}\) The defendant approved a donor heart for transplant that did not function, causing Mr. Longnecker's death.\(^ {235}\) The plaintiff alleged that the defendant failed to perform appropriate testing of the donor heart and failed to appropriately perform inspections of the heart.\(^ {236}\) However, the jury found for the defendant doctor on the negligence claim.\(^ {237}\)

While the case was decided in favor of the defendant physician, it does illustrate that physicians can be potentially held to the duty of inspecting the organ they are to implant.\(^ {238}\) This is analogous to the surgeon who implants artificial hips, who is required to observe the patient in case there are defects in the implant.\(^ {239}\) This could further lead one to deduce that surgeons who use 3-D printed organs could potentially have the duty of inspecting the organ they are about to transplant for defects - the failure of which could provide a claim of negligence against the physician.\(^ {240}\)

Another possible avenue of liability would be through the "learned intermediary" doctrine.\(^ {240}\) The "learned intermediary" doctrine requires physicians that prescribe a medical device have a duty to warn their patients of the danger of the medical device.\(^ {241}\) The rationale for this doctrine is that not only do patients need all the information they can get to make an informed decision, the doctor has to make an informed decision as well.\(^ {242}\) The doctor needs to know the effects of any medical device in order to weigh the benefits against the dangers and pass that information to the patient so the patient can weigh those same factors as well.\(^ {243}\) This will be especially important in the context of 3-D organs since they are still a relatively new breakthrough.\(^ {244}\) In fact, 3-D organs are still experimental and any company seeking approval from

\(^{232}\) 68 A.M. JUR. Trials 151 § 129 (2014).


\(^{234}\) \textit{Id.} at 957.

\(^{235}\) \textit{Id.} at 959.

\(^{236}\) \textit{Id.}

\(^{237}\) \textit{Id.} at 962.

\(^{238}\) \textit{See} Longnecker, 891 N.E.2d at 962 (allowing the plaintiff's complaint that the doctor failed to inspect the donor heart to go to trial).

\(^{239}\) \textit{See} 98 A.M. JUR. Trials 1 § 29 (2014) (showing that there may be malpractice when a doctor fails to monitor a patient for signs of prosthesis defect or failure).


\(^{242}\) \textit{See} Kirk, 513 N.E.2d at 392 (explaining the rationale for the doctrine in the context of prescription drugs).

\(^{243}\) \textit{Id.}

\(^{244}\) \textit{See} Lucas Mearian, \textit{The First 3D Printed Organ — a Liver — is Expected in 2014}, \textit{COMPUTER WORLD} (Dec. 26, 2013, 7:05 AM), http://www.computerworld.com/article/2486952/emerging-technology/the-first-3d-printed-organ—a-liver—is-expected-in-2014.html (stating that a bio-printing company expects to create the world's first printed organ, a human liver, in 2014, and it will be used for research only).
the FDA to market their product can expect to go through clinical trials and a review process that could take from three to ten years.\textsuperscript{245} Therefore, it is especially important that physicians avail themselves of the information available on the risks of using 3-D printed organs so that they can come to informed decisions on whether the use of a 3-D printed heart or liver would be proper.\textsuperscript{246}

Taking all of these potential avenues of liability for failure to follow medical standards when implanting 3-D organs, it is likely that physicians could be held liable for their actions if they are in fact negligent when implanting 3-D printed organs. However, until 3-D organs are approved for market use and becomes somewhat widespread, the questions of who will actually be liable for incidents involving 3-D organs will still be unanswered.\textsuperscript{247}

IV. RECOMMENDATION

A. FDA Regulation of 3-D Printed Organs

Current regulation on organs and medical devices, state and federal, do not seem to be on point for 3-D printed organs. An assessment of recent events concerning 3-D printing and 3-D printed products handled by the FDA though suggests that it will be the FDA who will regulate the manufacture and use of 3-D printed organs.\textsuperscript{248} It would also be ideal for the FDA to regulate the release of 3-D printed organs as it already has a rigorous testing process in order for medical devices to be released.\textsuperscript{249} Also, the FDA regulates a similar device, the artificial heart.\textsuperscript{250} Since the artificial heart is already regulated as a Class III device,\textsuperscript{251} it would seem 3-D printed organs, hearts, livers, kidneys, etc., would be regulated as Class III devices. Furthermore, the FDA spends an average of 1,200 hours reviewing each application for Class III devices.\textsuperscript{252}

In contrast, regulation through organ donation organizations would

\textsuperscript{245} Id.; Alexandra Sifferlin, 5 Discoveries that Will Change the Future of Organ Transplants: Printing 3D Organs, TIME (June 6, 2013), http://healthland.time.com/2013/06/06/5-discoveries-that-will-change-the-future-of-organ-transplants/slide/bioprinting-machine-for-organs/.
\textsuperscript{246} See Hansen v. Baxter Healthcare Corp., 764 N.E.2d 35, 42 (Ill. 2002) (holding that a doctor has a duty to convey warnings to their patients of the dangers of a prescribed medical device).
\textsuperscript{247} See Lucas Mearian, Bio-Printing Human Parts Will Spark Ethical, Regulatory Debate, COMPUTER WORLD (Jan. 29, 2014, 6:33 AM), http://www.computerworld.com/s/article/9245834/Bio_printing_human_parts_will.spark_ethical_regulatory.debate (stating that questions remain unanswered as to who will control the ability to produce 3-D organs and who will ensure the quality of those organs); Lyndsey Gilpin, The Dark Side of 3D Printing: 10 Things To Watch, TECH REPUBLIC (Mar. 5, 2014, 4:51 AM), http://www.techrepublic.com/article/the-dark-side-of-3d-printing-10-things-to-watch/ (stating that conversations about the moral, ethical, and legal issues of 3-D printing in the biomedical field have started).
\textsuperscript{248} See generally ORGAN PROCUREMENT & TRANSPLANTATION NETWORK supra note 127; ORGAN PROCUREMENT & TRANSPLANTATION NETWORK supra note 128; FDA, supra note 130 (indicating their existing ability in dealing with organ transplants).
\textsuperscript{250} FDA, supra note 18.
\textsuperscript{252} Riegel, 552 U.S. at 318.
delegate the evaluation process to the states.\textsuperscript{253} There are set standards by the federal government of evaluating the organs themselves.\textsuperscript{254} However, hospitals also have their own processes when evaluating organs for transplantation after donation.\textsuperscript{255} This could lead to different standards at different hospitals in different states. These varying standards may or may not be as rigorous as the standards set by the FDA when evaluating Class III devices.

Therefore, it is likely that the FDA will take over the regulation of 3-D printed organs. With a rigorous process already in place, it seems likely that the FDA is in the best position to take over the regulation of 3-D printed organs.\textsuperscript{256}

\textbf{B. Plaintiff's Claims Against Manufacturers and Physicians}

\textit{1. Getting Past MDA and Preemption}

Assuming that it will be the FDA’s responsibility in the regulation and review of 3-D printed organs, plaintiffs will run into one of the biggest obstacles for claims against the manufacturer, which is the MDA. Since the holding of \textit{Riegel}, plaintiffs have been forced to adapt their claims in response to the MDA.\textsuperscript{257} Common law claims against medical device manufacturers would be preempted if those claims were based on state regulations that imposed additional requirements on those manufacturers compared to federal regulations.\textsuperscript{258} However, if those common law claims are based on state regulations that “parallel” federal regulations, then those claims can be brought to trial.\textsuperscript{259} Therefore, plaintiffs that have evidence of medical device manufacturers that caused injury through defective medical devices should bring their claims through “parallel” state law regulations.

Another potential avenue of imposing products liability on a medical device manufacturer for faulty 3-D printed organs is if there is evidence that the manufacturer concealed information from the FDA. While that issue will not be addressed by the Supreme Court,\textsuperscript{260} it should be resolved in favor of the plaintiff. To prevent liability when a manufacturer knowingly hides safety data harms patients who depend on the devices that these manufacturers provide. However, even if manufacturers were granted PMA of Class III devices, imposing liability is still possible. If the manufacturer violates the CGMP after PMA approval, then the manufacturer could be held liable for defective 3-D printed organs.\textsuperscript{261}

\begin{itemize}
\item \textsuperscript{253} 42 U.S.C. § 273 (2012).
\item \textsuperscript{254} 42 U.S.C. §§ 273–74 (2012).
\item \textsuperscript{256} \textit{Riegel}, 552 U.S. at 317.
\item \textsuperscript{257} Wartman, supra note 177 at 299.
\item \textsuperscript{258} \textit{Riegel}, 552 U.S. at 330.
\item \textsuperscript{259} \textit{Id}.
\item \textsuperscript{260} See Medtronic, Inc. v. Stengel, 134 S. Ct. 2839 (2014) (denying writ of certiorari).
\item \textsuperscript{261} Bausch v. Stryker Corp., 630 F.3d 546, 556 (7th Cir. 2010).
\end{itemize}
2. Good Old Fashion Negligence Against Health Care Providers Still Applies

Even if the plaintiff fails to find evidence of negligence on the part of the manufacturer, imposing liability against the doctor who implanted the medical devices is still possible. Physicians have a duty to exercise reasonable care that a physician would apply. Physicians also have a duty to warn their patients of the dangers of the medical devices they use, otherwise known as the “learned intermediary” doctrine. Evidence of breaching either duty in conjunction with the use of 3-D printed organs would provide avenues of imposing liability of physicians and relief for injured patients.

V. CONCLUSION

3-D printing has brought about changes in the way we think about manufacturing and producing consumer goods. It has also provided a new way to potentially relieve the need of organs that causes the death of patients every day. 3-D printing may provide the answers to many of the problems we have today, but it also brings up just as many questions. These are questions about ethics, regulation, and ownership. Even more so in the medical standpoint of introducing 3-D printed organs into the medical device market. The introduction of these devices needs to be regulated and responsibility imposed on those who negligently manufacture defective organs that could save the lives of millions. When a defective organ could harm the hundreds of thousands that need organs every year, avenues of imposing liability against manufacturers are needed. For a manufacturer, 3-D printing an organ can be as simple as clicking print. Avoiding liability should not be.

265. Hsu, supra note 10.
266. U.S. DEP’T HEALTH & HUMAN SERVS., supra note 50.
268. See generally U.S. DEP’T HEALTH & HUMAN SERVS., supra note 48; U.S. DEP’T HEALTH & HUMAN SERVS., supra note 50 (indicating the number of individuals in need of an organ transplant).