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NARROWING IN ON THE PROBLEM: A COMPONENT-LEVEL ANALYSIS OF “HYBRID” MEDICAL DEVICES

Abstract: The Medical Device Amendments of 1976 (“MDA”) classify medical devices into three categories, each of which represents a different level of risk, and requires a different level of federal oversight. Class III devices, which pose the most risk, are subject to the highest level of oversight. Those devices are protected from any claims based on state laws that differ from or add to the requirements imposed by the MDA. On March 1, 2018, the United States Court of Appeals for the Third Circuit, in *Shuker v. Smith & Nephew, PLC*, considered the application of preemption under the MDA to a “hybrid” device, which was made up of various Class II components and one Class III device. The Third Circuit held that these devices are to be considered at the component level, thus allowing hybrid devices with Class III components to be protected from state-law claims. This Comment argues that the Third Circuit’s level of analysis, which looked at the requirements imposed on the specific component at issue rather than the device itself, was the proper method of evaluation.

INTRODUCTION

The principal objective of the Medical Device Amendments of 1976 (“MDA”) to the Federal Food, Drug, and Cosmetic Act is to maximize the safety and effectiveness of medical devices, especially as society becomes increasingly reliant on various types of medical equipment.¹ The MDA categorizes medical devices into three different classes by evaluating the level

¹ 21 U.S.C. § 321(h) (2012 & Supp. 2017) (the Federal Food, Drug, and Cosmetic Act defines “device” as “an instrument, apparatus, implant, machine, contrivance, implant, in vitro reagent, or other similar or related article”); see *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 474 (1996) (citing Medical Device Amendments of 1976 (“MDA”), Pub. L. No. 94-295, 90 Stat. 539 (1976)) (discussing the history and purpose behind the MDA). The FDCA originally set forth regulations requiring premarket approval only for new drugs but had no such requirements for the introduction of medical devices into the market. *Lohr*, 518 U.S. at 475 (citing H.R. REP. NO. 94-853, at 6 (1976); S. REP. NO. 93-670, at 1–2 (1974); David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW. & CONTEMP. PROB. 2, 40 (1939)). The technologies used in medical devices became increasingly sophisticated, however, thus resulting not only in increased reliance on these devices, but also in more serious injuries being incurred when they failed. See *id.* (pointing to a notable intrauterine contraceptive device from 1970 whose ineffectiveness and failure led to a substantial amount of unintended pregnancies, serious infections, and, in some cases, death). The higher level of public concern over the safety and reliability of these medical devices eventually led to Congress’s enactment of the MDA. *Id.* at 476.

of risk that each device presents and classifying them accordingly.² Each class of devices must therefore undergo different approval processes and meet different safety and effectiveness requirements before they can be marketed to the public.³ Class I medical devices are ones that pose little risk of harm to patients and are therefore subject to minimal federal oversight.⁴ Class II medical devices, which have the potential to be more dangerous, must comply with additional performance standards the federal government sets forth to be marketed.⁵ Class III medical devices pose the greatest risk of harm to patients and therefore receive the highest level of federal oversight, which often entails individualized requirements imposed on each device that condition the device’s ability to enter and remain on the market.⁶

² 21 U.S.C. § 360c(a)(1).

³ *Id.* For a detailed explanation of the different approval processes and requirements, see *infra* notes 4–6, 15–21 and accompanying text.

⁴ 21 U.S.C. § 360c(a)(1)(A) (identifying Class I medical devices as ones for which “general controls” are “sufficient to provide reasonable assurance of the safety and effectiveness of the device,” or, alternatively, as medical devices that lack sufficient information to establish that general controls would sufficiently assure that the device is both safe and effective but that the device is not intended to support or sustain human life and does not pose an unreasonable risk to patients’ health and safety); see *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008) (noting that examples of Class I devices are ones such as “elastic bandages and examination gloves”). Because they pose relatively low risks of harm, these devices are subject only to “general controls,” which are imposed on all medical devices. See 21 U.S.C. § 331 (prohibiting the “adulteration” and “misbranding” of medical devices); see, e.g., *id.* § 351 (setting forth the various ways in which a device may be deemed “adulterated,” such as by containing poisonous substances or being produced in insanitary conditions); *id.* § 352 (setting forth the ways in which a device may be deemed “misbranded,” including containing false or misleading labeling or lacking sufficient instructions and warnings on the label); see also *Riegel*, 552 U.S. at 322 (characterizing general manufacturing and labeling requirements as “applicable across the board to almost all medical devices”).

⁵ 21 U.S.C. § 360c(a)(1)(B) (identifying Class II medical devices as ones for which “general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance”); see *Riegel*, 552 U.S. at 316 (setting forth examples of Class II medical devices to include “powered wheelchairs and surgical drapes”). Class II medical devices are often subject to “special controls,” which entail additional safety and effective requirements such as “performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines” 21 U.S.C. § 360c(a)(1)(B).

⁶ 21 U.S.C. § 360c(a)(1)(C)(i)(I)–(II) (stating that a medical device will be categorized as Class III when the requirements imposed on either Class I or Class II devices are deemed insufficient to “provide reasonable assurance of the safety and effectiveness of the device” and the device is “purported or represented . . . to . . . support[] or sustain[] human life[,] . . . prevent[] impairment of human health,” or the device “presents a potential unreasonable risk of illness or injury”); see *Riegel*, 552 U.S. at 317 (identifying examples of Class III medical devices as “replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators”). Manufacturers of Class III medical devices must submit an extensive application to the Food and Drug Administration (FDA) in order to receive premarket approval. *Riegel*, 552 U.S. at 317–18. The FDA must then spend a significant amount of time reviewing the device’s application and will often subject these devices to individualized requirements or performance standards on which their approval to enter the market and ability to remain on the market are conditioned. *Id.* at 318–19.

The MDA also has a preemption provision that prohibits state and local governments from enacting requirements directed at the safety and effectiveness of medical devices if their requirements either differ from or add to those imposed under the MDA.⁷

In a case of first impression, the United States Court of Appeals for the Third Circuit, in *Shuker v. Smith & Nephew, PLC (Shuker II)*, considered the application of the MDA to a medical device that consisted of multiple components, one of which came from a different Class III device although the rest were components of a Class II device.⁸ Taking into consideration the fact that a device's classification affects the application of the preemption provision, the Third Circuit had to decide whether to analyze the device at the component-level, thus focusing on the Class III component that was the source of the plaintiffs' claims, or at the device-level, therefore regarding the overall system as a Class II device.⁹ After considering the text and application of the MDA, as well as guidance from the Food and Drug Administration ("FDA"), the court held that the device should be analyzed at the component-level.¹⁰

This Comment argues that the Third Circuit properly analyzed the device at the component-level.¹¹ Part I discusses the legal and factual history of *Shuker II*.¹² Part II sets forth the arguments made by the parties in favor of either a device-level or component-level approach.¹³ Lastly, Part III ar-

⁷ See 21 U.S.C. § 360k(a) (2012) (prohibiting state and local governments from imposing or continuing to impose on medical devices any requirement "which is different from, or in addition to, any requirement applicable under this Act" and "which relates to the safety or effectiveness of the device"); see also *Riegel*, 552 U.S. at 323–25 (applying the MDA's preemption provision to common-law claims against a Class III catheter that received premarket approval and concluding that the claims are preempted because they are premised upon safety and effectiveness requirements that differ from or add to device-specific federal requirements); *Lohr*, 518 U.S. at 493–94, 496–97 (finding that state-law claims of negligence against the manufacturers of a pacemaker are not preempted because the device was only subject to generically applicable federal requirements, rather than device-specific ones, and because some of the claims were based on state requirements that mirrored federal ones and were therefore not different or additional).

⁸ *Shuker v. Smith & Nephew, PLC (Shuker II)*, 885 F.3d 760, 768 (3d Cir. 2018) (referring to the hip replacement system as a "hybrid system" because it is a device itself but is made up of components that are Class II as well as Class III).

⁹ See *id.* at 767–68, 772 (noting that Class I and II devices do not receive preemption protections but that Class III devices may receive such protection, and addressing the issue of how to apply the preemption analysis to a hybrid device). See generally *infra*, notes 24–30 and accompanying text (discussing the ways in which a medical device's classification and approval process affects whether or not the preemption provision applies to that device).

¹⁰ See *Shuker II*, 885 F.3d at 772–74 (concluding that a component-level analysis is the proper approach); see also *infra* notes 45–50, 67–76 and accompanying text (describing the court's holding and reasoning).

¹¹ See *infra* notes 15–76 and accompanying text.

¹² See *infra* notes 15–50 and accompanying text.

¹³ See *infra* notes 51–66 and accompanying text.

gues in favor of the court’s ruling that hybrid devices should be analyzed at the component-level.¹⁴

I. LEGAL AND FACTUAL CONTEXT

Section A of this Part discusses the various classifications and approval processes under the MDA and the ways in which they affect a preemption analysis under the MDA.¹⁵ Section B of this Part examines the factual and procedural history of *Shuker II*.¹⁶

A. The Medical Device Amendments: Classifications and Preemption

The rigorous “premarket approval” process for a Class III device requires the manufacturer to submit a detailed report discussing the device’s safety and efficiency to the FDA and provide it with a sample of the device and its proposed labeling, which establishes the device’s conditions of use.¹⁷ The FDA spends, on average, approximately 1,200 hours reviewing these

¹⁴ See *infra* notes 67–76 and accompanying text.

¹⁵ See *infra* notes 17–30 and accompanying text.

¹⁶ See *infra* notes 31–50 and accompanying text.

¹⁷ See 21 U.S.C. § 360e(c)(1) (2012 & Supp. 2017) (requiring the report to include, for example, any pertinent information regarding the device’s safety and effectiveness, a description of the device’s components and properties as well as how the device is operated, and a detailed description of the device’s manufacturing); 21 C.F.R. § 814.20 (2018) (listing additional requirements for a premarket approval application); Daniel W. Whitney, *Guide to Preemption of State-Law Claims Against Class III PMA Medical Devices*, 65 FOOD DRUG L.J. 113, 115 (2010) (describing the premarket approval process). There are, however, two exceptions to the premarket approval requirement, which have led to a majority of Class III devices entering the market without undergoing the premarket approval process. See 21 U.S.C. § 360e(b)(1) (setting forth exceptions to the premarket approval requirement for Class III devices); see also *Riegel*, 552 U.S. at 317 (citing PETER B. HUTT ET AL., FOOD AND DRUG LAW 992 (3d ed. 2007) (noting that in 2005, 3,148 devices were approved through a process known as the Section 510(k) process while only thirty-two devices were approved through the premarket approval process); *Lohr*, 518 U.S. at 477, 479 (citing H.R. REP. NO. 101–808, at 14 (1990)) (identifying a general trend of Class III devices entering the market without receiving premarket approval and specifically noting a 1990 report that found that eighty percent of Class III devices instead entered the market through the Section 510(k) process). The first exception, which is often referred to as a “grandfathering provision,” allows a Class III device that was already on the market at the time the MDA was enacted to remain so until the FDA completes the premarket approval process for that device. See 21 U.S.C. § 360e(b)(1)(A) (requiring the granting of premarket approval to Class III devices that were “introduced . . . before the date of enactment”); see also *Lohr*, 518 U.S. at 478 (noting Congress’s intent to prevent existing devices from being pulled from the market). The second allows a new device to enter the market if the FDA finds it to be “substantially equivalent” to a pre-existing device on the market through what is referred to as the Section 510(k) process. See 21 U.S.C. § 360e(b)(1)(B) (requiring premarket approval for Class III devices that are “substantially equivalent to another device”); see also *Lohr*, 518 U.S. at 478 (noting Congress’s intent to “prevent manufacturers of grandfathered devices from monopolizing the market while new devices clear the PMA hurdle, and to ensure that improvements to existing devices can be rapidly introduced into the market”).

applications and, after weighing the device's possible benefits and risks, grants premarket approval only if the manufacturer has provided sufficient assurance that the device is both safe and effective.¹⁸

The FDA may impose additional requirements or restrictions on a Class III device as a condition to its approval to enter or remain on the market.¹⁹ After receiving premarket approval, the device must continue to be manufactured and marketed in a way that is entirely consistent with the requirements set forth in the FDA's premarket approval order.²⁰ Health care practitioners, on the other hand, are afforded much more discretion in that respect, and are thus not prohibited from prescribing or administering these devices for "off-label" usage for purposes other than what the FDA has approved.²¹

¹⁸ See 21 U.S.C. § 360c(a)(2)(C) (requiring that the benefits and risks of the device be weighed against each other in the analysis of a premarket approval application); *id.* § 360e(d) (describing the process by which premarket approval may be granted or denied); *Riegel*, 552 U.S. at 318 (providing a detailed description of the FDA's process and standards for reviewing premarket approval applications); *see also* 21 U.S.C. § 360c(a)(2) (requiring that, in its evaluation of a device's possible benefits and risks, the FDA must take into consideration the patients for whom the device is intended and the suggested conditions of use as provided by the label).

¹⁹ See 21 C.F.R. § 814.82 (stating, for example, the FDA may require periodic post-approval reports on the device's safety, post-approval reports on any clinician investigations, or the inclusion of specific information and warnings in any advertisements for the device); Whitney, *supra* note 17, at 116–17 (describing the reporting requirements for Class III devices after approval has been granted) *see, e.g.*, *Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 151–52, 160–61 (W.D. Pa. 2012) (discussing the obligation of the manufacturer of a hip replacement system to report any ongoing clinical investigations or studies).

²⁰ 21 C.F.R. § 814.80.

²¹ 21 U.S.C. § 396 (2012) ("Nothing in this Act . . . shall be construed to limit or interfere with the authority of a health care practitioner."); *see* *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (noting the widely accepted importance of giving health care practitioners the flexibility to use medical devices as they see fit, and explaining that although the FDA seeks to ensure patients' safety with regards to medical devices, the regulations it sets forth are not meant to "interfer[e] with the practice of medicine"); Jean Macchiaroli Eggen, *Navigating Between Scylla and Charybdis: Preemption of Medical Device "Parallel Claims,"* 9 J. HEALTH & BIOMEDICAL L. 159, 165–71 (2013) (noting the general lack of success of lawsuits against manufacturers in circumstances of off-label use). Off-label use of drugs and devices by physicians is common and many regard it as an important part of the practice of medicine. *See* Marcia Boumil, *FDA Approval of Drugs and Devices: Preemption of State Laws for "Parallel" Tort Claims*, 18 J. HEALTH CARE L. & POL'Y 1, 5 (2015) (noting the American Medical Association's support of physicians' off-label use of FDA-approved drugs and devices); John J. Smith, *Physician Modification of Legally Marketed Medical Devices: Regulatory Implications Under the Federal Food, Drug, and Cosmetic Act*, 55 FOOD & DRUG L.J. 245, 250–52 (2000) (providing an example in which a certain type of stent did not sufficiently address the medical needs of patients until physicians created custom stents made from multiple FDA-approved products); James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 72, 76–80 (1998) (noting the frequency of off-label use and that many within the medical community deem it to be an essential practice and that it leads to "state-of-the-art treatment," in part due to the fact that medical discovery may move at a faster rate than the FDA's regulatory process).

Class I and Class II medical devices, however, have a far less rigorous standard of review and are subjected to fewer requirements.²² These devices often undergo what is referred to as the “Section 510(k) process,” which requires the manufacturer to report to the FDA the device’s class and the steps that the manufacturer has taken to comply with the specific requirements imposed on that class.²³

By prohibiting state and local governments from imposing different or additional requirements on the safety or efficiency of medical devices, the MDA preempts many state-law actions that challenge a device’s compliance with such requirements.²⁴ Preemption is only afforded, however, when there are federal requirements that pertain specifically to the device in question

²² See 21 U.S.C. § 360c(a)(1)(A) (identifying Class I medical devices as ones for which general controls, such as universal labeling requirements, are sufficient to assure that the device is both safe and effective); *id.* § 360c(a)(1)(B) (identifying Class II medical devices as ones for which general controls do not provide sufficient assurance of the device’s safety and effectiveness and therefore require “special controls” such as performance standards or postmarket surveillance).

²³ See *id.* § 360(k) (setting forth requirements for the Section 510(k) process); see also *Lohr*, 518 U.S. at 478 (explaining that the Section 510(k) process, the name of which originates from its original section within the MDA, is also known as the “premarket notification” process and is the same process by which manufacturers notify the FDA of their intention to market a device that is “substantially equivalent” to a pre-existing device on the market). Because many of the evaluations that are made under the Section 510(k) process are focused on the device’s equivalence to another device, rather than its safety and effectiveness, this process does far less to protect patients. *Shuker II*, 885 F.3d at 767 (citing *Lohr*, 518 U.S. at 478).

²⁴ See *Riegel*, 552 U.S. at 324–25 (finding that the MDA bars certain claims based on state-imposed requirements and noting that the definition of a state requirement within the context of preemption under the MDA is not limited to state statutes and regulations, but rather also includes state common-law duties); 21 U.S.C. § 360k(a)(1) (prohibiting state and local governments from imposing safety requirements on medical devices that either differ from or add to federal requirements). Although the MDA preempts state-law claims based on requirements that are either different from or in addition to federal requirements, states are allowed to provide for damages for violations of state laws that simply mirror federal requirements, which are often referred to as parallel claims. 21 C.F.R. § 808.1(d)(2); see also *Riegel*, 552 U.S. at 330 (noting that the MDA does not preempt parallel claims, which are based on state laws that do not differ from or add to federal requirements). Moreover, in addition to being expressly preempted under § 360k(a), a claim may also be impliedly preempted when it conflicts with the overall federal statutory scheme. See *Buckman*, 531 U.S. at 348–50 (finding that a fraud-on-the-FDA claim was impliedly preempted because it conflicted with the FDA’s delegated authority to enforce the MDA, an authority that the Court finds to be critical to the MDA, because the claim rested only on violations of federal law rather than state law). When a state tort claim against a medical device relies exclusively on violations of federal requirements, it conflicts with Congress’s intention that the MDA be enforced only by the federal government and may therefore be impliedly preempted. See *id.* at 352 (noting Congress’s intent that the MDA be enforced exclusively by the FDA); see also Eggen, *supra* note 21, at 165–71 (discussing express and implied preemption under the MDA). Thus, although parallel claims are not expressly preempted, they may still be impliedly preempted and the Supreme Court has offered little guidance as to which claims may survive implied preemption. See *id.* at 168 (noting that the Supreme Court left open the question as to whether and when a parallel claim may overcome implied preemption and discussing disagreements amongst lower courts).

rather than generic requirements that are imposed on all devices.²⁵ The process by which a medical device has been approved has a significant impact on whether or not a manufacturer must answer to state law liability.²⁶ The Section 510(k) process, which evaluates a device's equivalence to a preexisting device, requires manufacturers to demonstrate only that they have complied with all generic requirements.²⁷ Accordingly, because it does not impose device-specific requirements, devices that are approved through this process do not receive preemption from common-law claims such as negligence or strict liability.²⁸ The premarket approval process, by contrast, is primarily concerned with the safety of devices and accordingly calls for an extensive review of each device in order to impose individualized requirements.²⁹ As such, Class III devices that have received premarket approval are entitled to preemption protections from any different or additional state law requirements for their safety or effectiveness, regardless of whether third parties actually use them in FDA-approved manners.³⁰

B. Shuker's Factual and Procedural History

In 2009, Walter Shuker received a total hip replacement surgery.³¹ The hip replacement system, called the R3 Acetabular System, was a Class II

²⁵ 21 C.F.R. § 808.1(d). To determine whether a claim is preempted, the *Riegel* Court set forth a two-step framework for analysis in which it first determined whether the individual device had specific requirements prescribed by the federal government, and second determined whether the plaintiff's claim was based on state requirements regarding the safety and effectiveness of that device that either add to or differ from the federal requirements. *Riegel*, 552 U.S. at 321–22.

²⁶ See *Riegel*, 552 U.S. at 322–23 (comparing the applicability of the MDA's preemption provision to devices approved through the Section 510(k) process and devices that received premarket approval); *Lohr*, 518 U.S. at 493–94 (declining to preempt claims against a device that received approval through the Section 510(k) process because it did not impose device-specific requirements); see also Keith N. Hylton, *An Economic Perspective on Preemption*, 53 B.C. L. REV. 203, 217, 219–20 (2012) (arguing that, among other factors, courts should generally be more willing to preempt state-law claims when the agency, which holds far more expertise, employs a more rigorous regulatory process).

²⁷ 21 U.S.C. § 360(k); see *supra* note 21 and accompanying text (noting that many of the Section 510(k) evaluations that are made are ones in which the FDA must determine whether a device is substantially equivalent to a preexisting one).

²⁸ See *Lohr*, 518 U.S. at 493–94 (declining to preempt certain state law claims against a device because it underwent the Section 510(k) process and therefore was not subject to any device-specific requirements).

²⁹ See *supra* notes 17–21 and accompanying text (explaining the premarket approval process).

³⁰ See *Riegel*, 552 U.S. at 323–25 (affording preemption to a Class III device because the premarket approval process subjected it to federal safety and effectiveness requirements and the state-law requirements were different or additional); *supra* note 21 and accompanying text (noting that manufacturers are not liable for off-label usage of medical devices as prescribed and administered by health care professionals and discussing the acceptance and necessity of off-label usage in the practice of medicine).

³¹ *Shuker v. Smith & Nephew PLC (Shuker I)*, No. 13-6158, 2015 WL 1475368, at *3 (E.D. Pa. Mar. 31, 2015), *aff'd* 885 F.3d 760 (3d Cir. 2018).

device that the FDA approved through the Section 510(k) process.³² The system was made up of numerous components, all of which were manufactured by Smith & Nephew.³³ One component of the system the plaintiff’s doctor used was called the R3 metal liner.³⁴ The R3 metal liner was a Class III device that received supplemental premarket approval as an additional component for a different Class III device, the Birmingham Hip Resurfacing System, which the defendant also manufactured.³⁵ Shortly after receiving supplemental premarket approval for the R3 metal liner, the defendant issued a press release announcing the new product as an option to use in the R3 Acetabular System.³⁶ The press release stated that the R3 metal liner was approved for the Birmingham Hip Resurfacing System but it did not mention the fact that the FDA had not considered its safety when used in the R3 Acetabular System.³⁷ Moreover, because the FDA had not approved the R3 metal liner for use in a total hip replacement system, the plaintiff’s doctor’s implementation of it consisted of an “off-label” use.³⁸

Nearly two years after the surgery, Mr. Shuker started feeling pain and discomfort around his hip.³⁹ His surgeon originally performed two procedures in an attempt to locate the source of his pain and alleviate it, but ulti-

³² *Id.* at *1 n.6 (the system contains four main components, each of which were individually approved through the Section 510(k) process and permitted to be used as a part of the R3 Acetabular System).

³³ *Id.* at *1 (the R3 Acetabular System, as approved by the FDA, consists of an acetabular shell, a polyethylene liner, a femoral head, and a femoral stem). The total hip replacement system implemented by Mr. Shuker’s doctor, however, differed from that approved by the FDA in that it replaced the polyethylene liner with an R3 metal liner. *Id.* at *3.

³⁴ *Id.* at *3.

³⁵ *Id.* at *2 (the R3 metal liner that the plaintiff’s doctor used had received supplemental premarket approval to be used in the pre-existing Birmingham Hip Resurfacing System, which also underwent the premarket approval process). The R3 metal liner’s approved labeling specifically stated that it was only meant to be used as a part of the Birmingham Hip Resurfacing System and warned that it should be replaced with a polyethylene liner if a total hip replacement system is implemented. *Id.*

³⁶ *Id.* at *3.

³⁷ *Id.*

³⁸ *Id.* (noting that Mr. Shuker’s surgeon’s implementation of the R3 metal liner in the system was an off-label use because the FDA had not approved it to be used in that context). A physician’s “off-label” use of a medical device is widely accepted. *See supra* note 21. The defendants, however, had issued a press release in February 2009 promoting the use of the R3 metal liner in total hip replacements without FDA approval. *Shuker I*, 2015 WL 1475368, at *3 n.12. This, the Shukers argued, constituted “off-label promotion,” which, unlike off-label usage, has been interpreted by many to be a violation of the MDA. *Id.* at *13; *see* Whitney, *supra* note 17, at 130 (characterizing medical devices that have been the subject of off-label promotion as misbranded and adulterated under the MDA). The defendants’ off-label promotion of the R3 metal liner was the premise of the plaintiffs’ parallel claims, which were dismissed for failure to state a claim. *Shuker I*, 2015 WL 1475368, at *14.

³⁹ *Shuker I*, 2015 WL 1475368, at *3.

mately had to remove and replace the entire system.⁴⁰ Mr. Shuker and his wife subsequently filed suit alleging violations of both common law and federal law.⁴¹ Smith & Nephew moved for summary judgment on the state law claims of negligence, strict liability, and breach of implied warranty, arguing that the MDA preempted the claims because they imposed different or additional requirements.⁴² The District Court for the Eastern District of Pennsylvania, in its opinion in 2015 in *Shuker v. Smith & Nephew PLC* (*Shuker I*), granted summary judgment in favor of the defendant, finding that the claims were preempted because the R3 metal liner had received premarket approval.⁴³ In addition, the court dismissed the Shukers' parallel claims, which based several state law tort claims on the defendant's off-label promotion of the R3 metal liner in violation of FDA regulations, for failure to state a claim.⁴⁴

The Third Circuit affirmed the district court's ruling that the state law claims based on the safety and effectiveness of the R3 metal liner were preempted and held that a hybrid device must be analyzed at the component-level.⁴⁵ In its reasoning, the court first pointed to the relevant statutory language of the Federal Food, Drug, and Cosmetic Act, which defines a

⁴⁰ *Id.* (the surgeon determined that the pain had been caused by “the degeneration of the metal-on-metal articulation of his artificial hip”).

⁴¹ *Id.* at *4 (the preempted claims set forth in the First Amended Complaint included “negligence/negligence per se, negligence based on violations of various FDA regulations, strict products liability, breach of express warranty, breach of implied warranties of merchantability, fraud and loss of consortium”).

⁴² *Id.* at *5.

⁴³ *Id.* at *4 (pointing to the fact that the R3 metal liner appeared to be the source of the plaintiff's injuries and “at the heart of” the claims). Moreover, the court notes the fact that the particular combination of components used was put together by the plaintiff's surgeon, thus qualifying this as an off-label use. *Id.* at *7.

⁴⁴ *Id.* at *13–14 (for example, the plaintiffs based a negligence claim on the fact that the defendants had engaged in false and misleading advertising by indicating in the press release that the R3 liner was a safe option for the R3 Acetabular System). Although these claims were not necessarily preempted because they were based on violations of federal laws that could be interpreted to prohibit off-label promotion, the district court dismissed these claims, finding that there were insufficient facts to support an inference that the press release was misleading enough to consist of off-label promotion, or that any off-label promotion by the defendants actually influenced Mr. Shuker's doctor to use the R3 metal liner instead of the poly liner. *Id.* The plaintiffs were given the opportunity to amend their complaint with respect to their parallel claims and ultimately their Third Amended Complaint based claims of negligence, loss of consortium and fraud on the defendants' off-label promotion of the liner, claiming that the off-label promotion was a violation of federal requirements. *Shuker v. Smith & Nephew PLC*, 211 F. Supp. 3d 695, 696, 699 (E.D. Pa. 2016), *aff'd in part, rev'd in part*, 885 F.3d 760 (3d Cir. 2018). The district court dismissed these claims, however, again finding that there were insufficient facts to support a reasonable inference that the defendants' press release actually promoted off-label use of the R3 metal liner. *Id.* at 704–05.

⁴⁵ *Shuker II*, 885 F.3d at 774–75.

“device” to include its components and accessories.⁴⁶ The court also noted the MDA’s anticipation and acceptance of third party off-label usage of devices and noted that the deconstructing of a device and extracting of an individual component for a separate use qualifies as such an accepted practice.⁴⁷ Lastly, the court pointed to the FDA’s stance, which was largely informed by the statutory definition of “device” and the acceptance of off-label usage, in concluding that the device should be analyzed at the component level.⁴⁸ As such, the Third Circuit held that a hybrid device is to be evaluated at the component level and accordingly applied the framework set forth in the Supreme Court’s 2008 opinion in *Riegel v. Medtronic, Inc.* to the R3 metal liner, affirming that its premarket approval preempted any claims against its safety and effectiveness that are based on state law.⁴⁹

With respect to the parallel claims, on the other hand, the court held that there were sufficient facts to adequately plead that Smith & Nephew’s characterization of the R3 metal liner as an option for the R3 Acetabular System consisted of off-label promotion that resulted in Mr. Shuker’s injuries and thus violated both state and federal laws.⁵⁰

⁴⁶ *Id.* at 772 (citing 21 U.S.C. § 321(h)). The court also noted that this is consistent with a foundational rule of statutory interpretation that seeks to give meaning to all parts of a statute. *Id.* at 774 (citing *Corley v. United States*, 556 U.S. 303, 314 (2009)). See generally 21 U.S.C. § 321(h) (“[t]he term ‘device’ . . . means an instrument, apparatus, implant, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory”) (emphasis added).

⁴⁷ *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 350 (2001); *Shuker II*, 885 F.3d, at 772–73 (citing 21 U.S.C. §§ 352(q)–(r), 360e(d)(1)(A)); Letter Brief at 8–9, *Shuker II*, 885 F.3d 760 (No. 16-3785), 2017 WL 4151264 at *8–9 (noting that manufacturers must still comply with the premarket approval requirements set forth by the federal government, regardless of how third parties use the device and that Congress intended to protect manufacturers who have done so from state law liability); see *supra* note 21 and accompanying text (discussing the benefits of off-label use).

⁴⁸ *Shuker II*, 885 F.3d at 773 (citing Letter Brief, *supra* note 47, at 7); see *infra* notes 64–66 and accompanying text (describing the FDA’s arguments). Although the court noted that it does not necessarily defer to agencies’ interpretation when it comes to preemption, these interpretations are given weight to the extent that they are persuasive. *Shuker II*, 885 F.3d at 773 (citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1994)); see *Jamelle C. Sharpe, Legislating Preemption*, 53 WM. & MARY L. REV. 163, 184–85 (2011) (discussing the deference that the Supreme Court has given to the FDA in preemption analyses and noting that the Court appears to be suggesting that “*Skidmore* deference” is proper, meaning that courts should base the weight that they give agency interpretations on its persuasiveness and thoroughness).

⁴⁹ *Shuker II*, 885 F.3d at 774–75 (applying the *Riegel* framework to the R3 metal liner and concluding, first, that the federal government did impose device-specific requirements through the premarket approval process and, second, that the Shukers’ claims of negligence, strict liability, and breach of implied warranty did impose requirements that are different from those imposed by the federal government).

⁵⁰ *Id.* at 776–79 (discussing the claims of negligence, loss of consortium, and fraud based on the defendants’ off-label promotion of the R3 metal liner). With respect to the negligence claim, the court noted that the fact that the R3 metal liner was approved only to be used in the Birmingham Hip Resurfacing System supported an inference that the defendants had a duty not to publish

II. A PRELIMINARY QUESTION TO THE *RIEGEL* FRAMEWORK: WHAT IS THE DEVICE AT ISSUE?

As the Third Circuit Court of Appeals noted in 2018 in *Shuker v. Smith & Nephew, PLC (Shuker II)*, before applying the preemption analysis to a medical device, it may be necessary to first determine what the device at issue is.⁵¹ Because the device in question in *Shuker II* was made up of components that fell into different classifications, it could either be analyzed by looking at the device as a whole, or by looking at the specific component at issue.⁵² Section A of this Part discusses the arguments the Shukers put forth in *Shuker II* in favor of analyzing the device as a whole.⁵³ Section B of this Part discusses the arguments in favor of analyzing the device at the component-level, which both Smith & Nephew and the FDA supported.⁵⁴

A. The Device-Level Approach

In arguing that the device as a whole should be analyzed, the Shukers contended that the hip replacement system was approved as a Class II device and could not be transformed into a Class III device merely because of one implemented Class III component that received premarket approval.⁵⁵ The Shukers also emphasized the fact that the FDA had never approved nor

false or misleading advertising, that the defendant's characterization of the R3 metal liner as an option for the R3 Acetabular System can be interpreted as a breach of that duty, and that Mr. Shuker's doctor was aware of, and thus potentially influenced by, this characterization when he decided to use the R3 metal liner instead of the polyethylene liner. *Id.* at 777–78. Next, the court found that the loss of consortium claim was derivative of the Shukers' claim of negligence and was therefore also adequately pleaded. *Id.* at 778. Although the court found that the fraud claim was not adequately pleaded because there were insufficient facts to support an inference that Mr. Shuker's doctor relied on the off-label promotion in his decision to use the R3 metal liner, the district court's dismissal of the fraud claim was reversed because the plaintiffs were not given a sufficient opportunity to amend their complaint. *Id.* at 778–79.

⁵¹ *Shuker v. Smith & Nephew, PLC (Shuker II)*, 885 F.3d 760, 772 (3d Cir. 2018) (noting that the two-step analysis set forth in the Supreme Court's 2008 opinion in *Riegel v. Medtronic, Inc.* has an implicit presumption that there is an agreement as to what the device in question is, and that in cases where there is no such agreement a preliminary determination of the device is required before applying the *Riegel* framework); *see supra* note 25 (describing the *Riegel* framework).

⁵² *Shuker II*, 885 F.3d at 772.

⁵³ *See infra* notes 55–59 and accompanying text.

⁵⁴ *See infra* notes 60–66 and accompanying text.

⁵⁵ *See* Brief of Appellants at 18–19, *Shuker II*, 885 F.3d 760 (No. 16-3786), 2017 WL 413755, at *18–19 (pointing to a number of district court decisions supporting this concept); *see, e.g.,* *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 736, 747 (S.D.W.V. 2014) (declining to preempt state-law claims against a Class II device despite the fact that one component was a Class III premarket-approved device); *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 487 (W.D. Pa. 2012) (finding a hip replacement system to be a Class III premarket-approved device despite the fact that one component was a Class II device approved through the Section 510(k) process).

analyzed the specific system implanted in Mr. Shuker—that being the particular combination of components his physician used.⁵⁶ Thus, the Shukers argued, the fact that the R3 metal liner was determined to be safe for its use in the Birmingham Hip Resurfacing System did not guarantee that it would be safe in other types of devices, including the R3 Acetabular System.⁵⁷ The plaintiffs also pointed to the logistics of the component-level approach, arguing that analyzing each particular component within a device would be overly complicated and illogical.⁵⁸ Lastly, they expressed concern that manufacturers could avoid liability simply by using one component that received pre-market approval in a device that was otherwise approved through the Section 510(k) process, thus undermining the primary purpose of the MDA, which is to ensure that all devices on the market are safe and effective.⁵⁹

B. The Component-Level Approach

The defendants, on the other hand, pointed to the fact that the FDA simply regulates devices, not the ways in which they may be used.⁶⁰ Although the FDA can impose requirements on a device’s manufacturing, design and label, including the proposed conditions of use, healthcare practitioners are not obliged to follow the FDA-approved label’s conditions of use.⁶¹ As such, a physician’s decision to use a device or its component in an

⁵⁶ See Brief of Appellants, *supra* note 55, at 22; see also *Huskey*, 29 F. Supp. 3d at 747 (finding that the premarket approval of one component does not inherently approve that component’s use in all medical devices because the FDA only considers its use in the specific device being analyzed).

⁵⁷ See Brief of Appellants, *supra* note 55, at 22; see also *Huskey*, 29 F. Supp. 3d at 747 (citing *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 760–762 (S.D.W.V. 2014)) (noting that the FDA found that a specific type of suture was safe when used in the recommended manner but they did not evaluate whether it would be safe when sewn together to create a mesh product).

⁵⁸ Brief of Appellants, *supra* note 55, at 19–22 (citing *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 780 (D. Minn. 2009)) (“[i]f components of a PMA-approved device work together as a single medical device, then tearing the components apart to apply a different preemption analysis ‘makes no sense’”); see also *Huskey*, 29 F. Supp. 3d at 748 (finding that a separate analysis of each component would “create chaos in a field that is already difficult to navigate”); *Gross*, 858 F. Supp. 2d at 487 (noting that the added level of complication of doing individual analyses was not contemplated by Congress); *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 780 (D. Minn. 2009) (finding that individual analyses of components “make[] no sense” when considered in light of the fact that the components function together as a single device).

⁵⁹ Brief of Appellants, *supra* note 55, at 22–23. See generally MDA, Pub. L. No. 94-295, 90 Stat. 539 (1976) (stating that the MDA is meant to “provide for the safety and effectiveness of medical devices”).

⁶⁰ See Answer Brief of Smith & Nephew, Inc. at 23–24, 885 F.3d 760 (16-3785), 2017 WL 1132944 at *23–24 (citing 21 U.S.C. § 360k; *Riley*, 625 F.Supp.2d at 779) (“Class III devices and components used off-label continue to fall within the protection of section 360k because the FDA does not regulate a device’s use. Rather, the FDA regulates *the device itself*.”).

⁶¹ *Id.* at 24, 26; see also *supra* note 21 and accompanying text (discussing the acceptance of physicians’ off-label use of medical devices).

off-label manner would not create liability on behalf of the manufacturer.⁶² Thus, according to the defendants, any challenges to the R3 metal liner's safety or effectiveness must be preempted because the component received premarket approval and had met the requirements imposed through that approval process.⁶³ The FDA, in an amicus brief, took a similar position as the defendants, arguing that the requirements the federal government imposed on a device or component were unaffected by a third party's off-label use and thus a preemption analysis should also remain unaffected by such a use.⁶⁴ Moreover, the FDA emphasized the fact that the statutory definition of "device" included each of the device's components.⁶⁵ Lastly, the FDA made a policy argument pointing to the fact that Congress delegated regulatory power to the FDA to set standards and requirements for medical devices and that manufacturers who adhered to these standards were warranted the benefits of preemption.⁶⁶

III. THE THIRD CIRCUIT PROPERLY EVALUATED THE "HYBRID" DEVICE AT THE COMPONENT-LEVEL

In its analysis of the system implanted in Mr. Shuker at the component-level, the Third Circuit Court of Appeals in 2018, in *Shuker v. Smith & Nephew, PLC (Shuker II)*, afforded the defendants preemption protection from any state law claims that challenged the safety or effectiveness of the R3 metal liner and were based on requirements that differed from or added to those the federal government imposed.⁶⁷ The court's consideration of the

⁶² Answer Brief of Smith & Nephew, Inc., *supra* note 60, at 26.

⁶³ *Id.* at 28.

⁶⁴ Letter Brief, *supra* note 47, at 7–8 (citing *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1344 (10th Cir. 2015)) ("FDA's premarket approval of the BHR system imposed requirements specific to the metal liner that preclude changes to the liner's design, manufacture, and labeling without further approval by FDA. Those requirements apply equally when third parties put the liner to an unapproved use.").

⁶⁵ *Id.* at 7 (citing 21 U.S.C. § 321(h)).

⁶⁶ *Id.* at 9 ("Congress entrusted FDA with determining which device designs should be approved for marketing, as well as how approved devices should be labeled Section 360k(a) acknowledges FDA's judgment in this respect and prevents states from pursuing competing judgments That provision also protects manufacturers that have complied with detailed federal requirements from being subjected to liability under state law for doing what federal law required."). The FDA also argues that those of the Shukers' claims that are not expressly preempted may still be impliedly preempted, pointing to the possibility that these claims may conflict with the overall scheme of the MDA. *Id.* at 6, 13–14. See generally *supra* note 24 (discussing implied preemption). They acknowledge, however, that the defendants did not raise such a defense and thus the court may be disinclined to address the issue of implied preemption. Letter Brief, *supra* note 47, at 6, 13–14. Ultimately, the Third Circuit found that because the defendants did not raise any implied preemption arguments, the analysis should be limited to express preemption principles. *Shuker II*, 885 F.3d at 770 n.8.

⁶⁷ *Shuker v. Smith & Nephew, PLC (Shuker II)*, 885 F.3d 760, 775 (3d Cir. 2018).

FDA’s interpretation of the issue is consistent with Supreme Court precedent, which has also relied heavily on the FDA’s position in interpreting ambiguities in the MDA, and the notion that the FDA has the unique expertise to interpret the laws that it implements.⁶⁸

Both the Third Circuit and the FDA correctly noted that the statutory definition of “device” includes any component of one.⁶⁹ Thus, as a matter of statutory interpretation, when the MDA affords manufacturers the benefits of preemption with regards to a device that has met all federally imposed requirements, these benefits should also be afforded when the component of a device has met these requirements.⁷⁰ The same is true as a matter of policy: a manufacturer that has complied with the specific requirements regarding a component’s safety and effectiveness should not be deprived of preemption protection merely because a third party has extracted the component to use it in a different device.⁷¹

⁶⁸ See 21 U.S.C. § 371(a) (2012) (vesting “[t]he authority to promulgate regulations for the efficient enforcement of [the Federal Food, Drug, and Cosmetic Act] . . . in the Secretary”); *Medtronic Inc. v. Lohr*, 518 U.S. 470, 495–96 (1996) (finding support for an interpretation of preemption under the MDA by looking to the FDA’s regulations that interpret the relevant statutory provisions and noting that, consistent with 21 U.S.C. § 371(a), the Secretary of Health and Human Services delegated authority to the FDA to promulgate regulations); *Hillsborough Cty. v. Automated Med. Labs.*, 471 U.S. 707, 714 (1985) (finding the FDA’s position to be “dispositive” in resolving a preemption issue); *Shuker II*, 885 F.3d at 773; 21 C.F.R. § 808.1(e) (2012) (granting the FDA authority to determine whether a specific state requirement falls within the scope of the MDA preemption provision). Although the Third Circuit Court of Appeals clarified in its 2018 opinion in *Shuker II* that they do not necessarily defer to the FDA’s stance in preemption analyses, they concluded that the FDA’s view is, in fact, “entitled to respect . . . to the extent [they] ha[ve] the power to persuade.” 885 F.3d at 773 n.11 (internal quotations omitted) (citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1994)); see *Skidmore*, 323 U.S. at 140 (“The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.”); Sharpe, *supra* note 48, at 186 (noting that *Skidmore* deference is likely the proper level of deference in preemption analyses and that agency views “will be informative but not dispositive”).

⁶⁹ *Shuker II*, 885 F.3d at 772; Letter Brief, *supra* note 47, at 7. See generally 21 U.S.C. § 321(h) (“The term ‘device’ . . . means an instrument, apparatus, implant, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory.”) (emphasis added).

⁷⁰ See *Shuker II*, 885 F.3d at 772–73 (finding support for the component-level approach in both the MDA’s definition of device, which includes components, and in the MDA’s contemplation and acceptance of off-label usage by third parties); Letter Brief, *supra* note 47, at 6 (noting that a component of a device that has received premarket approval is also considered a “device” and that the approval of such a component is often premised upon device-specific requirements). See generally *Corley v. United States*, 556 U.S. 303, 314 (2009) (“one of the most basic interpretive cannons [is] that [a] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, or void or insignificant”) (internal quotations omitted); Sharpe, *supra* note 48, at 179 (noting that the Supreme Court in 2008 in *Riegel v. Medtronic, Inc.* largely relied on the statutory language of the MDA in its decision).

⁷¹ See Letter Brief, *supra* note 47, at 9 (“[the preemption] provision also protects manufacturers that have complied with detailed federal requirements from being subjected to liability under

The court's holding is also consistent with the notion that, because the MDA was not enacted to interfere with the practice of medicine or overstep the judgment of physicians, a healthcare practitioner's off-label usage of a medical device is an acceptable, if not encouraged, practice under the MDA.⁷² Thus, a manufacturer that has complied with all federal requirements is still protected from liability when a health care practitioner uses the device in an off-label manner.⁷³ Given the statutorily equivalent treatment of devices and their components, it follows that a manufacturer should be afforded the same protection when a third party uses one of its device's components—rather than the device itself—in a way that is contradictory to the FDA-approved manner of usage.⁷⁴

Lastly, this interpretation of the MDA does not necessarily leave the plaintiffs, or others similarly situated, entirely without remedy; they can still allege parallel claims.⁷⁵ The Third Circuit's decision to allow the claims based on Smith & Nephew's off-label promotion to go forward is consistent with the MDA's preemption provision because, if there is a finding that the defendants in fact violated a federal regulation, it allows the plaintiffs to be

state law for doing what federal law required"); *see also infra* notes 72–74 and accompanying text (discussing off-label usage by third parties and its effect on preemption analyses).

⁷² *See* 21 U.S.C. § 396 ("Nothing in [the MDA] shall be construed to limit or interfere with the authority of a health care practitioner."); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (discussing the acceptance and importance of off-label usage of medical devices and noting that the MDA is not meant to constrain a physician's ability to use a device as he or she sees fit); *Beck & Azari, supra* note 21, at 72, 76–80 (discussing the importance of off-label use by physicians and arguing that it is an integral part of medicine by allowing doctors to treat patients by implementing new and effective uses for drugs and devices without having to go through the lengthy FDA-approval process).

⁷³ *See supra* notes 21, 72 and accompanying text (discussing the acceptance and necessity of off-label usage of medical devices as prescribed and administered by health care professionals).

⁷⁴ *See* Letter Brief, *supra* note 47, at 9 (arguing that a manufacturer's compliance with the "design, manufacture, or labeling" requirements, which are directed at the component's safety and effectiveness, should continue to warrant protection from liability when a third party uses the component in an unapproved manner); *supra* notes 69–70 and accompanying text (discussing the statutory treatment of the components of a device as devices themselves).

⁷⁵ *See Shuker II*, 885 F.3d at 776 (reversing the district court's dismissal of the plaintiffs' parallel claims that were based on the defendants' off-label promotion in violation of federal requirements). Thus, if the plaintiffs are able to prove on remand that the defendants' off-label promotion influenced the plaintiff's doctor to use that particular combination of components, they may still be able to recover some damages from the defendants. *Id.* Although there are uncertainties regarding the extent to which parallel claims may be impliedly preempted, some have noted that claims of off-label promotion may survive preemption. *See Boumil, supra* note 21, at 40–42 (discussing a case in which plaintiffs were able to reach an \$85 million settlement arising out of an off-label promotion claim); *Whitney, supra* note 17, at 129 (discussing ways in which plaintiffs may successfully bring claims based on off-label promotion); Kevin Costello & Eric Johnston, *Manufacturer Liability for Off-Label Uses of Medical Devices*, L.A. LAW., Apr. 2008, at 18–19 (noting that off-label promotion may be a source of liability for manufacturers but that plaintiffs may face substantial evidentiary burdens).

compensated for any violations of the requirements imposed by the MDA’s premarket approval process.⁷⁶

CONCLUSION

When it comes to predicting which medical devices will be afforded preemption under the MDA, the Supreme Court’s guidance seems pretty clear: Class III devices that have received premarket approval will receive preemption because they are subject to device-specific federal requirements, whereas Class II devices have no such requirements and will therefore remain subject to liability. It becomes less clear, however, when a physician implements a device that he or she altered by combining components from Class II and Class III devices.

The Third Circuit properly addressed this issue, holding that when a medical device is made up of components that fall into different classifications under the MDA, any preemption analysis must be applied to the specific component in question. This decision is consistent with the statutory definition of device under the MDA, which includes in it any components thereof. Moreover, it is congruent with the position of the FDA, to whom Congress granted a great deal of discretion due to their expertise. Lastly, it allows physicians to continue to utilize devices in off-label manners, a practice that is widely supported in both the legal and medical fields, in order to provide the best medical treatment for their patients without holding manufacturers liable for their decisions.

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⁷⁶ *Shuker II*, 885 F.3d at 776.