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FOREWORD: IS IT TIME FOR AN ABBREVIATED PREMARKET APPROVAL FOR MEDICAL DEVICES?

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This Symposium Issue of the William Mitchell Law Review focuses on recent developments in medical-device law. The world of medical devices is expansive. It includes everyday items, such as toothbrushes and sunglasses, as well as more exotic items, such as snakebite kits. Its reach spans from items permanently implanted in patients, such as pacemakers, to those that are only briefly in contact with patients, such as scalpels. It also covers those objects that are never physically in contact with patients, such as surgical lamps.

Many elements of medical-device law are rapidly changing, a transformation which the articles that follow explore. This

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1. A medical device is defined as “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article,” which is “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals” or “intended to affect the structure or any function of the body of man or other animals” and, to exclude drugs and foods, “does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.” 21 U.S.C. § 321(h) (2006).


3. Id. § 886.5850.

4. Id. § 872.5740.

5. Id. § 870.3610; see also, e.g., id. § 872.3630 (“Endosseous dental implant”); id. § 872.4760 (“Bone plate”).

6. Id. § 878.4800 (“Manual surgical instrument for general use”); see also, e.g., id. § 878.6265 (“Examination gloves”); id. § 880.2700 (“Stand-on patient scale”).

7. Id. § 878.4580; see also, e.g., id. § 892.1750 (“Computed tomography X-ray system”); id. § 862.2860 (“Mass spectrometer for clinical use”).
foreword will briefly describe the history and framework of medical-device law that underlie the discussions in many of these articles. It also will briefly point out an area of medical-device law that is stuck in the 1970s and suggest a potential solution.

Medical-device law came into its own with the enactment of the Medical Device Amendments of 1976 (MDA), which, among other things, added a regulatory approval process for devices to the Food, Drug, and Cosmetics Act (FDCA). Before that, the regulation was uneven, with medical devices sometimes subjected to the federal approval process for drugs. For example, prior to the MDA, the United States Supreme Court held that a laboratory diagnostic—one that never touched nor was even in the same room as the patient—was a drug and therefore was subject to the drug approval process. This exemplified the non-standard definition of “drug” in the FDCA. In addition to potentially being subjected to the federal drug approval process, medical devices were also subject to varied and potentially conflicting state-approval processes.

Congress attempted to clean up this morass by enacting the MDA. First, the MDA says that no state “may establish or continue in effect with respect to a device intended for human use any requirement” that is “different from, or in addition to, any requirement” of the MDA and “which relates to the safety or effectiveness of the device.” This broadly preempted state requirements and regulatory processes applicable to medical devices.

Second, the MDA created a premarket approval (PMA)
The PMA process is quite time-consuming and expensive to complete, requiring, among other things, information on the following: clinical investigations, principles of operation, and manufacturing facilities and controls. The PMA process, however, is not applicable to all medical devices. Instead, devices are classified based on the level of controls required to ensure safety and effectiveness. And only those devices requiring the highest level of controls—Class III devices—are subject to the PMA process.

There is one additional group of devices that are exempt from the PMA process: Class III devices that were already on the market at the time the MDA was enacted. The FDA may, however, override this default by regulation and require a PMA for even a pre-1976 device. In addition, to prevent pre-1976 devices from having a monopoly, a new device that is substantially equivalent to a pre-1976 device is not subject to the PMA process. Those substantially equivalent devices are typically subject to the less-rigorous premarket notification process, which is also known as the 510(k) process. Under the 510(k) process, a manufacturer notifies the U.S. Food and Drug Administration (FDA) that it intends to introduce a new device, asserts that it is substantially equivalent to a pre-1976 device, and waits for an order from the FDA clearing the device.

This dual-approval path creates an odd dichotomy triggered off of a date that is nearly forty years old. Most devices enter the market through the 510(k) process, which operates like the children’s game of telephone, in which a secret message is whispered from one child to the next. The manufacturers of new devices assert substantial equivalence to a recently introduced device, the manufacturers of which had previously asserted substantial equivalence to a slightly older device, and so on until the chain reaches a device introduced prior to 1976. And much

14. Id. § 360e.
15. See id. § 360e(c)(1)(A)–(G).
16. See id. § 360c(a)–(d).
17. Id. § 360e(a).
18. Id. § 360c(f)(1)(A)(i)(I). The FDA may, however, require a PMA for a pre-1976 device.
19. See id. § 360e(b).
20. Id. § 360c(f).
21. Id. § 360(k). Section 360(k) corresponds to section 510(k) of the FDCA.
22. Id.; id. § 360(n).
like the message that the child at the end of the line hears, the new
device may barely resemble the original one. Nonetheless, the
510(k) process works. It fosters competition by allowing
competitors to enter the market quickly. It also fosters innovation
and lower prices to end-users by allowing incremental
improvements to devices without the added expense of the PMA
process. These benefits are all available, so long as the new
device can be traced to a pre-1976 device for which the FDA has not
required a PMA.

But there are few shortcuts for competitors wishing to enter
the market for a Class III device introduced after 1976.\(^{23}\) Competitors typically may enter the market only after successfully
completing the rigorous, time-consuming, and expensive PMA
process. The PMA process often creates a barrier to entry that
allows the approved manufacturer to reap monopoly profits, much
like the holder of a patent. Accordingly, innovation and
competition may be stifled when it comes to devices subject to the
PMA process—specifically, those class III devices introduced after
1976.

A similar problem was addressed for pharmaceuticals in 1984
with the Hatch-Waxman Act.\(^{24}\) Hatch-Waxman created a bargain of
sorts. It created the abbreviated new drug application (ANDA)
process that focuses on similarity to an already approved “pioneer”
drug.\(^{25}\) It also created an exclusive period following the approval of
a new drug during which an ANDA cannot be approved.\(^{26}\) This
exclusive period serves to reward the manufacturer for bearing the
heavy burden of research and development and the new drug
regulatory process. But after that exclusive period expires,
competitors (i.e., generic drug manufacturers) may enter the
market through the ANDA process without going through the time
and expense of a new drug application.\(^{27}\) This has created a robust

\(^{23}\) There are two potential shortcuts. First, a manufacturer may petition the
FDA to down-classify the device. Id. § 360c(f)(2)–(3). Second, a manufacturer
may reference information (e.g., clinical trial data) in a PMA that was approved
more than six years earlier. Id. § 360j(h)(4).

U.S.C. § 355(j)).


\(^{26}\) Id. § 355(j)(2)(F). The period of exclusivity for a pioneer drug is based
on how different it is from previously approved drugs. For example, a pioneer
drug with an entirely new active ingredient will get five years of exclusivity, while
one with a new use of a known ingredient will get fewer. Id.

\(^{27}\) Id. § 355(j)(1), (j)(2)(A)(vii).
and competitive generic-drug market. It may be appropriate to enact a similar scheme for medical devices, which would make more sense than using an almost forty-year-old date to determine which regulatory process a device is subject to.

Although this aspect of medical-device law is stuck in the past, many other aspects are rapidly changing and continuing to develop. The articles in this Symposium Issue explore those changing areas of medical-device law.

Three of the articles in this symposium, in part, explore the impact of the MDA’s preemption section on state tort law. The Supreme Court’s 2008 decision in *Riegel v. Medtronic, Inc.* definitively interpreted that section, holding that state tort law, for the most part, preempted for those devices—often the highest risk devices—that were approved through the PMA process. Since *Riegel*, plaintiffs have been forced to explore alternative theories by which to seek compensation for injuries caused by a PMA-approved medical device.

In his article, Professor J. David Prince explores one route to avoid *Riegel*-preemption: pleading a parallel claim. A parallel claim is one in which the state requirement is the same as the federal requirement (i.e., it is not “different from, or in addition to” a federal requirement). Such claims are not expressly preempted by the MDA. His article explores recent decisions regarding parallel claims and articulates a test for recognizing a parallel claim. A parallel claim, however, may be impliedly preempted under the standard articulated in *Buckman v. Plaintiffs’ Legal Committee*, in which the Court held that there was no private right of action under the FDCA. Professor Prince also surveys the cases that have attempted to toe the line between *Buckman* and *Riegel*. And he discusses the pleadings challenges plaintiffs face when asserting a parallel claim given the lack of information available pre-discovery. He concludes that “[t]he precise contours of the narrow gap through which a plaintiff bringing a product

28. *Id.* § 360k(a) (“[N]o State . . . may establish or continue in effect with respect to a device intended for human use any requirement . . . which is different from, or in addition to, any requirement applicable under [the MDA] to the device, and which relates to the safety or effectiveness of the device.”).
31. 21 U.S.C § 360k(a).
defect claim against a medical device manufacturer must sail in order to avoid having her claims preempted are not yet clear.” 33

In their article, practicing attorneys Christiana C. Jacxsens, Sara E. Deskins, and Sean P. Jessee discuss another tactic that plaintiffs have employed to get around Riegel: “Since the Riegel decision, plaintiffs have attempted to assert novel claims to avoid preemption by focusing on the alleged conduct of sales representatives.” 34 Drawing on a wealth of practical experience, the trio explores the multitude of “avenues for sales representative liability” 35 and the potential defenses that are available to such claims. The authors also discuss the recent increase in government enforcement actions against sales personnel and civil products liability actions based on that government enforcement action.

Practicing attorneys David T. Schultz and D. Scott Aberson discuss a third technique plaintiffs have attempted to use to avoid Riegel-preemption—arguing that the FDA “limited its premarket approval to only certain aspects or components of a particular medical device or system.” 36 As their article explains, this (perhaps clever) argument, ultimately fails. They discuss a number of cases involving PMA-approved devices that incorporate components that had previously been brought to market through the 510(k) process. In these cases, the plaintiffs argued that the PMA and Riegel-preemption only applied to the components of the devices that had not previously been marketed using the 510(k) process. Sometimes, the plaintiffs even asked the FDA to clarify and narrow the approval letter. In all cases, these petitions and these arguments have been rejected. Accordingly, the authors conclude “there is simply no such thing as a limited PMA.” 37

Patent attorneys Suneel Arora, Timothy J. Christman, Ashley N. Mays, and Andrew Schmidt contribute an article about the intersection of patent law and the 510(k) process. 38 They first

33. Prince, supra note 30, at 1084.
35. Id. at 1088.
37. Id. at 1159.
discuss the tension between patent law and the 510(k) process. On the one hand, while seeking to introduce a new medical device via the 510(k) process, a manufacturer will assert that the device is substantially equivalent to a preexisting device. But on the other hand, while seeking a patent on that same device, the manufacturer will claim that the same device is novel and non-obvious. Additionally, the authors discuss the impact of an assertion of substantial equivalence in a 510(k) notification on a defendant in a patent infringement lawsuit brought by the manufacturer of the predicate device. The article provides practical advice on how to coordinate regulatory and patent submissions to address these challenges and emphasizes the importance of “[i]nfusing knowledge of the interplay between the patent and FDA processes.”

Dr. Bruce Patsner, a medical doctor and professor of law, surveys the landscape of direct-to-consumer-advertising (DTCA) of medical devices. He contrasts the DTCA of medical devices with the DTCA of pharmaceuticals. In both cases, the FDA has developed extensive regulations relating to the DTCA by manufacturers. In the pharmaceutical world, these regulations have been the subject of multiple First Amendment–based challenges. Dr. Patsner explains that, unlike pharmaceutical manufacturers, medical device manufacturers rarely engage in DTCA. Rather, it is hospitals and physicians that advertise medical devices to consumers. He then evaluates these advertisements, finding that they often fall short of the regulations that would apply if the advertisements were from the manufacturer. In some cases he finds that the advertisements are even false or misleading. He concludes that in the context of medical device DTCA, “prevention of consumer fraud, not protection of the First Amendment rights of corporations against government encroachment, is where the battle line should be drawn.”

This Symposium Issue concludes with two dueling perspectives on deactivating implanted cardiac-assist devices. First, Professor Lars Noah introduces the thorny issue of where the line is between a patient’s right to refuse medical treatment and physician-assisted

39. Id. at 1206.
41. Id. at 1215.
suicide in the context of deactivating implanted cardiac-assist devices. He first discusses the growing use of implantable cardiac-assist devices among the elderly and the potentially painful and traumatic end-of-life issues associated with these devices. He then surveys the perspectives in the medical-ethics literature on this issue, and determines that medical ethics may inform, but does not answer the legal question. He then looks for analogies in cases relating to withdrawal of treatment and physician-assisted suicide. Noting that medical devices straddle the lines between treatment, property, and self, he concludes that these cases fail to provide an adequate analogy for the deactivation of cardiac-assist devices and that, in order to eliminate the associated uncertainty, states should address this issue legislatively.

In response, David Orentlicher, a medical doctor and professor of law, argues that in most cases a medical device is a form of treatment and that a patient has an unconditional right to refuse it or request its withdrawal. Prof. Orentlicher then describes a framework for evaluating the deactivation of implanted cardiac devices to distinguish between permissible withdrawal of treatment and euthanasia. He concludes that only if a medical device were a complete and perfect replacement for an organ would it be impermissible euthanasia to disable the device. Clearly, this debate will not be settled for some time. But these two articles provide new perspectives that are sure to influence it.