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Nothing Generic About It: Promoting Therapeutic Access by Overcoming Regulatory and Legal Barriers to a Robust Generic Medical Device Market

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NOTHING GENERIC ABOUT IT:
PROMOTING THERAPEUTIC ACCESS BY
OVERCOMING REGULATORY AND LEGAL
BARRIERS TO A ROBUST GENERIC MEDICAL
DEVICE MARKET*

ZACHARY E. SHAPIRO,** ADAM PAN,*** KETURAH JAMES,**** MEGAN S.
WRIGHT***** & JOSEPH J. FINS*****

This Article addresses a paradox in American healthcare technology: a thriving market for generic drugs but a paucity of generic medical devices. Despite the

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success of generic pharmaceuticals in reducing healthcare costs, no analogous market exists for generic medical devices. This plays a part in keeping prices high while limiting access to affordable therapies. In this Article, we highlight the regulatory and legal barriers currently impeding the development of a generic medical device market in the United States. We explore differences between generic drugs and generic devices in FDA regulation, products liability, and patentability, all of which contribute to the absence of medical devices in clinical practice. We conclude with recommendations to foster more widespread development of generic medical devices.

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INTRODUCTION: THE NEED FOR A GENERIC MEDICAL DEVICE MARKET

In 2016, eighty-nine percent of prescription drugs dispensed in the United States were generic pharmaceuticals.¹ Once the patent on an innovator drug expires, competitors can develop and sell lower-cost, generic versions of the drug. Generic pharmaceuticals provide a multitude of benefits. The U.S. Food and Drug Administration (“FDA”) has acknowledged that the availability of generic drugs is the primary driver for reducing drug prices, and the use of generic alternatives to name brand pharmaceuticals has saved the U.S. healthcare system nearly \$1.5 trillion over the past ten years.² Furthermore, the marketplace for generic drugs allows manufacturers to adopt pharmaceuticals after the original innovator-drug manufacturer has exited the market but while the drugs still provide significant clinical benefits to patients. Indeed, generic drugs may be the only option for patients who rely on a particular pharmaceutical if the original drug manufacturer has exited the market.

Despite the success of the generic drug market, no analogous generic market currently exists for high-risk medical devices. Instead, significant regulatory and legal barriers continue to hamper the development of, and limit access to, generic medical devices, especially risky devices that would be classified as Class III.³ At the same time, the medical device market accounts

1. OFF. OF GENERIC DRUGS, U.S. FOOD & DRUG ADMIN., 2016 OGD ANNUAL REPORT 2 (Jan. 2017).

2. *Id.*; see also Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 NEW ENG. J. MED. 1993, 1993 (2007) (noting that the expansion of generic drugs has been linked to a tempering of price increases for prescription drugs); Charles B. Holmes et al., *Use of Generic Antiretroviral Agents and Cost Savings in PEPFAR Treatment Programs*, 304 JAMA 313, 313 (2010) (discussing the FDA’s use of a premarket generic drug approval mechanism for reducing the cost of antiretroviral drugs); Aaron S. Kesselheim, Jerry Avorn & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States*, 316 JAMA 858, 861 (2016) (“The only form of competition that consistently and substantially decreases prescription drug prices occurs with the availability of generic drugs, which emerge after the monopoly period ends.”).

3. See, e.g., Joseph J. Fins, *Devices, Drugs, and Difference: Deep Brain Stimulation and the Advent of Personalized Medicine*, in HANDBOOK OF NEUROETHICS 607, 607–18 (Jens Clausen & Neil Levy eds., 2015) (explaining regulatory challenges faced in the medical device industry); see also Joseph J. Fins & Nicholas D. Schiff, *Conflicts of Interest in Deep Brain Stimulation Research and the Ethics of Transparency*, 21 J. CLINICAL ETHICS 125, 127–28 (2010) (discussing personal experiences and difficulties in developing a Class III medical device). Class I medical devices are those devices that have a low to moderate risk to the patient and/or user, such as elastic bandages, tongue depressors, manual stethoscopes, and bedpans. Class II medical devices have a moderate to high risk to the patient and include powered wheelchairs and some pregnancy test kits. Class III medical devices have a high risk to the patient and include cardiac pacemakers, deep brain stimulation probes and electrodes, and hip

for a significant segment of healthcare expenditures, with net sales of \$136 billion in 2014.⁴ Patented devices make up a substantial portion of the U.S. medical device market. For example, for over a decade Mylan held a dominant share of the epinephrine autoinjector market, at around ninety-five percent of the market share.⁵ Only recently have other generic manufacturers been able to capture more than single-digit percentages of the medical device market.⁶

Currently, there are fields of medicine where generic medical devices simply do not exist. For instance, in the fields of neuroscience and neurosurgery,⁷ essential tools of treatment and discovery such as neuroprosthetics and deep brain stimulation (“DBS”) implants and electrodes exist only as innovator medical devices—there are no generic devices available.⁸ Patients and doctors thus have little choice but to use branded devices that are tightly controlled by the manufacturers and, given their exclusivity in the field, expensive. Not only does this mean that there are many types of medical devices for which there is no downward pricing pressure, but the lack of generic devices also restricts access to medical devices for patient therapy because patients simply cannot afford them. This can make translation of discoveries from the lab ultimately less accessible at the bedside.

While the absence of a broad generic device market keeps prices high, it also means that many medical devices face little generic competition. If generic versions of medical devices were more readily available, distributive justice concerns related to access could be ameliorated. Manufacturers would have an incentive to allow access to medical devices for investigational purposes because there might be a market downstream to justify the initial capital investment.⁹ This would mean that the knowledge generated by medical devices could be more widely developed and disseminated.

implants. For an in-depth discussion of different categories of medical devices, see discussion *infra* Section II.A.

4. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-15-635R, MEDICAL DEVICE COMPANIES: TRENDS IN REPORTED NET SALES AND PROFITS BEFORE AND AFTER IMPLEMENTATION OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT 5 (2015).

5. Chelsea Rice, *Prescriptions Jump for EpiPen Alternatives*, ATHENA INSIGHT (Mar. 3, 2017), <https://www.athenahealth.com/insight/sites/insight/files/3.03%20Prescriptions%20jump%20for%20EpiPen%20alternatives.pdf> [<https://perma.cc/52ZM-59BB>].

6. *See id.*

7. *See generally* JOSEPH J. FINS, RIGHTS COME TO MIND: BRAIN INJURY, ETHICS, AND THE STRUGGLE FOR CONSCIOUSNESS (2015) (providing an overview of ethical, medical, and legal issues that arise when considering patients with disorders of consciousness and severe brain injury).

8. In this Article, the term “innovator device” refers to a patented device that is first to market. This terminology mirrors that used by the FDA referring to patented drugs as “innovator drugs,” sometimes also referred to as “brand-name drugs.” In contrast, “generic devices” are unpatented devices that are based on an innovator device predicate, again mirroring the terminology of “generic drugs.”

9. We do not mean to imply that generic devices should be used in clinical research. Rather, we suggest that a generic market would help catalyze research that might not otherwise occur.

For patients, lower costs would allow cutting-edge medical devices to be more widely available. Increased access to low-cost medical devices should have a positive impact on public health by allowing greater utilization of medical devices to improve the health of those who need them. Access issues create a strong, independent ethical argument for greater availability of generic medical devices beyond the expected economic benefits that generic devices could bring to the healthcare system by lowering healthcare costs. The law is an excellent way to shift incentives in this marketplace, and thus lawyers have a role to play in advancing public health¹⁰ by helping shift society towards the widespread use of generics. However, currently, the generic device market is nearly nonexistent for many medical devices, limiting interest in initial investment in novel therapeutics with small market shares.¹¹

One reason for the lack of success of generic medical device manufacturers is that they are not afforded the same level of regulatory and legal protection that generic drug manufacturers receive. This is particularly problematic for the makers of Class III devices, which come with a troubling safety profile due to their high-risk nature. Indeed, the FDA does not provide a classification for “generic medical devices” like it does for generic drugs. Furthermore, while courts have been willing to extend to generic devices certain patent protections available for generic drugs, Congress and the courts have provided divergent regulatory systems for medical devices and prescription drugs in terms of products liability.¹² This Article will analyze potential regulatory and legal drivers for a generic device market, explore how generic drugs and generic devices are treated differently, and offer recommendations for expanding the generic medical device market.

The analysis proceeds in three parts. Part I highlights the benefits of generic medical devices, from both an ethical and economic perspective that is focused on access, before discussing why generic devices cannot be expected to provide the exact same fiscal advantages to the healthcare system as generic drugs. Part II examines regulatory differences, products liability, and patentability issues in order to highlight the disparity between generic drugs

10. See Zachary E. Shapiro, *Field Notes: Bioethics in the Law*, HASTINGS CTR. REP., Jan.–Feb. 2017, at inside front cover (highlighting the law’s role in supporting science, such as determining qualifications for disability benefits, overseeing clinical trial protocols, and patenting new medical devices).

11. See Fins & Schiff, *supra* note 3, at 125–26 (highlighting the difficulty in obtaining funding for medical research into deep brain stimulation).

12. See, e.g., *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 634 (2011) (“Notably, although Congress enacted an express pre-emption provision for medical devices in 1976, it included no such provision in the Hatch-Waxman Amendments eight years later.” (citing Act of May 28, 1976, Pub. L. No. 94-295, § 521, 90 Stat. 539, 574 (codified at 21 U.S.C. § 360k(a) (2018)))); *Wyeth v. Levine*, 555 U.S. 555, 567 (2009) (“[W]hen Congress enacted an express pre-emption provision for medical devices in 1976, . . . it declined to enact such a provision for prescription drugs.” (citing 21 U.S.C. § 360k(a) (2018))).

and devices. Part III argues that regulatory and legal protections available to generic drugs should be extended to generic medical devices so that generic devices can be properly incentivized and more widely employed. To this end, the Article closes with a series of proposals and recommendations designed to better incentivize the development of generic medical devices. Our goal is to enable greater access to medical devices, ultimately improving care and reducing healthcare system costs.

I. CONSIDERING BENEFITS AND LIMITATIONS OF GENERIC DEVICES

The disparate treatment of generic medical devices and generic drugs results in a severely diminished market for generic medical devices. The absence of generic medical devices contributes to high prices because there is simply no viable alternative for cost-conscious patients. The lack of competition is especially stark when considering higher-risk medical devices, such as Class II and Class III devices,¹³ where there is little to no generic competition. This part first discusses anticipated benefits of a generic medical device market before discussing its limitations.

A. *Anticipated Benefits*

The lack of generic medical devices creates a market inefficiency—one that, if addressed, could realize many of the same benefits to patients, doctors, and the healthcare system as generic drugs do. Beyond economic inefficiency, the absence of generic devices presents an ethical dilemma. Because access to many medical devices is restricted, the branded devices remain expensive, maintaining a corporate monopoly and ultimately restricting access for both patients and doctors. This makes it more burdensome, and in some cases impossible, for individuals to utilize devices that could improve their health.

The obvious benefit of a generic medical device market—beyond promoting greater access to generic devices—would be to lower healthcare costs associated with medical devices. Lowering the cost of generic medical devices would improve access, allowing such devices to be utilized more broadly by both doctors and patients once research has been completed.¹⁴

13. See *infra* notes 72–74 and accompanying text.

14. Of course, increasing access to generic devices is by no means the only way to make cutting-edge medical devices more available. For instance, one of the authors has proposed deferring the intellectual property (“IP”) rights provided by the Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200–211 (2018)). See Joseph J. Fins, *Deep Brain Stimulation, Free Markets and the Scientific Commons: Is It Time To Revisit the Bayh-Dole Act of 1980?*, 13 NEUROMODULATION 153, 156–57 (2010). The suggestion involves delaying IP transfer “until Phase II studies are ready to commence,” allowing the federal government and private actors to jointly fund Phase I trials of medical devices. *Id.* at 156. This would allow the investigators most familiar with the work to shepherd their studies through pivotal early stages of research, without having to place a market valuation on their ideas. *Id.* Doing so would avoid financial conflicts of interest that often disqualify

There is a strong ethical argument to be made for increasing access to generic medical devices.¹⁵ Many doctors are sensitive to treatment costs and often consider price as a factor when making medical recommendations.¹⁶ While medical devices can provide genuine therapeutic benefits, the cost they impose on patients and healthcare systems can be significant.¹⁷ Given that expense is one of the most significant downsides to employing medical devices, generic medical devices are well positioned to effectively reduce healthcare costs and expand access to medical devices by introducing competition and driving down the price in otherwise stagnant device sectors.

There are numerous examples of the significant cost savings generated by generic medical devices. For instance, one generic medical device, a Universal Sling System for female urinary incontinence, was reported to potentially save hospitals twenty-five to fifty percent in cost as compared to its name brand counterparts.¹⁸ One Texas hospital allegedly saw savings of \$44,000 in a single year after switching to the generic Universal Sling System.¹⁹ Another example comes from the rise of generic asthma inhalers. After generic asthma inhalers became available, from the mid-2000s through the end of 2008, ninety-six percent of the fifty million chlorofluorocarbon albuterol inhalers consumed were generic.²⁰

More recently, the FDA approved a generic alternative to EpiPen and EpiPen Jr. (epinephrine) autoinjectors for the emergency treatment of allergic

even the best-qualified investigators from formative research. *Id.*; see also Fins & Schiff, *supra* note 3, at 130.

15. See, e.g., Joseph J. Fins et al., *Ethical Guidance for the Management of Conflicts of Interest for Researchers, Engineers and Clinicians Engaged in the Development of Therapeutic Deep Brain Stimulation*, J. NEURAL ENGINEERING, May 10, 2011, at 1, 2 (“Investigators should not be driven by self-interest . . . but rather motivated by a desire to pursue important scientific work to enhance access to novel interventions.”).

16. Andrew Pollack, *Cost of Treatment May Influence Doctors*, N.Y. TIMES (Apr. 17, 2014), <https://www.nytimes.com/2014/04/18/business/treatment-cost-could-influence-doctors-advice.html> [<https://perma.cc/2MZQ-T4VC> (dark archive)].

17. See Chuck Dinerstein, *An Overlooked Health Care Cost - The Medical Device Market*, AM. COUNCIL SCI. & HEALTH (Oct. 3, 2018), <https://www.acsh.org/news/2018/10/03/overlooked-health-care-cost-medical-device-market-13468> [<https://perma.cc/G3WK-H84R>] (discussing the revolution in vascular surgery heralded by the stent while acknowledging its cost); Katherine Hobson, *Cost of Medicine: Are High-Tech Medical Devices and Treatments Always Worth It?*, U.S. NEWS & WORLD REP. (July 10, 2009), <https://health.usnews.com/health-news/best-hospitals/articles/2009/07/10/cost-of-medicine-are-high-tech-medical-devices-and-treatments-always-worth-it> [<https://perma.cc/Q8RV-7B5Z>] (discussing “technology creep” as a major driver of increasing healthcare costs).

18. Laura Ruth, *The Future of Devices Is Generic*, MED. DEVICE & DIAGNOSTIC INDUSTRY (Sept. 23, 2011), <https://www.mddionline.com/future-devices-generic> [<https://perma.cc/N6FS-3XLL>].

19. *Id.*

20. Use of Ozone-Depleting Substances; Remove of Essential-Use Designations, 70 Fed. Reg. 17,168, 17,185 (Apr. 4, 2005) (codified as amended at 21 C.F.R. § 2.125 (2019)).

reactions.²¹ The high cost and lack of an accessible generic device had received widespread media attention and even prompted congressional intervention.²² Already, there are reports of reduced costs to patients, with costs falling from \$600 for the nongeneric autoinjector to as little as \$10 for the generic alternative.²³ Some studies show that, in a pharmaceutical context, more than one generic manufacturer needs to be involved to reduce long-term costs.²⁴ That is all the more reason, however, to expand the market of generic medical devices to cover Class II and Class III devices, to create downward pressure on price.

By lowering costs, increased access to generic medical devices will promote public health through the widespread implementation of effective and life-changing therapies. Lowering the price of the medical device through use of generics enables more patients to employ the device. In this way, there is a public health argument to be made for greater access to generic devices,²⁵ as expanded access can result in greater availability of medical care. Research shows that high costs of healthcare can deter patients from complying with, or seeking, proper medical treatment.²⁶ This imposes a cost not only on individuals but also on the healthcare system as a whole. It is well established that delaying treatment can lead to worsening conditions that ultimately result in more costly emergency room visits.²⁷ Having less expensive generic medical device alternatives available for a wider range of procedures will reduce the financial burden of medical devices generally, allowing more individuals to access the

21. *FDA Approves First Generic Version of EpiPen*, U.S. FOOD & DRUG ADMIN. (Aug. 16, 2008), <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm617173.htm> [<https://perma.cc/92SN-Z8AM>].

22. Dan Mangan, *Congress Will Hold a Hearing on Mylan's Big EpiPen Settlement with Justice Department*, CNBC (Oct. 27, 2016, 11:23 AM), <https://www.cnbc.com/2016/10/27/congress-will-hold-a-hearing-on-mylans-big-epipen-settlement-with-justice-department.html> [<https://perma.cc/N6FS-3XLL>].

23. See Ginger Skinner, *The EpiPen Alternative That Costs Just \$10*, CONSUMER REP. (Feb. 3, 2017), <https://www.consumerreports.org/drug-prices/epipen-alternative-that-costs-just-10-dollars/> [<https://perma.cc/SFP3-CYTW>].

24. See Jonathan D. Alpern & William M. Stauffer, *Does a Generic EpiPen Mean Lower Prices? Don't Hold Your Breath*, STAT (Sept. 7, 2018), <https://www.statnews.com/2018/09/07/generic-epipen-teva-lower-prices/> [<https://perma.cc/KQ2B-U2K4>].

25. See generally Christine M. Baugh & Zachary E. Shapiro, *Concussions and Youth Football: Using a Public Health Law Framework To Head-Off a Potential Public Health Crisis*, 2 J.L. & BIOSCIENCES 449 (2015) (explaining how law can look to public health research and theory in order to help design better legal systems and interventions to improve public health).

26. See, e.g., Trent Gillies, *Why Health Care Costs Are Making Consumers More Afraid of Medical Bills than an Actual Illness*, CNBC (Apr. 22, 2018, 11:15 AM), <https://www.cnbc.com/2018/04/22/why-health-care-costs-are-making-consumers-more-afraid-of-medical-bills-than-an-actual-illness.html> [<https://perma.cc/2W4V-JT9T>].

27. See Aurel O. Iuga & Maura J. McGuire, *Adherence and Health Care Costs*, 7 RISK MGMT. & HEALTHCARE POL'Y 35, 36–37 (2014) (addressing the impact of nonadherence to pharmaceutical prescriptions on overall healthcare costs); Sarah Kliff, *Emergency Rooms Are Monopolies. Patients Pay the Price.*, VOX (Dec. 4, 2017, 8:00 AM), <https://www.vox.com/health-care/2017/12/4/16679686/emergency-room-facility-fee-monopolies> [<https://perma.cc/GV2A-D2BB>].

care they need and, ideally, increasing compliance with care instructions. This should have the result of reducing healthcare system costs, even beyond what simply lowering device prices might suggest.²⁸

Furthermore, a robust generic device market would encourage companies to support broader research with their devices by reducing barriers to entry in the medical device market, such as costs of regulatory compliance and market risk. This would expand the marketplace for all devices. Device manufacturers would understand that the best avenue for increased market share would come through eventually working with a generic device company or even producing generic devices themselves. Currently unprofitable devices could become feasible once the longer life of the generic market is taken into account, especially if a manufacturer could project revenue from developing licensing agreements and collecting royalty fees from future generic device sales. Furthermore, there is always the opportunity for joint-business ventures where innovators pair with generic companies.

A generic device marketplace could help incentivize the creation of new medical devices that might not have been feasible to fund before. This longer-sustained market share, coupled with the potential of licensing fees and royalties once generic devices begin to enter the market, would help create markets for ideas that might otherwise not get funded or supported by industry. Expansion of the medical device market should spur increased use of devices in research, as device makers recognize a wider market and thus erect fewer barriers for researchers.

A wider market would not be the only benefit for device manufacturers. Greater access to generic devices could also improve patient safety and data collection. Access to generic devices should allow a larger, more diverse patient population to use a particular device. In Phase IV (postmarket) trials, the larger patient population would increase the potential for aftermarket data gathering. The data would be correspondingly more robust because more individuals than before would be able to use the device, so there would be a more heterogeneous patient population. This should result in improved longitudinal data, helping improve efficacy and safety for both branded and subsequent generic medical devices.²⁹ As a result, device manufacturers would be able to more accurately recognize defects or problems in their devices, deficits that can go unnoticed

28. See Brian P. Wallenfelt, *Hatch-Waxman and Medical Devices*, 40 WM. MITCHELL L. REV. 1407, 1416, 1420, 1422 (2014) (explaining the benefits of a competitive medical device market and the significance of reducing the cost of creating medical devices due to the financial burden of manufacturing such goods).

29. See Xinji Zhang et al., *Overview of Phase IV Clinical Trials for Postmarket Drug Safety Surveillance: A Status Report from the ClinicalTrials.gov Registry*, 6 BMJ OPEN 11, e10643 (Nov. 23, 2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5168517/> [<https://perma.cc/RL8D-6PH7>] (arguing that a large sample size for Phase IV medical drug trials is imperative to ensure patient safety).

when devices are used in a smaller patient population. Moreover, these larger patient populations may demonstrate degrees of efficacy in subpopulations not previously discernable with smaller samples.

B. *Limitations*

While there are many potential benefits to increasing use of generic devices, generic devices cannot be expected to have exactly the same benefits as generic drugs. Indeed, we recognize that, compared to generic pharmaceuticals, generic devices are less likely to be as widely adopted or as effective at lowering prices. For instance, given the practical and financial difficulties associated with building many cutting-edge devices, not all medical devices will be good candidates for generic alternatives. This is particularly true with riskier and more technologically complex medical devices.³⁰ Many of these devices rely on closely protected external algorithms and monitoring devices in addition to the sophisticated, often proprietary, hardware of the device itself. These devices require updates to their operating system and firmware, and some will require regular maintenance. Building generic equivalents to such devices could prove difficult and costly given the secrecy with which many companies protect their medical device blueprints and specifications.³¹ Even with significant reverse engineering and testing, creating a line of generic devices may be too burdensome and too expensive for many device manufacturers.

There is also the natural concern that, as medical understanding and technology evolve, many medical devices may quickly become obsolete as newer and more effective devices replace them. For some devices, it will be hard for generic device manufacturers to keep up, making investment unlikely even if those devices are afforded greater legal and regulatory protections. These concerns would particularly impact generic medical devices for higher-risk procedures, which rely on advanced technology and need to remain on the cutting edge of development. For these devices, it may never make sense for a generic manufacturer to invest the time, expense, and resources needed to eventually bring the generic device to market. However, there is no reason that

30. See, e.g., Gary Marcus & Christof Koch, *The Future of Brain Implants*, WALL ST. J. (Mar. 14, 2014, 7:30 PM), <https://www.wsj.com/articles/the-future-of-brain-implants-1394839583> [<https://perma.cc/E6CS-B6VQ> (dark archive)]; Mike Vintges, *ICD Manufacturers Must Increase Battery Life To Cut Costs, Improve Care*, DIAGNOSTIC & INTERVENTIONAL CARDIOLOGY (July 31, 2012), <https://www.dicardiology.com/article/icd-manufacturers-must-increase-battery-life-cut-costs-improve-care> [<https://perma.cc/RA8P-7MYW>] (describing the risks associated with changing out pacemakers when their batteries run out). These particular cutting-edge Class III devices—implantable pacemakers and neuroimplants—are just two examples of devices that might not be ideal candidates for generic alternatives.

31. See Emma Dolan, *Price Variation and Confidentiality in the Market for Medical Devices*, HEALTH CARE BLOG (Feb. 14, 2012), <http://thehealthcareblog.com/blog/2012/02/14/deja-vu-all-over-again-price-variation-and-confidentiality-in-the-market-for-medical-devices/> [<https://perma.cc/TM6G-5KSR>].

generic devices could not meet a safe and effective minimal standard for various other applications.

It is possible that pricing benefits of generic devices may not be as apparent, and therefore persuasive, to doctors as they are with generic drugs. Studies show that price transparency of medical devices is limited, and many doctors simply do not know how expensive the medical devices they use are.³² One study found that attending physicians correctly estimated the cost of the medical device only twenty-one percent of the time, and residents did so only seventeen percent of the time.³³ Costs for these devices are often embedded in complex hospital bills and/or intermingled with operative costs, making itemization difficult for the doctor or consumer to discern. Accordingly, it is impossible to expect the same level of broad cost reduction, or immediate significant uptick in the use of generic devices, as occurred with generic drugs.

There is also limited data available concerning how broadly employed generic medical devices would be compared to innovator counterparts. Indeed, there are still groups of patients who are resistant to the use of generic pharmaceuticals due to mostly unfounded concerns about inferior quality.³⁴ This perception may also be present for generic medical devices, limiting their ability to serve as a true replacement for many high-risk medical devices. However, just as consumer fears have not severely reduced usage of generic pharmaceuticals,³⁵ these issues very well may not significantly hamper the uptake of generic medical devices.

Additionally, several mechanisms exist to ensure that generic medical devices will produce a high-quality product that adheres to basic manufacturing quality standards. First, as with drugs, the FDA requires all device manufacturers to comply with the Good Manufacturing Practice (“GMP”) regulations.³⁶ Failure to comply with GMP can result in enforcement action by the FDA, including civil penalties and device recalls.³⁷ Second, according to at

32. See, e.g., John Tozzi, *What's a New Hip Cost? Surgeons Have No Idea*, BLOOMBERG BUSINESSWEEK, Jan. 27, 2014, at 28, 28.

33. Kanu Okike et al., *Survey Finds Few Orthopedic Surgeons Know the Costs of the Devices They Implant*, 33 HEALTH AFF. 103, 105 (2014).

34. See Alice Iosifescu et al., *Beliefs About Generic Drugs Among Elderly Adults in Hospital-Based Primary Care Practices*, 73 PATIENT EDUC. & COUNSELING 377, 381–82 (2008).

35. Mohamed A.A. Hassali et al., *Consumers' Views on Generic Medicines: A Review of the Literature*, 17 INT'L J. PHARMACY PRAC. 79, 87 (2009) (concluding that patient knowledge and confidence about generic medicines have steadily increased since the 1970s).

36. 21 C.F.R. §§ 820.1, 820.5 (2019).

37. See 21 U.S.C. §§ 331(a), (g), 333(f)(1)(A) (2018); see also CPG Sec. 390.300 *Assessment of Civil Penalties Against Manufacturers and Importers of Electronic Products*, U.S. FOOD & DRUG ADMIN. (Apr. 2005), <https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073913.htm> [<https://perma.cc/6EJ2-5ZU9>]; *What Is a Medical Device Recall?*, U.S. FOOD & DRUG ADMIN. (Sept. 26, 2018), <https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall> [<https://perma.cc/J4FJ-34NW>].

least one circuit court, federal preemption does not shield generic manufacturers from state-law tort claims if such claims lie in a manufacturing defect. In *Bass v. Stryker Corp.*,³⁸ the plaintiff, who received an artificial hip implant from the defendant and was subsequently injured due to his implant, filed an action for state-law tort claims.³⁹ The district court found that his claims were preempted by 21 U.S.C. § 360k.⁴⁰ On appeal, the Fifth Circuit held that, while some of the plaintiff's claims were preempted, any manufacturing defects that resulted from violations of the FDA's GMP regulations were not preempted by federal law.⁴¹ The court further held that the plaintiff's claims were also not preempted by 21 U.S.C. § 337(a),⁴² which provides that "all such proceedings for the enforcement, or to restrain violations, of this Act . . . shall be by and in the name of the United States."⁴³ The court held that this did not prohibit state-law tort claims, which were distinguished from a "freestanding federal cause of action based on violation of the FDA's regulations."⁴⁴ Thus, the court held that the plaintiff's claims based on manufacturing defects survived federal preemption.⁴⁵ This prospect of expanded liability is a good incentive for device makers to enact extra precautions in the manufacturing and production process.



While there are unknowns about how broadly employed generic devices will be, these unanswered questions should not deter us from trying to reap the potential benefits discussed above. Indeed, some of the concerns discussed previously, such as questions about safety and uptake in use, were also raised about generic drugs, especially when generics were first beginning to enter the market and compete with trusted and well-known branded pharmaceuticals.⁴⁶ However, the history of generic drugs and the current effects of the few existing generic devices highlight opportunities for addressing the systemic need for lower-cost generic alternatives for medical devices.

The lack of generic devices in the market presents a particular problem for neuroscientists, especially those who rely on Class III devices for which there are few generic alternatives. Indeed, device manufacturers' failure to pursue the

38. 669 F.3d 501 (5th Cir. 2012).

39. *Id.* at 505.

40. *Id.* at 506–07.

41. *Id.* at 512–13.

42. *Id.* at 513–14.

43. 21 U.S.C. § 337(a) (2018).

44. *Bass*, 669 F.3d at 514.

45. *Id.* at 514, 518.

46. See generally Jaime R. Hornecker, *Generic Drugs: History, Approval Process, and Current Challenges*, 34 U.S. PHARMACIST (GENERIC DRUG REV.) 26, 26–27, 30 (2009) (describing the history of the rise and eventual acceptance of the generic drug industry).

development and marketing of generic devices runs the risk of disproportionately disadvantaging fields of medical and scientific inquiry that depend on medical devices, such as neuroscience. While the exact benefits of greater access to generic devices might be unknown, the potential for reduced cost, combined with increased accessibility and wider use, are too important to simply ignore.

II. REGULATORY AND LEGAL OBSTACLES FOR GENERIC DEVICES

Currently, the regulatory and legal system treats generic drugs and generic devices very differently. The result of these differences is that generic drugs are afforded a range of regulatory and legal protections that are not available to generic medical devices. This has stymied the development and production of generic medical devices, thus depriving society of the potential benefits of greater use of generic devices. This part first describes how the FDA approval process differs for drugs and devices, leading to a generic drug market but not a generic device market. Then, it describes how products liability jurisprudence may discourage prospective generic device manufacturers from entering the market. Next, it discusses patentability issues for generic drugs and generic devices. It concludes by considering what effect the regulatory and legal treatment of generic devices has had on the market.

A. *FDA Approval Process*

To understand the current regulatory scheme for generic medical devices, it is useful to compare the approval process of devices with that of generic pharmaceuticals.

All drugs and devices have to receive approval from the FDA prior to being marketed. As both the oldest and most comprehensive consumer protection agency in the United States, the FDA was initially conceived as the Bureau of Chemistry by Congress with the passage of the 1906 Pure Food and Drugs Act.⁴⁷ It was not until three decades later that the FDA, as we know it, was brought into existence by the 1938 Federal Food, Drug, and Cosmetic Act (“FDCA”).⁴⁸ The FDCA was later amended by numerous acts of Congress, including the 1976 Medical Device Amendments Act,⁴⁹ the 1990 Safe Medical Devices Act,⁵⁰ the 1997 Food and Drug Administration Modernization Act,⁵¹

47. Pub. L. No. 59-384, 34 Stat. 768 (repealed 1938).

48. Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301–399i (2018)).

49. Pub. L. No. 94-295, 90 Stat. 539 (codified as amended at 21 U.S.C. §§ 360c–360k, 379–379a, and 42 U.S.C. § 3512 (2018)).

50. Pub. L. No. 101-629, 104 Stat. 4511 (codified as amended in scattered sections of 21 and 42 U.S.C.).

51. Pub. L. No. 105-115, 111 Stat. 2296 (codified as amended in scattered sections of 21 and 42 U.S.C.).

the 2007 Food and Drug Administration Amendments Act,⁵² the 2012 Food and Drug Administration Safety and Innovation Act,⁵³ and the 2016 21st Century Cures Act.⁵⁴

The FDA has broad authority concerning the regulation of food, drugs, and medical devices. Under section 201(g) of the FDCA, drugs are defined as including any “articles [including any component of an article] intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals” as well as “articles [including any component of an article] (other than food) intended to affect the structure or any function of the body of man or other animals.”⁵⁵ Courts, experts, and FDA officials have recognized that the definition of the word “drug” is intended to be expansive and a “purposefully broad delegation of discretionary powers by Congress.”⁵⁶ Under section 201(h) of the FDCA, the definition for “device” includes any

instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, 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 which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.⁵⁷

52. Pub. L. No. 110-85, 121 Stat. 823 (codified as amended in scattered sections of 21 and 42 U.S.C.).

53. Pub. L. No. 112-144, 126 Stat. 993 (codified as amended in scattered sections of 21 U.S.C.).

54. Pub. L. No. 114-255, 130 Stat. 1033 (codified as amended in scattered sections of 21 and 42 U.S.C.).

55. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, § 201(g), 52 Stat. 1040, 1041 (1938) (codified as amended at 21 U.S.C. § 321(g) (2018)).

56. JAMES T. O'REILLY, FOOD AND DRUG ADMINISTRATION § 6:1 (2d ed. 2005); see *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 164–65 (2000) (Breyer, J., dissenting) (providing a detailed review of the legislative history of the definition of “drug” in the FDCA); *A Bill To Prevent the Manufacture, Shipment, and Sale of Adulterated or Misbranded Food, Drink, Drugs, and Cosmetics, and To Regulate Traffic Therein; To Prevent the False Advertisement of Food, Drink, Drugs, and Cosmetics; and for Other Purposes: Hearings on S. 2800 Before the S. Comm. on Commerce*, 73d Cong. 516 (1934) (statement of Walter G. Campbell, Chief of the FDA), reprinted in 2 FDA, A LEGISLATIVE HISTORY OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND ITS AMENDMENTS 519 (1979) (“This definition of ‘drugs’ is all-inclusive.”); *A Bill To Prevent the Manufacture, Shipment, and Sale of Adulterated or Misbranded Food, Drink, Drugs, and Cosmetics, and To Regulate Traffic Therein; To Prevent the False Advertisement of Food, Drink, Drugs, and Cosmetics; and for Other Purposes: Hearings on S. 1944 Before a Subcomm. of the S. Comm. on Commerce*, 73d Cong. 15–16 (1933) (statement of Walter G. Campbell, Chief of the FDA), reprinted in 1 FDA, *supra*, at 107–08 (discussing the “inclusive[,] . . . wide definition” of the word “drug”).

57. Federal Food, Drug, and Cosmetic Act § 201(h), 21 U.S.C. § 321(h) (2018).

The modern definition of device explicitly disclaims software related to medical decisionmaking.⁵⁸ The similarity in the language used to define “drugs” and “devices” has long been recognized by courts as a clear indicator of Congress’s intent for the definition of “devices” to be just as all-encompassing as the definition of “drugs.”⁵⁹

1. Dual Regulatory Pathways for Drugs and Devices

Through the FDCA and its amendments, Congress has directed the FDA to create separate pathways for the regulation of drugs and medical devices. Pursuant to this mission, the FDA has established the Center for Drug Evaluation and Research (“CDER”) to regulate drugs⁶⁰ and the Center for Devices and Radiological Health (“CDRH”) to regulate devices.⁶¹

CDER regulates based on three major categories: (1) “new” drugs; (2) generic drugs; and (3) over-the-counter (“OTC”) drugs. Like the definition of “drug,” the definition of “new drug” is expansive and includes any drug not generally recognized as safe (“GRAS”)⁶² or safe for its intended use.⁶³ Many litigants have tried and failed to restrict this definition of “new drug,” such as in the context of restricting “new” intended uses to only curable diseases,⁶⁴

58. *See id.* (“The term ‘device’ does not include software functions excluded pursuant to section 360j(o) of this title.”); *id.* § 360j(o) (excluding software that provides administrative support for healthcare facilities; maintains or encourages healthy lifestyles; serves electronic patient records; or transfers, stores, converts, or displays laboratory test data).

59. *United States v. An Article of Drug Bacto-Unidisk*, 394 U.S. 784, 798 (1969) (“The historical expansion of the definition of drug, and the creation of a parallel concept of devices, clearly show, we think, that Congress fully intended that the Act’s coverage be as broad as its literal language indicates—and equally clearly, broader than any strict medical definition might otherwise allow.”).

60. *Center for Drug Evaluation and Research*, U.S. FOOD & DRUG ADMIN. (Oct. 28, 2019), <https://www.fda.gov/about-fda/fda-organization/center-drug-evaluation-and-research-cder> [<https://perma.cc/9TQ8-UN7Q>].

61. *Center for Devices and Radiological Health*, U.S. FOOD & DRUG ADMIN. (July 12, 2019), <https://www.fda.gov/about-fda/office-medical-products-and-tobacco/center-devices-and-radiological-health> [<https://perma.cc/95VQ-E4JP>].

62. “Generally Recognized As Safe” is a term of art that has largely fallen out of usage in the modern drug approval context and is only invoked when the FDA regulates food additives or ingredients. *See Generally Recognized as Safe (GRAS)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/> [<https://perma.cc/7368-WM72>].

63. 21 U.S.C. § 321(p)(1).

64. *United States v. Rutherford*, 442 U.S. 544, 551 (1979) (“The Federal Food, Drug, and Cosmetic Act makes no special provision for drugs used to treat terminally ill patients.”).

restricting it to only finished products and not ingredients,⁶⁵ or even to resolve cases on the margin of whether a particular drug constitutes a “new drug.”⁶⁶

If CDER determines that a proposed drug product is a “new drug,” the drugmaker must apply for an Investigational New Drug (“IND”) application consisting of the proposed clinical testing that will demonstrate that the drug is both safe and effective as required by the FDCA.⁶⁷ Approval of the IND application authorizes the drugmaker to perform the required clinical testing.⁶⁸ The drugmaker may then submit a new drug application (“NDA”) containing “full reports” of the results of the investigation demonstrating whether the drug is both “safe” and “effective” for its intended use.⁶⁹ If the FDA approves the NDA, the applicant is then authorized to market the drug.⁷⁰ For manufacturers, the approval of a new drug is costly, time-consuming, and risky.⁷¹

CDHR, in contrast, classifies devices based on risk categories: low-risk devices (“Class I”), moderate-risk devices (“Class II”), and high-risk devices (“Class III”).⁷² Unlike drugs, medical devices are typically not classified according to whether they are “new” medical devices. Instead, under the risk-based classification, regulatory approval is gated by “General Controls,” “Special Controls,” and “Premarket Approval.”⁷³ Furthermore, “[r]egulatory control increases from Class I to Class III.”⁷⁴ General controls refer to regulatory requirements under the FDCA, which provide basic reporting,⁷⁵

65. See *Pharmanex v. Shalala*, 221 F.3d 1151, 1160 (10th Cir. 2000) (declining to restrict the definition of “new drug” within 21 U.S.C. § 321(ff)(3)(B) to only finished products on the grounds of the “broad terminology” Congress used to craft the provision, and finding that this ambiguity merited *Chevron* deference to the FDA’s interpretation of the term “new drug”).

66. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 627 (1973) (“We do not accept the invitation to hold that FDA has no jurisdiction to determine whether a particular drug is a ‘new drug’ and to decide whether an NDA should be withdrawn.”).

67. See 21 U.S.C. § 355(d) (2018) (outlining the grounds for refusing drug applications, including if the drug is unsafe or ineffective).

68. See § 355(i); 21 C.F.R. § 312.1 (2019).

69. See 21 U.S.C. § 355(b)(1).

70. *Id.*

71. See Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 20 (2016) (estimating the cost of developing a new drug at \$2 to 3 billion).

72. *Classify Your Medical Device*, U.S. FOOD & DRUG ADMIN. (Aug. 31, 2018), <https://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/ucm2005371.htm> [<https://perma.cc/ZAQ3-XXRL>].

73. *Id.*

74. *Overview of Device Regulation*, U.S. FOOD & DRUG ADMIN. (Aug. 31, 2018), <https://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/default.htm> [<https://perma.cc/AGQ6-UEGA>].

75. 21 U.S.C. § 360i (2018).

labeling,⁷⁶ and notification requirements⁷⁷ to which all medical devices must conform.

2. Accelerated Pathways

In addition to standard approval pathways, the FDA offers accelerated approval pathways for both drugs and devices. These pathways are available to classes of drugs and devices that are based on an approved predicate, with requirements for predicate drugs being different from predicate devices.

The FDA codifies the approval process for new generic drugs in its Abbreviated New Drug Application (“ANDA”).⁷⁸ Through ANDA, generic manufacturers are able to circumvent the time-consuming and expensive NDA process.⁷⁹ While an NDA requires significant preclinical and clinical data to establish safety and effectiveness,⁸⁰ an ANDA requires only that manufacturers demonstrate bioequivalence of the generic version of the drug to the predicate innovator drug.⁸¹ The ANDA does not require the applicant to obtain any agreements from the original innovator drug manufacturer (i.e., rights of reference for the safety and efficacy data) as the safety and efficacy of the drug are presumptive once bioequivalence is proven.⁸² As a result, generic manufacturers are able to bring generic drugs to market at a significantly lower investment cost than their innovator counterparts.⁸³ Furthermore, the ANDA process ensures that the generic drug applicant is bioequivalent to a drug that has already been approved by the FDA. This requirement ensures that drugs approved through the ANDA process are therapeutically equivalent to drugs that are already on the market. The FDA gives significant guidance on the standards that a drug manufacturer must meet to establish bioequivalence.⁸⁴

On the other hand, since the FDA does not specifically recognize generic medical devices, there is no abbreviated approval process for generic medical

76. *Id.* § 352.

77. *Id.* § 360h.

78. 21 C.F.R. §§ 314.92–99 (2019); see *Abbreviated New Drug Application (ANDA)*, U.S. FOOD & DRUG ADMIN. (May 22, 2019), <https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda> [https://perma.cc/T22G-ZJ7J].

79. 21 C.F.R. §§ 314.50–90 (2019); see *New Drug Application (NDA)*, U.S. FOOD & DRUG ADMIN. (June 10, 2019), <https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/newdrugapplicationnda/default.htm> [https://perma.cc/EZ8M-DLSP].

80. See *New Drug Application (NDA)*, *supra* note 79.

81. See *Abbreviated New Drug Application (ANDA)*, *supra* note 78.

82. See *id.* With respect to drugs, “[r]ight of reference or use is the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of an NDA, including the ability to make available the underlying raw data from the investigation for FDA audit, if necessary.” 21 C.F.R. § 314.3 (2019).

83. See Kesselheim et al., *supra* note 2, at 861.

84. See 21 C.F.R. §§ 320.21–38 (2019) (outlining the procedures for determining the bioavailability or bioequivalence of drug products).

devices. Instead, device approvals are based on two criteria. First, the FDA categorizes the device under one of the three risk categories described earlier: Class I (low risk), Class II (moderate or controlled risk), or Class III (high risk).⁸⁵ Then, the FDA determines if a predicate or substantially equivalent device currently exists on the market.

For devices that carry low to moderate risk, and for which a substantially equivalent predicate exists, the FDA allows for an approval process known as a section 510(k) clearance.⁸⁶ Under this approval process, the manufacturer only needs to demonstrate substantial equivalence to a device already placed into one of the three classification categories.⁸⁷ However, unlike the ANDA, eligibility for the section 510(k) process is also based on the risk associated with the device and not solely on whether a predicate exists.⁸⁸ Therefore, most high-risk medical devices are precluded from the fast-track 510(k) approval process.⁸⁹

Class III devices typically require Premarket Approval (“PMA”).⁹⁰ Under the PMA process, a device manufacturer must demonstrate a “reasonable assurance” of the safety and efficacy of the proposed device, usually through clinical data.⁹¹ As a result, high-risk medical devices, such as deep brain stimulation probes, can only be brought to market by manufacturers capable of investing significant capital into getting PMA for their device.

Some high-risk devices currently qualify for an alternate expedited approval pathway known as the Humanitarian Device Exemption (“HDE”). However, this pathway is limited to rare diseases, and there are problems with

85. 21 U.S.C. § 360c(a)(1)(A)–(C) (2018); *see also Medical Device Overview*, U.S. FOOD & DRUG ADMIN. (Sept. 4, 2018), <https://www.fda.gov/industry/regulated-products/medical-device-overview> [<https://perma.cc/D3KS-SHX8>].

86. *See 510(k) Clearances*, U.S. FOOD & DRUG ADMIN. (Sept. 4, 2018), <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/> [<https://perma.cc/UC9J-F7D8>]. For certain low-risk Class I devices, the FDA may exempt the device entirely from premarket approval. *See Class I / II Exemptions*, U.S. FOOD & DRUG ADMIN. (July 1, 2019), <https://www.fda.gov/medical-devices/classify-your-medical-device/class-i-ii-exemptions> [<https://perma.cc/B6SB-T9GF>].

87. *See 510(k) Clearances*, *supra* note 86.

88. *See id.*

89. *See Premarket Approval (PMA)*, U.S. FOOD & DRUG ADMIN. (May 16, 2019), <https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma> [<https://perma.cc/BD3Q-44WC>] (“Due to the level of risk associated with Class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of Class III devices.”).

90. 21 U.S.C. § 360e (2018); *see also Premarket Approval (PMA)*, *supra* note 89.

91. § 360c(a)(1)(C); *see also* 21 C.F.R. §§ 814.1–.84 (2019) (outlining regulations that govern the PMA process).

the HDE pathway.⁹² These include the potential for misuse of the HDE⁹³ combined with the fact that the “less rigorous HDE process need not demonstrate efficacy,”⁹⁴ making the HDE poorly suited as a mechanism to reliably bring generic medical devices to the market in a safe and responsible manner. The HDE regime is wholly unlike the NDA and ANDA, which allow for expedited—but scientifically rigorous—approvals of life-saving medications such as cancer drugs⁹⁵ and HIV antiretroviral medications.⁹⁶

There are other significant problems with the device approval process. Since the section 510(k) process does not require therapeutic equivalence, defined as when two interventions have the exact same clinical effect and safety profile, manufacturers are allowed to circumvent the PMA process if they submit a series of section 510(k) applications, each making a small change from the previous model. Several critics of the section 510(k) process have analyzed this effect, showing that only a small percentage of devices approved through this process were supported by scientific evidence of any kind.⁹⁷ Thus, instead of promoting widespread adoption of proven technology, the current section

92. 21 U.S.C. § 360j(m) (2018); *see also* Joseph J. Fins et al., *Misuse of the FDA's Humanitarian Device Exemption in Deep Brain Stimulation for Obsessive-Compulsive Disorder*, 30 HEALTH AFF. 302, 303–05 (2011) [hereinafter Fins et al., *Misuse of HDE*] (arguing that applying an HDE to deep brain stimulation to study obsessive-compulsive disorder potentially undermines enrollment in randomized clinical trials utilizing an HDE); *Humanitarian Device Exemption*, U.S. FOOD & DRUG ADMIN. (Sept. 5, 2019), <https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarket submissions/humanitariandeviceexemption/default.htm> [<https://perma.cc/2KYC-RQD5>].

93. *See, e.g.*, Joseph J. Fins & Zachary E. Shapiro, *Deep Brain Stimulation, Brain Maps and Personalized Medicine: Lessons from the Human Genome Project*, 27 BRAIN TOPOGRAPHY 55, 58–59 (2014) (explaining that use of DBS electrodes originally developed to treat Parkinson's in the treatment of obsessive-compulsive disorder constituted a misuse of the HDE process).

94. Joseph J. Fins, Gary S. Dorfman & Joseph J. Pancrazio, *Challenges to Deep Brain Stimulation: A Pragmatic Response to Ethical, Fiscal, and Regulatory Concerns*, 1265 ANNALS N.Y. ACAD. SCI. 80, 84 (2012) [hereinafter Fins et al., *Pragmatic Response*].

95. Dominique Levêque, *Generic Drugs in Oncology*, 18 LANCET ONCOLOGY e63, e63 (Feb. 2017), [http://thelancet.com/journals/lanonc/article/PIIS1470-2045\(17\)30033-5/fulltext](http://thelancet.com/journals/lanonc/article/PIIS1470-2045(17)30033-5/fulltext) [<https://perma.cc/ZW7G-JBXU>].

96. *See, e.g.*, *Antiretroviral Drugs Used in the Treatment of HIV Infection*, U.S. FOOD & DRUG ADMIN. (May 14, 2018), <https://www.fda.gov/patients/hiv-treatment/antiretroviral-drugs-used-treatment-hiv-infection> [<https://perma.cc/9EQG-ZKAK>] (compiling all the approved generic versions of HIV antiretroviral medications).

97. *See* INST. OF MED. OF THE NAT'L ACADS., PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS 29–31 (Theresa Wizemann ed., 2010); Elisabeth M. Dietrich & Joshua M. Sharfstein, *Improving Medical Device Regulation: A Work in Progress*, 174 JAMA INTERNAL MED. 1779, 1779–80 (2014); Josh Rising & Ben Moscovitch, Opinion, *The Food and Drug Administration's Unique Device Identification System: Better Postmarket Data on the Safety and Effectiveness of Medical Devices*, 174 JAMA INTERNAL MED. 1719, 1719–20 (2014); Diana Zuckerman, Paul Brown & Aditi Das, *Lack of Publicly Available Scientific Evidence on the Safety and Effectiveness of Implanted Medical Devices*, 174 JAMA INTERNAL MED. 1781, 1781 (2014) (“Despite the legal requirement that scientific evidence of scientific equivalence be publicly available for medical devices by the FDA through the 510(k) process, such information is lacking for most implanted medical devices cleared between 2008 and 2012, as well as for their predicates.”).

510(k) process incentivizes innovators to make small, incremental improvements to differentiate themselves in the marketplace. These product evolutions are subject to only weak standards, enabling “predicate creep”: where an FDA-approved section 510(k) device, as a result of many minor changes over time, evolves to the point that it “can be made from different materials, use different power sources, and have indications for different anatomical sites.”⁹⁸

A solution to this problem must address the issues discussed above. Attempting to include all high-risk devices under the current section 510(k) process would lead to more potentially harmful predicate creep, and the goal of incentivizing a generic marketplace—and de-incentivizing incremental stagnation—is best achieved by requiring therapeutic equivalence.

B. *Products Liability*

In the field of products liability, Congress and the courts have significantly diverged in their treatment of drug products and medical devices. While the general underlying principles of products liability apply to both categories of products, the courts’ treatment of generic drugs has conferred significant advantages that medical device manufacturers do not enjoy.

The landmark cases for generic drug products liability are *PLIVA, Inc. v. Mensing*⁹⁹ and *Mutual Pharmaceutical Co. v. Bartlett*.¹⁰⁰ In *Mensing*, plaintiffs brought several state tort actions against generic drug manufacturers for failure to provide adequate warning labels for generic versions of metoclopramide, a drug used to treat gastroesophageal diseases.¹⁰¹ The defendant drug manufacturers argued that under federal statutes and FDA regulations, it was impossible for a generic manufacturer to unilaterally amend warning labels, which are set by the innovator manufacturer of a drug, in accordance with state law requirements.¹⁰² Under the impossibility preemption doctrine, state law needed to give way to federal law when the defendants could not “independently do under federal law what state law requires of it.”¹⁰³ The Supreme Court agreed with the defendants and held that generic drug manufacturers could not be found liable under state tort law for failing to provide adequate warning labels.¹⁰⁴

In *Bartlett*, a case about a generic drug that caused a life-threatening skin disorder in an individual, resulting in her losing sixty percent of her skin,

98. U.S. FOOD & DRUG ADMIN., REVIEW OF THE REGEN MENAFLEX 3 (2009), <https://www.fda.gov/media/77734/download> [<https://perma.cc/7PBT-4E73>].

99. 564 U.S. 604 (2011).

100. 570 U.S. 472 (2013).

101. See *PLIVA, Inc.*, 564 U.S. at 609–10.

102. See *id.* at 610.

103. See *id.* at 620.

104. See *id.* at 624.

preemption and design defects were considered after a failure-to-warn claim was dismissed.¹⁰⁵ Ultimately, the Court was faced with an allegation of design defect, a different species of products liability tort.¹⁰⁶ Rejecting the plaintiff's argument that the drug manufacturer could simply "stop selling" the accused product to comply with both federal and state law, the Court applied *Mensing* and extended impossibility preemption to generic drug design defects.¹⁰⁷

Mensing and *Bartlett* were decided in the aftermath of the Court's prior holding in *Wyeth v. Levine*.¹⁰⁸ In *Wyeth*, the Court held that innovator drug manufacturers were required to comply with both federal and state labeling requirements and declined to find impossibility preemption.¹⁰⁹ In that decision, the Court found that while labeling changes typically required drug manufacturers to obtain FDA approval, an innovator drug manufacturer could "add or strengthen" portions of the label related to "safe use of the drug product" through the FDA's "changes being effected" regulation.¹¹⁰ The Court held that because it was "physically possible" for Wyeth to have complied with both federal and state law,¹¹¹ impossibility preemption would not result.¹¹²

After *Mensing* and *Bartlett*, generic drug manufacturers may only be found liable for drug manufacturing defects and not for product design defects or failure to warn. Some liability is essential, as there are still instances of poor manufacturing practice and negligence by generic drug manufacturers,¹¹³ and patients harmed by these actions need a legal mechanism for recovery. However, in an industry where nearly one-third of all drug products result in postmarket safety events,¹¹⁴ protection against certain forms of liability is an important, and perhaps essential, incentive for generic drug manufacturers. Weighed against the high cost of drug products liability, where drug manufacturers often pay millions in damages and settlements for failure-to-

105. *Bartlett*, 570 U.S. at 478–79.

106. *Id.* at 479.

107. *See id.* at 488–89.

108. 555 U.S. 555 (2009).

109. *Id.* at 581.

110. *Id.* at 568.

111. *Id.* at 591 (Thomas, J., concurring). Despite the fact that Wyeth could have amended the label without FDA approval, the risk was high. If the FDA found that Wyeth's amended label was "false or misleading," it could withdraw approval for Wyeth's drug and require the drug manufacturer to perform a costly market recall. *See* 21 U.S.C. § 355(e) (2018).

112. *Wyeth*, 555 U.S. at 591 (Thomas, J., concurring).

113. *See, e.g.,* Maggie Fox, *FDA Recalls Are a Reminder that China Controls Much of World's Drug Supply*, NBC NEWS (Aug. 14, 2018, 5:39 PM), <https://www.nbcnews.com/health/health-news/fda-recalls-are-reminder-china-controls-much-world-s-drug-n900716> [https://perma.cc/XHH8-6X35] (highlighting the challenge the FDA faces in regulating a generic drug market that is "increasingly outsourced to other countries, especially China").

114. *See* Nicholas S. Downing et al., *Postmarket Safety Events Among Novel Therapeutics Approved by the US Food and Drug Administration Between 2001 and 2010*, 317 JAMA 1854, 1855 (2017).

warn claims,¹¹⁵ the effect of this generic manufacturer immunity cannot be overstated.

In contrast, device manufacturers are largely shielded from failure-to-warn claims through a different mechanism. Unlike drug regulation, Congress expressly included a preemption clause for medical devices in the Medical Device Amendments of 1976.¹¹⁶ In *Riegel v. Medtronic, Inc.*,¹¹⁷ the Supreme Court was called upon to interpret this preemption clause in the context of a balloon catheter intended for angioplasty.¹¹⁸ The Court construed 21 U.S.C. § 360k(a) to preempt any state products liability claims that conflicted with a federal requirement imposed by the FDA.¹¹⁹ However, crucially, the Court in *Riegel* declined to extend this protective power to all medical devices, limiting preemption to Class III devices that have gone through the rigorous process of PMA.¹²⁰ The Court reasoned that only the stringent requirements of the PMA process imposed a sufficient federal duty on device manufacturers to preempt state regulations. Thus, devices approved through section 510(k), which focused on equivalence and not on safety, would not receive protection under § 360k(a).¹²¹

As a result, the relative positions of innovator manufacturers and generic manufacturers appear to invert in the medical device context. Innovators are shielded from state tort liability while “generic” manufacturers, despite showing equivalence to an existing FDA-approved device, are liable for not only manufacturing defects but also design defects and failure to warn. Therefore, generic device manufacturers that introduce products based on existing medical devices will inevitably seek approval through section 510(k) if available and are at a significantly higher risk of litigation than their generic-drug-manufacturer counterparts. Given this liability and the high cost of producing medical devices, coupled with the reduced profit margin for any generic as compared to the brand name, there are simply insufficient incentives for manufacturers to produce high-risk generic medical devices.

115. See Han W. Choi & Jae Hong Lee, *Pharmaceutical Product Liability*, in PRINCIPLES AND PRACTICE OF PHARMACEUTICAL MEDICINE 688, 696–98 (Lionel D. Edwards, Anthony W. Fox & Peter D. Stonier eds., 3d ed. 2011).

116. Pub. L. No. 94-295, § 521, 90 Stat. 539, 574 (codified at 21 U.S.C. § 360k(a) (2018)) (“Except as provided in [21 U.S.C. § 360k(b)], no State . . . may establish or continue in effect with respect to a [medical device] any requirement (1) which is different from, or in addition to, any requirement under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.”).

117. 552 U.S. 312 (2008).

118. *Id.* at 320.

119. See *id.* at 330.

120. See *id.* at 322–23; see also *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 492 (1996) (declining to extend § 360k(a) express preemption to devices approved through 510(k) because it “imposes no ‘requirement’ on the design of [the medical device]”).

121. See *Riegel*, 552 U.S. at 323.

C. Patentability

In contrast to products liability, in the fields of intellectual property and patents courts have been willing to afford generic medical devices many of the same legal protections available to generic drugs. Notably, the Supreme Court extended patent protection, originally offered to generic drugs in the Hatch-Waxman Act of 1984,¹²² to generic medical devices in *Eli Lilly & Co. v. Medtronic, Inc.*¹²³

In this case, plaintiff, Eli Lilly's predecessor-in-interest, filed suit to enjoin defendant Medtronic's testing and marketing of an implantable cardiac defibrillator, a generic medical device for use in patients with life-threatening cardiac arrhythmias.¹²⁴ Eli Lilly argued that Medtronic's testing infringed two of its patents.¹²⁵ Medtronic argued that its activities were undertaken to develop and submit to the government information necessary to obtain PMA for the device under section 515 of the FDCA and were therefore exempt from a finding of infringement under 35 U.S.C. § 271(e)(1), which authorizes the manufacture, use, or sale of a patented device "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs."¹²⁶ However, the district court disagreed with Medtronic, concluding that the exemption did not apply to the development and submission of information relating to medical devices on the basis that § 271(e)(1) only applied to generic drugs, not generic devices.¹²⁷ On appeal, the United States Court of Appeals for the Federal Circuit reversed.¹²⁸

The Supreme Court affirmed the Federal Circuit and reasoned that, taken as a whole, the 1984 Hatch-Waxman Act supported Medtronic's interpretation.¹²⁹ The Court therefore held that patent protection necessary for premarket testing and approval should protect generic medical devices in the same way it protects generic drugs. Writing for the majority, Justice Scalia reasoned that "[i]t seems most implausible to us that Congress, being demonstrably aware of the dual distorting effects of regulatory approval requirements in this entire area . . . should choose to address both those distortions only for drug products."¹³⁰

122. Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 21 and 35 U.S.C.).

123. 496 U.S. 661 (1990).

124. *See id.* at 664.

125. *Id.*

126. *Id.* at 665.

127. *Eli Lilly & Co. v. Medtronic, Inc.*, 696 F. Supp. 1033, 1034 (E.D. Pa. 1988).

128. *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 406 (Fed. Cir. 1989).

129. *See Eli Lilly*, 496 U.S. at 669-74.

130. *Id.* at 672.

Writing in dissent, Justice Kennedy argued that “the section refers only to the actual regulation of drugs and does not exempt the testing of a medical device from patent infringement.”¹³¹ He pointed out that

like medical devices, some drugs have a very high cost. Testing a patented medical device, however, often will have greater effects on the patent holder’s rights than comparable testing of a patented drug. As petitioner has asserted, manufacturers may test generic versions of patented drugs, but not devices, under abbreviated procedures. These procedures, in general, do not affect the market in a substantial manner because manufacturers may test the drugs on a small number of subjects, who may include healthy persons who otherwise would not buy the drug. By contrast, as in this case, manufacturers test and market medical devices in clinical trials on patients who would have purchased the device from the patent holder.¹³²

The dissent focused on the reasons why generic medical devices and generic pharmaceuticals might not be treated the same way by Congress, but only Justice White agreed with Justice Kennedy.¹³³ In the end, the Court affirmed the Federal Circuit’s judgment, extending patent protection to generic medical devices.¹³⁴

Eli Lilly highlights that there are instances where courts are willing to treat generic medical devices in a manner similar to generic pharmaceuticals. However, since generic devices still lag far behind generic drugs, despite qualifying for similar patent protections, it is clear that more has to be done to properly incentivize the development of generic medical devices.

D. *Effect on Market*

As a result of the regulatory and legal pressures discussed above and given the paucity of legal protections afforded to generic devices, there is currently little incentive for manufacturers to produce high-risk generic medical devices in a manner analogous to generic drug manufacturers. Without radical changes to the system, there will remain limited economically efficient pathways for a high-risk, generic Class III device to enter the market. Further buttressing the obstacles of bringing a high-risk generic device to market would be the reduced potential for profit from a generic medical device as compared to the innovator device. This is in part because all Class III device manufacturers—whether they produce an innovator device or if they were able to create a generic—exist on a

131. *Id.* at 682 (Kennedy, J., dissenting).

132. *Id.* (citations omitted).

133. *Id.* at 679.

134. *Id.* at 677–79 (majority opinion).

level playing field with respect to products liability, in that both generic and innovator devices receive the protection of statutory preemption.¹³⁵

Indeed, due to the cost of obtaining regulatory approval for Class III devices and the risk of liability if the device is particularly high-risk, generic device manufacturers instead focus on low- to medium-risk medical devices that are subject to the more expedient section 510(k) approval pathway.¹³⁶ Unlike Class III devices, there is generally no federal statute that protects manufacturers of section 510(k) devices from certain types of products liability exposure. While these devices are, by definition, lower risk than their Class III counterparts, their manufacturers are paradoxically subject to more products liability risk.

This leads to a situation where the largest generic device manufacturers in the United States do not reproduce Class III devices but instead focus on Class I and some Class II medical devices, such as asthma inhalers.¹³⁷ For their part, brand-name manufacturers have supported this trend, as the lack of generic market participants ensures that manufacturers of Class III devices are insulated from generic competition. However, as medical device profits and costs continue to increase,¹³⁸ there is growing significant regulatory and public pressure for greater access to generic medical devices.

Given the regulatory obstacles for many types of Class III generics and the ethical rationale promoting more generic devices, it is clear that an alternative pathway for approval and preemption is needed. Fundamentally, something needs to be done to better encourage the production of generic medical devices. This must start with regulatory and legal changes to promote access while also recognizing the need to better protect generic device manufacturers from liability.

III. OPTIONS FOR PROMOTING MEDICAL DEVICE INNOVATION

Based on the success of the generic drug market and the significant savings it confers to healthcare systems and taxpayers, along with research and public health benefits, the inherent potential of a robust generic device market is clear. In order to improve access, it is important to try new ideas to fix long-standing

135. See 21 U.S.C. § 360k(a) (2018).

136. See *supra* notes 86–98 and accompanying text.

137. See, e.g., Greg Kemper, *The Benefits of Generic Medical Devices*, KEMPER MED., INC. (Sept. 14, 2015), <http://www.kempermedical.com/blog/the-benefits-of-generic-medical-devices/> [https://perma.cc/VKQ4-G46] (“It should be noted that [Generic Medical Devices, a generic device company,] is not focusing on highly complex devices that are considered life-critical but those that are standard-of-care and which have undergone minimal technological innovation, making them easy to replicate.”).

138. See U.S. GOV’T ACCOUNTABILITY OFFICE, *supra* note 4, at 5.

problems.¹³⁹ We recommend two changes that would incentivize more generic device manufacturers to enter into the market for Class III devices: (1) the FDA should create a new abbreviated premarket approval process (“APMA”) analogous to its ANDA process that allows device manufacturers to receive approval for medical devices by demonstrating equivalence to an existing FDA-approved medical device; and (2) courts or legislators should extend the *Mensing/Bartlett* preemption doctrine to generic medical devices, similar to the way courts interpret patent protections to apply to generic devices.

A. *The Abbreviated Premarket Approval*

The FDA should create a new category of premarket approval that covers all classes of medical devices for which a predicate FDA-approved device exists. Changing the regulatory approval pathway is particularly important given the documented problems in the current section 510(k) process. While a full discussion of the shortcomings of the current section 510(k) procedure is beyond the scope of this Article, it is important to recognize that the section 510(k) pathway has been the subject of substantial criticism and debate.¹⁴⁰

Indeed, in 2010, the Institute of Medicine (“IOM”) released a report critiquing the section 510(k) process.¹⁴¹ The report emphasized the risks in simply looking to predicate devices to determine substantial equivalence, highlighting that such a process is unable to truly demonstrate safety or efficacy.¹⁴² These concerns led the IOM to recommend the abolition of the section 510(k) process for all Class II devices.¹⁴³ Courts have also recognized the shortcomings of the current section 510(k) paradigm, with Justice Stevens writing that “[t]here is no suggestion in either the statutory scheme or the legislative history that the § 510(k) exemption process was intended to do anything other than maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents.”¹⁴⁴ Given the problems with the current section 510(k) pathway, a new paradigm, which

139. See, e.g., Zachary E. Shapiro, *Savior Siblings in the United States: Ethical Conundrums, Legal and Regulatory Void*, 24 WASH. & LEE J.C.R. & SOC. JUST. 419, 422 (2018) (exploring the potential use of “savior siblings” to “provid[e] biological material that can help treat or cure an existing terminally ill child”).

140. See, e.g., Fins et al., *Pragmatic Response*, *supra* note 94, at 82–86 (critiquing the 510(k) clearance process as it applies to Class III medical devices, including deep brain stimulation electrodes).

141. See generally INST. OF MED. OF THE NAT’L ACADS., *supra* note 97 (providing a comprehensive report of the 510(k) clearance process of medical devices at the request of the FDA).

142. See *id.* at 127 (“Class II approvals should be based on objective performance criteria that ensure safe and effective use, when appropriate based on comparison to predicate devices recognized as meeting those standards.”).

143. See *id.* at 126 (recommending that regulators should “[c]reate a class II approval process [because t]he 510(k) procedure deserves its own home outside the historical work around of cobbling together a ‘clearance’ (aka approval) process with registration and listing”).

144. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 494 (1996).

differs from the section 510(k) process in key ways, would better incentivize the safe creation and dissemination of generic medical devices.

First, the section 510(k) paradigm is not only designed for copies of existing medical devices that do not have a new use but also for iterative changes that do not substantially alter the safety and efficacy of existing devices. Therefore, the testing methodologies adopted by the section 510(k) program are targeted towards incremental improvements to existing devices. In section 510(k) parlance, “substantially equivalent” includes both devices that have the “same technological characteristics as the predicate device” as well as devices that have “different technological characteristics” but are “substantially equivalent to the predicate device.”¹⁴⁵ These “different technological characteristics” can include significant changes in the “materials, design, energy source, or other features of the device from those of the predicate device”¹⁴⁶ as there is leeway in how a section 510(k) device may differ from a predicate device. Therefore, to help ensure safety and efficacy, we propose that the APMA define “substantial equivalence” according to § 360c, namely that the device must have “the same technological characteristics as the predicate device.” This is equivalent to the ANDA requirement that a generic drug must be bioequivalent to its predicate.

Of course, this would require access to technical information about the medical device. A possible solution to this concern would be to simply require innovator manufacturers to disclose blueprints or specifications for certain classes of complex medical devices, information that is often already submitted to the FDA as part of the premarket approval process.¹⁴⁷ Currently, manufacturers seeking either a 510(k) or PMA bear the burden of providing manufacturing and design control data to demonstrate the safety and efficacy of their proposed devices. Under FDA regulations, an applicant manufacturer may reference information contained in another application with permission from the original manufacturer that submitted the application.¹⁴⁸ This permission must be submitted to the FDA in a “letter of authorization” (“LOA”), which grants the applicant the right of reference to relevant information contained in the original manufacturer’s device master files (“MAF”).¹⁴⁹ Currently, the process by which manufacturers provide or decline

145. 21 U.S.C. § 360c(i)(1)(A) (2018).

146. *Id.* § 360c(i)(1)(B).

147. *See Master Files*, U.S. FOOD & DRUG ADMIN. (Nov. 14, 2017), <https://www.fda.gov/medical-devices/premarket-approval-pma/master-files> [https://perma.cc/9F9E-JDBR].

148. *See id.*

149. *See, e.g., id.* (explaining the authorization process and providing an example of a letter of authorization).

to provide LOAs lacks transparency since the manufacturers, unlike the FDA, are not subject to transparency laws such as the Freedom of Information Act.¹⁵⁰

In addition to these concerns, a manufacturer would be strongly disincentivized (1) to release potentially confidential or trade secret information contained in the MAF or (2) to provide a right of reference to a potential generic competitor. This is why countervailing market forces associated with generic medical devices are especially important to help incentivize participation by industry. Analogies abound to the generic drug marketplace, where brand-name manufacturers have developed a slew of tactics to slow the introduction of generic drugs.¹⁵¹ Accepting the potential merit of such a suggestion, a more critical element would be to incorporate transfer of the MAF into such a recommendation for a novel generic medical device pathway. As part of the PMA, a device manufacturer should agree to allow the FDA to release MAFs to follow-on generic manufacturers. In turn, the FDA can indemnify the device manufacturer (i.e., pay a fair royalty for the generic manufacturer's use of the MAFs) through its User Fee Program and pass on some, or all, of the costs to generic manufacturers.¹⁵²

Currently, the section 510(k) paradigm applies only to Class I and certain Class II devices. Devices requiring a PMA are not eligible predicate devices under section 510(k). Since the APMA will be designed for devices with identical characteristics to predicate devices, there is no concern that generic manufacturers will introduce design changes altering the safety and efficacy of their generic devices. Therefore, the APMA should be available for substantial equivalents of all classes of medical devices. This change is key to allowing generic device manufacturers to participate in all levels of the medical device market, particularly in incentivizing generic device manufacturers to create higher-risk devices.

Finally, the APMA would follow similar labeling standards to the ANDA. Under the APMA, generic device manufacturers would be required to submit a proposed label that contains the same information as the predicate device and would be required to update their labels following any changes to the label for the predicate device.

150. See Michael L. Kelly et al., *Barriers to Investigator-Initiated Deep Brain Stimulation and Device Research*, 82 *NEUROLOGY* 1465, 1467 (2014) (“The criteria by which manufacturers process outside requests for right of reference authorization are underreported.”).

151. See, e.g., C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 *N.Y.U. L. REV.* 1553, 1553 (2006) (discussing reverse patent payment settlement or “pay-for-delay” schemes to delay generic drugs); Amy Kapeczynski, Chan Park & Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of ‘Secondary’ Pharmaceutical Patents*, *PLOS ONE*, Dec. 5, 2012, at 2 (discussing “evergreening” of drug patents to prevent the entry of generic competitors).

152. *FDA User Fee Programs*, U.S. FOOD & DRUG ADMIN. (Aug. 2, 2019), <https://www.fda.gov/forindustry/userfees/default.htm> [<https://perma.cc/FT6P-FMSJ>].

Some aspects of the ANDA process, however, cannot be directly applied to the device context. Unlike drugs, medical devices can sometimes vary in material, composition, or design without a corresponding change in therapeutic function. For example, the choice of material for a printed circuit board (“PCB”) in a cardiac pacemaker would almost certainly not make a difference in the safety or function of the pacemaker, since the PCB does not need to be made of biocompatible materials, as long as the PCB is enclosed in the pacemaker’s biocompatible casing. This is akin to when generic drug manufacturers use differing manufacturing processes or reagents to create generic drug equivalents of innovator drugs.

A close analogue to the device model exists in the regulatory approval of biosimilars and interchangeable products. Biosimilars and interchangeable products are a relatively new class of biological products introduced in the Biologics Price Competition and Innovation Act of 2009, which was integrated as Title VII of the Patient Protection and Affordable Care Act.¹⁵³ Unlike nonbiological drugs, biological products—or biologics—are typically very large molecules derived from human, animal, or microorganism sources.¹⁵⁴ For example, vaccines are a type of biologic. According to the FDA, “[i]n contrast to most drugs that are chemically synthesized and their structure is known, most biologics are complex mixtures that are not easily identified or characterized.”¹⁵⁵ It is possible for chemical or steric variations of a biologic to achieve the same therapeutic effect. Thus, the generic pathway for biologics includes not only exact replicas of a biologic, but also similar biologics (i.e., “biosimilars”).

Unlike the ANDA, the biosimilar approval pathway accepts two tiers of biosimilars. The higher standard, called “interchangeable” biologics, closely mirrors the ANDA requirement for generics: a manufacturer must meet a rigorous standard of proof that the proposed biosimilar will “be expected to produce the same clinical result as the reference product in any given patient.”¹⁵⁶ Furthermore, “the risk in terms of safety or diminished efficacy of alternating or switching between use of the [biosimilar] and the reference product [must not be] greater than the risk of using the reference product without such alternation or switching.”¹⁵⁷ Under the lower standard, a biologic may also be approved as a biosimilar—but not interchangeable—product if the

153. Pub. L. No. 111-148, §§ 7001–7003, 124 Stat. 804, 804–21 (2010) (codified at 42 U.S.C. § 262 (2018)).

154. U.S. FOOD & DRUG ADMIN., BIOLOGICAL PRODUCTS DEFINITIONS 1, <https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf> [<https://perma.cc/NJ5Y-5LFP>].

155. *What Are “Biologics” Questions and Answers*, U.S. FOOD & DRUG ADMIN. (Feb. 6, 2018), <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm> [<https://perma.cc/VWA8-Z44R>].

156. 42 U.S.C. § 262(k)(4)(A)(ii) (2018).

157. *Id.* § 262(k)(4)(B).

manufacturer provides proof that the biological product is “highly similar to the reference product notwithstanding minor differences in clinically inactive components; and there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency of the product.”¹⁵⁸ The statutory requirements under the Biologics Price Competition and Innovation Act of 2009 are strikingly similar to the statutory requirements of section 510(k), which requires a device to be “substantially equivalent” to a predicate device.¹⁵⁹

We believe that the FDA model for biosimilar applications could be translated to generic medical devices to great effect. Like biosimilars, the FDA can create two tiers of review for the APMA: a lower tier in which a manufacturer must provide scientific or clinical evidence that demonstrates that the proposed device has no clinically meaningful difference compared to the predicate and a higher tier in which a manufacturer must meet the evidentiary burden that the proposed device is clinically interchangeable with the predicate. This system strengthens the FDA approval pathway for devices by allowing generic device manufacturers to enjoy expedited approvals while limiting the amount of misuse by manufacturers for predicate creep. Thus, innovator manufacturers would be encouraged to innovate, while generic manufacturers would be confident in using tried-and-true device designs. In this way, generic devices could finally be properly incentivized from a regulatory approval perspective.

By narrowing the focus of the approval process, the APMA process would likely be substantially simpler than the current section 510(k) paradigm while ameliorating some of the criticisms of the section 510(k) pathway discussed above. A simple, streamlined process under the APMA would reduce transaction costs and shorten approval times, resulting in a reduction of administrative burden to the FDA. A new regulatory approval pathway thus would not only benefit patients and the healthcare system in general but would also be beneficial to manufacturers and the FDA.

B. *Extending Generic Drug Preemption Doctrine to Generic Medical Devices*

Just as courts have extended patent protection available to generic drugs to generic medical devices, we propose that courts definitively extend impossibility preemption under the *Mensing/Bartlett* standard to the field of medical devices. Courts should rule that device manufacturers who submit through the proposed APMA and certain section 510(k) pathways would not be able to independently comply with both FDA regulations and state duty-to-warn laws. This would harmonize drug product and medical device liability and

158. *Id.* § 262(i)(2)(A)–(B).

159. *See* 21 U.S.C. § 360c(i) (2018).

remove a major liability that generic device manufacturers currently bear. Importantly, and most critically, federal preemption will not shield generic manufacturers from state-law tort claims concerning manufacturing defects. Under our proposal, it is undeniable that patients seeking to recover damages from generic devices manufacturers would face an uphill battle. However, we posit that such policies would have a net positive effect on society as they would incentivize manufacturers to create generic devices, resulting in greater access to medical devices and a reduction in costs to the healthcare system as a whole while still allowing patients harmed by a generic device a legal mechanism to recover damages.

The legal analysis for applying *Mensing/Bartlett* to the APMA is straightforward, but the application of impossibility preemption to section 510(k) devices warrants additional analysis. First, under section 510(k), any major modification—including a label change—to device design that “could significantly affect the safety or effectiveness of the device” must be submitted to the FDA before a manufacturer can enact a change.¹⁶⁰ Second, any products liability action brought under the risk-utility approach would require the plaintiff to demonstrate that the device manufacturer could have “either increase[ed] the ‘usefulness’ of [the] products or reduce[d] its ‘risk of danger.’”¹⁶¹ In essence, a plaintiff would have to prove that “redesign” of the device was possible.¹⁶² But if such a redesign occurred, then the device would no longer be a generic and should lose associated preemption flowing from the predicate device.¹⁶³ Therefore, a manufacturer is statutorily barred from the “unilateral” action that the court in *Mensing* deemed necessary to defeat impossibility preemption.¹⁶⁴ Thus, even under our current preemption doctrine, generic device manufacturers may theoretically raise a preemption defense against state products liability claims.

However, the Supreme Court rejected a similar argument in *Medtronic, Inc. v. Lohr*¹⁶⁵ when it held that neither “the statutory scheme or legislative history [suggests] that the section 510(k) exemption process was intended to do anything other than maintain the status quo,” which included the possibility that a medical device manufacturer would have to defend itself against state-

160. 21 C.F.R. § 807.81(a)(3)(i) (2019).

161. *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 483 (2013).

162. *See id.*

163. Previously, one author of this Article argued that predicate approvals, under the HDE, should be waived if an approved device is being used for a different purpose. *See, e.g., Fins et al., Misuse of HDE, supra* note 92, at 308 (critiquing the use of an approved DBS stimulator device, approved for Parkinson’s disease, for obsessive-compulsive disorder).

164. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 614 (2011) (“[C]hanges unilaterally made to strengthen a generic drug’s warning label would violate the statutes and regulations requiring a generic drug’s label to match its brand-name counterpart’s.”).

165. 518 U.S. 470 (1996).

law negligent design claims.¹⁶⁶ The Court's holding in *Lohr* is limited to the express preemption clause under § 360k as opposed to the general doctrine of impossibility preemption.¹⁶⁷ In particular, the Court's decision turned on whether section 510(k) imposed "federal requirements" as defined under § 360k.¹⁶⁸ Thus, the issue of impossibility preemption remains a plausible avenue for preemption, but an abundance of lower court decisions suggests that courts are unwilling to disturb the established broad interpretation of *Lohr*.¹⁶⁹

While the example of *Eli Lilly* shows that courts may be willing to protect generic devices on their own, relying on judges to fashion a remedy to incentivize generic devices is risky. This would require a case with the right set of circumstances, heard before a jurist who understands the issues at stake, combined with excellent lawyering and advocacy to make sure that the best arguments are put forward. In litigation, there would be significant resistance from current brand-name device manufacturers, and the adversarial nature of a trial muddies the water. Even if a court decided to extend preemption doctrine to generic medical devices, the decision could ultimately be overturned on appeal or reversed later and therefore would not provide the certainty and clarity necessary for device manufacturers to undertake the significant financial commitments needed to produce generic medical devices. A serious question would still remain concerning whether such a ruling would be within the proper scope of the judiciary, which would be engaging in de facto policymaking in the field of public health.

For these reasons, legislation specifically concerning generic devices would provide the best form of protection. The specific form of this legislation would depend on whether the APMA process is codified. Even if Congress codifies the APMA process, § 360k may not necessarily extend to all generic medical devices, as it is unclear if the APMA process would impose "requirements" under the statute.

Thus, Congress may take this opportunity to include express language that specifies the extent of state-law liability for generic medical devices, as well as generic drugs and biosimilars. This type of legislation could have the added

166. *Id.* at 494; *cf.* *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322–23 (2008) (contrasting the PMA process and the 510(k) process).

167. *Lohr*, 518 U.S. at 484 ("[W]e are presented with the task of interpreting a statutory provision that expressly pre-empts state law.").

168. *Id.* at 493–94 (finding that the 510(k) process did not "require [defendant's device] to take any particular form for any particular reason").

169. *See, e.g., In re Bard IVC Filters Prods. Liab. Litig.*, No. MDL 15-02641-PHX DGC, 2017 WL 5625547, at *14 (D. Ariz. Nov. 22, 2017) (rejecting an impossibility preemption defense to a state-law failure-to-warn claim based on section 510(k)); *Mullins v. Ethicon, Inc.*, 147 F. Supp. 3d 478, 482 (S.D. W. Va. 2015) ("[D]efendants have not demonstrated that it was the clear and manifest purpose of Congress to immunize medical device makers from state tort liability, and so have not overcome the presumption against preemption." (citing *Lohr*, 518 U.S. at 485)).

benefit of harmonizing the legal and regulatory pathways for devices, drugs, and biosimilars. Legislation could end up addressing potential shortcomings in the federal common law, as well as clarifying Congress's stance on whether federal preemption should extend to biosimilar products. For example, Congress may decide that while generic manufacturers should be protected from some tort claims, said liability protection should be conditioned on the manufacturer's cooperation with the regulatory scheme (e.g., promptly submitting safety data) or only apply when the public interest for a device outweighs the public harm of restricting state tort liability (e.g., devices used to treat rare diseases). Congress may also elect to extend limited forms of protection to device manufacturers participating in the section 510(k) process. Congress may either amend § 360k such that section 510(k) is considered a "federal requirement" or, alternatively, implement changes to the section 510(k) process itself that would impose a requirement if certain conditions were met. For example, protection may be extended to manufacturers who agree to participate in additional postapproval safety data-gathering programs.¹⁷⁰

Considering and passing proper legislation would enable Congress to properly weigh the evidence, hear from a variety of stakeholders, devise proper checks and balances between generic and innovator devices, and chart the best course forward. Despite the current political gridlock, we are confident that, if Congress seriously considered the status and potential of generic medical devices, it could devise an effective policy to protect and promote generic medical devices.¹⁷¹

CONCLUSION

The success of generic pharmaceuticals has provided a glimpse of the benefits that generic medical devices might bring. However, several legal and regulatory barriers must be overcome before a generic device marketplace can be realized. While generic drug reform such as the Hatch-Waxman Act and the Supreme Court's decisions in *Mensing* and *Bartlett* provide some guidance for the first steps towards a generic device marketplace, several challenges unique to medical devices remain. First, federal statutes and regulations do not contemplate generic devices at all. The current paradigm for follow-on medical

170. See U.S. FOOD & DRUG ADMIN., POSTMARKET SURVEILLANCE UNDER SECTION 522 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 4-5 (May 16, 2006), <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm268141.pdf>. [<https://perma.cc/F6AM-KGQA>] (outlining a potential postmarket surveillance program to monitor the safety and efficacy Class II and III devices).

171. See, e.g., Berkeley Lovelace Jr., *Senate Finance Committee Unveils Bipartisan Bill To Lower Prescription Drug Prices for Seniors*, CNBC (July 23, 2019, 3:43 PM), <https://www.cnbc.com/2019/07/23/key-senate-panel-unveils-bipartisan-bill-to-lower-drug-prices-for-seniors.html> [<https://perma.cc/L4BZ-VC2Y>].

device approval prioritizes iterative changes and does not reward equivalency in safety and efficacy. Second, unlike innovator drug manufacturers, innovator device manufacturers are able to protect their device designs despite being required to submit this information to the FDA. Third, generic device manufacturers tend to receive *less* legal protection from products liability suits than innovator device manufacturers, an inversion of the state of products liability in the generic drug marketplace, despite qualifying for similar patent protections.

The current design of the regulatory and legal regime heavily disfavors the entry of generic device manufacturers. Without reform, patients will continue to be forced to purchase medical devices from a marketplace without the benefit of generic competition. In a recent statement, the FDA emphasized the importance of promoting generic drug competition to “complex drugs.”¹⁷² Noting that complex drugs “continue to face no generic competition” because they are hard to “genericize,” the FDA plans to advance policies to promote generic competition.¹⁷³ Many of the proposed policies, such as guidance for “develop[ing] complex drugs that are hard to copy,” “establishing active ingredient sameness,” and creating “new analytical tools” to support generic approval, would also be effective in promoting the development of generic medical devices.¹⁷⁴

However, without changes to the regulatory and legal systems described above, generic medical devices will continue to lag behind their pharmaceutical counterparts. The creation of a generic device marketplace strongly aligns with the FDA’s mission to promote patient access to innovative therapies, whatever form they take. It is our hope that the above observations and recommendations will shift the balance towards generic medical devices, thus expanding access to innovative and cost-conscious therapies.

172. Press Release, Scott Gottlieb, U.S. Food & Drug Admin., Statement -on 2019 Efforts To Advance the Development of Complex Generics To Improve Patient Access to Medicines (Jan. 30, 2019), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm630160.htm>. [<https://perma.cc/F6AM-KGQA>].

173. *Id.*

174. *Id.*