INNOVATING PREEMPTION OR PREEMPTING INNOVATION?

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ABSTRACT—Medical devices diagnose disease, prolong life, and improve health. But when defective, they can injure, disable, and kill. To successfully sue manufacturers for injuries caused by medical devices, patients must overcome the defense that federal law preempts, or displaces, state law claims. The Supreme Court has provided a framework for answering this question with respect to most devices. However, it has never confronted how it would apply the framework to an innovative but growing class of devices—de novo devices—that may incorporate novel technologies like artificial intelligence and machine learning. This Essay tries to answer this question as a predictive and normative matter. From a predictive perspective, the Essay argues that the Court’s increasingly textualist orientation suggests it will reject preemption of claims against manufacturers of de novo devices, though the result is not certain. From a normative perspective, the Essay argues that allowing claims against de novo device manufacturers forces risk internalization, provides a regulatory failsafe for innovative technology, and preserves innovation without sacrificing patient health.

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INTRODUCTION

Over the past thirty years, the Supreme Court has developed a stable, if contested, framework for determining when federal law expressly preempts, or blocks, state law liability for medical “devices” regulated by the Food and Drug Administration (FDA).¹ Through three central cases, the Court has held that federal law expressly preempts claims against manufacturers that undergo the most stringent form of regulatory review (Premarket Approval or PMA)—which applies to high-risk devices such as implantable pacemakers, defibrillators, or cardiac stents—but not against manufacturers of moderate to low-risk devices regulators found to be “substantially equivalent” to a legally marketed device (510(k) clearance).² Lower courts have applied this doctrine relatively consistently in cases where plaintiffs allege injury caused by devices ranging from tubal ligation clips³ to implantable intravascular filters.⁴ There are, however, a growing number of devices that incorporate novel technology like artificial intelligence/machine learning (AI/ML) to which this doctrine’s application is untested: devices granted “de novo” authorization.

Unlike the 510(k) and PMA devices, de novo devices reach the market through a newer pathway created by Congress to provide quicker market

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¹ Claims may also be “impliedly” preempted when they do no more than allege that the defendant violated a federal regulation. This article is about express preemption only. See infra Section I.A.
⁴ E.g., In re Bard IVC Filters Prod. Liab. Litig., 969 F.3d 1067,1071 (9th Cir. 2020).
access to devices with novel technologies. For example, one device that received a de novo grant from the FDA uses AI/ML to “quantify” pain and enables physicians to dose pain medication in response. Another uses AI/ML to detect pathologies in images of the prostate. The increasing prevalence of these devices, the risks they pose, and their novelty are sure to raise liability questions in the near term. Because the Court dictates the boundaries of preemption, its eventual decision on the subject will shape the type and nature of claims available against manufacturers of de novo devices.

The Court’s eventual resolution of this unresolved question will have far-reaching consequences for device development. On the one hand, if express preemption does not apply to de novo devices, firms will face increased liability risk that could chill investment in novel technologies. As a result, firms, which have begun using the de novo pathway with more frequency, may abandon novel device technology or bring them to market through a more expensive pathway. Both options carry the risk of potentially raising costs and limiting access to de novo devices.

On the other hand, liability risk can serve as an important tool to monitor and police these new innovations given that they do not undergo the most searching FDA review. These considerations are particularly acute here where the devices present unique risks because of their technological and chronological novelty. Resolution of the express preemption question is important because the current state of the law creates uncertainty (or the potential for miscalculation) for manufacturers which can alter investment decisions.

While the outcome of this question at the Court remains unclear, it seems poised to evaluate these competing considerations differently than it did in its last major express preemption decisions on devices in 1996 and 2008. In those decisions, the Court emphasized the importance of state law in providing both redress to injured plaintiffs and an incentive for manufacturers to provide timely and accurate information about product risk. Since then, the Court has become more textualist (suggesting that statutory and regulatory language may cabin the scope of state law claims) and more

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6 Software to Enhance Confidence in Prostate Cancer Diagnosis, PAIGE, https://info.paige.ai/prostate [https://perma.cc/6VH5-PALG].

7 Jaime Bonnin Roca & Eoin O’Sullivan, The Role of Regulators in Mitigating Uncertainty within the Valley of Death, 109 TECHNOVATION 102157 1, 3 (2022).

hostile to the administrative state (perhaps opening a window through which state law claims may slide).

This Essay argues that, even in light of the Court’s jurisprudential shift, manufacturers should not be able to use express preemption to successfully defend claims brought by plaintiffs alleging that a de novo device caused their injuries. It contends that the Court’s jurisprudence, even interpreted using a more textualist lens, should not be read to expressly preempt state law claims against manufacturers of de novo devices. Beyond the legal arguments, this Essay contends that there are also compelling policy reasons not to apply preemption to de novo devices, many of which dovetail with the Court’s modern jurisprudence.

To understand the argument, one must understand both device regulation and the Court’s preemption jurisprudence. Parts I and II lay this groundwork. Part I explains preemption generally and how the Court has applied it to medical devices. It highlights what one of us has called the thoroughness principle, which adjusts the extent of preemption depending on how thoroughly the FDA has evaluated a device’s safety and efficacy. It shows that the Court has applied this principle to limit express preemption only to PMA devices and not 510(k) devices. In the process, we explain how the Court’s textualist focus has influenced the outcomes in express preemption cases related to devices.

Part II explains the typical pathways to market for devices, the costs of moving through these pathways, and the newer de novo pathway. In analyzing the de novo pathway, Part II explores how it differs from the more typical pathways to market.

With the framework of both preemption and device regulation in place, Part III argues that applying the Court’s preemption framework, including the thoroughness principle, to preemption yields positive returns for state law claims: express preemption should not apply to de novo devices. In short, the thoroughness principle suggests that de novo review is not rigorous enough to merit the protections of preemption under existing Supreme Court doctrine. Importantly, Part III also analyzes how the composition of the current Court along with existing regulatory changes may influence whether the thoroughness principle will apply in the same way the Court has applied it in the past. We argue that even if the Court takes a more textualist approach, the best doctrinal arguments suggest express preemption should not apply to de novo devices. Even if the doctrinal arguments yield uncertain results, there are compelling policy reasons that should influence the Court’s

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10 Id.
textualist analysis and counsel against applying express preemption to de novo devices.

I. PREEMPTION

Patients injured by devices can attempt to sue for recovery under state law, typically in contract or tort. But other state laws, such as consumer protection statutes, can also offer possible avenues of relief. Each type of claim differs in substance—even claims within tort and contract laws have distinct elements that require different kinds of proof. 11 Commonly, however, patients base their claims on the device being defective in some way—either because of how the devices are manufactured, designed, or marketed or because they are not fit for their marketed use. 12 Often, though not always, these claims involve risks of adverse events that manufacturers did not disclose or appropriately communicate to doctors or patients. 13 Manufacturers, however, can defend these claims by arguing that federal law preempts them. In the remainder of Part I, we explain the types of preemption and how the Court has applied express preemption to devices.

A. Express & Implied

Preemption is derived from the Supremacy Clause of the United States Constitution, which dictates that federal law trumps state laws. 14 When Congress includes a provision preempting state law in a duly enacted statute, preemption is “express.” Because express preemption occurs when a federal statute contains language stating that it preempts state law, the extent to which federal law preempts state law is a matter of statutory interpretation. 15 For example, the Federal Cigarette Labeling and Advertising Act states that “[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.” 16 This clause, in both form and effect, expressly prohibits states from imposing advertising and labeling requirements on cigarettes that conform with federal law. But what it means for a

11 Id.
12 E.g., id. at 1096, 1111, 1121 (defining types of defect-based torts). U.C.C. § 2-314 (addressing the implied warranty of merchantability). This tracks roughly the distinction between tort and contract claims.
13 Id.
14 U.S. CONST. art. VI.
“requirement or prohibition” to “be based on smoking and health”—and hence subject to this provision—is matter of interpretation.\(^{17}\)

When there is no express preemption provision or a court determines it does not apply, federal law may still \textit{impliedly} preempt state law.\(^{18}\) There are two types of implied preemption: field and conflict. Field preemption occurs when federal regulation is so pervasive that it demonstrates Congressional intent to occupy an entire “field.”\(^{19}\) Conflict preemption can occur either when complying with both federal and state law simultaneously is impossible, or, if not impossible, when complying with state law would pose an obstacle to Congress’ objectives in regulating the area.\(^{20}\) While implied preemption does not involve a statutory provision, the question for a court is often similar: whether and to what extent does federal law displace state law?

\section*{B. The Court’s Preemption Jurisprudence Relating to Devices}

Preemption of drugs and devices involves both the express and implied types. While it is possible that the Court may reconsider its implied preemption jurisprudence, it is unlikely to do so.\(^{21}\) The main point of controversy with respect to de novo devices will be whether federal law expressly preempts state law claims against their manufacturers.

Express preemption is at issue in the device space because when Congress passed the first comprehensive federal law regulating devices, the Medical Device Amendments of 1976 (MDA), it included a preemption provision. Section 360k of the MDA expressly prohibits States from “establish[ing] or continu[ing] in effect with respect to a device intended for human use any requirement which is different from, or in addition to, any requirement applicable under this chapter to the device [that] relates to the safety or effectiveness of the device . . . .”\(^{22}\) While short, this language has become one of the most contested provisions in the MDA.

The Court interpreted this provision in two major decisions—\textit{Medtronic v. Lohr}\(^{23}\) in 1996 and \textit{Riegel v. Medtronic}\(^{24}\) in 2008. In \textit{Lohr}, the Court began its interpretation with two key interpretive moves. The first was

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\item\(^{17}\) E.g., Altria Grp., Inc. v. Good, 555 U.S. 70 (2008).
\item\(^{18}\) See Simon, \textit{supra} note 9, at 1108–13.
\item\(^{19}\) E.g., Arizona v. United States, 567 U.S. 387, 399 (2012).
\item\(^{21}\) At least in the drug context, the Court has repeatedly relied on its implied preemption jurisprudence without hinting that it should be changed. E.g., Wyeth v. Levine, 555 U.S. 555, 580–81 (2009); PLIVA, Inc. v. Mensing, 564 U.S. 604, 609 (2011); Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 476 (2013); Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1672 (2019).
\item\(^{22}\) 21 U.S.C. § 360k.
\item\(^{23}\) Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996)
\item\(^{24}\) Riegel v. Medtronic, Inc., 552 U.S. 312 (2008).
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to tee up the analysis by reiterating the presumption against preemption of state laws, particularly in matters of health and safety. Second, and in a move that the current Court may not follow, it reiterated that the fundamental question for preemption is congressional purpose.

With this backdrop in mind, the Court turned to the two key interpretive questions presented by provision of the MDA. First was the meaning of the phrase “any requirement” as it appeared in the relevant provision. The fundamental question was whether “any requirement” included only duly enacted state laws and regulations or also included state court judgments. The plurality of the Court in Lohr interpreted this phrase to include only state laws passed by the legislature. However, in a dissent joined by Justices Rehnquist, Scalia, and Thomas, Justice O’Connor argued that state requirements must also include state court judgments, which had the practical effect of imposing “requirements” on manufacturers. Breyer made a similar point in his concurrence.

The Lohr dissenters advanced a position the Court later adopted in the next express preemption case involving the MDA’s “any requirement” language: Riegel. Because state court judgments counted as “requirements,” the upshot of Riegel was to preempt any plaintiff’s state law claim that would require imposing liability on the manufacturer if it was “different from or in addition to any [federal] requirement . . . .” Relying heavily on the text, the 8-1 Majority of the Court held that Congress eliminated state law recourse for “consumers injured by FDA devices.” The statute was so unambiguous, according to the Court, that it did not require any deference to agency views on the matter. The Court found that even if some kind of deference were ordinarily warranted, it was undercut in Riegel because the FDA had shifted its positions on the meaning of the statute. The Court’s holding included even the preemption of successful state law-based lawsuits for defects in warning and design. In other words, lawsuits alleging

\[25\] Lohr, 518 U.S. at 485.
\[26\] Id. at 485–86. Notably, Ginsburg was the only dissenting justice in Riegel, and she began her analysis by emphasizing the purposive approach. Riegel, 552 U.S. at 334.
\[28\] Id. at 509.
\[29\] Id. at 505–06.
\[30\] Riegel, 552 U.S. at 324–25.
\[31\] 21 U.S.C. § 360k.
\[32\] Riegel, 552 U.S. at 326.
\[33\] Id. at 329–30. An exception to this rule exists when the state law claim parallels the federal requirement. Id. at 330. See Simon, supra note 9, at 1101–23 (discussing express and implied preemption).
a device was defectively designed or failed to adequately warn of risks not on the label would be preempted.

The second key interpretive question under the MDA focused on the comparator courts should use to evaluate whether state law conflicted with federal law. What did it mean to compare a state law to “any requirement applicable under this chapter” to determine when the state law was “different from or in addition to” it? In other words, what constituted a federal “requirement” that was “applicable” to the device? In Lohr, the plurality drew from the Court’s previous seminal preemption decision, a distinction between “general” and “specific” requirements.

Some federal requirements, the Lohr Court said, were “general” because they applied to devices broadly, such as misbranding and manufacturing requirements. Although these were literally device-specific “requirements” (i.e., labeling specific to a device), they were “general” in the sense that they “reflect[ed] important but entirely generic concerns about device regulation generally . . . .” Specific requirements, by contrast, meant requirements established by the FDA as to the particular device itself (i.e., requirements established under PMA). The distinction between the two categories was outcome-determinative: specific ones would be preempted while general ones would not be.

In Riegel, the Court—with the majority comprising eight Justices: Scalia, Stevens, Roberts, Kennedy, Souter, Thomas, Bryer, and Alito—solidified this distinction. The Court developed a framework to identify which category a device fell into based on the thoroughness of the FDA’s review of the device. Devices undergoing the FDA’s most searching review—PMA—are approved with specific requirements that address safety. Most devices, however, undergo a different and less rigorous review—510(k) clearance—that involves a determination only of “equivalence, not safety.”

Unlike the Lohr Court, however, the Riegel Court was far more concerned with the text of the statute than with its “purpose.” This focus on

35 Cipollone, 505 U.S. 504.
36 Lohr, 518 U.S. at 501.
37 Id.
38 Id. at 498–99.
39 Id. at 492–93.
40 Scalia, who authored the majority, did not mention either the presumption against preemption or the statute’s purpose. Riegel v. Medtronic, Inc., 552 U.S. 312, 315–30 (2008). Justice Ginsburg, the lone dissenter, began her dissent with a discussion of congressional purpose. Id. at 333–34. The only other justice to discuss history and purpose of the statute was Stevens, who concurred in the judgment. Id. at 331–33.
text over purpose is evident in the Riegel Court’s analysis and categorization of the PMA and 510(k) pathways. PMA approval, according to the Court, requires the FDA to grant an application that mandates certain requirements that apply only to that device and from which the manufacturer cannot deviate. 41 510(k) clearance, however, does not involve the establishment of requirements but rather functions “as a [statutory] qualification for an exemption rather than a requirement.”42 Importantly, “while the FDA does not ‘require’ that a device allowed to enter the market as a substantial equivalent ‘take any particular form for any particular reason,’ the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application . . . .”43 PMA requirements, then, unlike more relaxed 510(k) requirements, are “the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements.”44 In other words, the text of the statute, which exempts 510(k) devices from the strict PMA approval process, suggests that the process does not impose requirements—indeed, it is a way to avoid them.

The fact that express preemption applies to claims against manufacturers of PMA devices and not 510(k) devices does not mean, however, that PMA manufacturers are completely immune from suit. Nor does it mean that 510(k) manufacturers are completely exposed to liability under state law. For PMA manufacturers, plaintiffs can push through “parallel claims”: those that allege a violation of a specific federal requirement and an identical, or “parallel,” state law requirement. For example, an injured plaintiff may allege that the manufacturer failed to report adverse events or follow good manufacturing practices as required by federal law.45 If the plaintiff can show that either violation also subjected the manufacturer to liability in negligence or strict liability, then the state law claim would not be preempted because it was “parallel” to the federal requirements.

41 Riegel, 552 U.S. at 323.
42 Id. at 322.
43 Id. at 323 (quoting Lohr, 518 U.S. at 493).
44 Lohr, 518 U.S. at 501.
Parallel claims are not always enough to escape preemption. Another doctrine, implied preemption, bars claimants from seeking to enforce provisions of federal device law through private lawsuits. For example, an injured plaintiff could not sue based solely on the manufacturer’s misrepresentation to the FDA during the review process—so-called “fraud-on-the-FDA.” The doctrine requires the plaintiff’s claim to allege a violation of a state law that “predates the federal requirement.” In other words, whatever claim the plaintiff brings, it must be based on a state law or duty that predates and is independent of any federal requirements applicable to the device. Implied preemption works with or without express preemption, but the plaintiff does not need to allege a parallel claim to succeed when no express preemption applies.

C. Lessons from the Court’s Preemption Jurisprudence

There are two important lessons to draw from the Court’s preemption jurisprudence. First, the FDA’s method of review matters. The Court’s decision to apply express preemption to PMA devices and not 510(k) devices was based in part on the thoroughness of the FDA review. As described in Part II, PMA review is more thorough than 510(k) review in part because it expressly focuses on “safety, not equivalence.” PMA review is rigorous and typically includes the examination of clinical trial data about the safety of the device in question; not simply a comparison to a device that is legally marketed. The Courts emphasize this point by categorizing the two types of review into “general” and “specific” because one is based on “equivalence” and the other on “safety.” This distinction also demarcates why preemption is a defense in one context but not the other. For PMA devices, preemption prevents a jury from second guessing the FDA’s expert determination as to a device’s safety. For 510(k) devices, on the other hand, the FDA has not evaluated safety (at least not to the same extent as for PMA devices), and preemption need not operate to prevent a jury from second-guessing the FDA’s expert determination on a device’s safety.

Second, it appears that the composition of the Court mattered to the jurisprudential approach and, potentially, the case’s ultimate outcome. While the plurality in Lohr thought state court judgments did not impose

47 Simon, supra note 9, at 1104.
48 Riegel, 552 U.S. at 323.
49 Id. at 318.
50 Id. at 322–23.
51 There is some tension between these two observations—namely, the Court is becoming more functionalist by becoming more textualist.
“state requirements” that would trigger express preemption, the Riegel Court reached the opposite conclusion. Part of this change can be explained by changes to the Court’s membership. When Justice Stevens wrote for the plurality in Lohr, he was joined by Justices Kennedy, Ginsburg, and Souter. Dissenting in relevant part were Justices Rehnquist, O’Connor, Scalia, and Thomas, with Justice Breyer concurring with the dissent’s reasoning on this point. By the time the Court decided Riegel in 2008, Justices O’Connor and Rehnquist had been replaced by Justices Alito and Roberts, both of whom were decidedly more textualist.

The difference in the Court’s composition is relevant in other respects as well. First, Justice Scalia’s majority opinion in Riegel does not even mention what the Lohr Court considered to be the “touchstone” of the express preemption analysis: congressional purpose.\textsuperscript{52} Instead, the Riegel Court used as its lodestar the text and formal structure of the MDA. Second, Justice Scalia’s Riegel opinion fails to mention the “presumption against preemption” that was highlighted by the Lohr Court.\textsuperscript{53} By removing a potential thumb on the scale against preemption, the Riegel Court implicitly elevated the text of the statute above an interpretive canon that could threaten the Justices’ ability to interpret the text. The implied removal of this canon makes it more difficult for Justices to limit the scope of preemption on interpretive grounds. Finally, the Riegel Court cemented the textualist position—emphasizing and reasserting the primacy of its interpretive power—by downplaying an alternative source of interpretive meaning: the FDA. Specifically, the Court was unwilling to defer to the FDA’s interpretation of a regulation that purported to limit the reach of preemption,\textsuperscript{54} an approach generally at odds with how the Court deferred to agency interpretations through the 2000s.\textsuperscript{55}

While the Court’s composition may not fully explain the differences between Lohr and Riegel, it adds texture to the shift away from Lohr—a shift that may continue as a result of the conservative and textualist approaches of the Court’s recent additions: Justices Gorsuch, Kavanaugh, and Barrett. We explore how this shift may influence the Court’s ultimate analysis in Part III. The next Part, though, provides the foundation needed to engage in that analysis, explaining and comparing the pathways by which devices reach the market.

\textsuperscript{52} Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996).
\textsuperscript{53} Id.
\textsuperscript{54} Riegel, 552 U.S. at 328.
II. DE NOVO AUTHORIZATION AND INNOVATION

Each of these lessons—the emphasis on the FDA’s thoroughness of review and the Court’s shifting balance of power—provides clues as to how the Court might (and should) decide the preemption question for de novo devices. But that analysis requires a more in-depth understanding of all the available pathways to market and how they differ, both in substance and in form. Section A discusses the three traditional pathways to market: exempt, 510(k), and PMA. Section B then explains the mechanics of how a device reaches the market through these pathways. Finally, Section C describes the de novo pathway and how it functions.

A. Traditional Pathways to Market

Prior to Congress creating the de novo pathway in 1997, a device manufacturer had three principal pathways to market. Each pathway was designed to provide “reasonable assurance of safety and effectiveness” according to the risk of the product: (1) exempt devices, (2) 510(k) devices, and (3) PMA devices.

Exempt devices: low-risk devices (Class I and some Class II) for which “general controls,” such as labeling and misbranding requirements under federal law, do not generally require FDA review. Most devices, from tongue depressors to Band-Aids, reach the market via this pathway. The FDA relies on these “general controls” combined with (the threat of) enforcement actions to maintain reasonable assurance of safety and effectiveness.

510(k) clearance: moderate-risk (Class II) and some high-risk (Class III) devices that the manufacturer can demonstrate are substantially equivalent to a legally marketed device, or what is called a “predicate” device.

To demonstrate a substantial equivalence determination and pass through the 510(k) pathway, the applicant must demonstrate that the device and the predicate have either (1) (a) the same intended use and (b) the same technological characteristics; or (2) (a) the same intended use, (b) different technological characteristics that do not raise different questions of safety and effectiveness, and (c) are equally safe and effective based on information submitted by the applicant. Most devices raise questions of technological

56 Infra Section II.C.
58 21 U.S.C. §§ 360k(a)(1)(B), (i)(1)(A); 360(k); 21 C.F.R. §§ 807.21–.100.
59 21 C.F.R. § 807.100(b).
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differences. So the FDA suggests that applicants provide information about device design, materials used, energy sources, and other key technological information. Applicants typically provide this information using a table to show a side-by-side comparison.

For example, a manufacturer seeking to obtain clearance for a PCR COVID-19 nasal swab test may point to an existing legally marketed PCR test for COVID-19. A manufacturer upgrading the device with new features may point to its own previously cleared predicate. Manufacturers seeking clearance for devices with different technologies, such as knee replacement systems with different components or sizes, can provide information about why the device is still safe and effective despite those differences. Importantly, an applicant may rely on any “predicate device” that was legally marketed, even if the device is no longer available or has since been recalled for safety reasons.

If a manufacturer can show that its device is substantially equivalent to a predicate, the FDA will “clear” the device for marketing. 510(k) clearance stipulates conditions of marketing that typically include “special controls”: requirements related to performance standards, postmarket surveillance, patient registries, special labeling requirements, premarket data requirements, and guidelines.

Premarket Approval (PMA): high-risk devices (Class III)—those that support or sustain human life—are either of substantial importance in preventing impairment of human health or present a potential and unreasonable risk of illness or injury. Therefore, the manufacturer must

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63 See, e.g., U.S. FOOD & DRUG ADMIN., 510(K) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY, https://www.accessdata.fda.gov/cdrh_docs/pdf17/K170648.pdf [https://perma.cc/4MY4-CBK5].


demonstrate a reasonable assurance of safety and effectiveness using clinical data.\textsuperscript{66}

PMAs are appropriate when neither general nor special controls provide reasonable assurance of safety and effectiveness. As a result, the FDA typically requires manufacturers to provide clinical trial data.\textsuperscript{67} For example, a manufacturer seeking to market a Deep Brain Stimulation system—a device implanted in the brain to treat symptoms of Parkinson’s not otherwise controlled by medication—must provide detailed clinical trial data.\textsuperscript{68}

\textbf{B. Practical Differences Between Pathways to Market}

Under this pre-1997 regulatory regime, any new device was automatically classified as high-risk and subject to PMA unless it was exempt or a manufacturer could obtain a clearance under the 510(k) pathway. A key difference between PMA and 510(k) review is the kind and quantity of evidence required to satisfy the FDA. The “substantial equivalence” standard of 510(k) review does not typically require a manufacturer to submit clinical trial data to support the submission.\textsuperscript{69} Of course, 510(k) is not \textit{just} a paper submission—it requires design controls\textsuperscript{70} which typically include performance data (through nonclinical bench testing\textsuperscript{71}) to compare to the predicate device. PMA devices, on the other hand, do require clinical data.\textsuperscript{72} While human clinical trials are not universal, they are usually required in addition to laboratory testing.

Costs associated with each pathway to market influence manufacturer behavior. An exempt device, for example, is the cheapest and quickest regulatory approach to bring a product to market but is not available

\begin{itemize}
\item \textsuperscript{66} 21 U.S.C. § 360c(a)(1)(C); 21 C.F.R. § 814.
\item \textsuperscript{67} Even when trials are required, they may not always be double-blinded and randomized (as they are in the drug context).
\item \textsuperscript{68} U.S. Food & Drug Admin., Summary of Safety and Effective Data 14–58, https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140009B.pdf [https://perma.cc/JW4R-GBDM].
\item \textsuperscript{69} The FDA may require animal or human testing, but the manufacturer can also solicit whether such information is necessary in a pre-submission.
\item \textsuperscript{70} 21 C.F.R. § 820.30.
\item \textsuperscript{71} “Bench testing” refers to evaluating the performance and functionality of a device in a non-clinical setting. This can include running software and battery checks, but it may also include testing the device’s performance in human or animal tissue. U.S. Food & Drug Admin., Recommended Content and Format of Non-CLINICAL BENCH PERFORMANCE TESTING INFORMATION IN PREMARKET SUBMISSIONS (Dec. 20, 2019), https://www.fda.gov/media/113230/download [https://perma.cc/NP9D-K6PX].
\item \textsuperscript{72} 21 U.S.C. §§ 360c, 360e(c)(1)(A), (c)(2)(A)(v). The FDA published a template for submitting a summary of safety and effectiveness data. U.S. Food & Drug Admin., FDA Summary of Safety and Effectiveness Data Template (SSED), Office of Product Evaluation and Quality Template, https://www.fda.gov/media/113810/download [https://perma.cc/L4UD-B9Q9]. There are different methods for pursuing PMA. \textit{E.g.}, 21 C.F.R. § 814.19. (providing an approved PMA for class III devices for which a product development protocol has been completed).
\end{itemize}
to most manufacturers with moderate- to high-risk devices. For devices requiring additional review, the 510(k) pathway is cheaper and faster than the PMA route but still requires the manufacturer to show substantial equivalence to a predicate device. It is, therefore, considerably more expensive for the manufacturer to bring such a device to market than an exempt device. Perhaps unsurprisingly, then, over 99% of all non-exempt devices that reach the market are cleared through the 510(k) pathway.\footnote{COMM. ON THE PUB. HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS, MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 191 (2011), https://nap.nationalacademies.org/catalog/13150/medical-devices-and-the-publics-health-the-fda-510k-clearance [https://perma.cc/98E8-XATR].}

It is important to note that, despite manufacturers’ preferences, some products simply do not have the option of a 510(k) pathway. Until recently, a manufacturer of a nonexempt device without predicate had only one remaining option, which also would have been the most expensive and time-consuming: try to obtain a PMA.

\section*{C. \textit{De Novo} Pathway}

In 1997, Congress created the \textit{de novo} pathway\footnote{Food and Drug Administration Modernization Act, Pub. L. No. 105-115, 111 Stat. 2340 (1997) (codified as amended at 21 U.S.C. § 360c(f)).} to “avoid the needless [use of] . . . resources that would occur if lower risk devices were” forced through PMA review.\footnote{FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT (FDAMA), S. REP. NO. 105-43 (1997), https://www.congress.gov/congressional-report/105th-congress/senate-report/43/1 [https://perma.cc/EY7S-YXXV].} Without displacing these other pathways, \textit{de novo} authorization offered a new, lower-cost option for manufacturers of low-to-moderate-risk devices without a predicate device: bypass the automatic classification into Class III by requesting reclassification into Classes I or II.\footnote{Prior to 2014, an applicant first had to file a 510(k) application and receive a NSE determination before pursuing a \textit{de novo} application. See infra note 87.} We refer to devices authorized through the \textit{de novo} process as “\textit{de novo} devices.”
Table 1. Cost of Application, User Fees for 510(k), de novo, and PMA\textsuperscript{77}

<table>
<thead>
<tr>
<th>Pathway</th>
<th>Standard Fee</th>
<th>Small Business Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>510(k)</td>
<td>$21,128.00</td>
<td>$5,440.00</td>
</tr>
<tr>
<td>PMA</td>
<td>$483,560.00</td>
<td>$120,890.00</td>
</tr>
<tr>
<td>De Novo</td>
<td>$145,068.00</td>
<td>$36,267.00</td>
</tr>
<tr>
<td>Total</td>
<td>$649,756.00</td>
<td>$162,597.00</td>
</tr>
</tbody>
</table>

To satisfy de novo review, the manufacturer must provide “detailed information” demonstrating that the requested level of FDA regulation provides a “reasonable assurance” of the device’s safety and effectiveness.\textsuperscript{78} Among other things, the FDA requires\textsuperscript{79} the manufacturer of a device to submit information that includes: how and why the device is not amenable to other pathways to market;\textsuperscript{80} existing alternative practices and procedures to the device aimed at the same disease or condition or that affect the body in the same way;\textsuperscript{81} the device’s risks and mitigation measures;\textsuperscript{82} and how the health benefits of the device exceed the potential risk of injury from using it.\textsuperscript{83}

The content of the de novo application is therefore more extensive than the substantial equivalence typically required for a 510(k) application but less extensive than the clinical trials typically required for PMA applications.

While manufacturers cannot obtain de novo authorization only by demonstrating substantial equivalence to a predicate device, they are free to reference marketed devices to provide evidence of the required elements of the application. The manufacturer must still provide some data, though the precise amount and types of data will differ from the data required for a 510(k) clearance.\textsuperscript{84} So while both 510(k) and de novo devices will often

\begin{itemize}
  \item \textsuperscript{77} U.S. FOOD & DRUG ADMIN., MEDICAL DEVICE USER FEES FOR FISCAL YEAR 2024 (July 28, 2023), https://www.federalregister.gov/documents/2023/07/28/2023-15919/medical-device-user-fees-for-fiscal-year-2024 [https://perma.cc/M8V8-QCK3].
  \item \textsuperscript{78} E.g., 21 C.F.R. §§ 860.220(a)(10)–(11), (19), 860.260(c)(7)–(8), (10). Note that § 860.260(c)(8), which concerns nonclinical study subjects, speaks only of “reasonable assurance of safety.”
  \item \textsuperscript{79} Medical Device De Novo Classification Process, 86 Fed. Reg. 54826 (Oct. 5, 2021) (codified at 21 C.F.R. § 860.220(d)).
  \item \textsuperscript{80} 21 C.F.R. § 860.220(a)(8)(I)(C).
  \item \textsuperscript{81} 21 C.F.R. § 860.220(a)(7).
  \item \textsuperscript{82} 21 C.F.R. § 860.220(a)(9).
  \item \textsuperscript{83} 21 C.F.R. § 860.220(a)(14).
\end{itemize}
require regulatory restrictions beyond what the federal law provides, the content of the special controls for each will be different.

While the de novo pathway was meant to reduce unnecessary expenditures on PMA for “lower risk” devices that did not have a predicate,\textsuperscript{85} it has become a pathway to authorize novel technologies that do not fit well within the preexisting pathways. For example, the first 113 devices authorized through the de novo pathway also had corresponding 510(k) clearances.\textsuperscript{86} Since Congress enabled applicants to request de novo authorization absent a not substantially equivalent order (NSE), almost no manufacturer has first attempted to obtain a 510(k) clearance before obtaining de novo authorization.\textsuperscript{87} In other words, manufacturers have almost universally filed a de novo application prior to attempting to obtain a decision that their proposed 510(k) device was not substantially equivalent to a predicate.

Because de novo authorization offers a lower regulatory burden and the relatively quick time to market entry (and thus into patient care) compared to PMA, device manufacturers may favor de novo review over the more rigorous PMA if given a choice. And this preference may result in “authorization creep”—where the pathway designed for low- to moderate-risk devices gradually becomes the default pathway for higher-risk devices.

Consider IDx-DR,\textsuperscript{88} a software-based device used with a special camera to “automatically detect more than mild diabetic retinopathy . . . in adults diagnosed with diabetes who have not been previously diagnosed with diabetic retinopathy.”\textsuperscript{89} Other examples include: The Cooral System, which preventatively treats oral inflammation from chemotherapy and radiation;\textsuperscript{90}

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\textsuperscript{86} A corresponding 510(k) clearance means only that the applicant originally submitted a 510(k) application, resulting in the FDA issuing a NSE determination. The dropoff in these numbers results from the changes made by Congress in 2012 to allow for de novo authorization. See infra note 87.


\textsuperscript{89} U.S. FOOD & DRUG ADMIN., DEVICE CLASSIFICATION UNDER SECTION 513(f)(2)(DE NOVO), https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180001.pdf [https://perma.cc/9SRT-JA8F].

\textsuperscript{90} COOLPREVENT, https://www.coolprevent.com/ [https://perma.cc/T2QU-BY3M] (“The Cooral® System reduces the risk of mouth sores (oral mucositis) when being treated for cancer using chemotherapy.”).
Vibrant, a “drug-free, state-of-the-art treatment for adults with chronic idiopathic constipation”;\(^91\) BrainTemp Neonate System, a noninvasive device that measures brain temperature in neonates;\(^92\) Sunrise, a small device affixed below the lower lip that diagnoses sleep apnea at home;\(^93\) and Given Pillcam, a capsule that contains a camera to visualize the small intestine.\(^94\) These are perhaps emblematic of a trend of de novo “devices that are pushing towards the higher end of the Class II risk spectrum.”\(^95\)

While these particular examples are illustrative, it is also useful to consider the entire population of de novo authorizations in relation to the other forms of authorization by the FDA. Although the vast majority of devices are cleared through the 510(k) pathway, the number of de novo device authorizations has demonstrated a steady upward trajectory.\(^96\) The pace of authorizations picked up in 2011–12, reaching a peak in 2018 (44) before falling off in 2019 (23) just before and continuing after the initiation of the COVID-19 pandemic: 2020 (26), 2021 (30), and 2022 (20). The spikes in 2012 and 2018 may have been a result of the Congressional action to streamline the de novo process\(^97\) and liberalize de novo requests,\(^98\) respectively, along with the FDA’s subsequent updated guidance (2017) on the same.\(^99\)

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\(^{93}\) U.S. Food & Drug Admin., De Novo Classification Request for Sunrise Sleep Disorders Diagnostic Aid, https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN210015.pdf \([https://perma.cc/JDJ6-LCXS]\).


\(^{96}\) The data presented here were downloaded in .xls files directly from the FDA’s website.

\(^{97}\) Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), Pub. L. 112–144 § 607 (2012) (codified at 21 U.S.C. § 360c(f)(2)) (eliminating the requirement that de novo applicant must first submit a 510(k) and receive from the FDA a NSE determination).


Meanwhile, the PMA pathway seems to have fallen in popularity, with its use trending downward. As use of the PMA pathway has fallen and the use of the de novo pathway has grown, de novo devices now occupy a greater share of total devices approved under either the PMA-approved devices or de novo devices (Figure 1).

While these data points are simple descriptive statistics, they show that more devices are now moving through the de novo pathway. Increasing use of the de novo pathway, then, at minimum increases the probability that patients may encounter—and potentially be injured by—de novo devices.

III. APPLYING JURISPRUDENTIAL LESSONS TO EXPRESS PREEMPTION OF DE NOVO DEVICES

Because of its lower costs, faster review time, and resulting quicker use in patient care, manufacturers have used the de novo pathway more frequently in the past ten years than ever before. As new technologies like AI/ML continue to develop, the de novo pathway is likely to emerge as a focal point in device litigation. Devices may autonomously determine when a patient’s pain level merits additional medication and simultaneously dispense the dose it computes to reduce the pain to acceptable levels. A malfunctioning device may then under or overdose a patient, potentially causing serious injury. Likewise, an AI device may misdiagnose cancer or fail to diagnose it altogether, possibly leading to unnecessary surgery, chemotherapy, or radiation or even premature death. If these devices receive
de novo grants from the FDA, express preemption could bar the claims of potential plaintiffs in these cases. This Part addresses two issues about whether federal law will preempt these claims. First, how is the Court likely to analyze and resolve these claims? Second, how should the Court do so?

A. The Supreme Court’s Preemption Framework

Recall the two lessons from the Court’s express preemption jurisprudence: method of review and composition of the Court are important to the outcome of any preemption determination. Method matters because the thoroughness of FDA review can influence whether the requirements it imposes are “specific” or “general.” Composition matters because who decides the case influences the jurisprudential approach taken by the Court. We address both lessons in tandem, assessing the potential application of the principles of Lohr and Riegel with the understanding that the Court has become considerably more textualist since those decisions.

Because of this jurisprudential shift, the Court’s interpretation of the express preemption provision of the MDA is now more likely to begin and end with the text. Just as in Lohr and Riegel, the central question remains whether FDA regulations are federal “requirement[s] applicable . . . to this device.” In other words, the Court will need to determine, just as in Lohr and Riegel, what constitutes a federal “requirement.” To answer this question under the current framework, the Justices must first ask themselves whether the FDA “requirements” (i.e., regulations) relating to a de novo device are “general” or “specific.”

Here the text provides limited answers. On the one hand, a de novo request is also a request to classify a device that would otherwise be classified as Class III and therefore shunted into the PMA process. The text of both federal law and regulations makes the de novo classification request similar to the 510(k) request to reclassify a device: both are exceptions to the otherwise automatic classification into Class III. The difference is that the de novo pathway is available specifically when the 510(k) pathway is not—that is, for devices without a predicate. The de novo pathway, in other words, is designed to facilitate “classification into

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100 See supra Section I.B.
101 See supra Section I.C.
102 And, given that the Court overruled Chevron, it almost certainly will not continue to defer to the FDA’s interpretation of the statute. Loper Bright Enters. v. Raimondo, 144 S. Ct. 2244 (2024).
[C]lass I or [C]lass II” where the 510(k) process is unavailable. This design suggests that the de novo pathway is a replacement for the 510(k) process and therefore also an exception to the specific requirements of PMA in the same way the 510(k) pathway is an exception to those same specific requirements.

A counterargument, though one not based on the text, is that the de novo process is now a distinct requirement for a particular kind of device. Historically, the argument goes, the de novo pathway was treated as an alternative to the 510(k) pathway once the FDA determined the device had no predicate. But today, a manufacturer can use the de novo pathway without seeking a NSE determination. This suggests that this pathway is not an exception in the same way the Court described the 510(k) pathway. The problem with this argument, however, lies with the text. As explained above, the MDA describes the de novo pathway in the same way it describes the 510(k) pathway—as a request for reclassification.

Another, perhaps stronger, argument that finds some support in the text is that the distinguishing feature between the 510(k) and PMA pathways—evaluation for safety—fails to distinguish PMA from de novo review. Under the statute, 510(k) devices must demonstrate that they are “substantially equivalent” to a predicate device. But de novo review requires the manufacturer to include in its request special controls “that are necessary, in conjunction with general controls, to provide reasonable assurance of safety and effectiveness and a description of how the special controls provide such assurance.”

For the textualist, this language may seem dispositive. Indeed, one commentator, attorney James Beck, has argued that proposed rule changes to the de novo process—significant portions of which the FDA adopted in 2021—should (supplement this reading and) be interpreted to bar preemption of de novo devices. For example, the rules require de novo applicants to provide “an initial draft proposal for applicable special controls and a description of how those special controls provide reasonable assurance of safety and effectiveness.” Beck argues that preemption follows from the proposed rules’ “emphasis on determinations of device ‘safety and effectiveness’ throughout, as well as its reliance on ‘special controls’

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106 21 C.F.R. § 860.200(a).
customized to each de novo request . . . ”\textsuperscript{111} In his view, these new proposed rules—and presumably the ones adopted verbatim or in similar form—are meant to expressly provide reasonable assurance of safety and effectiveness of devices, precisely the thing that is required of PMA devices. In other words, they are “specific requirements” that should trigger express preemptive effect. He therefore interprets this proposed rule as an unqualified distinction from the 510(k) process, especially since there is no “fig leaf” of substantial equivalence.\textsuperscript{112}

But we disagree. Even a textualist Court does not interpret words in a vacuum or without definitions.\textsuperscript{113} And if the meaning of substantial equivalence is given any credence, the difference in statutory language is not substantive. Why? “Substantial equivalence” typically also requires 510(k) devices to be subject to special controls, the point of which are to “provide reasonable assurance of safety and effectiveness” for a Class II device.\textsuperscript{114} But the fact that special controls, just like general controls, are designed to “provide reasonable assurance of safety and effectiveness” says nothing about whether they are “specific” federal requirements of the sort that trigger preemption—indeed, the Court’s jurisprudence seems to suggest the opposite.

The supposed textual difference, then, is overstated for two reasons. First, the special controls that are supposed to help provide reasonable assurance of safety and efficacy can be required for either 510(k) or de novo devices if the device is in Class II or neither if the device is in Class I (where general controls are sufficient). Second, the definition of the phrase “substantial equivalence” also includes the requirement that the applicable requirements—whether general or special controls or PMA—provide reasonable assurance of safety and effectiveness.\textsuperscript{115} That requirement is just part of the device classification process. Emphasizing that de novo applications may require “specific” special controls misses the point that special controls are not “device-specific requirements.”\textsuperscript{116}

Perhaps the best way around this textualist argument is by relying on Riegel’s emphasis on the output of each regulatory pathway. The FDA requires PMA devices to enter the market with “almost no deviations from”

\begin{footnotesize}
\begin{itemize}
\item[\textsuperscript{112}] Id.
\item[\textsuperscript{113}] Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996); Loper Bright Enters. v. Raimondo, 144 S. Ct. 2244, 2261 n.4 (2024).
\item[\textsuperscript{114}] 21 C.F.R. § 860.3.
\item[\textsuperscript{115}] 21 U.S.C. § 360c(a).
\item[\textsuperscript{116}] Riegel v. Medtronic, Inc., 552 U.S. 312, 322 (2008).
\end{itemize}
\end{footnotesize}
the approved application while 510(k) clearance comes with some other flexibilities.\textsuperscript{117} It is not clear exactly what the Court meant by this—and it seems a flimsy reed on which to rest injured patients’ potential redress. Special controls may include specific requirements for 510(k) and de novo devices; that does not turn them into the kind of requirements present in the PMA.

In short, we think that, as a predictive matter, the Court’s preemption jurisprudence will likely result in an approach that does not apply express preemption to de novo devices—even with its decidedly textualist orientation. We also think that this is the right result as a normative matter, which we explain in the next two Sections.

B. A More Balanced Application of the Supreme Court’s Framework

While de novo regulations provide some textual support for preemption, the textualist argument may also be undercut by Congressional inaction. If Congress wanted the preemption provision of the MDA to apply to de novo devices, it could have explicitly done so in 1997 when it created the pathway just one year after the Court decided \textit{Lohr}.\textsuperscript{118} In the drug context, the Court has stated that such contemporaneous silence “is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.”\textsuperscript{119}

While one might interpret this silence as evidence that Congress was not interested in preempting claims against de novo manufacturers, the textualist Court may have a different view.\textsuperscript{120} This difference in interpretation is exactly why we think that such debates, along with the argument described above, focus too much on technical language and not enough on the nature of the review process nor the potential consequences of allowing preemption to extend to de novo devices. A better focus is to assess the case for preemption in the context of the thoroughness principle, the practical

\textsuperscript{117} Id. at 323.

\textsuperscript{118} This has been called the Acquiescence Rule. William N. Eskridge, \textit{Interpreting Legislative Inaction}, 87 MICH. L. REV. 67, 69 (1988).


\textsuperscript{120} See, e.g., Michigan v. Bay Mills Indian Cnty., 572 U.S. 782, 826 (2014) (Thomas, J. dissenting) (citation omitted) (“As a practical matter, it is ‘impossible to assert with any degree of assurance that congressional failure to act represents’ [sic] affirmative congressional approval of” one of this Court’s decisions.”); Gamble v. United States, 587 U.S. 678, 723 (2019) (Thomas, J. dissenting) (citation omitted) (“Moreover, to the extent the Court has justified statutory \textit{stare decisis} based on legislative inaction, this view is based on the ‘patently false premise that the correctness of statutory construction is to be measured by what the current Congress desires, rather than by what the law as enacted meant.’”); \textit{see also} Halliburton Co. v. Erica P. John Fund, Inc., 573 U.S. 258, 299 (2014) (Thomas, J., concurring, joined by Scalia and Alito, JJ.) (“At any rate, arguments from legislative inaction are speculative at best.”).
realities of device litigation, and the desired balance between access and safety.

At first blush, however, applying the thoroughness principle seems likely to result in legal arguments that cut either way. On the one hand, de novo devices seem to involve more rigorous review than 510(k) devices in addition to costing more to submit and often requiring data that 510(k) devices do not.\(^{121}\) On the other hand, they require less rigorous review than PMA, and were originally designed for low-risk, rather than high-risk, devices.\(^{122}\) Otherwise put, the central question a court ought to ask, given the existing jurisprudence, is this: are de novo authorized devices more like PMA-authorized devices (state tort law claims largely preempted) or 510(k)-authorized devices (subject to most state tort law claims)?

De novo and 510(k) reviews are more alike than de novo and PMA reviews. Both 510(k) and de novo devices require special controls—a marked difference from PMA devices, where general and special controls are not sufficient to provide a reasonable assurance of safety and effectiveness. While it is true that the Supreme Court has not ruled out special controls as constituting federal “requirements” under the MDA, it has generally been skeptical of them.\(^{123}\) Additionally, devices approved through the de novo pathway, unlike PMA devices, do not generally require clinical trials in humans. Thus, although FDA review may be more thorough for de novo devices than 510(k) devices, it is still significantly less than that for PMA devices. For these reasons, the thoroughness principle suggests that preemption should not apply to claims against manufacturers of de novo devices.

\[\text{C. Policy Reasons Not to Apply Preemption to De Novo Devices}\]

Beyond the question of legal similarities, there are four compelling policy reasons that counsel against extending preemption to cover de novo devices, some of which the Court has addressed and others it has not. Even if these prove unconvincing to the Court, they provide support for why Congress may consider adding a new express preemption clause to the MDA that excludes de novo devices from its reach.

First, allowing state law claims against manufacturers of de novo devices forces them to internalize risks that physicians and patients will otherwise have to bear. This is important because, without risk

\(^{121}\) See supra Section III.A.

\(^{122}\) Indeed, this argument presumes that recent changes to federal law make the 510(k) pathway itself fair game for preemption.

internalization, recent research suggests that physicians may change their behavior to avoid the risk by simply not using the device—potentially undermining the innovative use of the pathway. Limited evidence for this practice comes from a recent study, which found that the Supreme Court’s preemption decision in Riegel to provide greater immunity from state claims for PMA devices than 510(k) devices may affect some firms’ and physicians’ behavior by making it more likely that certain manufacturers would use the PMA pathway than the 510(k) pathway. Why? Manufacturers that use the PMA have greater protection from the preemption shield than manufacturers of 510(k) devices. Because the manufacturer has greater protection from liability, the physician (or provider) using the device is more likely to become the primary defendant, potentially increasing damage awards against physicians. In response, physicians may attempt to shift some of this liability back to manufacturers by using 510(k) devices, which enjoy a less robust preemption shield than PMA devices.

At the same time, however, Riegel’s net effect on patients is less certain because physicians are less likely to use devices that have undergone the most thorough review. Not applying preemption would therefore ensure that manufacturers internalized the risk associated with their devices rather than off-loading this risk to physicians, patients, and the healthcare system writ large. This approach would preserve the use of the de novo pathway while incentivizing manufacturers to design, manufacture, and market devices in ways that are safer than if they were not otherwise exposed to liability for these activities. Manufacturers, of course, may have a slightly decreased incentive to pursue de novo devices because of the increased liability risk. And this may increase the ultimate costs of the device if it moves through the PMA pathway instead. Ultimately, however, that is a financial decision a firm will be in a better position to make than regulators—and it is one that channels the highest-risk devices into the pathway with the most thorough review.

Second, not preempting state law claims provides an important regulatory backstop for risks identified after marketing authorization. This is particularly important because devices that undergo any kind of review may still have concerning safety profiles. Two examples help illustrate this point. First, a manufacturer issued a Class I recall (where use of the device could

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124 Elissa P. Gentry & Benjamin J. McMichael, Responses to Liability Immunization: Evidence from Medical Devices, 17 J. EMPIRICAL LEGAL STUD. 789, 807–09 (2020). The study is limited in a number of important ways. For example, the authors measured physician behavior only with respect to patients who suffered heart attacks and strokes. Id. at 803. The authors also studied a wider range of devices than those at play in the patient population studied.

125 Id. at 812.
result in serious problems or death) in 2023 for certain models of its bronchofiberscopes and bronchovideoscopes—devices that allow physicians to see inside the upper and lower airways—because they “may lead to fires and burns.”\(^{126}\) Second, a manufacturer of “infusion pumps” that deliver liquid to patients issued a Class I recall because the devices may fail to detect “air in the line,” which “can lead to blockage in a blood vessel (embolism), causing complications such as unstable blood pressure, stroke, heart attack, or even death.”\(^{127}\)

Although the data here is not definitive, it does reveal that there should be concern about safety events for novel devices that the FDA may not be able to anticipate ex ante, suggesting an important role for claims that identify risks ex post.\(^{128}\)

Intuition suggests devices that have less rigorous review are more likely to have a greater number of safety-related events. A recent study, though, has shown that even PMA devices can have worrying safety issues—indeed, PMA devices had a higher rate of serious recalls (5.2%) during the study window than 510(k) devices (0.08%).\(^{129}\) Expanding to look at Class I and Class II recalls—the latter of which means that use of the device may cause temporary or reversible harm—the rate of recall for PMA devices is still worse (27.1%) than 510(k) devices (10.7%).\(^{130}\)

If devices approved through the most rigorous pathway turn out to be riskier than devices approved through less rigorous evidence, it seems to create something of a paradox: more rigorous review results in worse outcomes than less rigorous review. One might think this insight counsels in favor of preemption for de novo devices since they undergo less strict review than PMA devices.

But several factors cut against this conclusion. First, some of these findings might be category specific. For example, a recent study found lower rates of recalls for moderate- and high-risk otolaryngologic devices that went


\(^{128}\) Simon, supra note 9, at 1134.


\(^{130}\) Id. One other study found a similar aggregate rate (11.4%) of recalls for 510(k) devices. Alexander O. Everhart et al., Association Between Regulatory Submission Characteristics and Recalls of Medical Devices Receiving 510(k) Clearance, 329 JAMA 144, 147 (2023).
through the PMA pathway (3.2%) as compared to those that went through 510(k) (11.4%). Notably, though, the study did include four Class I recalls applicable only to the 510(k) devices, which the other studies excluded. A similar study replicated in surgery, where the risk of recall for a 510(k) device (11.6%) far exceeded the recall risk for a PMA device (2.3%).

Second and relatedly, PMA devices are generally higher-risk devices to begin with and thus the risks they present may be inherently more significant than those posed by 510(k) and de novo devices. A higher proportion of risky devices could explain why PMA devices may have higher serious recall rates than 510(k) devices, which span a much wider risk spectrum.

Third, that PMA devices may not be as safe as 510(k) devices seems like a reason to increase, rather than reduce, ex post enforcement measures such as tort liability. This is especially important given de novo devices’ limited track record and increasing tendency to incorporate cutting edge technology like AI/ML.

Finally, applying preemption to bar a wide swath of claims for new technology would ignore the historical, though carefully circumscribed, role of tort law in providing redress for injured patients and policing new risks as they arise. Private lawsuits by injured patients “uncover unknown . . . hazards[,] provide incentives for . . . manufacturers to disclose safety risks promptly[,]” and perform a “distinct compensatory function that may motivate injunred persons to come forward with [new safety] information.” Providing preemption protection would not only eliminate such incentives, it would “[grant] complete immunity from . . . liability to an entire industry that, in the judgment of Congress, needed more stringent regulation in order ‘to provide for the safety and effectiveness of medical devices intended for human use.’”

In cases of new technology with uncertain safety effects, particularly with higher-risk devices, it is reasonable to take a cautious approach. As noted above, the Supreme Court has endorsed tort law as a legitimate mechanism for policing product safety ex post. There is no reason to think tort law will not do an adequate job of this in the de novo device context—

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134 Id. (discussing drug context preemption).
indeed, high profile lawsuits against drug and device companies are already regular fixtures of products liability litigation, suggesting that tort law can play an important role in policing these risks.

In the meantime, the FDA can collect data on its de novo process and the safety of the technology it reviews. The FDA may try to reduce uncertainty in the interim by issuing regulations or publishing guidance documents. If it does, the best approach is to allow the legal system to evaluate claims for injuries caused by de novo devices. Allowing tort claims to proceed is a reasonable way to keep device manufacturers honest, police safety concerns, and compensate those harmed by unsafe devices.

CONCLUSION

Innovative medical devices are vital to improving human health but can pose serious risks to patients who use them. In this Essay, we attempted to explain why balancing innovation with safety entails allowing injured patients to sue manufacturers of innovative devices—devices that are neither substantially equivalent to legally marketed devices nor of sufficient risk to merit the most rigorous form of regulatory review. We made this argument from two different perspectives. The first was predictive. Drawing on the Supreme Court’s preemption jurisprudence and changing composition, we suggested that its current members would likely support a textualist approach that disfavored preemption, though that result was not mortally certain. The second was normative. We argued that, as a matter of policy, the Court should find that claims against manufacturers of certain innovative devices are important to force manufacturers to internalize risk and to police a market with new and innovative products that, by definition, work differently from their predecessors.