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BREAKTHROUGH OR BREAKAWAY INNOVATION?

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This article argues that expedited regulatory review programs for innovative products, like the Food and Drug Administration's (FDA) Breakthrough Devices Program (BDP), should not be paired with immunity from tort liability for those products and their developers. Doing so both limits the ability of regulators to manage the risks of new products while simultaneously undermining incentives for their developers to adopt internal systems that address those risks. In non-emergency contexts, expedited review and liability immunity together could elevate innovation as a policy goal in the short-term above the more fundamental principles of safety and effectiveness for those new products over time and across populations. At minimum, if these two policies are deployed at once, they should only occur in the context of heightened regulatory supervision over those products both during and after review, backed up by a strong legal mandate for the regulator and adequate resources to conduct supervision.

To make this argument, the article provides an in-depth analysis of the FDA's Breakthrough Devices Program, an initiative from the 21st Century Cures Act for promoting innovation in medical devices by reducing scrutiny of their safety and effectiveness. The analysis applies doctrinal and empirical approaches to explore the Program's legal foundations, current operations, and implications of liability preemption for patients and device manufacturers. Some patients have already been harmed by breakthrough devices and, while the Cures Act leaves some legal uncertainty, doctrinal analysis shows those patients appear likely to have limited

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remedies in tort law against some of these devices due to federal liability preemption. The article argues for loosening the current federal preemption of state-level tort liability for medical devices that were approved through the BDP, paired with greater regulatory supervision by the FDA both during and after the Program. While innovation remains an important policy goal, it should never surpass safety as a core regulatory imperative for novel products.

I. INTRODUCTION

Whether implanted in the body, used in surgeries, or guiding decisions with software like artificial intelligence (AI), medical devices increasingly incorporate new technologies in efforts to deliver safer, more effective, and more useful clinical interventions. Medical devices—new or old—can also cause significant risks and harms, leading to potential morbidity and mortality.[1] This sets up a fundamental

[1] *E.g.*, Mitch Weiss & Holbrook Mohr, Associated Press, *Medical Devices for Pain, Other*

tension in the law and policy regulating medical products, including devices, between seeking to promote innovation and patient access to innovative devices versus seeking to ensure safety, effectiveness, and robust regulatory supervision for devices with less understood technological bases.[2]

In the latest move to balance these tradeoffs, the U.S. Congress in 2016 codified a new initiative at the Food and Drug Administration (FDA) through the 21st Century Cures Act: the Breakthrough Devices Program (BDP, or, the Program).[3] The Program provides regulatory flexibility to medical device developers with innovative and promising products, doing so by relaxing or modifying the FDA's typical processes for evaluating safety and effectiveness of devices.[4] The cutting-edge products using the BDP might include AI, neurotechnology, and genomic diagnostic tests.[5]

While innovative, these types of products also bring significant uncertainty about their potential risks and benefits or may raise entirely novel problems, both in general and for particular classes of patients.[6] In this setting, a striking number of devices and firms are participating in or have completed the Program. By August 2025, almost 1,200 medical products had received a Breakthrough Device Designation from the FDA, with at least 160 devices now authorized and available to patients, showing a significant level of uptake over the Program's seven year life.[7] By comparison, the agency authorized 120 novel devices in all of 2024, where

Conditions Have Caused More Than 80,000 Deaths Since 2008, STAT NEWS (Nov. 25, 2018), https://www.statnews.com/2018/11/25/medical-devices-pain-other-conditions-more-than-80000-deaths-since-2008/ [https://perma.cc/73YX-3G9W] (reporting on medical devices that have caused significant harm); Jeanne Lenzer & ICIJ Reporters, *Medical Device Industry: International Investigation Exposes Lax Regulation*, 363 BMJ, art. no. k4997 (2018).

[2] *See infra* Part VI.

[3] Pub. L. 114–255, 130 Stat. 1033, § 3051 (2016) (codified as 21 U.S.C. § 360e–3 (2024)) (While the FDA had launched a very similar initiative through administrative guidance in 2015, the Cures Act codifies and slightly modifies that precursor program.); *see infra* Part III.A.

[4] U.S. FOOD & DRUG ADMIN., BREAKTHROUGH DEVICES PROGRAM: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2023), https://www.fda.gov/media/162413/download [https://perma.cc/MYF8-4PK7] [hereinafter BDP Guidance]; *see* James L. Johnston, Sanket S. Dhruva, Joseph S. Ross & Vinay K. Rathi, *Early Experience with the FDA's Breakthrough Devices Program,* 38 NATURE BIOTECHNOLOGY 933, 933-37 (2020) (detailing early evidence on the operation of the BDP).

[5] *Infra* Part IV.

[6] *E.g.*, Jianxing He et al., *The Practical Implementation of Artificial Intelligence Technologies in Medicine*, 25 NAT. MED. 30 (2019) (describing some challenges of using AI in health care); Saskia Hendriks et al., *Ethical Challenges of Risk, Informed Consent, and Posttrial Responsibilities in Human Research with Neural Devices: A Review*, 76 JAMA NEUROL. 1506 (2019) (discussing the ethical challenges of neurotechnology-based device research).

[7] *Breakthrough Devices Program*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program [https://perma.cc/EZ7N-SJK8] [hereinafter BDP Website] (last visited Sept. 23, 2025); *see also infra* Part IV.

42 were breakthrough devices.[8] While expedited review programs for the regulation of drugs have attracted notable analysis and criticism,[9] accelerated review for medical devices in the U.S. has not yet received the same degree of attention.

As a notable example, Elon Musk made headlines and received applause during a 2020 live event by announcing the FDA had admitted his company Neuralink's first brain-computer interface (BCI) device into the BDP.[10] This class of cutting-edge device, under development by several firms, would be implanted in the brain of a patient with paralysis to enable them to operate an external device such as a computer by only using their brain activity.[11] While these devices have the potential to restore autonomy to patients, they pose numerous challenges around long-term safety and effectiveness, as well as other challenges such as privacy concerns and ethical issues.[12] Moreover, while Neuralink plans to offer brain-computer interfaces at first to patients with paralysis, Musk and others hope to scale these devices up, such that they can be used for many other categories of patients and potentially people with no therapeutic use for them—which, under the off-label doctrine, would not require further FDA approval.[13] These and other types of innovative devices have already entered and appear to have benefited from the BDP,

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[8] U.S. FOOD & DRUG ADMIN., CTR. FOR DEVICES & RADIOLOGICAL HEALTH, ANN. REP. 2024, 3-4 (2024), https://www.fda.gov/media/185234/download?attachment [https://perma.cc/PHA5-YRZA]. This count of "novel" devices excludes many (but not all) devices authorized by the FDA through the 510(k) and Emergency Use Authorization mechanisms. *See* Jeff Shuren & William Maisel, *Reflections on a Record Year for Novel Device Innovation Despite COVID-19 Challenges*, U.S. FOOD & DRUG ADMIN. (Feb. 16, 2021), https://www.fda.gov/news-events/fda-voices/reflections-record-year-novel-device-innovation-despite-covid-19-challenges [https://web.archive.org/web/20210216170816/] (reviewing novel medical devices and breakthrough devices authorized in 2020).

[9] *Infra* pp. 209-10.

[10] Rebecca Robbins & Erin Brodwin, *Elon Musk's Neuralink Unveils Prototype of Brain Implants — And Looks Toward Clinical Trials*, STAT NEWS (Aug. 28, 2020), https://www.statnews.com/2020/08/28/elon-musks-neuralink-unveils-prototype-of-brain-implants-and-looks-toward-clinical-trials/ [https://perma.cc/6QUD-BYDH].

[11] *E.g.*, Liam Drew, *The Brain-Reading Devices Helping Paralysed People to Move, Talk and Touch*, NATURE (Apr. 20, 2022), https://www.nature.com/articles/d41586-022-01047-w [https://perma.cc/LR66-6ATZ] (covering the development and expansion of brain-computer interfaces); Ujwal Chaudhary, Niels Birbaumer & Ander Ramos-Murguialday, *Brain-Computer Interfaces for Communication and Rehabilitation*, 12 NAT. REV. NEUROL. 513 (2016) (describing the use of brain-computer interfaces for patients with forms of paralysis or who are in motor rehabilitation).

[12] Laura Victoria García & David E. Winickoff, *Brain-Computer Interfaces and the Governance System: Upstream Approaches* 16-18 (OECD Science, Technology and Industry, Working Paper 2022/01, 2022).

[13] Sarah Marsh, *Neurotechnology, Elon Musk and the Goal of Human Enhancement*, GUARDIAN (Jan. 1, 2018), https://www.theguardian.com/technology/2018/jan/01/elon-musk-neurotechnology-human-enhancement-brain-computer-interfaces [https://perma.cc/H8DV-8VG9]. *See generally* Henry T. Greely et al., *Towards Responsible Use of Cognitive-Enhancing Drugs by the Healthy*, 456 NATURE 702, 703 (2008) (showing how drugs can be used "off label" for non-therapeutic purposes such as cognitive enhancement).

with some advancing to clinical trials or receiving market authorization.[14]

This article argues that expedited regulatory review programs for innovative products, like the Breakthrough Devices Program, should not be paired with immunity from tort liability for those products and their developers. Doing so limits the ability of regulators to manage the risks of new products while simultaneously undermining incentives for their developers to adopt internal systems that address those risks. This arrangement elevates innovation as a policy goal in the short-term above the more fundamental principles of safety and effectiveness of those new products over time and across populations. Such a dynamic is particularly alarming when innovative products incorporate emerging technologies, such as AI or brain-computer interfaces, where their risks are clouded by uncertainty. The risks and benefits of innovative technologies often only become clearer once they gain widespread adoption, but that adoption consequentially makes legal and policy reform more costly—a concept referred to as the "Collingridge dilemma."[15] Given this uncertainty and the difficulty of later regulatory intervention, an expedited review undercuts regulators in anticipating risks while liability immunity prevents injured patients from recovering once those risks manifest.[16] Such a legal arrangement leaves patients or consumers bearing an unacceptable level of risk for innovative products and therefore should be read as an unacceptable combination of legal tools in innovation policy.[17] Of course, as explained in the Conclusion, the argument in this article should be read as applying primarily to non-emergency contexts[18] and still acknowledges the merit of promoting innovation as a policy goal.

At minimum, if expedited regulatory review and liability immunity are deployed at once, they should only occur alongside other legal and regulatory interventions. These should include heightened regulatory supervision over those products both during and after review for approval, backed by a strong legal mandate for the regulator and adequate resources to conduct supervision.[19] Engaging with these legal and policy arguments will be important as lawmakers

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[14] *See infra* Part III; Robbins & Brodwin, *supra* note 10; *see generally* K. Michelle Patrick-Krueger, Ian Burkhart & Jose L. Contreras-Vidal, *The State of Clinical Trials of Implantable Brain-Computer Interfaces*, 3 NATURE REVS. BIOENGINEERING 50 (2025) (discussing the clinical trials of products approved through the BDP).

[15] Audley Genus & Andy Stirling, *Collingridge and the Dilemma of Control: Towards Responsible and Accountable Innovation*, 47 RES. POL'Y 61, 63-64 (2018).

[16] *See infra* Part VI.

[17] It should be noted that this is intended as a normative argument about the allocation of risk, not an economic argument about Pareto-style efficiency. I would like to thank Timothy Lytton for encouraging me to make this distinction. For more on mixing legal tools in regulatory regimes, *see generally* Neil Gunningham & Darren Sinclair, *Regulatory Pluralism: Designing Policy Mixes for Environmental Protection*, 21 LAW & POL'Y 49, 49 (1999) (evaluating positive and negative interactions between different combinations of regulatory instruments in the context of environmental protection).

[18] *Infra* Conclusions (see difference between "normal" times and times of public health emergencies).

[19] *Infra* Part VI.B.

and regulators continue to consider more flexible pathways to market for innovative products and services, such as regulatory sandboxes.[20]

To support this argument, the article provides the first in-depth analysis of the FDA's Breakthrough Devices Program in the legal literature. It applies doctrinal and empirical approaches to explore its legal foundations, current operation, and liability implications for patients and device manufacturers. These analyses should be of interest to scholars and stakeholders of medical device regulation, FDA law and policy, and innovation law and policy more broadly.

Part II begins by offering an overview of the typical medical device regulatory framework at the FDA and the role of federal law in preempting tort liability. Medical device legislation contains preemption provisions,[21] which have been interpreted by the U.S. Supreme Court as preempting state-level causes of action including negligence and strict liability for some—but not all—medical devices.[22] Part III then explores the legislative and regulatory features and history of the Breakthrough Devices Program. The Breakthrough Device Program enables the FDA to relax clinical data expectations and allow firms to conduct clinical studies at least in part after devices have already been authorized.[23] These features aim at accelerating patient access to innovative medical devices but also prompt concerns about the safety and effectiveness of these devices.[24] Part IV empirically examines the operations of the BDP through late 2024, finding that the number of authorized breakthrough devices is growing rapidly over time, especially for devices authorized through the premarket approval and 510(k) pathways at the FDA. It also finds at least one Class I recall (the highest severity) of a breakthrough device has occurred, a device where at least one nonfatal injury occurred, and several other patients were affected.[25] These findings suggest that the medium- or longer-term safety and effectiveness of breakthrough devices will not be completely settled once they arrive on the U.S. market.[26]

If the BDP can modify clinical studies for medical devices and subsequent injuries have already occurred, then a natural next question would be about the potential for tort liability to enable recovery for injured patients. However, Part V analyzes how many of the higher-risk breakthrough devices may benefit from immunity from state-level tort liability. The BDP and its authorizing statute, the

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[20] *See generally* Walter G. Johnson, *Caught in Quicksand? Compliance and Legitimacy Challenges in Using Regulatory Sandboxes to Manage Emerging Technologies*, 17 REG. & GOVERNANCE 709, 709 (2023) (a framework to characterize regulatory sandboxes); Jacob S. Sherkow, *Regulatory Sandboxes and the Public Health*, 2022 U. ILL. L. REV. 357, 360-62 (2022) (uses the FDA's Emergency Use Authorization program to develop a model of regulatory sandboxes).

[21] 21 U.S.C. § 360k(a)(1) (2024).

[22] Riegel v. Medtronic, Inc., 552 U.S. 312, 322-23 (2008); Medtronic Inc. v. Lohr, 518 U.S. 470, 487, 493-94 (1996).

[23] *See infra* Part III.C.

[24] *See infra* Parts II, III.

[25] *See infra* Part IV.

[26] *Id*.

21st Century Cures Act, do not specifically address how they interact with existing preemption rules, leaving legal uncertainty here on liability for breakthrough devices.[27] However, the doctrinal analysis below finds it likely that at least some breakthrough devices will continue to receive liability immunity from federal preemption.[28] These are predictive, not normative, assessments. Preemption of liability for some breakthrough devices appears likely even where devices have received regulatory relief and benefits such as modified clinical studies and pushing data collection into the postmarket setting, after a device has already been placed on the market and is in use by patients.

The article then argues in Part VI that legal and policy reforms are required to rebalance safety and innovation within the BDP. It argues that liability preemption should be loosened for breakthrough devices that currently appear to benefit from this immunity, and examines several legal mechanisms for achieving these ends.[29] The Part also calls for greater FDA supervision of breakthrough devices both during and after participation in the Program, especially if preemption reform does not occur.[30] This can be achieved with the FDA's current statutory authorities, though further legislative reforms and granting more resources to the agency could enhance these efforts.[31] Of course, the current Administration's dramatic reductions in the federal workforce and other efforts to prompt resignations across health agencies, including at the FDA, present challenges for implementing such reforms.[32]

The article concludes by returning to the argument that expedited regulatory approval should not be paired with liability immunity and broadens this argument to models of approval regulation more generally—not simply for the FDA and the Breakthrough Devices Program. The conclusion reflects on the insights gained from the analyses in this article and connects them to broader debates around risk-based regulation and approval regulation, where regulatory approval is legally required before products can enter a marketplace.[33] It concludes that while expedited regulatory approval can generally be justified on innovation grounds, pairing this policy with liability immunity becomes normatively unacceptable for innovative products incorporating emerging technologies and containing

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[27] *See* 21 U.S.C. § 360e–3 (2024) (statute regulating breakthrough devices); U.S. FOOD. & DRUG. ADMIN., BREAKTHROUGH DEVICES PROGRAM: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2023), https://www.fda.gov/media/162413/download [https://perma.cc/MYF8-4PK7].

[28] *See infra* Part V.

[29] *See infra* Part VI.A.

[30] *See infra* Part VI.B.

[31] *Id*.

[32] Executive Order No. 14210, 90 Fed. Reg. 9669 (2025); Christina Jewett & Benjamin Mueller, *H.H.S. Finalizes Thousands of Layoffs After Supreme Court Decision*, N.Y. TIMES (July 15, 2025), https://www.nytimes.com/2025/07/15/us/politics/hhs-layoffs.html [https://perma.cc/VQ9H-E2RN].

[33] *See generally* Julia Black & Robert Baldwin, *Really Responsive Risk-Based Regulation*, 32 LAW & POLICY 181 (2010); Daniel Carpenter et al., *Approval Regulation and Endogenous Consumer Confidence: Theory and Analogies to Licensing, Safety, and Financial Regulation*, 4 REGULATION & GOVERNANCE 383, 383-85 (2010).

significant uncertainty around risks. These two policies together curtail both direct regulation and self-regulation of risk at once, leaving the public to bear the consequences of poorly managed risks flowing from innovation.[34]

II. FEDERAL REGULATION OF DEVICES AND PREEMPTION OF LIABILITY

Grappling with the BDP requires first understanding the typical forms of medical device regulation at the FDA—which the Program augments rather than replaces—as well as the potential for federal law to preempt state-level tort law causes of action. This Part first reviews the statutory underpinnings of the overall risk-based framework for medical device regulation at the FDA. It then details three common mechanisms used to review and authorize devices to go onto the U.S. market at the agency, including premarket approval (PMA), 510(k) clearance, and the De Novo pathway.[35] These pathways to market are currently the only pathways eligible for consideration for breakthrough designation and the BDP.[36]

The Part then turns to review how federal law on medical devices can preempt not only state legislation and regulation, but also state-level common law causes of action. Under current preemption doctrine from the U.S. Supreme Court in *Lohr* and *Riegel*, many state-level tort law claims can be preempted by federal medical device law for devices approved through the PMA pathway—but not for devices authorized by the FDA under the 510(k).[37] For devices receiving premarket approval, tort law claims "different from, or in addition to, any requirement applicable" from the PMA approval can be expressly preempted.[38] At the same time, state-level tort law claims that look too similar to the FDA's statutes can also be conflict preempted.[39]

A. Typical Medical Device Regulation at the FDA

The FDA has broad authority to regulate medical devices in the United States to provide a "reasonable assurance of the safety and effectiveness of devices intended for human use."[40] This occurs primarily through the agency's Center for

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[34] *See infra* Conclusion.

[35] This article uses the terms "authorized" or "authorization" as generic terms to refer to an FDA determination that a device can proceed onto the U.S. markets. While the language is slightly awkward, the term "approve" is tightly associated with premarket approval (PMA), while "clearance" is associated with the 510(k) pathway. The FDA and device stakeholders generally view it as inappropriate to use "approved" or "cleared" outside of those contexts, so "authorized" becomes a more generic term. *See How to Determine if Your Product is a Medical Device*, U.S. FOOD & DRUG ADMIN. (Sept. 29, 2022), https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device [https://perma.cc/CQY8-CNHA].

[36] 21 U.S.C. § 360e–3(c).

[37] Riegel v. Medtronic, Inc., 552 U.S. 312, 322-23 (2008); Medtronic, Inc. v. Lohr, 518 U.S. 470, 487, 493-94 (1996).

[38] 21 U.S.C. § 360k(a)(1) (2024).

[39] Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 347-48 (2001).

[40] 21 U.S.C. § 393(b)(2)(C) (2024). Statutory language defines "devices" broadly: "an

Devices and Radiological Health (CDRH), which also oversees "combination products" that are primarily devices but may be combined with drugs or biologics in various ways.[41] Within this framework, device developers can take multiple pathways to market through the FDA, where devices moving through the three most common are also eligible for the Breakthrough Devices Program: premarket approval, the 510(k) process, and the De Novo process.

The FDA's central statutory authority to regulate medical device products arises from the Medical Device Amendments of 1976, charging the agency to regulate medical devices to promote their safety and effectiveness.[42] After years of debate in Congress, lawmakers enacted the Amendments shortly after a major scandal with poorly regulated intrauterine devices that harmed a significant number of women.[43] Amending the agency's organic statute—the Federal Food, Drug, and Cosmetic Act[44]—these Amendments set out a new system for overseeing devices that would be distinct and separate from the regulation of drug products. Among the most notable differences from the approach to drugs includes that medical device legislation requires the FDA to categorize devices by their level of risk and regulate those classes in different manners. Over the decades, several revisions and amendments have been made through newer legislation.[45] Yet, the basic regulatory framework set out in the Amendments is still largely intact.

This risk-based regime classifies products into low- (Class I), moderate- (Class II), and high-risk (Class III) medical devices. Class I devices pose the lowest risks to patients and are thus only subject to "general controls" under the statute.[46] Such

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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." 21 U.S.C. § 321(h)(1).

[41] 21 C.F.R. § 3.2(e) (2025) (defining combination product broadly, including "A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity").

[42] Medical Device Amendments of 1976, Pub. L. 94-295, 90 Stat. 539 (1976); *see* 21 U.S.C. § 360c(a)(1) (requiring devices across risk categories to "provide reasonable assurance of its safety and effectiveness").

[43] Anna Pisac & Natalia Wilson, *FDA Device Oversight From 1906 to the Present*, 23 AMA J. ETHICS 712, 712-13 (2021) (discussing the Dalkon Shield scandal).

[44] Federal Food, Drug, and Cosmetic Act, Pub. L. 75-717, 52 Stat. 1040 (1938).

[45] *E.g.*, Safe Medical Devices Act of 1990, Pub. L. 101-629, 104 Stat. 4511 (1990) (amendment requiring adverse reporting for manufacturers of medical devices); Food and Drug Administration Modernization Act of 1997, Pub. L. 105-115, 111 Stat. 2296 (1997) (amendment improving the regulation of food, drugs, devices, and biological products); Medical Device User Fee and Modernization Act of 2002, Pub. L. 107-250, 116 Stat. 1588 (2002) (amendment establishing user fees for medical devices); 21st Century Cures Act, Pub. L. 114-255, 130 Stat. 1033 (2016) (law accelerating the discovery, development, and delivery of medical innovations).

[46] 21 U.S.C. § 360c(a)(1)(A).

low-risk devices might include products such as surgeon's gloves or dental floss.[47] General controls cover a number of basic rules to promote the safety and effectiveness of devices and are applied to all FDA-regulated medical devices, including Class I, unless otherwise exempted. These include requirements around good manufacturing practices, rules against misbranding, repairing or replacing devices, adverse event reporting, and registering with the agency.[48] Moderate-risk, Class II devices receive both general and any applicable "special" controls that the FDA may set for that type of device, which layer on additional requirements for demonstrating safety and effectiveness.[49] These may include certain performance standards that test or measure how devices function or require additional monitoring for devices after they come to market.[50] The range of devices in the medium-risk zone vary widely, from electronic stethoscopes to radiation therapy devices.[51]

At the higher-risk end, Class III devices are subject to a process called premarket approval (PMA) before they can be sold on the U.S. market.[52] These devices have greater risk and therefore invite greater regulatory scrutiny because they are intended "for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" or "present a potential unreasonable risk of illness or injury."[53] The archetypal example of a high-risk device would be a novel, implanted device, such as a pacemaker or brain stimulation device,[54] but not all Class III devices are implantable. The PMA pathway is the most rigorous review process for devices at the FDA and requires the agency to find that the device is safe and effective, based on "valid scientific evidence."[55] Meeting these standards requires data from clinical studies with the device, as well as information on the device's components and functions, intended use, and labeling.[56] Device manufacturers typically need to obtain an Investigational Device Exemption (IDE) from the FDA to begin the clinical studies needed for premarket approval.[57]

While the statutory default is for all devices after the enactment of the 1976 Amendments to be treated as Class III, various exceptions exist to the default and

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[47] "Non-Powdered Surgeon's Glove," 21 C.F.R. § 878.4460 (2025); "Dental Floss," 21 C.F.R. § 872.6390 (2025).

[48] *See* 21 U.S.C. §§ 351, 352, 360, 360f, 360h, 360i, 360j(f) (statutes governing good manufacturing practices, against misbranding, repairing or replacing devices, adverse event reporting, and registration with the agency).

[49] 21 U.S.C. § 360c(a)(1)(B).

[50] 21 U.S.C. §§ 360d, 360l.

[51] 21 C.F.R. §§ 870.1875, 892.5050 (2025).

[52] 21 U.S.C. § 360c(a)(1)(C).

[53] 21 U.S.C. § 360c(a)(1)(C)(ii).

[54] 21 C.F.R. §§ 870.3610, 882.5820 (2025).

[55] 21 U.S.C. § 360c(a)(1)(C); 21 C.F.R. § 860.7(c) (2025).

[56] 21 U.S.C. § 360e(c) (2024); 21 C.F.R. § 814.20 (2025).

[57] 21 C.F.R. §§ 812.1-812.150 (2025).

create a variety of pathways to market other than the PMA.[58] Two of the most prominent include the 510(k) Program and the De Novo Program. The 510(k) pathway, also known as premarket notification, requires a showing that the device is "substantially equivalent" to a predicate device—meaning, "the device is as safe and effective as a legally marketed device" and "does not raise different questions of safety and effectiveness than the predicate device."[59] To do so, manufacturers must submit to the FDA information about the device at least 90 days before they plan to market it, so the agency can make a determination about whether it meets the substantial equivalence standard.[60] Submissions will generally include details on the design, materials, and data from any clinical or nonclinical tests.[61] Clinical studies, however, are not necessarily required.[62] The requirement for 510(k) premarket notification is a default for most devices, though most Class I and some Class II devices are exempted.[63] The agency distinguishes devices authorized through this pathway as being "cleared" rather than "approved" through a PMA.[64]

When no appropriate predicate device exists to use the 510(k) program, the De Novo pathway offers another way to avoid a Class III designation and the premarket approval process. Manufacturers with a novel type of device they believe could fall into Classes I or II can submit a De Novo request to the FDA.[65] This can happen at two stages, either through a direct De Novo submission requesting the reclassification or after an unsuccessful 510(k) submission (when the agency finds the submitted device is not substantially equivalent to a relevant predicate product).[66] Submissions generally should describe the device and its intended use, then discuss the absence of relevant existing devices to use as predicates, why the device would be low-enough risk to fall into Class I or II, any clinical or nonclinical data for the device, and any further special controls that might be needed.[67] The

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[58] *See* 21 U.S.C. § 360c(f)(1) (stating that all devices after the 1976 Amendments will be treated as Class III, unless a specific exception applies).

[59] 21 U.S.C. § 360c(i).

[60] 21 U.S.C. §§ 360(k), 360(n)(1).

[61] 21 C.F.R. §§ 807.87 (2025).

[62] *See* U.S. FOOD & DRUG ADMIN., THE 510(K) PROGRAM: EVALUATING SUBSTANTIAL EQUIVALENCE IN PREMARKET NOTIFICATIONS [510(K)]: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 22-23 (2014), http://fda.gov/media/82395/download [https://perma.cc/3H54-489T].

[63] 21 U.S.C. §§ 360(l)-(m).

[64] *See Premarket Notification 510(k)*, U.S. FOOD & DRUG ADMIN. (Aug. 22, 2014), https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k [https://perma.cc/GG5B-PSCQ].

[65] 21 U.S.C. § 360c(f)(1)-(2); 21 C.F.R. § 860.200 (2025).

[66] 21 U.S.C. § 360c(f)(2)(A); 21 C.F.R. § 860.200(b) (2025); *see* U.S. FOOD & DRUG ADMIN., DE NOVO CLASSIFICATION PROCESS (EVALUATION OF AUTOMATIC CLASS III DESIGNATION): GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 6-7 (2017), https://www.fda.gov/media/72674/download [https://perma.cc/P39Z-3DLT].

[67] 21 C.F.R. §§ 860.200-860.220 (2025); *see generally* U.S. FOOD & DRUG ADMIN., ACCEPTANCE REVIEW FOR DE NOVO CLASSIFICATION REQUESTS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2019), https://www.fda.gov/media/116945/download [https://perma.cc/4RCV-F8PH].

FDA must generally find that no appropriate predicate device is available and that the novel device category would be best classified as low-to-moderate risk, rather than Class III.[68] A successful De Novo submission creates a new device category at the FDA, which can be used to support future 510(k) submissions for other devices.[69]

Other pathways to market exist for devices, such as the Humanitarian Device Exemption or Emergency Use Authorization programs.[70] However, devices utilizing these pathways are not eligible for the Breakthrough Devices Program and so will not be discussed here.

B. Principles of Federal Preemption Law

Grounded in the Supremacy Clause of the U.S. Constitution, federal law generally preempts state law when certain types of competition between law at different levels might arise.[71] Of course, courts will not find that preemption has occurred lightly, given the role of states as parallel sovereigns in the U.S. federal system.[72] However, when preemption occurs through this Constitutional scheme, "all conflicting state provisions be without effect."[73] Crucially for medical device regulation and liability, preemption can target not only state legislation and regulations, but also state-level common law causes of action—including many common types of tort liability such as negligence and strict liability.[74]

The Supreme Court has clarified that the Supremacy Clause can act through both express and implied means. Both demand close attention to the statutory intent of Congress, though courts will often presume intent in the case of express preemption.[75] In express preemption, "express language" in a statute enacted by Congress triggers the Supremacy Clause.[76] This express mode involves inquiry into the "plain wording of the [statutory] clause, which necessarily contains the best evidence of Congress' preemptive intent."[77] It also requires courts to "identify the

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[68] 21 U.S.C. § 360c(f)(2)(A)(iv).

[69] U.S. FOOD & DRUG ADMIN, *supra* note 67, at 16.

[70] *See* 21 U.S.C. §§ 360j(m), 360bbb-3.

[71] U.S. CONST. art. VI, cl. 2.

[72] *E.g.*, Medtronic Inc. v. Lohr, 518 U.S. 470, 485 (1996) (citing Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947) ("So we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.")).

[73] Maryland v. Louisiana, 451 U.S. 725, 746 (1981).

[74] Riegel v. Medtronic, Inc., 552 U.S. 312, 323-25 (2008); *see* Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 522-24 (1992).

[75] *E.g.*, *Cipollone*, 505 U.S. at 516; Retail Clerks Int'l Ass'n, Loc. 1625, AFL-CIO v. Schermerhorn, 375 U.S. 96, 103 (1963) (holding "[t]he purpose of Congress is the ultimate touchstone" for preemption analyses); *cf. Lohr*, 518 U.S. at 484, 487-91.

[76] Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 541 (2001).

[77] Chamber of Com. of U.S. v. Whiting, 563 U.S. 582, 594 (2011).

domain expressly pre-empted."[78]

Implied preemption can instead arise in several types of situations where federal statutory language does not clearly seek preemption. One form, conflict preemption, may take place where federal and state law directly conflict. The Court has held that these conflicts exist where state "law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" or "where compliance with both federal and state regulations is a physical impossibility."[79] On the other hand, in field preemption, "the States are precluded from regulating conduct in a field that Congress, acting within its proper authority, has determined must be regulated by its exclusive governance."[80]

C. Liability and Preemption for Medical Devices

The Medical Device Amendments of 1976 contains a provision precluding "any [state] requirement . . . which is different from, or in addition to" federal regulations on medical devices that "relates to the safety or effectiveness of the device."[81] Courts have interpreted this provision as authorizing express preemption of state law.[82] Beyond this basic preemption provision, the statute also provides that, for device manufacturers, complying with an FDA notification or recall order "shall not relieve any person from liability under Federal or State law."[83]

The U.S. Supreme Court has intervened on tort liability for medical devices on several occasions, though arguably without crafting a complete or comprehensive doctrine.[84] This preemptive scheme is not comprehensive even before considering the Breakthrough Devices Program.[85] Together, though, the case law enables preemption for significant state tort law causes of action for devices approved through a PMA, but not for devices cleared through the 510(k) pathway.

Beginning in 1996 with *Medtronic Inc. v. Lohr*, the Court opened the legal possibility that preemption of state tort law causes of action was possible under the Medical Device Amendments, before concluding this did not cover devices

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[78] *Cipollone*, 505 U.S. at 517.

[79] *See* Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-43 (1963); *id.* at 165 n.11 (White, J., dissenting) (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).

[80] Arizona v. United States, 567 U.S. 387, 399 (2012).

[81] *See* 21 U.S.C. § 360k(a) (2024); 21 C.F.R. § 808.1(b) (2025).

[82] *See* Riegel v. Medtronic, Inc., 552 U.S. 312, 316 (2008) (interpreting this statutory provision of the Medical Device Amendments as providing express preemption).

[83] 21 U.S.C. § 360h(d).

[84] *See generally* Demetria D. Frank-Jackson, *The Medical Device Federal Preemption Trilogy: Salvaging Due Process for Injured Patients*, 35 S. ILL. U. L.J. 453, 453-54 (2011) (discussing the continued difficulty the Supreme Court has had with medical device preemption cases).

[85] *See generally* David A. Simon, Carmel Shachar & I. Glenn Cohen, *Innovating Preemption or Preempting Innovation?*, 119 NW. U. L. REV. ONLINE 137, 138-41 (2024) (reviewing the Supreme Court's preemption framework against the "unresolved question" of its application to De Novo devices).

authorized under the 510(k) pathway.[86] The Court read the above provision of the statute as constituting express preemption.[87] At issue was an implantable pacemaker device with a Class III designation that had received 510(k) authorization from the FDA.[88] The device failed after being implanted in a patient, who subsequently had a cardiac episode and needed to undergo emergency surgery to correct it, and the patient and her husband brought several state tort law claims against the manufacturer.[89] The manufacturer, Medtronic, responded with a preemption defense tied to the Medical Device Amendments.[90]

The majority in *Lohr* ultimately determined that the 510(k)'s focus "on equivalence, not safety" meant that it did not establish new "requirements" for a device.[91] This determination undermined the preemptive defense sought in the case, since the statute only expressly preempts state "requirements."[92] A plurality of the Court appeared to have believed this ruling would be limited in scope, since few common law standards have been developed specifically about medical devices, and rejected the argument that all common law causes of action could constitute "requirements" under the federal statute.[93] The remaining Justices, however, disagreed that preemption of common law causes of action under the Medical Device Amendments would be "rare,"[94] leaving open questions about exactly how preemption would operate and for which types of claims.

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[86] The *Riegel* Court took the finding of the *Lohr* Court as settled law. *Riegel*, 552 U.S. at 323-24. However, the majority opinion of the *Lohr* Court appears cautious of clearly confirming that the statute authorizes a federal preemptive defense, while concurring opinions state this more outrightly. *Compare* Medtronic, Inc. v. Lohr, 518 U.S. 470, 487, 493-95 (1996) *with id.* at 503-04 (Breyer, J., concurring in part and concurring in the judgment) *and id.* at 509 (O'Connor, J., concurring in part and dissenting in part).

[87] *Lohr*, 518 U.S. at 509 (O'Connor, J., concurring in part and dissenting in part); *see supra* Part II.B.

[88] *Id*. at 477, 480-81.

[89] *Id*. at 480-81.

[90] *Id*. at 481.

[91] *See id.* at 492-93 (describing that 510(k) focuses on "equivalence, not safety" (internal citations and emphases omitted)); *see also id*. at 513 (O'Connor, J., concurring in part and dissenting in part) (agreeing with the majority that the "510(k) process merely evaluates whether the Class III device . . . is substantially equivalent to a device that was on the market . . . plac[ing] no 'requirements' on a device"); U.S. INST. OF MED., MEDICAL DEVICES AND THE PUBLIC'S HEALTH, 36-37 (2011) [hereinafter U.S. INST. OF MED.], https://nap.nationalacademies.org/download/13150 [https://perma.cc/497Y-GSUZ] (restating the holding in *Lohr*). It should also be noted that Justice Steven's opinion in *Lohr* represented a majority of the Court for most, but not all, of its sections. *See id.*at 473-74. Writing for a plurality of the Court, Justice Stevens also expanded on the majority's judgment by analyzing the Congressional intent behind the Medical Device Amendments, finding that the purpose of the 510(k) provision was primarily to enable competition with devices on the market prior to the 1976 legislation, rather than to promote safety and effectiveness. *Id*. at 474, 486-91.

[92] *Lohr*, 518 U.S. at 503; *see* 21 U.S.C. § 360k(a).

[93] *Lohr*, 518 U.S. at 486-88, 491, 502.

[94] *Id*. at 508 (Breyer, J., concurring in part and concurring in the judgment); *id*. at 509-10 (O'Connor, J., concurring in part and dissenting in part).

A decade later, a majority of the Supreme Court in *Riegel v. Medtronic, Inc.* found that the premarket approval process instead does create "requirements" for devices that can preempt negligence, strict liability, and implied warranty causes of action under state law.[95] In doing so, the majority reads *Lohr* to very clearly support a rule that "common-law causes of action for negligence and strict liability do impose 'requirement[s]' and would be pre-empted by federal requirements specific to a medical device."[96] The case again involved a Class III Medtronic device—this time a balloon catheter that the FDA had approved through the PMA process.[97] The catheter burst in a patient during surgery after allegedly being misused by the surgeon, prompting further emergency surgeries, and the patient and his wife brought several state tort law claims against the manufacturer.[98]

The *Riegel* Court distinguishes devices that have undergone the PMA process from those that have been authorized through the 510(k) pathway. It found the PMA process involves the FDA determining the safety and effectiveness of a device through a rigorous process that imposes safety and effectiveness rules specific to each device that receives approval.[99] Therefore, when "[s]afety and effectiveness are the very subjects of . . . common-law claims," the majority determined those claims are clearly preempted as "different from, or in addition to" federal law for devices with a PMA.[100] However, while the opinion provides a more concrete scheme than *Lohr* alone, it still leaves open several questions. Notably, it remains unclear exactly which types of common law claims will be considered as centering safety and effectiveness and how this type of "very subjects" analysis should proceed.

Together, *Riegel* and *Lohr* also leave open the potential for "parallel" state tort law claims to survive federal preemption, without clarifying how this would occur. In *Lohr*, the majority insisted that the statutory preemption provision does not remove from states "the right to provide a traditional damages remedy for violations of common-law duties when those duties *parallel* federal requirements."[101] The *Riegel* Court again recognizes this possibility for parallel claims to survive preemption but declined to rule on the matter.[102] Nor do the opinions make clear how to distinguish these "parallel" causes of action ones from "different from, or in addition to" federal law.[103]

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[95] Riegel v. Medtronic, Inc., 552 U.S. 312, 320, 322-25 (2008).

[96] *Id*. at 323-24.

[97] *Id*. at 320.

[98] *Id*.

[99] *See id*. at 322-23 (distinguishing the Premarket Approval process from 510(k) clearance, finding "[w]hile 510(k) is focused on equivalence, not safety, premarket approval is focused on safety, not equivalence" (internal citations omitted) and noting that a device that receives PMA can have "almost no deviations from the specifications in its approval application").

[100] *See id*.; 21 U.S.C. § 360k(a) (2024).

[101] Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996) (emphasis added).

[102] *Riegel*, 552 U.S. at 330.

[103] *See* 21 U.S.C. § 360k(a).

The Court has, separately, also used preemption doctrines to deny common law causes of action that mirror provisions in the medical device statutes the FDA administers.[104] In *Buckman v. Plaintiff's Legal Committee*, patients who alleged harms from hardware placed in their spines during back surgery brought claims against the device manufacturer under state common law.[105] The devices had been cleared by the FDA through the 510(k) pathway based on information provided by the manufacturer.[106] However, rather than using traditional tort law theories such as negligence, the plaintiffs instead advanced tort claims that "but for" the "fraudulent representations" the manufacturer made to the FDA about the operation of the devices, they would not have been injured.[107]

The *Buckman* majority concluded that the 1938 Food, Drug, and Cosmetic Act and Medical Device Amendments worked to preempt the plaintiffs' claims of fraudulent representation to the FDA made under state tort law.[108] As opposed to the express preemption involved in *Lohr* and *Riegel*, the *Buckman* Court instead argued the statutes impliedly enabled conflict preemption of state tort law claims—since "the very subject matter" of the common law claims mirrored statutory provisions.[109] The majority determined both that the FDA has sufficient statutory authority to enforce issues of fraudulent representations on its own, but also that other provisions in the FDA's organic statute suggest that Congress intended for these types of harms to be enforced only at federal law.[110] In doing so, the opinion reiterates the lack of a private right of action, at state tort law, to enforce claims for medical device related harms that could arise under the FDA's device statutes.[111]

D. Doctrinal Uncertainty on Liability and the De Novo Pathway

The above analysis examines liability preemption for medical devices that proceed through the PMA and 510(k) pathways at the FDA. The third pathway that is eligible for the Breakthrough Devices Program, the De Novo program, however, continues to raise unanswered doctrinal questions on preemption of liability.[112]

The De Novo pathway only became a more formal and utilized process years after the *Riegel* decision (though not because of that decision),[113] complicating

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[104] Buckman v. Plaintiffs' Legal Comm., 531 U.S. 341, 353 (2001).

[105] *Id*. at 343.

[106] *Id*. at 346.

[107] *Id*. at 343, 346-47.

[108] *Id*. at 347-48.

[109] *Id.* at 347-48, 350; *see supra* Part II.

[110] *Buckman*, 531 U.S. at 348-49, 352; *see* 21 U.S.C. § 337(a).

[111] *Buckman,* 531 U.S. at 353.

[112] *See* Simon, Shachar & Cohen, *supra* note 85, at 138-41.

[113] *See* Food and Drug Administration Safety and Innovation Act (FDASIA), Pub. L. 112-144, 126 Stat. 993, § 607 (2012) (codifying the De Novo pathway); *see also* Mateo Aboy, Cristina Crespo & Ariel Stern, *Beyond The 510(K): The Regulation of Novel Moderate-Risk Medical Devices, Intellectual Property Considerations, and Innovation Incentives in the FDA's De Novo Pathway*, 7

analysis of whether these devices should or should not receive immunity from tort law claims. The U.S. Supreme Court has not clarified whether or how preemption from medical device legislation should apply to devices authorized via the De Novo route.

The *Riegel* Court indicates that the PMA creates preemptive "requirements" because "premarket approval is specific to individual devices."[114] Yet, the De Novo pathway arguably does not create device-specific regulatory norms, but applies either the FDA's general controls for devices (if reclassified as Class I) or a combination of general and specific controls (if reclassified as Class II)—where specific controls apply to a category of device rather than an individual one.[115] It is true that De Novo applications may involve device manufacturers proposing new special controls for a De Novo application resulting in a Class II device classification, yet these special controls are not device-specific in the same way that PMA requirements are and can also apply to 510(k) authorized devices, which still do not receive liability preemption.[116]

The available doctrine, then, leaves open the question of whether a device authorized through the De Novo pathway would receive preemption under medical device legislation. Lower courts in general have also not directly weighed in on this question, though a federal district court recently permitted preemption of some tort law claims against a manufacturer of a De Novo-authorized device.[117]

III. OVERVIEW OF THE BREAKTHROUGH DEVICES PROGRAM

This Part reviews the legislative and regulatory foundations of the Breakthrough Devices Program and the types of benefits it offers to participating medical device firms. In doing so, it outlines the BDP's relationship to typical medical device regulation and the regulatory benefits available to participants that deviate from the typical device oversight system. It also explores potential legal issues or limits on the ability of the FDA to take enforcement actions both during and after a medical device firm participates in the Program.

A. Legislative and Regulatory History of the BDP

The Breakthrough Devices Program at the FDA formally arises from the 21st Century Cures Act of 2016.[118] Signed into law in the final weeks of the Obama Administration in December 2016, the Cures Act deployed significant funding to

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NPJ DIGITAL MED., art. no. 29, Feb. 2024, at 2-3 (explaining that use of the De Novo pathway was relatively small before 2013 and has increased notably since then).

[114] Riegel v. Medtronic, Inc., 552 U.S. 312, 322-33 (2008).

[115] 21 C.F.R. §§ 860.3, 860.220 (2024); *see* U.S. FOOD & DRUG ADMIN., *supra* note 65, at 4.

[116] Simon, Shachar & Cohen, *supra* note 85, at 157-58.

[117] Dickson v. Dexcom Inc., No. 2:24-CV-00121, 2024 WL 3417392, at *14-17 (W.D. La. July 15, 2024); *see* Sara Gerke & David A. Simon, *New Case Law and Liability Risks for Manufacturers of Medical AI*, 388 SCIENCE 1138, 1139-40 (2025).

[118] 21st Century Cures Act, Pub. L. 114-255, 130 Stat. 1033 (2016).

several key health and scientific initiatives at the National Institutes of Health and beyond but also reformed FDA regulation for medical products in several ways.[119] Perhaps most significant for medical device policy, the statute authorized what would become the BDP.[120]

Notably, however, the Cures Act establishing the BDP in many ways merely codified the agency's existing Expedited Access Pathway (EAP) that it had launched the previous year.[121] That program can be traced back to principles from a 1994 FDA memorandum establishing "expedited review" for medical devices that would undergo a PMA or 510(k) submission.[122] The memorandum seeded many of the basic qualifying criteria for devices that would go on to be included in the BDP—including if a device represents a "breakthrough" in the sense that it has "a clear clinically meaningful advantage over existing technology."[123] Though the agency arguably did not then have clear statutory authority to establish such a program, expedited review was partially formalized by Congress—for devices subject to PMAs—in the Food and Drug Administration Modernization Act of 1997.[124] Over the next two decades before the Cures Act, the agency continued to apply some form of expedited review to devices beyond those requiring a PMA and created new features that were eventually folded into the Expedited Access Pathway and Breakthrough Devices Program.[125]

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[119] *See generally id.* §§ 1001-3102 (funding NIH initiatives and amending multiple provisions addressing patient-focused drug development, clinical-trial design, regenerative medicine, and medical-device regulation).

[120] *Id*. § 3051.

[121] *See generally* U.S. FOOD & DRUG ADMIN., EXPEDITED ACCESS FOR PREMARKET APPROVAL AND DE NOVO MEDICAL DEVICES INTENDED FOR UNMET MEDICAL NEED FOR LIFE THREATENING OR IRREVERSIBLY DEBILITATING DISEASES OR CONDITIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (Apr. 13, 2015), https://wayback.archive-it.org/7993/20180907200008/https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM393978.pdf [https://perma.cc/4H6G-D94R]. Similar events have occurred previously in the FDA's history, with the Safe Medical Device Act codifying the agency's 510(k) pathway that was not clearly grounded in its then-statutory authority. *See* U.S. INST. OF MED., *supra* note 91, at 33-35 (2011).

[122] "PMA/510(k) Expedited Review (5/20/94): General Program Memorandum #G94-2," *in* U.S. FOOD & DRUG ADMIN., INVESTIGATIONAL DEVICE EXEMPTIONS MANUAL, HHS PUBLICATION FDA 96-4159, 4--42–
4--45 (1996), https://books.google.com/books?id=89AaUS7YrloC&printsec=frontcover&source=gbs_ViewAPI#v=onepage&q&f=false [https://perma.cc/S6EG-NQSY].

[123] *Id*. at 4-43.

[124] Food and Drug Administration Modernization Act of 1997, Pub. L. 105-115, 111 Stat. 2296, § 202 (1997) (codifying and slightly modifying the criteria for expedited review the FDA crafted in its 1994 memorandum, including for devices using "breakthrough technologies"). That statutory provision was repealed by the Cures Act to make room for the BDP. *See* Pub. L. 114-255, 130 Stat. 1033, § 3051(c) (2016).

[125] *See* U.S. FOOD & DRUG ADMIN., *supra* note 122, at 6 (describing features of the FDA's 2011 Innovation Pathway that were rolled into the EAP); U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF: PRIORITY REVIEW OF PREMARKET SUBMISSIONS FOR DEVICES at 5 (May 17, 2013), https://wayback.archive-

The Cures Act declares the purpose of the Breakthrough Designation system is to create "efficient and flexible approaches to expedite the development of, and prioritize the Food and Drug Administration's review of, devices that represent breakthrough technologies."[126] The statute, however, does not define what constitutes a breakthrough or breakthrough technology, only suggesting these are beneficial somehow. The BDP applies to medical devices and combination products with primarily device characteristics, though Congress expanded the scope of the Program in 2018 to also include "non-addictive medical products intended to treat pain or addiction."[127]

Since the Cures Act in 2016, the FDA has worked to rapidly implement the BDP. The legislation itself directs the FDA to develop and release guidance to clarify the substance and processes for the program described in the statute.[128] The agency released final guidance initially in 2018, then updated final guidance in 2023 to refine what the features of the Program would look like for regulated actors.[129] In doing so, the agency reiterates that the "Breakthrough Devices Program is intended to help patients have more timely access to designated medical devices by expediting their development, assessment, and review" but without compromising its statutory standards of safety and effectiveness for devices.[130] The FDA has also implemented a closely related program, apparently grounded in the same statutory provisions of the Cures Act, called the Safer Technologies Program (STeP).[131] Designed with nearly identical elements, STeP would target medical devices with intended uses for conditions "less serious than those eligible for the Breakthrough Devices Program" that nonetheless have the potential to make innovations in the safety of existing device treatments.[132]

B. Entry into the BDP

The Breakthrough Devices Program represents a new feature of medical device regulation at the FDA, installed by the 21st Century Cures Act, but is not a unique pathway to market. Instead, medical devices are only eligible for breakthrough

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it.org/7993/20170721215042/https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089698.pdf [https://perma.cc/29C2-VV7N] [hereinafter PRIORITY REVIEW GUIDANCE] ("While Section 515(d)(5) of the FD&C Act only applies to PMAs, because of the potential public health importance of devices warranting priority review status, FDA also has applied the priority review criteria to all premarket submissions").

[126] 21 U.S.C. § 360e-3(a) (2024).

[127] SUPPORT for Patients and Communities Act, Pub. L. 115-271, 132 Stat. 3932, § 3001(a)(4) (2018); *see* 21 U.S.C. § 321(h)(1).

[128] 21 U.S.C. § 360e-3(f).

[129] BDP Guidance, *supra* note 4, at 1, 5. The guidance also clarifies that the BDP eclipses two former programs the FDA had launched with similar policy aims but prior to the Cures Act, the Expedited Access Pathway and the Priority Review Program. *Id*. at 5.

[130] BDP Guidance, *supra* note 4, at 5.

[131] U.S. FOOD & DRUG ADMIN., SAFER TECHNOLOGIES PROGRAM FOR MEDICAL DEVICES GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (Jan. 6, 2021), at 5 n.15, https://www.fda.gov/media/130815/download [https://perma.cc/2WHR-4FF6].

[132] *Id*. at 1.

designation if they will ultimately be submitted to the FDA under the PMA, 510(k), or De Novo Pathways but have not yet been submitted.[133] Breakthrough designation, then, is an additional and voluntary regulatory process that becomes layered onto another pathway for authorization.[134]

To participate in the BDP, the FDA must determine that a medical device meets the statutory requirements outlined in the Cures Act. While the statute does not define "breakthrough," it offers several criteria for a device to receive the designation. To qualify, medical devices must meet (1) a probable effectiveness standard and (2) one of four criteria designed to show innovation or patient benefit.[135] The FDA has additionally provided that it will evaluate (3) the potential for advancing health equity when considering a designation request.[136]

First, the effectiveness criteria in the Cures Act specifies that a breakthrough device should "provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions" and must be met for designation.[137] In their guidance, the FDA softens the standard by emphasizing that firms need only show a "reasonable expectation" their device could have greater effectiveness than interventions considered the standard of care in the U.S., which does not require clinical studies to demonstrate.[138] By tying the regulatory norm to the national standard of care, the guidance focuses on comparisons against other interventions that are in mainstream medical use nationally, preventing the need to demonstrate a device could be more effective than all available treatments. Since novel medical devices can struggle to find quick uptake into mainstream medical practice,[139] it may also lower the threshold by setting regulatory attention more on established treatments as a reference.

Second, devices must meet at least one of four standards that show either innovation or patient benefit. One option requires these devices to "represent breakthrough technologies," which the FDA clarifies refers to either devices that apply new technologies or those that use current techniques in new ways to provide greater effectiveness in a clinical intervention.[140] A second focuses on situations where no FDA-authorized device is available for a particular clinical use.[141] The agency again interprets in that it will only compare to authorized devices that are

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[133] 21 U.S.C. § 360e–3(c).

[134] The FDA has a similar set of related programs for "breakthrough" drug and biologic products that function in similar ways to the BDP, though they predate the BDP for devices. *See, e.g.*, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY EXPEDITED PROGRAMS FOR SERIOUS CONDITIONS – DRUGS AND BIOLOGICS 1, 10-13 (2014), www.fda.gov/media/86377/download [https://perma.cc/8SKS-3KSW].

[135] 21 U.S.C. § 360e–3(b).

[136] BDP Guidance, *supra* note 4, at 18-20.

[137] 21 U.S.C. § 360e–3(b)(1).

[138] BDP Guidance, *supra* note 4, at 12.

[139] *See generally* Michael D. Greenberg, *Medical Malpractice and New Devices: An Elusive Standard of Care*, 19 HEALTH MATRIX: J.L. MED. 423 (2009).

[140] *See* 21 U.S.C. § 360e–3(b)(2)(A); BDP Guidance, *supra* note 4, at 13.

[141] 21 U.S.C. § 360e–3(b)(2)(B) (2025).

within the U.S. standard of care,[142] potentially relaxing the comparative effort.

As a third option for the second criteria, devices can demonstrate they "offer significant advantages over existing approved or cleared alternatives," including by offering greater effectiveness in treatment and diagnosis or reducing side effects or adverse events.[143] Finally, as a catch-all, firms can argue their devices are "in the best interest of patients."[144] The FDA conceptualizes this to include devices with public health benefits such as diagnostics for pathogens or products that offer less harmful alternatives than existing treatments and may account for patient perceptions of risks versus benefits within the standard.[145]

Additionally, the FDA indicates that it will, at times, interpret effectiveness standards with reference to health equity. The more recent guidance suggests that devices may receive some level of greater consideration if they promise to provide "more effective treatment or diagnosis in populations that exhibit health and health care disparities," by addressing existing disparities in health outcomes or increasing access to devices for underserved populations.[146] While not a freestanding requirement for designation, the FDA signals that equity considerations will influence its interpretation and implementation of the other criteria. This interpretation came in 2023 and appears to be an agency response to the Biden Administration's priorities on equity, including in health.[147] The FDA has not yet retracted this guidance, though the second Trump Administration's radically different views on the role of equity in federal policy may lead to further changes.[148]

Procedurally, firms must submit a request to the FDA to enter the Program, though the agency may also prompt good candidates to send such a request as well.[149] Device developers can make the designation request any time before making their final submission for market authorization from the FDA, and the agency has 60 days to grant or deny breakthrough status after receiving the request.[150] The request should detail the device and its intended use, justify how the device meets the statutory requirements for designation and which authorization pathway they will use, and specify which features of the program in which the firm would like to participate.[151] The Cures Act also requires the agency to assign a team to review designation requests that includes senior managers.[152]

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[142] BDP Guidance, *supra* note 4, at 14.

[143] 21 U.S.C. § 360e–3(b)(2)(C) (2025); BDP Guidance, *supra* note 4, at 15.

[144] 21 U.S.C. § 360e–3(b)(2)(D) (2025).

[145] BDP Guidance, *supra* note 4, at 15-17.

[146] *Id*. at 19.

[147] See, *e.g.*, Exec. Order No. 13985, 86 Fed. Reg. 7009 (2021).

[148] *See* Exec. Order No. 14151, 90 Fed. Reg. 8339 (2025).

[149] 21 U.S.C. § 360e–3(c) (2025); BDP Guidance, *supra* note 4, at 20-21.

[150] 21 U.S.C. § 360e–3(d)(1) (2025); BDP Guidance, *supra* note 4, at 17.

[151] BDP Guidance, *supra* note 4, at 11, 17, 22, 27-28.

[152] 21 U.S.C. § 360e–3(d)(2) (2025).

C. Regulatory Features of the BDP

In practice, the Breakthrough Devices Program offers a customizable set of regulatory benefits for which firms can apply if they have a medical device that will undergo the PMA, 510(k), or De Novo authorization processes. These features of the Program generally aim to support firms as they develop their device by clarifying regulator expectations for and resolving potential issues around data collection and the eventual market authorization application. Firms that receive breakthrough designation for their devices will receive several regulatory benefits by default and may participate in one or more additional features of the Program (Table 1).

Basic Features	**Optional Features**
Faster communication, access to senior FDA officials, notice for engaging external experts	Sprint discussions on particular decisions
Flexibility in clinical study designs	Data development plans, pre- and postmarket plans
Priority review	Binding clinical protocol agreements
For PMAs, shift to postmarket data collection and manufacturing inspections	Regular meetings with FDA
	Stakeholder engagement program

Table 1: Features of the Breakthrough Device Program

Default benefits largely involve heightened communications with or reviews from regulators as well as lightening or shifting the amount or type of data required for a market authorization. These include "interactive and timely communication" between the firm and a dedicated internal team at FDA assigned to the firm and including experts on that type of device, as well as senior agency management promptly becoming involved in dispute resolution between the firm and internal team.[153] The Program permits the use of "efficient and flexible" clinical study designs, including the use of surrogate or composite endpoints—which can reduce the time, amount, or burden of data collection but are often less precise—or endpoints designed to show the "minimum clinically meaningful effect."[154] Prior studies have found the FDA has authorized at least some breakthrough devices without demonstrating their effectiveness or with safety studies that were not

[153] 21 U.S.C. § 360e–3(e)(1)(A)–(D); BDP Guidance, *supra* note 4, at 6-9.

[154] 21 U.S.C. § 360e–3(e)(2)(B) (2025); BDP Guidance, *supra* note 4, at 8. *See generally* Thomas R. Fleming, *Surrogate Endpoints and FDA's Accelerated Approval Process*, 24 HEALTH AFF. 67 (2005).

randomized or blinded, potentially shifting a full evaluation of device safety and effectiveness to the postmarket setting.[155]

Designated devices also receive priority review when fully submitted to the FDA, meaning that their submission for market authorization will be reviewed by regulators before other submissions.[156] Should the agency consult external experts about the device or review process, designated developers must be given at least five days' notice and the opportunity to suggest actors to be consulted.[157] For devices that require a PMA, further basic benefits apply. The agency "may accept a greater extent of uncertainty of the benefit-risk profile for these devices if appropriate under the circumstances," including by deferring some data collection to the postmarket setting and weighing the potential benefit to patients of early access to the device against lesser clinical data.[158] The FDA may also require less information about good manufacturing practices in the PMA and defer an inspection of manufacturing sites until after approval.[159]

Firms can then request one or more additional features as part of their Breakthrough experience, most of which aim to provide greater predictability for device developers through either greater communication or clarifying regulatory expectations. These include regular meetings for the developer and FDA to meet and update one another on the device or "sprint" discussions to quickly resolve a single, but complex and "potentially novel" issue.[160] Firms can work with the agency to develop a "data development plan" that would outline the FDA's expectations for data collection likely to be required in both the pre- and post-market settings.[161] Developers can also request the FDA sign a binding agreement laying out what clinical protocols will involve for the device, though these may be collectively changed by the agency and firm—or voided in the case that the FDA identifies a "a substantial scientific issue essential to determining the safety or effectiveness of the device."[162]

Further implementing the Breakthrough Devices Program, the FDA in 2022 agreed to create an additional voluntary feature called the Total Product Life Cycle Advisory Program (TAP).[163] Though still in a pilot phase, the TAP would assign FDA staff to a breakthrough designated device for even greater communication options and to "facilitate engagement with FDA and non-FDA parties that can help program participants identify strategic options to streamline the path to patient

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[155] Johnston et al., *supra* note 4, at 935-36.

[156] BDP Guidance, *supra* note 4, at 9.

[157] 21 U.S.C. § 360e–3(e)(1)(F) (2025).

[158] 21 U.S.C. § 360e–3(e)(2)(C) (2025); BDP Guidance, *supra* note 4, at 7-8.

[159] 21 U.S.C. § 360e–3(e)(1)(E) (2025); BDP Guidance, *supra* note 4, at 9-11.

[160] BDP Guidance, *supra* note 4, at 22-25.

[161] 21 U.S.C. § 360e–3(e)(2)(A) (2025); BDP Guidance, *supra* note 4, at 25.

[162] 21 U.S.C. § 360e–3(e)(2)(D) (2025); BDP Guidance, *supra* note 4, at 25-26.

[163] U.S. Food & Drug Admin., MDUFA PERFORMANCE GOALS AND PROCEDURES, FISCAL YEARS 2023 THROUGH 2027 (2022), 24-26, www.fda.gov/media/158308/download [https://perma.cc/BC3Z-U7UG].

access to their devices."[164] The TAP feature enables participating developers to "request early interactions" with third parties including patients, healthcare providers, and insurers to receive a better appreciation for how their device could be taken up and used in a real clinical setting.[165]

These elements all create a notably favorable environment for regulated actors and direct the agency to spend significant resources, in terms of staffing and time in particular, on accelerating the progress of included devices through the authorization process. These echo the Cures Act's policy emphasis on innovation and flexibility by creating a space that privileges emerging technologies and unmet patient needs for special regulatory treatment.[166] Moreover, the FDA cannot revoke a breakthrough designation if it authorizes a second breakthrough device that would undermine the first's claim to novelty,[167] suggesting an emphasis on bringing devices to market over purely patient access to devices.

D. Withdrawal of Breakthrough Designation

The Cures Act offers clear, if broad, standards for entry into the Breakthrough Devices Program.[168] However, the statute does not provide clear guidance around enforcement within the Program. The Cures Act places an express limit on when the FDA can "withdraw a designation," which would result in removal from the Program and the regulatory benefits available to participants.[169] The FDA cannot remove a medical device from the Program because another breakthrough device receives market authorization.[170] This presumably would address the potential for devices to lose eligibility for breakthrough designation if the authorization of a second device would undermine the first's claims that no alternative exists or that it could offer significant advantages over alternatives.[171]

The statute imposing limits on when the FDA can withdraw breakthrough

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[164] *TAP Overview,* U. S. FOOD & DRUG ADMIN. (Oct. 1, 2024), https://www.fda.gov/medical-devices/total-product-life-cycle-advisory-program-tap/tap-overview [https://web.archive.org/web/20250825052943/https://www.fda.gov/medical-devices/total-product-life-cycle-advisory-program-tap/tap-overview].

[165] U.S. Food. & Drug. Admin., *TAP Pilot Engagement Tips* (2024), 4, 6-8, 10-11, https://www.fda.gov/media/182363/download [https://perma.cc/V6LF-EZNW].

[166] 21 U.S.C. § 360e–3(a) (2025).

[167] 21 U.S.C. § 360e–3(d)(3) (2025).

[168] 21 U.S.C. § 360e–3(b) (2025).

[169] 21 U.S.C. § 360e–3(d)(3) (2025).

[170] 21 U.S.C. § 360e–3(d)(3)(A) (2025). This also includes the approval of devices that participated in the FDA's former Priority Review Program for the PMA pathway, which was absorbed into the BDP. 21 U.S.C. § 360e–3(d)(3)(B) (2025); BDP Guidance, *supra* note 4, at 5; *see generally* PRIORITY REVIEW GUIDANCE, *supra* note 125.

[171] *See* 21 U.S.C. § 360e–3(b)(2)(B)-(C). Similarly, but unrelated, the FDA's units on drugs and biologics have issued draft guidance illustrating that the similar Breakthrough Therapy Designation for pharmaceuticals can be "rescinded" under certain conditions as clinical studies proceed. U.S. Food & Drug Admin., *Considerations for Rescinding Breakthrough Therapy Designation: Guidance for Industry: Draft Guidance* (2022), 2-3, https://www.fda.gov/media/159359/download [https://perma.cc/8JBS-6D3F].

designation implies that the agency can legitimately remove device developers from the Program. Yet, the Cures Act does not explicitly address when withdrawal is permitted and under what conditions, nor does available case law speak to this issue. The FDA has interpreted the statute to allow for removal from the Program "at any time upon written notice" in at least two circumstances.[172] First, the FDA may withdraw breakthrough status if it determines, "based on available information," that the device no longer meets the statute's eligibility criteria (other than in the case of a second device's authorization that may affect those criteria).[173] The agency does not provide further guidance on when a device may no longer meet the entry standards, though it is possible to envision such scenarios. For instance, data collection on a device during its participation in the Program may reveal new, troubling information about its potential safety or effectiveness that could undermine developer's prior claims that the device could be more effective than alternatives or in the best interest of patients.[174] Second, the agency may remove a firm from the BDP if it discovers that the device developer submitted false information or withheld vital information when applying for breakthrough designation.[175] The FDA does not indicate in its online materials how many breakthrough designations it has revoked or on what grounds.[176]

At least some concern exists already that the FDA may need enforcement powers to sanction firms once they enter the Program. In an anti-retaliation suit, a former employee of a device developer—hired to ensure FDA compliance—alleged that senior firm management withheld vital information from him about the device and filed for Breakthrough Device Designation with the FDA without his input, prompting suspicion that the firm may have submitted false or incomplete information.[177] The suit was dismissed for failure to state a claim, and did not establish whether the firm indeed provided false or misleading data to the FDA to secure breakthrough designation.[178] Yet, the allegations raise concerns that firms may have incentives to alter or fabricate data to obtain breakthrough designation for their devices—which the developer here successfully did—which may prompt the need for enforcement actions once in the Program.

The ambiguity around entry and removal standards from the Cures Act may prompt legal challenges over FDA decisions to confer, deny, or withdraw breakthrough designations, or otherwise take enforcement actions within the Program. The Administrative Procedure Act (APA) enables and steers judicial

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[172] BDP Guidance, *supra* note 4, at 21-22.

[173] *Id*. at 22.

[174] *See* 21 U.S.C. § 360e–3(b).

[175] BDP Guidance, *supra* note 4, at 22.

[176] *Cf.*, BDP Website, *supra* note 7 (not specifying how many breakthrough designations the FDA has revoked or on what grounds).

[177] Hennrick v. miR Scientific, LLC, No. 21-CV-4945, 2021 WL 6052118, at *1-2 (S.D.N.Y. Dec. 21, 2021).

[178] *Id*. at 3; *see generally* Fed. R. Civ. P. 12(b)(6) (permitting dismissal of a suit when the plaintiff fails "to state a claim upon which relief can be granted").

review of agency "actions."[179] The Medical Device Amendments also specifically authorize judicial review for FDA rules and decisions.[180] The potential for judicial review provides regulated actors with tools to litigate FDA decisions including entry and removal from the BDP. For instance, device developers could argue that these agency decisions were made in an arbitrary or capricious manner or in a way that exceeded the authority provided by the Cures Act.[181]

Already, at least one firm has brought these types of claims under the APA to challenge the FDA's decision not to offer breakthrough designation to their device.[182] The developer in that case alleged that FDA staff was aware of a separate enforcement action against the firm by the U.S. Securities and Exchange Commission, and this could have improperly influenced the FDA's denial.[183] The court found the firm failed to provide facts demonstrating that this information swayed the actual decision-making staff at the FDA nor did the firm specifically contest the formal reasons the FDA provided in its decision letter denying designation.[184] Available case law, then, provides limited guidance on how suits under the APA may be resolved for rejection or removal from the Breakthrough Devices Program. Of course, the unpublished opinion appears to leave open the possibility that such decisions could be properly challenged under the APA if the FDA denied entry based on factors ungrounded in the Cures Act.[185]

Additionally, since the FDA's guidance is not a binding rule published in the Code of Federal Regulations but the agency's current interpretation of the Cures Act,[186] regulated actors could also aim to invalidate entry or removal decisions by arguing that the FDA should have engaged in notice-and-comment rulemaking, rather than issuing interpretive guidance, to create legally enforceable designation or withdrawal standards. This approach, however, appears unlikely to succeed.[187]

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[179] 5 U.S.C. § 551(13) ("agency action includes the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act"); *see also* 5 U.S.C. § 701(b)(2) (2024) (defining "agency action" as the meaning given by § 551(13)). For the APA, *see generally* 5 U.S.C. §§ 551-59, 701-06 (governing the procedures of federal administrative law). In general, the U.S. Supreme Court has determined there is "strong presumption that Congress intends judicial review of administrative action," grounded in the APA and its legislative history. Bowen v. Mich. Acad. of Family Physicians, 476 U.S. 667, 670-73 (1986).

[180] 21 U.S.C. § 360g.

[181] 5 U.S.C. § 706(2)(A).

[182] Nova Oculus Partners, LLC v. U.S. Food & Drug Admin., No. 20-CV-1174, 2020 WL 7230678, at *5 (D.D.C. Dec. 8, 2020). At the time of writing, a search of the Westlaw database produces only this single, unpublished opinion involving an FDA decision on a breakthrough device designation in the U.S.

[183] *Id*. at 3-4.

[184] *Id*. at 7-9.

[185] *See id*. at 6-10.

[186] BDP Guidance, *supra* note 4, at 5.

[187] *See* 5 U.S.C. § 553(b)(A); *cf.*, Am. Mining Cong. V. Mine Safety & Health Admin., 995 F.2d 1106, 1107-09, 1112-13 (D.C. Cir. 1993) (finding that a particular agency norm was an "interpretive rule" exempt from ordinary notice-and-comment rulemaking procedures under the APA, rather than a "legislative rule" subject to such procedures).

The Cures Act itself directs the FDA to issue guidance after soliciting and accepting public comments on a draft, and the agency has comported with these procedural directions from Congress.[188]

Instead, regulated firms could also call on courts to review the FDA's interpretation of the Cures Act for the purpose of entry standards or enforcement—a process which would interact with the rapidly shifting doctrinal environment of judicial review for agency interpretations of statutes. Most notably, the U.S. Supreme Court in *Loper Bright* overturned the longstanding doctrine of *Chevron* deference in 2024.[189] Previously, *Chevron* deference directed courts to defer to an agency's reasonable construction of statutory provisions authorizing their action, where the legislation was genuinely ambiguous.[190]

Chief Justice Roberts concluded in *Loper Bright*, however, that this mode of deference was incompatible with the APA's judicial review provisions.[191] The Court crafted the new norm that the judiciary, in every case, "must exercise their independent judgment in deciding whether an agency has acted within its statutory authority."[192] Of course, under *Skidmore*, agency interpretations can still have "power to persuade, if lacking power to control,"[193] though this analysis offers significantly less deference. These moves also coincide with a broader deregulatory turn at the Court, including its 2022 codification of the Major Questions Doctrine, which seeks to advance nondelegation goals by questioning and quashing regulator's efforts to develop new rules and frameworks unless a clear and often narrowly constructed statutory provision supports the precise move sought by the agency.[194]

These shifting standards of judicial review reduce the legal certainty that the FDA's current implementation of the BDP will remain durable. The agency's interpretation of the Cures Act to give it power to remove firms from the BDP, or take other potential enforcement actions within the Program, could become vulnerable if litigated. The FDA's 2023 determination that health equity can assist in qualifying for breakthrough designation could also become subject to judicial

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[188] 21 U.S.C. § 360e–3(f). *See* Breakthrough Devices Program; Guidance for Industry and Food and Drug Administration Staff; Availability, 88 Fed. Reg. 63582, 63583 (Sept. 15, 2023); Breakthrough Devices Program; Guidance for Industry and Food and Drug Administration Staff; Availability, 83 Fed. Reg. 65169, 65170 (Dec. 19, 2018).

[189] Loper Bright Enter. v. Raimondo, 603 U.S. 369, 412 (2024).

[190] Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842-43 (1984). The Court had previously also offered significant deference to agency's interpretations of their own rules as well. Auer v. Robbins, 519 U.S. 452, 461 (1997).

[191] *Loper Bright*, 603 U.S. at 396, 398-99; *see also* 5 U.S.C. § 706 ("[T]he reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action.").

[192] *Loper Bright*, 603 U.S. at 412.

[193] *Id*. at 402; Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944).

[194] West Virginia v. Env't Prot. Agency, 142 S. Ct. 2587, 2602-04, 2609-10 (2022); *see* Daniel T. Deacon & Leah M. Litman, *The New Major Questions Doctrine*, 109 VA. L. REV. 1009, 1011-16 (2023).

review, as the principle is not specifically mentioned in the statute.[195] This lack of legal predictability from courts increases the challenges of the FDA in complying with administrative law and may disincentivize enforcement within the BDP.[196]

E. Postmarket Regulation After the BDP

The Breakthrough Device Program enables the FDA to relax clinical data expectations such that firms can conduct clinical studies at least in part after devices have already been authorized.[197] This feature aims at accelerating patient access to innovative medical devices but also prompts concerns about whether postmarket clinical studies will be completed and how the FDA will monitor and take enforcement actions on breakthrough devices already on the U.S. market.

Even prior to the Program, the FDA had well-established authority to require postmarket data collection on authorized devices and take enforcement actions if needed. The agency can "require a manufacturer to conduct postmarket surveillance" for many moderate- and high-risk devices, where firms must propose and receive agency approval for a surveillance plan.[198] In general, device manufacturers must also keep records of information about the safety and effectiveness of their authorized devices and report to the FDA within 30 days if the product has or may have "caused or contributed to a death or serious injury" or other adverse events.[199] Firms can voluntarily take action to recall or repair their medical devices but must report this to the FDA.[200] If the agency determines such a device presents an "unreasonable risk of substantial harm to the public health" once it is already on the U.S. market, it can also require firms to notify healthcare providers, patients, and others of the issues.[201] Especially if a firm does not voluntarily take action, the FDA can also issue orders to cease distribution of or recall a device from the market entirely if it "would cause serious, adverse health consequences or death."[202] The agency can also order developers to repair, replace, or refund medical devices, though only in limited, statutorily permitted circumstances.[203]

The 21st Century Cures Act gestures toward these existing authorities in permitting the FDA to allow some breakthrough devices to rely at least partially on postmarket data collection instead of requiring all clinical or nonclinical data to be

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[195] BDP Guidance, *supra* note 4, at 18-20; *see supra* Part III.B.

[196] *See* SIMON HALLIDAY, JUDICIAL REVIEW AND COMPLIANCE WITH ADMINISTRATIVE LAW 156, 165-67 (2004); Jonas J. Monast, *Major Questions About the Major Questions Doctrine*, 68 ADMIN. L. REV. 445, 478-80 (2016).

[197] *See supra* Part III.C.

[198] 21 U.S.C. § 360l.

[199] 21 U.S.C. § 360i(a); 21 C.F.R. §§ 803.1-803.58 (2024). Hospitals and many other healthcare organizations also must report to the FDA and the device developer if they discover a device used in their institution has or could have led to serious health issues or death. 21 U.S.C. § 360i(b).

[200] 21 U.S.C. § 360i(g); 21 C.F.R. §§ 7.3, 7.40-7.59.

[201] 21 U.S.C. § 360h(a).

[202] 21 U.S.C. § 360h(e); 21 C.F.R. §§ 810.10-810.17.

[203] 21 U.S.C. § 360h(b).

generated before approval. The statute permits this push toward postmarket data collection for higher-risk devices seeking approval through the PMA pathway, to enable "expedited and efficient development and review," "when scientifically appropriate."[204] FDA guidance confirms the agency permits a shift to postmarket clinical studies for designated devices going through a PMA and enables firms to build a data development protocol with the agency that can map out how data collection will proceed both before and after market authorization.[205] Current guidance does not speak to whether or how the FDA might apply or modify reporting, recall, or other enforcement authorities to authorize breakthrough devices.[206]

Limited empirical research has evaluated the outcomes of authorized breakthrough devices over time, though recalls (including Class I recalls) for these devices have already taken place.[207] However, available work prompts at least some concerns about the long-term safety and effectiveness of breakthrough devices and the ability of the FDA to take enforcement actions once they are on the U.S. market. For instance, one study found that medical devices approved after FDA priority review—which has become a feature of the BDP—experienced recalls more often and sooner after becoming available to patients than devices undergoing ordinary review for approval.[208] Another reported that firms with breakthrough devices generally reported adverse events to the FDA faster than for other devices, *except* in the case of serious adverse events involving a patient death—where deaths from breakthrough devices were reported to the FDA late (after the 30 day period required by regulation) twice as often as for non-breakthrough devices.[209] More broadly, the Government Accountability Office, Congress's oversight agency, has previously found the FDA has struggled to effectively monitor the medical device industry and utilize its recall authority.[210]

While greater research on the BDP over time is needed, similar debates about the value of postmarket studies and the potential for FDA to meaningfully enforce them have already played out more extensively in the FDA's accelerated approval processes for drugs. The agency's Accelerated Approval Program and related pathways for pharmaceutical products have attracted concern for relaxing clinical

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[204] 21 U.S.C. § 360e–3(e)(2)(C).

[205] BDP Guidance, *supra* note 4, at 7-8, 25.

[206] *Cf. id*. (not specifying how the FDA may modify enforcement authorities for breakthrough devices).

[207] *See supra* Part IV.

[208] Caroline Ong, Vy K. Ly & Rita F. Redberg, *Comparison of Priority vs Standard US Food and Drug Administration Premarket Approval Review for High-Risk Medical Devices*, 180 JAMA INTERNAL MED. 801, 802-03 (2020).

[209] Alexander O. Everhart et al., *Late Adverse Event Reporting from Medical Device Manufacturers to the US Food and Drug Administration: Cross Sectional Study*, 338 BMJ, art. no. e081518, 4 (2025). Device firms are required to report adverse events to the FDA within 30 days. *See* 21 C.F.R. § 803.10(c)(1).

[210] U.S. GOV'T ACCOUNTABILITY OFF., MEDICAL DEVICES: FDA SHOULD ENHANCE ITS OVERSIGHT OF RECALLS 14, 24 (2011), https://www.gao.gov/assets/gao-11-468.pdf. [https://perma.cc/9WBM-6EQ2].

study expectations and shifting data collection to the postmarket setting—similar to elements of the BDP. Several studies have found that some drugs approved through accelerated pathways either fail to complete the required postmarket studies, take substantially longer than initially expected or required, continue to use modified rather than standard study designs (such as with surrogate endpoints), and occasionally fail to corroborate a drug's benefit to patients.[211] In one case, a drugmaker was three years late in completing the required postmarket clinical studies.[212] Poor results from the postmarket studies led the FDA to conclude that data did not support the effectiveness of the drug, but the firm would not voluntarily remove its product and has aggressively contested the agency's efforts to withdraw the drug.[213]

These experiences from the drug regulatory space raise further questions for the Breakthrough Device Program as implementation continues. Whether clinical studies shifted to the postmarket setting will be completed or if the FDA will have sufficient capacity to enforce study completion and take action if they reach suboptimal or poor results, remain open questions for breakthrough devices.

F. Medicare Coverage of Breakthrough Devices

Beyond FDA regulation specifically, a parallel policy conversation began following the launch of the BDP on whether and how insurance providers should cover breakthrough designated devices. Some stakeholders appeared concerned that even if a device received breakthrough designation from the FDA and moved onto U.S. markets, payors may still be hesitant to cover those devices.[214] Insurers may be averse to covering innovative devices with limited clinical data to support their utility, and the BDP enables some devices to be authorized before generating as much clinical data as might otherwise be required for FDA authorization.[215] In 2019, an Executive Order from President Trump specifically called for the Department of Health and Human Services (HHS) to reform Medicare by

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[211] Bishal Gyawali, Spencer Phillips Hey & Aaron S. Kesselheim, *Assessment of the Clinical Benefit of Cancer Drugs Receiving Accelerated Approval*, 179 JAMA INTERNAL MED. 906, 906, 910-11 (2019); Huseyin Naci, Katelyn R. Smalley & Aaron S. Kesselheim, *Characteristics of Preapproval and Postapproval Studies for Drugs Granted Accelerated Approval by the US Food And Drug Administration*, 318 JAMA 626, 626, 634-35 (2017). *See generally* Fleming, *supra* note 153 (discussing the use of surrogate endpoints in the FDA's accelerated approval process).

[212] Daniel G. Aaron, I. Glenn Cohen & Eli Y. Adashi, *The FDA Struggle to Withdraw Makena: Problems with the Accelerated Approval Process*, 328 JAMA 2394, 2394 (2022).

[213] *Id*. at 2394-95.

[214] *See* David Lim, *Industry Lobbying CMS for Speedy Medicare Coverage of Breakthrough Devices*, MEDTECH DIVE (Sept. 25, 2018), https://www.medtechdive.com/news/industry-lobbying-cms-for-speedy-medicare-coverage-of-breakthrough-devices/533142/ [https://perma.cc/4D9Z-2GXS].

[215] *See supra* Part III.C; Neha K. Prasad, et al., *FDA Breakthrough Device Designation: Clinical*
Evidence and Medicare Payment Policies, HEALTH AFF. (2024), https://www.healthaffairs.org/content/forefront/fda-breakthrough-device-designation-clinical-evidence-and-medicare-payment-policies [https://perma.cc/83K4-TCMQ].

"streamlining the approval, coverage, and coding process" for "innovative products . . . including breakthrough medical devices."[216]

In January 2021, the Centers for Medicare and Medicaid Services (CMS) finalized a rule responding to the 2019 Executive Order. The Medicare Coverage of Innovative Technology (MCIT) rule would have established a coverage pathway for automatic Medicare coverage of medical devices that first received breakthrough designation and then market authorization from the FDA.[217] Notably, the rule would enable automatic Medicare coverage for up to four years to virtually any breakthrough device otherwise eligible for Medicare coverage because they had received a breakthrough designation.[218] In September 2021, with a new Presidential Administration in office, CMS then retracted the coverage rule and began work on a revised mechanism.[219]

By August 2024, CMS announced a new coverage pathway that would continue the promise of coverage for some breakthrough devices upon gaining FDA authorization, though with more limitations.[220] In finalizing the new Transitional Coverage for Emerging Technologies (TCET) Pathway, CMS indicated it would likely only accept up to five breakthrough devices for coverage through this program.[221] Device manufacturers interested in the pathway should submit a letter of intent to CMS prior to FDA authorization that includes an Evidence Development Plan indicating how they would continue to collect data to support the utility of the breakthrough device once it enters the market, and Medicare coverage would only last until "timely generation of sufficient evidence" could occur.[222]

While the medical device industry lobbied hard for a new Medicare coverage rule after the first had been withdrawn,[223] several concerns with the potential for

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[216] Protecting and Improving Medicare for Our Seniors, Exec. Order 13890, 84 Fed. Reg. 53573 § 6(a) (Oct. 8, 2019).

[217] U.S. Ctrs. Medicare & Medicaid Servs., Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary," 86 Fed. Reg. 2987 (Jan. 14, 2021).

[218] *Id*. at 2987-88; *see* Prasad, et al., *supra* note 215.

[219] U.S. Ctrs. Medicare & Medicaid Servs., Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary," 86 Fed. Reg. 62944 (Nov. 15, 2021); *see* Lee A. Fleisher & Jonathan D. Blum, *A Vision of Medicare Coverage for New and Emerging Technologies—A Consistent Process to Foster Innovation and Promote Value*, 182 JAMA INTERNAL MED. 1241 (2022).

[220] U.S. Ctrs. Medicare & Medicaid Servs., Medicare Program; Transitional Coverage for Emerging Technologies, 89 Fed. Reg. 65724 (Aug. 12, 2024).

[221] *Id*. at 65724-25.

[222] *Id*. at 65737-38, 65746; *see* U.S. Ctrs. Medicare & Medicaid Servs., *Final Notice — Transitional Coverage for Emerging Technologies (CMS-3421-FN)* (Aug. 7, 2024), https://www.cms.gov/newsroom/fact-sheets/final-notice-transitional-coverage-emerging-technologies-cms-3421-fn [https://perma.cc/6HJS-U2A7].

[223] Lizzy Lawrence, *Medical Device Lobby Says It's Tired of Waiting on Medicare to Cover Breakthrough Devices*, STAT NEWS (Mar. 1, 2024), www.statnews.com/2024/03/01/medical-device-lobby-medicare-cms-breakthrough-fda/ [https://perma.cc/AV7S-5J65].

early insurance coverage of breakthrough devices have been raised.[224] Since at least some breakthrough devices are likely to have less evidence than otherwise may be required for FDA authorization, early coverage could result in spending Medicare funds on devices with limited or no clinical utility or even paying for harmful devices.[225] Separately, investigative journalists have reported that the medical device industry and investors have seen a significant financial boon in the Breakthrough Devices Program, at least in part due to the potential for rapid Medicare coverage.[226] The potential to gain more investments and earlier insurance coverage appears to have contributed to more medical device manufacturers seeking to use the BDP—including some that apparently withdrew their already submitted final marketing applications to the FDA just so they could apply to be in the BDP first.[227]

More recent efforts in 2025 have seen the device industry and other stakeholders advocate for greater automatic coverage for breakthrough devices based on AI.[228] Such efforts would not be as expansive as the earlier MCIT rule but would raise the same political economic concerns as above to a potentially greater set of breakthrough devices.

IV. DESCRIPTIVE ASSESSMENT OF THE BREAKTHROUGH DEVICES PROGRAM

The Breakthrough Devices Program is not a niche process at the FDA that only serves a few products. The agency claims to have awarded breakthrough designation to 1,176 different medical devices from 2016 to June 2025.[229] To better ground analyses in the subsequent sections, this Part explores how quickly the BDP has proliferated and probes trends in its use. This Article has assembled a dataset from publicly available information on the 160 medical devices which have received Breakthrough Designation from the FDA and then subsequently been authorized through the PMA, 510(k), or De Novo pathways (as of June 2025).[230]

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[224] Prasad, et al., *supra* note 215.

[225] *Id*.

[226] Katie Palmer & Mario Aguilar, *FDA's Breakthrough Device Program, Meant to Benefit Patients, Is Delivering the Biggest Gains for Companies*, STAT NEWS (Apr. 18, 2022), www.statnews.com/2022/04/18/fda-breakthrough-device-designation-investigation/ [https://perma.cc/4BHY-9K85].

[227] *Id*.

[228] *See* Katie Palmer, *For AI-Based 'Breakthrough' Medical Devices, Medicare Coverage May Become Easier*, STAT NEWS (July 30, 2025), https://www.statnews.com/2025/07/30/fda-breakthrough-ai-medical-devices-may-get-automatic-medicare-coverage/ [https://perma.cc/67J9-E25X].

[229] BDP Website, *supra* note 7.

[230] Dataset available on request with the author. Data obtained from the following website and links to other FDA databases located on the page: BDP Website, *supra* note 7; *see also Medical Device Databases*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases [https://perma.cc/2XDT-M78Z] (last visited Sept. 23, 2025) (providing a list of the FDA's medical device databases); *Recalls (Biologics)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/vaccines-blood-biologics/safety-

Data were initially collected from February to April 2025, with a subsequent round of data collection in September 2025 following a new wave of data released by the FDA. The dataset aggregates data from the FDA's list of authorized breakthrough devices, FDA databases on PMA, 510(k), and De Novo authorizations, and the agency's database on medical device recalls.

Notably, despite almost 1,200 devices being involved in the BDP, there are no publicly available records from the FDA of which products it has designated as breakthrough devices, nor which have applied for the designation, and no records of designations for STeP.[231] The only further information the agency provides about this larger pool of devices includes reporting on how many products received the designation in each fiscal year and a breakdown of the clinical specialties of those products. Table 2 illustrates that the number of breakthrough device designations has risen notably over the last decade of the program and its precursors. However, this rise may in part be due to rising application rates from industry and the Cures Act providing the FDA with limited discretion to decline applications.[232]

2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025*
11	12	19	55	110	151	206	116	145	165	136

Table 2: FDA-Reported Breakthrough Device Designations, per Fiscal Year[233]

While the FDA does not report which devices have received breakthrough designation, it does provide a list of the subset of 160 products that have received market authorization after participating in the Program (through June 30, 2025). Further information can be found by cross-referencing this list with the agency's databases on authorized devices. The data show that the number of authorized breakthrough devices is rising quickly, moving from 21 in 2022, to 31 in 2023, 44 in 2024, and 21 in just the first six months of 2025 (Figure 1).[234] In just the past three years, the FDA has authorized at least ten more breakthrough devices each

availability-biologics/recalls-biologics [https://perma.cc/PN5K-W4GH] (last visited Sept. 23, 2025) (providing a list of the FDA's biologics recalls).

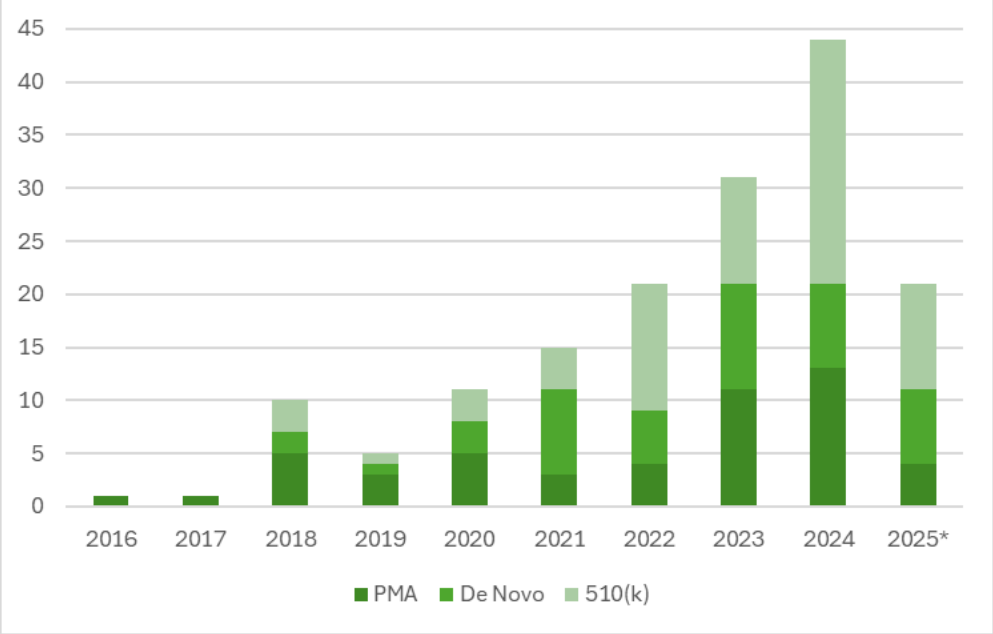
[231] Third parties have assembled partial databases of breakthrough designated devices by tracking announcements of designation from the device developers themselves (not from the FDA), but these efforts have still not accounted for the total number of devices the FDA claims to have designated. *See* Lizzy Lawrence, Katie Palmer, J. Emory Parker & Mario Aguilar, *An Authoritative Database of FDA's Fast-Tracked Medical Devices*, STAT NEWS, https://www.statnews.com/feature/stat-plus/breakthrough-device-designation-fda-tracker/ [https://perma.cc/2F4V-3HPT] (last visited Sept. 23, 2025).

[232] *See* 21 U.S.C. § 360e–3(d)(1), 357 (2024) ("[T]he Secretary *shall* designate the device" if it meets the entry criteria. (emphasis added)). I would like to thank Patricia Zettler for making this point.

[233] Where the fiscal year runs from October to September. Notably, data from the 2025 fiscal year are only available through June 30 at this time. BDP Website, *supra* note 7.

[234] An annual report from the FDA claims that 42 breakthrough devices received authorization in 2024, rather than the 44 now shown on the agency's website. *See* CTR. FOR DEVICES & RADIOLOGICAL HEALTH, ANN. REP., *supra* note 8, at 4. The reason for the discrepancy is not immediately clear.

year over the previous one. Further, the percentage of authorized breakthrough devices moving through the 510(k) pathway—generally with lower levels of regulatory review—is notably greater over the last three years, as shown in Figure 1. This could suggest the Program has become more attractive or visible to firms with lower-risk devices over time, without displacing its use by developers of higher-risk devices.



**Data from 2025 only run through June 30, not the full calendar year*

Figure 1: FDA Device Authorizations After Breakthrough Designation

The FDA does not make its justifications for granting breakthrough status clearly visible on its website for the Program, nor does it appear to publish the designation decision letters it sends to applying firms.[235] However, most (but not all) of the summary of safety and effectiveness data (SSED) documents that the agency publishes in its PMA database after it approves a Class III device contain at least some reference to the approved device's breakthrough status and when designation was granted.[236] Of the 160 authorized devices with breakthrough designation, 47 SSED documents had mention of designation. Two 510(k)- and two De Novo-authorized devices also had reference to their breakthrough status in the summary documents available in the relevant FDA databases.

Within that pool of 51 devices with summary documents mentioning

[235] *See* BDP Guidance, *supra* note 4, at 21; Nova Oculus Partners, LLC v. U.S. Food & Drug Admin., No. 20-CV-1174, 2020 WL 7230678, at *1 (D.D.C. Dec. 8, 2020) (referencing the "denial letter" the FDA sent to a firm denying its request for breakthrough status).

[236] *See* 21 C.F.R. § 814.9(f)(1) (2025).

breakthrough status, 18 of those documents provided no rationale for designation—or, they simply stated something akin to "the device meets the Breakthrough criteria" without making clear reference to the statutory criteria in question.[237] The 33 remaining documents contained some kind of justification (or, for earlier devices, entry into the Priority Review or Expedited Access Pathways).[238] However, documents typically provide curt rationales and very little, if any, substantive analysis of how the device met the statutory criteria. Some simply noted a product entered the Program for "meeting several criteria (1, 2A, 2C and 2D)."[239] Even those that provided longer rationales were in some cases vague about which criteria applied. For instance, several documents use language that make it unclear if the device met the 2A or 2C conditions, or both.[240] The documents for both De Novo products do not mention the mandatory first standard at all, only using language that appears to reference 2B. Table 3 shows the most commonly applied secondary criteria was the best interest of the patient standard, though it was used in combination with one or more other secondary criteria in all but three cases.[241]

Statutory Criteria	**n**
1. Effectiveness	26
2a. Breakthrough	13
2b. No Alternative	8
2c. Significant Advantage	14
2d. Best Interest of Patients	18

Table 3: Uses of Statutory Criteria as Rationale for Breakthrough Designation

[237] *E.g.*, U.S. FOOD & DRUG ADMIN., PREMARKET APPROVAL NO. P230014, SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED), at 1 (2024), https://www.accessdata.fda.gov/cdrh_docs/pdf23/P230014B.pdf [https://perma.cc/T2KT-C68L].

[238] These data appear largely consistent with a previous study that found only seven of the then 15 authorized breakthrough devices publicly available as of the beginning of 2020 had an accessible rationale for designation. Johnston et al., *supra* note 4, at 935.

[239] U.S. FOOD & DRUG ADMIN., PREMARKET APPROVAL NO. P230017, SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED), at 1 (2023), https://www.accessdata.fda.gov/cdrh_docs/pdf23/P230017B.pdf [https://perma.cc/T2KT-C68L].

[240] *E.g.*, U.S. FOOD & DRUG ADMIN., PMA NO. P200010, SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED), at 1 (2020), https://www.accessdata.fda.gov/cdrh_docs/pdf20/P200010B.pdf [https://perma.cc/5T59-56YJ] (finding the device "represents a breakthrough technology that provides a clinically meaningful advantage over existing legally marketed technology"). *See also* 21 U.S.C. § 360e–3(b) (2024).

[241] It should be noted that in some cases it is difficult to determine which criteria decision-makers applied, and that the EAP and Priority Review criteria applied before the Cures Act are slightly different from those of the BDP.

Further, the instances of the FDA providing a rationale for breakthrough designation in these summary documents appear to be falling over time, relative to the total number of authorized breakthrough devices in a given calendar year (Table 4). Moving beyond designation rationale, only three SSED documents noted whether or how clinical study design or other rules were modified because of participation in the Program. Only one of those three contained more than minimal detail and an indication of how designation enabled a shift toward postmarket clinical studies.[242] For the 46 products where the agency indicates the date of breakthrough designation, these data also show that devices spend an average of 3.2 years between entering the Program and receiving market authorization—with outliers spending almost nine years at the high end or only a few months at the low end.

Year	Total Devices	Devices with Rationale	Percent Devices with Rationale
2016	1	1	100
2017	1	1	100
2018	10	5	50
2019	5	2	40
2020	11	6	54.5
2021	15	2	13.3
2022	21	3	14.3
2023	31	4	12.9
2024	44	6	13.6
2025*	21	3	14.3

Table 4: Rate of FDA-Provided Designation Rationales for Authorized Devices[243]

The types of authorized breakthrough devices vary widely in their medical applications. While some incorporate emerging technologies in some capacity, others appear more to represent advances in existing techniques. These devices

[242] U.S. FOOD & DRUG ADMIN., PMA NO. P230013, SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED), at 13 (2024), https://www.accessdata.fda.gov/cdrh_docs/pdf23/P230013B.pdf [https://perma.cc/JM8V-GHJ5].

[243] Data from the 2025 fiscal year is only available through June 30 at this time.

might include new heart valve replacement systems, diagnostic kits to test for traumatic brain injuries, or artificial intelligence (AI) that evaluates radiological imaging for bone density.[244] Though not yet approved, Neuralink's brain-computer interface has clearly received designation, illustrating what further types of innovative products might enter the Program.[245] The FDA review panels or advisory committees assigned to devices also demonstrate in which medical areas products could be used (Figure 2). The largest category of authorized breakthrough devices went through a cardiovascular panel (36), followed by orthopedic (25) and neurology (22) before dropping to single digit results.

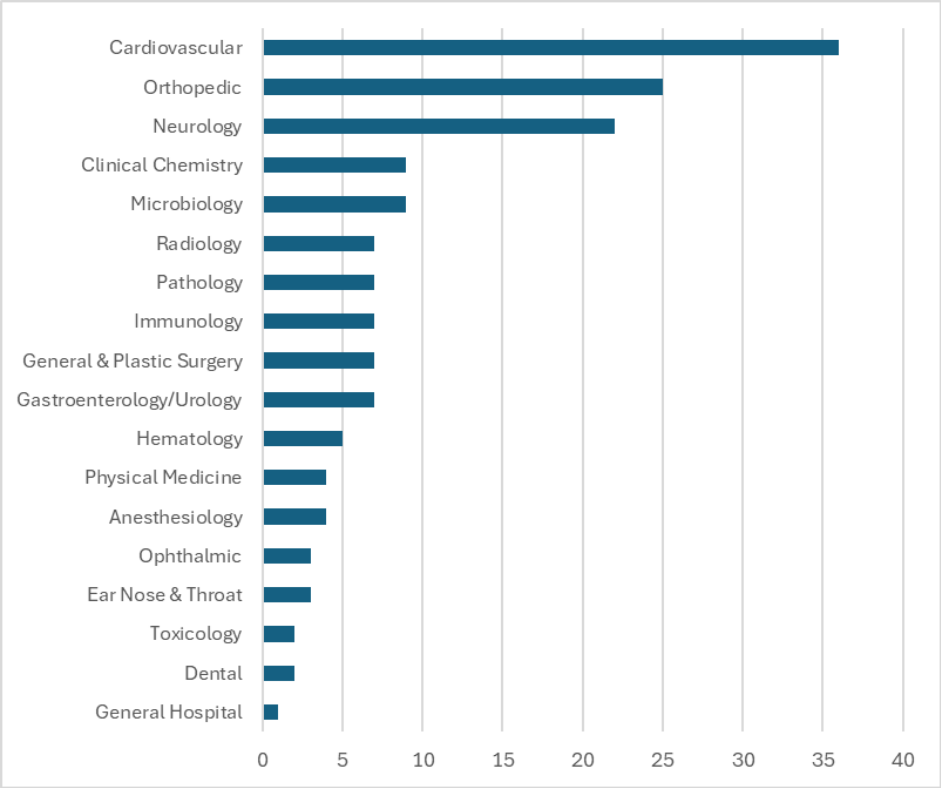


Figure 2: Authorized Breakthrough Devices by Clinical Specialty

Cross-referencing the FDA database on medical device recalls also shows that 17 of the 160 authorized breakthrough devices have been the subject of recalls (typically voluntarily initiated by the firm), as shown in Table 5. Of those 17 products, one has been subject to a Class I recall—which (confusingly, for devices)

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[244] U.S. FOOD & DRUG ADMIN., 510(K) NO. K223602, 510(K) PREMARKET NOTIFICATION,, (2023), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K223602 [https://perma.cc/HE9P-L9GE]; U.S. FOOD & DRUG ADMIN., DE NOVO NO. DEN230023, DEVICE CLASSIFICATION UNDER SECTION 513(F)(2) (DE NOVO) (2024), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN230023 [https://perma.cc/92HG-36V6]; U.S. FOOD & DRUG ADMIN., PMA NO. P230013, PREMARKET APPROVAL (PMA), (2024), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230013 [https://perma.cc/4EKD-U2M2].

[245] *See* Robbins & Brodwin, *supra* note 10.

refers to the highest-level recall scenario "in which there is a reasonable probability the device "will cause serious adverse health consequences or death."[246] The recalled breakthrough product was a cardiac implant meant to support a faulty heart valve, receiving breakthrough status after the FDA determined it met effectiveness, breakthrough, significant advantage, and best interest entry criteria.[247] However, reports emerged after the device entered the market that the approved product could break away from the catheter used to place it in the body during surgery, affecting six patients and resulting in at least one non-fatal injury.[248] The remaining 16 devices have been the subject of one or more Class II recalls, which indicate a moderate-level recall such that the device "may cause temporary or medically reversible adverse health consequences" with only a "remote" risk of more severe issues.[249]

Class I	1
Class II	16

Table 5: Breakthrough Devices Subject to a Recall

Another notable point in the dataset comes from the manufacturers who have achieved multiple authorizations with breakthrough designation. While many startups have obtained designation for their devices, the developers that have multiple authorizations after going through the BDP are primarily large, incumbent firms in the medical device space (Table 6). The top firms are Abbott and Medtronic, with other notable entrants in this list including major medical device and diagnostics firms such as Roche and Boston Scientific.

Devices	**Manufacturer**
7	Abbott
6	Medtronic
4	Carlsmed, icotec, Roche

[246] 21 C.F.R. §7.3(m)(1) (2025).

[247] U.S. FOOD & DRUG ADMIN., PREMARKET APPROVAL NO. P200046, SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED), at 1 (2021), https://www.accessdata.fda.gov/cdrh_docs/pdf20/P200046B.pdf [https://perma.cc/7ASG-HN93].

[248] U.S. FOOD & DRUG ADMIN., PMA NO. P200046, CLASS 1 DEVICE RECALL HARMONY DELIVERY CATHETER SYSTEM, (Apr. 18, 2022), www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=192430 [https://perma.cc/9HZ3-UU6Q]; U.S. FOOD & DRUG ADMIN., MEDTRONIC RECALLS HARMONY DELIVERY CATHETER, PART OF TRANSCATHETER PULMONARY VALVE (TPV) SYSTEM, FOR RISK OF CAPSULE BREAK DURING USE (Apr. 26, 2022), https://web.archive.org/web/20220426162818/https://www.fda.gov/medical-devices/medical-device-recalls/medtronic-recalls-harmony-delivery-catheter-part-transcatheter-pulmonary-valve-tpv-system-risk?utm_medium=email&utm_source=govdelivery.

[249] 21 C.F.R. §7.3(m)(2) (2025).

3	Avita Medical, Boston Scientific, Foundation Medicine, Si-Bone, W.L. Gore & Associates
2	Argentum Medical, Bonesupport, Fujirebio Diagnostics, Merit Medical System, Selux Diagnostics, Ultromics

Table 6: Firms with Multiple Authorizations After Breakthrough Designation

Overall, the Breakthrough Devices Program appears to be expanding quickly in not only its utilization, but in actually delivering new medical devices to the U.S. market. However, it is often unclear from publicly available materials why the FDA provided designation and how clinical study or other rules were modified as a result, while recalls for some authorized breakthrough devices have already begun. Further, not all fields of medicine appear to benefit equally, nor has participation been dispersed evenly across the industry. These data suggest that while use of the BDP seems to be accelerating, its positive and negative impacts could be distributed unevenly through the U.S. healthcare system.

V. BREAKTHROUGH LIABILITY

Since the Breakthrough Devices Program enables the FDA and device manufacturers to modify regulatory expectations—and at least one Class I recall and notable injury has occurred from a breakthrough device on the market—the potential for tort liability becomes a natural next legal consideration. There has long been a recognition that patients or their loved ones may have a legal interest in recovering from injuries caused by medical devices.[250]

However, the Breakthrough Devices Program interacts with existing law on tort liability preemption for medical devices in unclear and potentially troubling ways. The 21st Century Cures Act does not specify whether or how statutory or doctrinal preemption law should interact with the Breakthrough Devices Program, raising legal uncertainty.[251] At the time of writing, federal courts have not opined on whether or how the BDP may interact with preemption law either. Meanwhile, liability preemption for devices authorized through the De Novo route, with or without the BDP, remains legally unsettled.[252]

This Part analyzes the federal preemptive scheme for medical devices in the context of the BDP and the potential for liability for device manufacturers. It first explores how amendments to federal legislation that governs medical devices have failed to clarify how expedited review programs should relate to liability preemption. It then examines whether participation in the Program could establish new federal "requirements," for preemptive purposes under a *Riegel* analysis, or if

[250] *See generally* Edward M. Swartz, *Products Liability: Manufacturer's Responsibility for Defective or Negligently Designed Medical and Surgical Instruments*, 18 DEPAUL L. REV. 348 (1968).

[251] *Id. See supra* Part V.A.

[252] *Id*. *See supra* Part V.D.

it could modify current presumptions of when FDA determinations amount to "requirements." The Part then examines how the BDP interacts with the doctrinal uncertainty around whether medical devices authorized through the De Novo pathway receive liability preemption.

A. Preemption of Liability and Breakthrough Device Legislation

The Breakthrough Devices Program interacts with federal preemption law in unclear ways. This flows in large part from the 21st Century Cures Act, which does not expressly indicate whether or how liability preemption from the Food, Drug, and Cosmetic Act or Medical Device Amendments should apply to medical devices that move through the BDP.[253] Even the Act's "Rule of Construction" section, that outlines other features of FDA law and policy the BDP should be read as *not* affecting, provides no clarity on liability preemption.[254] The lack of specificity from the statute raises a degree of legal uncertainty for both breakthrough device manufacturers and patients who undergo treatment from breakthrough devices.

Notably, Congress's previous attempt to codify an expedited review pathway at the FDA for "breakthrough" medical devices undergoing a PMA, in the 1997 Food and Drug Modernization Act, also made no reference to liability preemption.[255] It is unclear from legislative text alone whether Congress clearly intended for either of these expedited review pathways (the BDP or 1997 precursor) for devices to change, or not change, liability preemption. The silence on liability preemption is striking, especially since both the 1997 and 2016 statutes amend the Medical Device Amendments, from which the express preemption provision originates. [256] The express preemption provision in the Medical Device Amendments itself, though, also contains no explicit rationale about why preemption should occur, providing little guidance.[257] Nor has the FDA amended or proposed to amend its codified regulations on preemption for medical devices, which implements the statute's preemption provision.[258]

The absence of textual guidance in legislation or regulation would appear to leave courts with the interpretive task of clarifying the relationship between the BDP and preemption. At present, though, neither the Supreme Court nor lower federal courts have directly opined on how federal preemption law may apply to or interact with the Breakthrough Devices Program. Nor does it appear that litigation has yet been filed that directly raises such questions.

In the absence of clear statutory text, current doctrinal law from the Supreme Court suggests that breakthrough devices would continue to receive preemptive

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[253] *C.f.*, 21 U.S.C. § 360e–3(a)–(g) (2024) (establishing and structuring the BDP, but without addressing preemption).

[254] 21 U.S.C. § 360e-3(g).

[255] *See* Pub. L. 105-115, 111 Stat. 2296, § 202 (1997); *see also supra* Part III.A.

[256] 21 U.S.C. § 360k(a)(1) (2024).

[257] 21 U.S.C. § 360k (2024).

[258] *See* 21 C.F.R. § 808 (2024).

immunity if they ultimately go through the PMA, but not for the 510(k) pathway to market. Both *Lohr* and *Riegel* place great legal importance on whether the ultimate authorization decision by the FDA imposes binding and specific "requirements" on the device.[259] The Breakthrough Devices Program, however, is not a final, binding authorization decision. It is a largely voluntary program in which manufacturers may participate if they apply and are granted entry.[260] Manufacturers *can only* participate in the Program prior to submitting their final application for market authorization, which must occur through the PMA, 510(k), or De Novo pathways.[261]

The emphasis of the *Riegel* Court on preemption flowing from binding conditions placed on specific medical devices as a part of a PMA final decision suggests that participation in the voluntary BDP would have no meaningful effect on liability preemption.[262] If the FDA imposes federal "requirements" on medical devices whenever they undergo premarket approval,[263] then participation in the BDP prior to the FDA's approval decision would appear to have no legal effect on these "requirements" for preemptive purposes. Even if clinical trial protocols deviate from normal practices as a part of the Program,[264] if the FDA approves the device, then it stands to reason that it would continue to receive immunity from many state-level tort law causes of action.

On the 510(k), preemption doctrine for devices subject to this type of clearance also appears unaltered by the BDP. The 510(k) on its own does not impose federal "requirements,"[265] and the BDP is a voluntary program, so it would appear that tort law liability remains possible for these devices. Notably, an increasing number of devices moving through the BDP appear to be using the 510(k) pathway, so significant litigation remains possible for at least some low-to-moderate risk breakthrough devices.[266]

B. Does the BDP Create New Preemptive "Requirements"?

Even assuming that the BDP does not directly modify preemption doctrine for PMA or 510(k) authorized devices, it could still be asked if the Program could create new "requirements" that may generate a new determination of preemption. If the BDP could produce unique requirements, it could lend new preemptive immunity to manufacturers of breakthrough devices authorized via the 510(k) or De Novo pathways.

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[259] Riegel v. Medtronic, Inc., 552 U.S. 312, 322-23 (2008); Medtronic Inc. v. Lohr, 518 U.S. 470, 487, 493-94 (1996); *see* 21 U.S.C. 360k(a)(1) (2024).

[260] 21 U.S.C. § 360e–3(c) (2024); BDP Guidance, *supra* note 4, at 4.

[261] 21 U.S.C. 360k(a)(1) (2024).

[262] *See* 552 U.S. 312, 322-23 (2008).

[263] *Id*.

[264] *See supra* Part III.C.

[265] Medtronic Inc. v. Lohr, 518 U.S. 470, 493-95 (1996).

[266] *See supra* Part IV.

Of course, a device manufacturer's choice to apply to the Program is voluntary.[267] However, as a part of the BDP, device developers can also request Clinical Protocol Agreements with the FDA that the agency "will consider binding" on both itself and the developer.[268] Again, firms with breakthrough devices that will go through the PMA are also eligible to shift clinical data collection into the postmarket setting.[269] Neither the Cures Act nor the FDA guidance is clear about whether the Clinical Protocol Agreements should be considered binding only in the premarket setting, or will also be considered binding if the protocol extends to data collection after the device receives initial approval. Nor would these agreements appear to result in any codified regulation from the FDA.

The presence of "binding" Clinical Protocol Agreements that apply in the postmarket setting could potentially be considered federal "requirements" for preemptive purposes—since it could be read as imposing "requirements specific to the device in question."[270] Were courts to recognize Clinical Protocol Agreements with protocols that extend studies into the postmarket setting as providing device-specific requirements for breakthrough devices, this could further support the determination that breakthrough devices that go through the PMA will continue to receive significant tort liability preemption.

However, only devices going through the PMA are eligible for shifting clinical data collection to the postmarket setting under the BDP (not for the 510(k) or De Novo pathways).[271] Therefore, this potential for new requirements likely only applies to breakthrough devices receiving approval through the PMA, and thus likely does not alter the overall scheme that a PMA provides liability preemption while the 510(k) does not. Since these "binding" agreements likely do not extend to De Novo devices in the postmarket setting, they also do not clarify the question of whether the De Novo pathway provides preemption at all.

C. Does the BDP Enable Tort Law Claims in New Ways?

The mirror question from the previous section could also be asked: could the BDP enable plaintiffs to overcome preemption in new ways? Could a device's participation in the BDP modify which FDA determinations courts will understand as "requirements" for preemption purposes, or add new rationales for permitting "parallel" claims? Ultimately, however, this looks unlikely.

For example, creative plaintiffs could potentially assert novel theories associated with the BDP in an attempt to circumvent preemption for breakthrough devices that receive a PMA. Participation in the BDP can alter and arguably lower

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[267] 21 U.S.C. § 360e–3(c) (2024) (providing that "[a] sponsor of a device *may* request that the Secretary designate such device" as a breakthrough (emphasis added)); *see* BDP Guidance, *supra* note 4, at 4.

[268] 21 U.S.C. § 360e–3(e)(2)(D); BDP Guidance, *supra* note 4, at 25.

[269] 21 U.S.C. § 360e–3(e)(2)(C).

[270] Riegel v. Medtronic, Inc., 552 U.S. 312, 322 (2008).

[271] *See* 21 U.S.C. § 360e–3(e)(2)(C) (indicating only devices going through the PMA are eligible for postmarket data collection through the BDP).

the typical standards of clinical studies and other inputs required for a PMA and has the statutory purpose of accelerating access to devices, without clear reference to safety or effectiveness.[272] On this basis, plaintiffs could assert that premarket approval for a breakthrough device does not create the same type or quality of "requirements" as a normal PMA. This or other untested theories could raise the potential for future litigation, and reduce predictability for device developers.

However, based on the primary logic of *Riegel*, these types of theories appear unlikely to prevail. The *Riegel* Court does not analyze the quality of the FDA "requirements" imposed on approved devices, but appears to simply presume that any PMA involves rigorous review that generates such requirements.[273] This doctrinal logic suggests that even lowering clinical trial expectations as a part of the BDP would not affect determinations that a PMA nonetheless enables tort liability preemption.

Plaintiffs could also seek to use a device's breakthrough status to invoke the "parallel" claims exception to preemption that both the *Riegel* and *Lohr* Courts allow. Both opinions leave open the possibility that state legislative or common law tort claims like negligence can survive preemption when they provide "parallel" requirements (rather than being "different from, or in addition to" federal requirements).[274] Dicta from *Lohr* suggests that these parallel state-level claims may need to focus more on providing novel remedies even if the claim "might be 'different from' the federal rules in a literal sense."[275] However, the Supreme Court has not provided guidance on how parallel requirements for devices should be understood separately from "different" or "additional" ones. Presumably, escaping preemption would also require persuading courts that Congress did not intend to preempt the type of rule or remedy contained in a "parallel" requirement.[276] It would also appear to require avoiding implied preemption under a *Buckman* analysis, so plaintiffs would need to establish their claims are distinguishable from the standards contained in the FDA's device legislation.[277]

Nonetheless, patients have struggled to invoke the parallel claims exception in previous litigation over devices approved through a PMA (without the BDP).[278]

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[272] *See* 21 U.S.C. § 360e–3(a) (2024); *see supra* Parts II.A, II.C.

[273] *Riegel*, 552 U.S. at 322-23 (2008).

[274] *Id.* at 330; Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996).

[275] *Lohr*, 518 U.S. 470, 495 (1996). Justice Stevens, for the majority, writes that "[t]he presence of a damages remedy does not amount to the additional or different 'requirement' that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law." *Id*.

[276] *E.g.*, Arizona v. United States, 567 U.S. 387, 399 (2012); *see Riegel*, 552 U.S. at 330 (2008) (indicating the possibility the possibility of "parallel" tort claims surviving preemption).

[277] Buckman v. Plaintiffs' Legal Committee, 531 U.S. 341, 347-48 (2001).

[278] *See, e.g.*, Frank-Jackson, *supra* note 84, at 484 (discussing how plaintiffs have faced significant obstacles invoking the "parallel claims" exception following Riegel v. Medtronic, particularly for devices approved through the PMA process); Robert L. Rabin & Alyssa J. Picard, *Reassessing the Regulation of High-Risk Medical Device Cases*, 68 DEPAUL L. REV. 309, 323-25 (2019).

The BDP could offer a new setting or justification for permitting these parallel claims. Yet, the legislative and regulatory features of the program itself do not appear to provide new pathways through the deeply unclear doctrinal framework for advancing a parallel claim.[279] Success with parallel claims may require courts to entertain new theories regarding parallel claims as a whole, given the difficulties plaintiffs have experienced in advancing these claims historically.

Common law claims that device manufacturers misrepresented information about their device in order to obtain breakthrough status or FDA agreements on modified or lightened clinical trial protocols would also likely be conflict preempted under the logic of *Buckman*. While this type misrepresentation has already been alleged as part of the BDP, courts have not yet opined on the adequacy of tort claims related to them.[280] The FDA retains the statutory authority to modify any clinical trial protocols it agreed to if it discovers "a substantial scientific issue essential to determining the safety or effectiveness."[281] In its most recent final guidance, the agency also indicates that it reserves the authority to withdraw breakthrough designation if "information submitted in support of a request . . . contained an untrue statement of material fact or omitted material information."[282] The *Buckman* analysis, that conflict preemption can occur where tort law claims would mirror FDA device statutes and the FDA retains the authority to enforce those statutes,[283] would likely then extend to tort law claims related to entry into and certain regulatory features of the Breakthrough Devices Program.

VI. REBALANCING INNOVATION AND SAFETY

The Breakthrough Devices Program joins a long line of initiatives and reforms in U.S. medical device policy aimed at achieving two different and, at times, contrasting policy goals: safety and innovation.[284] Safety and effectiveness, of course, remain the preeminent statutory goal of the FDA on medical devices. Yet, Congress has also directed the FDA to promote innovation in devices and patient access to those innovation devices through several initiatives, most recently including the Breakthrough Devices Program itself.[285] Especially when considering the potential benefits but uncertain risks of incorporating emerging technologies

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[279] *See supra* Parts II.A, II.C.

[280] *See* Hennrick v. miR Scientific, LLC, No. 21-CV-4945, 2021 WL 6052118, 1-2 (S.D.N.Y. Dec. 21, 2021).

[281] 21 U.S.C. § 360e–3(e)(2)(D)(ii) (2024).

[282] BDP Guidance, *supra* note 4, at 22.

[283] Buckman v. Plaintiffs' Legal Committee, 531 U.S. 341, 347-51 (2001).

[284] *See, e.g.*, U.S. INST. OF MED., *supra* note 122 (discussing the historical tension in U.S. medical device policy between promoting innovation and safety); Walter G. Johnson, *A Balancing Act: Safety, Innovation, and Resources in the Implementation of Medical Device Legislation*, 12 J. SCI. POL'Y & GOVERNANCE (2018); Matthew Perrone, *At FDA, A New Goal, Then A Push for Speedy Device Reviews*, AP (Nov. 27, 2018), https://apnews.com/article/health-north-america-us-news-ap-top-news-implant-files-9f8ea03a4d324d1ba5585680d280804b [https://perma.cc/233R-9CR3].

[285] 21 U.S.C. § 360e-3(a) (2024).

into medical products,[286] device policy faces difficult tradeoffs between maximizing premarket checks on the safety of products and enabling rapid access to new interventions that could prove therapeutically useful.

The Breakthrough Devices Program clearly aims at resolving this tension in new ways by providing medical device manufacturers with new types of flexibility while still formally declining to reform the three primary pathways to market (PMA, 510(k), De Novo).[287] Yet, the analyses above raise concerns that the Program may move too far toward promoting innovation at the potential expense of securing patient safety and public health.

These analyses paint a portrait of the Breakthrough Devices Program that potentially erodes standards and pressures for patient safety in both the premarket and postmarket settings. Especially for PMA approved breakthrough devices, these devices may have to clear lower barriers demonstrating safety or effectiveness before receiving FDA approval, yet continue to receive immunity from tort liability through federal preemption.[288] Innovative device developers may, then, receive both *ex ante* regulatory flexibility and *ex post* liability protections, which may weave together to diminish both regulatory and self-regulatory levers for promoting safe and effective breakthrough devices. While the Program may facilitate innovation, which the growing number of authorized breakthrough devices may indicate to an extent, there are real concerns that it may do so at the potential or real expense of patient safety, public health, or clinical utility of devices.[289]

Of course, only one nonfatal but significant injury from a breakthrough device has been reported in a Class I recall as of early 2025.[290] Yet, the growing number of authorized breakthrough devices and limited transparency about the kinds of regulatory relief provided should elevate concerns that further, future injuries could be approaching.[291] These trends together suggest that while drastic reform may not yet be necessary, some degree of targeted reform is normatively desirable now and greater scrutiny and oversight of the BDP is warranted moving forward.

This Part argues that both liability reform and regulatory reform are warranted to rebalance innovation and safety within the Breakthrough Devices Program. It argues for and charts legal mechanisms to achieve (1) loosening the federal preemption of tort liability, at least for breakthrough devices that have received FDA authorization, (2) increasing regulatory supervision of breakthrough devices during the Program, and (3) boosting FDA surveillance of and postmarket enforcement for breakthrough devices following their authorization. In arguing for these reforms, this Part brings together the previous discussions of federal

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[286] *See generally* Genus & Stirling, *supra* note 15, 63-64 (analyzing how limited knowledge at early stages and entrenched technologies later on create the "Collingridge dilemma," complicating efforts to govern emerging innovations responsibly).

[287] *Supra* Part III.B.

[288] *See supra* Parts I, IV.

[289] *See supra* Part IV.

[290] *Id*.

[291] *Id*.

preemption of tort liability for breakthrough devices, the BDP's legislative and regulatory scheme, and the empirical data on its operations thus far.

A. Loosen Liability Preemption for Breakthrough Devices

Loosening preemption for tort liability from which breakthrough devices could benefit offers a simple, effective path to rebalancing safety and innovation. This solution would not require modifying the substance of the Breakthrough Devices Program, nor would it impede the ability of the FDA and device manufacturers to work together to find expedited pathways through regulatory review for innovative devices. While not impeding innovation goals, it would also enable patients to recover for injuries caused by those innovative devices. This would have the dual purposes of making plaintiffs whole following injury while also incentivizing device manufacturers to deploy meaningful self-regulation following FDA authorization in efforts to avoid liability. Loosening liability preemption for breakthrough devices could thus facilitate greater public health and individual patient recovery without significantly interfering with the BDP and Congress's goal of using it to boost innovation in medical devices.

Liability preemption could be loosened in at least three ways. First, perhaps the most straightforward would be for Congress to amend the Medical Device Amendments or Cures Act to specify whether and how preemption of liability should occur for authorized breakthrough devices. In the last several years, Lawmakers in Congress have even been debating a potential Cures 2.0 Act to follow up and further expand on the 2016 21st Century Cures Act.[292] This type of legislation could offer a vehicle for reforming and clarifying liability preemption for the BDP. However, lawmaker and stakeholder discussion over the Cures 2.0 Act has been ongoing for several years now, especially with the broad range of issues it would address, and the most recent full draft introduced in Congress had no mention of liability for the BDP.[293] While legally straightforward, the legislative path could become politically challenging. Nonetheless, this article argues that Congress should take an opportunity such as a Cures 2.0 to legislate on liability preemption for breakthrough devices, as the legislative path would provide the most clarity and certainty for both patients and device developers. Legislation should recognize that patient harms have already occurred from breakthrough devices, though not in such high numbers as to question the overall merit of the BDP.[294]

An elegant path to rebalancing safety and innovation would be to temporarily remove preemptive protections for eligible breakthrough devices once they are approved through a PMA but then enable liability preemption to return once the FDA is satisfied that all postmarket clinical studies have been completed at a sufficient level of quality. Legislation should clarify that 510(k) cleared breakthrough devices continue to receive no liability immunity from federal preemption at any time. This article also joins others in calling for Congress to

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[292] Cures 2.0 Act, H.R.6000, 117th Cong. (2021).

[293] *Id*.

[294] *See supra* Part IV.

clarify that De Novo authorized devices should not receive liability preemption[295] and further argues that legislation should specify that this absence of immunity continues even if the De Novo device received a breakthrough designation.

This kind of temporary preemption waiver would achieve multiple goals at once. It would directly incentivize device manufacturers to complete all postmarket clinical studies by attaching their completion to the tangible benefit of liability protection, addressing issues in drug regulation where postmarket studies are often not completed.[296] It would enable patients greater access to justice and legal remedies should they be harmed by breakthrough devices which have undergone expedited review, enabling patients to be made whole alongside promoting innovation as a policy goal. Such an arrangement could also incentivize breakthrough device developers to take greater measures to use their internal systems and controls to manage risk through self-regulation. It would further enable the FDA to take actions such as modifying the conditions of approval or triggering recall authorities should the postmarket studies return unclear or poor results.[297] A temporary mechanism may also provide politically more palatable than completely removing liability preemption for breakthrough devices.

Second, should Congress choose not to or fail to enact legislation, courts could also work to recognize parallel claims for breakthrough devices. Of course, based on the analysis above, this appears to be a difficult path for medical devices in general and the involvement of the BDP does not appear to significantly alter that legal calculus.[298] Ultimately, courts should prioritize developing new doctrinal frameworks for clarifying how "parallel" claims can survive preemption for medical device litigation. The significant confusion around applying the doctrine already calls for clarification, but also the Program provides new grounds and urgency for making these types of clarifications. Further doctrinal work will be required here to develop a comprehensive framework for parallel claims, yet courts seem to be reticent to develop doctrine in this area,[299] which signals this pathway to reform may be unlikely.

If litigated, courts should also find that the De Novo pathway does not provide federal preemption for tort liability. This both appears to be the most appropriate interpretation of current legislation for devices in general,[300] and it also would support the policy goal of rebalancing safety and innovation for the BDP in particular. With more breakthrough devices moving through the De Novo over time,[301] courts clarifying that these devices are still subject to liability could prompt

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[295] *See* Simon, Shachar & Cohen, *supra* note 85, at 137; Gerke & Simon, *supra* note 117, at 1140.

[296] *See* Gyawali, Hey & Kesselheim, *supra* note 211, at 906, 910-11; Naci, Smalley & Kesselheim, *supra* note 211, at 626, 634-35.

[297] *See supra* Part III.E.

[298] *See supra* Part V.

[299] *See* Frank-Jackson, *supra* note 84, at 484.

[300] *See* Simon, Shachar & Cohen, *supra* note 85, at 138-41; *see supra* Parts I.C, I.D.

[301] *See supra* Part IV.

stronger incentives for device developers to engage in self-regulation of risks for this potentially growing category of authorized products while still allowing those devices to go to market and enabling access to their potential benefits.

Third, as a final option, the FDA itself could also consider using its authority under the Medical Device Amendments to exempt individual states or localities from federal preemption of tort liability for breakthrough devices.[302] This option offers a less robust solution, as it would appear to require each individual state to apply—and the FDA to individually review and approve—for exemption to preemption for certain state-level tort law causes of action with regards to the BDP. These applications would likely take notable time and resources for both the state and the agency, and state policymakers would need to become aware of this option and prioritize preparing such applications. This route could also have an undesirable patchwork result. Different patients could receive different levels of legal remedy in tort law based on factors such as whether their state has applied for, and received an exemption, or if the substance of different state exemptions differs.

B. Greater FDA Supervision During and After the BDP

Loosening liability preemption may be challenging and time intensive for several of the reasons described above. However, breakthrough devices have already caused some patient harm and may cause further injuries given the accelerating rate of authorization for these innovative devices.[303] While loosening liability preemption remains a worthy goal for legal reform, other reforms to the Breakthrough Devices Program and the FDA's implementation of the initiative could also support realigning safety and innovation policy priorities.

The FDA should take steps to increase regulatory supervision and postmarket oversight of breakthrough devices during and after the BDP, respectively. Especially for breakthrough devices that use new technologies with uncertain risk-benefit profiles, promoting public health and safety will benefit from heightened FDA scrutiny of breakthrough devices during the Program and willingness to take enforcement actions including withdrawing breakthrough designation. Greater surveillance after breakthrough devices receive authorization, and taking enforcement actions if significant adverse events arise, will help achieve safety outcomes as well. This is especially true for breakthrough devices approved through the PMA that had some of their clinical trials deferred to the postmarket setting, as well as for 510(k) and De Novo authorized breakthrough devices that often have little to no clinical data at the time of authorization.

Importantly, the FDA already has sufficient statutory authority to do so in both the premarket and postmarket settings. The agency's postmarket surveillance and enforcement tools are well established in legislation and regulation and continue to apply to breakthrough devices equally to other devices.[304] Even standard

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[302] 21 U.S.C. § 360k(b) (2025); 21 C.F.R. § 808 (2025).

[303] *See supra* Part IV.

[304] *See supra* Part III.E.

randomized control trials may fail to detect low probability risks or risks uncommon to the trial population,[305] so the FDA's established postmarket regulation provides an important toolkit for overseeing breakthrough devices as they begin to be used by more and more patient populations following authorization.

Prior to market authorization, the FDA should maintain a high level of scrutiny of applications for breakthrough status and all communications and submissions of data during the BDP—backed up by the potential to withdraw designation from a device and eject it from the Breakthrough Devices Program. Early signs during the Program that a breakthrough device may lack safety or effectiveness should trigger further scrutiny or even withdrawal of breakthrough designation, as early enforcement actions will ultimately serve to promote safety and public health. Moreover, available case law already suggests it is possible that some manufacturers could submit fraudulent data to the FDA to secure breakthrough status.[306] The willingness to use withdrawal in serious cases will be important to communicate to the regulated industry the seriousness of complying with all valid agency requests within the scope of the BDP.[307] FDA enforcement or withdrawal will also be important since a *Buckman* analysis will likely prevent plaintiffs from using tort law to enforce a device manufacturer's alleged deceit or fraud on the FDA in order to gain breakthrough designation or other benefits within the BDP such as a Clinical Protocol Agreement or Data Development Plan.[308] Under *Buckman*, it will likely lie to the FDA itself to take enforcement actions during the Program.[309]

If litigated, courts should affirm the FDA's legal authority to withdraw breakthrough designation and remove device manufacturers from the Program as well.[310] The Cures Act was unfortunately not clear about the conditions under which the FDA could remove breakthrough status, although the agency has provided a reasonable and well-tailored approach to withdrawal.[311] Those withdrawal conditions the agency has identified include if a device no longer would qualify for the statutory eligibility criteria—such as if a device no longer appears to provide "significant advantages" over existing alternatives—or if manufacturers

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[305] *See* NAT'L ACAD. SCI. ENG'G & MED., IMPROVING REPRESENTATION IN CLINICAL TRIALS AND RESEARCH: BUILDING RESEARCH EQUITY FOR WOMEN AND UNDERREPRESENTED GROUPS 23-25 (Kirsten Bibbins-Domingo and Alex Helman eds.2022); Jesse A. Berlin, Susan C. Glasser & Susan S. Ellenberg, *Adverse Event Detection in Drug Development: Recommendations and Obligations Beyond Phase 3*, 98 AM. J. PUB. HEALTH 1366, 1366, 1367 (2008).

[306] *See* Hennrick v. miR Scientific, LLC, No. 21-CV-4945, 2021 WL 6052118, at *1–2 (S.D.N.Y. Dec. 21, 2021); *See supra* Part III.D.

[307] *See generally* IAN AYRES & JOHN BRAITHWAITE, RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE 19 (1992).

[308] *See* Buckman v. Plaintiffs' Legal Committee, 531 U.S. 341, 347-48 (2001); *See supra* Parts I.C, IV.C., II.C.

[309] Buckman, 531 U.S. at 347-49.

[310] On the legal dimensions of the agency's withdrawal authority, *see supra* Part III.D.

[311] *Id*.

have provided false or misleading information to obtain designation.[312] These conditions are tightly connected to the authorizing statute itself by grounding withdrawal in the statutory eligibility criteria, as well as fraud, which offers a clear rationale for administrative action.[313] The clear connection of the FDA guidance on withdrawal to legislative provisions should make it clear to courts that the agency has interpreted its statutory authority properly. Even under the current doctrine from *Loper Bright*, courts can still consider agency interpretations of statutes as persuasive, even if they must go on to conduct their own independent analysis.[314] Courts do not need to defer to the FDA's interpretation to be persuaded by its reasonable reading of breakthrough withdrawal authority under the Cures Act.

Of course, the FDA may experience political difficulties in increasing supervision of breakthrough devices during or after the BDP. Industry actors will likely contest greater interventions, perhaps criticizing the potential for imposing higher compliance costs on smaller- and medium-sized start-ups. Of course, many large device manufacturers are benefiting significantly from the BDP—this article found that most of the firms that have received more than one FDA authorization for a breakthrough device are large, incumbent firms in the industry.[315] Policymakers should therefore be skeptical of actors using these types of appeals to argue for never raising scrutiny on breakthrough devices during or after the Program.

Raising regulatory supervision of breakthrough devices will also require significant resources at the FDA, including budgetary and personnel resources. Especially since breakthrough devices may be innovative and use new technologies, recruiting and maintaining staff at the agency with expertise in new techniques such as AI or neurotechnologies becomes an important condition of appropriate regulatory supervision.[316]

Ideally, Congress should appropriate more funding to the FDA for the express purpose of increasing supervision of the BDP and retaining experts on staff who can contribute to good regulation of devices using emerging technologies. Yet, requests for more funding for an agency are politically challenging any year and may be difficult as this Congress looks to cut current spending in various ways.[317]

Lawmakers should alternatively consider adding new industry "user fees" for

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[312] BDP Guidance, *supra* note 4, at 15, 21-22.

[313] 21 U.S.C. § 360e–3(b) (2024); *see generally* 21 U.S.C. § 331–34; *Buckman*, 531 U.S. at 347-51.

[314] Loper Bright Enter. v. Raimondo, 603 U.S. 369, 402, 412 (2024); Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944).

[315] *Supra* Part III, at Table 6.

[316] *See* BDP Guidance, *supra* note 4, at 13.

[317] *E.g.*, Ahmed Aboulenein & Mariam E Sunny, *Trump Administration Proposes Cutting FDA Budget by 5.5%*, REUTERS (May 22, 2025), www.reuters.com/business/healthcare-pharmaceuticals/trump-proposing-68-bln-budget-us-fda-commissioner-says-2025-05-22/ [https://perma.cc/KSC4-GEW3]; Scott Neuman & Lexie Schapitl, *Congress Rolls Back $9 Billion in Public Media Funding and Foreign Aid*, NPR (July 18, 2025), https://www.npr.org/2025/07/18/nx-s1-5469912/npr-congress-rescission-funding-trump [https://perma.cc/QJ7C-D885].

breakthrough devices to increase FDA resources dedicated to the BDP. Congress has empowered the FDA to collect fees from the device industry when they submit market authorization applications, and the user fee schedules and expectations attached to them are renegotiated and reauthorized by Congress every five years.[318] The most recent user fee agreements for devices were reauthorized in 2022 but had no explicit mention of fees for the Breakthrough Devices Program.[319] Lawmakers and stakeholders should strongly consider attaching new user fees for industry submissions for a breakthrough device designation during the upcoming negotiations on the 2027 reauthorization of device user fees. User fees for breakthrough device submissions would provide a valuable new funding stream to increase FDA resources for overseeing the Program and would not require directly appropriating taxpayer funds. Adding user fees for breakthrough device applications may also assist in counteracting the heavy political economic incentives that appear to be leading the device industry to overuse the Program.[320] User fees for breakthrough device submissions could also be reduced for small businesses to ensure regulatory fairness and minimize the costs on potentially innovative startup firms developing breakthrough devices.[321]

Were Congress to amend the substance of the BDP through legislation such as the Cures Act 2.0,[322] lawmakers should also consider other policy options for ensuring the FDA has sufficient capacity to supervise breakthrough devices during and after the BDP. In particular, lawmakers should consider granting the FDA more authority to reject applications for breakthrough status or even consider capping the number of devices that can be within the Program at any given time. Regulators with other types of expedited or flexible review programs have recently used this "cohort" model to limit the number of regulated actors that require supervision,[323] which may be of particular value for improving the quality of supervision and learning in the BDP. To ensure the FDA is not overwhelmed by too many breakthrough devices to supervise in the Program, Congress should also strongly consider undoing the CMS rule that provides for automatic, temporary coverage of several breakthrough devices per year after they are authorized.[324] This program

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[318] 21 U.S.C. § 379j, 379j–1 (2024); *see* U.S. FOOD & DRUG ADMIN., MEDICAL DEVICE USER FEE AMENDMENTS (MDUFA) (last visited Oct. 3, 2024), www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa [https://perma.cc/8HYP-T6N4].

[319] *See* FDA User Fee Reauthorization Act of 2022, Pub. L. No. 117-180, 136 Stat. 2139 (2022).

[320] *See supra* Part III.F.

[321] User fees for small businesses are already discounted in the current fee schedule. *See* 21 U.S.C. § 379j(a)(3)(B)(ii), 379j(d)–(e); U.S. FOOD & DRUG ADMIN., *supra* note 318 (indicating the FDA may waive user fees for small businesses "who demonstrate that paying the fee represents financial hardship as determined by the FDA").

[322] *See* Cures 2.0 Act, H.R.6000, 117th Cong. (2021); *supra* Part VI.A.

[323] *See, e.g.*, U.K. FIN. CONDUCT AUTH., REGULATORY SANDBOXES LESSONS LEARNED REPORT, at 4 (2017), https://www.fca.org.uk/publication/research-and-data/regulatory-sandbox-lessons-learned-report.pdf [https://perma.cc/2QBH-Q5ND] (describing the cohort model for this regulatory sandbox).

[324] *Supra* Part III.F.

creates very strong incentives for device manufacturers to apply for breakthrough designation that could easily contribute to overwhelming FDA staff managing the BDP.[325]

Complicating this reality, the second Trump Administration has set out to reduce the size of the federal workforce, including through several rounds of terminations and incentives for resigning at the FDA and HHS.[326] Staffing reductions have affected CDRH, the medical device division within the FDA, and may be resulting in remaining staff juggling too many tasks or the agency missing statutory deadlines for reviewing market authorization applications for devices.[327] Such aggressive staffing reductions raise further questions about whether the FDA will have the resources needed to supervise during the BDP and monitor postmarket clinical studies for breakthrough devices, or take enforcement actions as needed.

VII. CONCLUSION

Policymakers seeking to promote innovation should not combine expedited regulatory review with liability immunity. Either legal approach can serve to advance technological breakthroughs in their own ways, but together they threaten to sacrifice safety and public health in the pursuit of innovation. While reduced *ex ante* regulation can provide flexibility to regulated actors experimenting with novel products and technologies and *ex post* liability immunity offers certainty to those developers, both together provide patients or consumers with fewer protections against the risks that innovation also produces. Fusing both policies shifts an unacceptable amount of risk away from product developers and onto patients and consumers.

The FDA's Breakthrough Devices Program has offered an instructive case study into these legal dynamics. The BDP offers multiple types of regulatory relief and benefits to developers of eligible innovative medical devices, such as surgically implanted brain-computer interfaces that may enable new forms of treatment for patients with paralysis.[328] These regulatory benefits include potentially modifying clinical study expectations and deferring some (otherwise required) clinical data collection for higher-risk devices to the postmarket setting.[329] Some patients have already been injured by breakthrough devices, though federal preemption law will likely prevent many types of recovery for those patients or others who may be

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[325] *See* Palmer & Aguilar, *supra* note 226 ("Submissions for breakthrough status surged from about 250 in 2019 to nearly 400 in 2020.")

[326] *See* Exec. Order No. 14210, 90 Fed. Reg. 9669 (2025); Christina & Mueller, *supra* note 33; Sheryl Gay Stolberg, Christina Jewett & Apoorva Mandavilli, *Mass Layoffs Hit Health Agencies That Track Disease and Regulate Food*, N.Y. TIMES (Apr. 1, 2025), https://www.nytimes.com/2025/04/01/us/politics/trump-federal-layoffs-health-food.html [https://perma.cc/3J8Y-X8JB].

[327] *See* Patrick Wingrove, *Exclusive: FDA Staff Struggle to Meet Product Review Deadlines After DOGE Layoffs*, REUTERS (Mar. 27, 2025), https://www.reuters.com/business/healthcare-pharmaceuticals/fda-staff-struggle-meet-product-review-deadlines-after-doge-layoffs-2025-03-27/ [https://perma.cc/MPZ9-PNFQ].

[328] *See supra* Part III.C; Chaudhary et al., *supra* note 11, at 513.

[329] *See supra* Part III.

harmed by high-risk breakthrough devices that have received approval through the PMA pathway.[330] Courts may begin to immunize novel, moderate-risk medical devices from some tort liability as well—when authorized through the FDA's De Novo pathway—which would extend protections to a greater swath of these breakthrough devices.[331] The potential use of emerging technologies in breakthrough devices creates extra reason for concern, as regulators, developers, and other stakeholders may not have enough information on their risks. Yet, they will continue to receive at least some liability immunity following expedited regulatory review if those devices receive certain kinds of authorization from the FDA.

More broadly, the Breakthrough Devices Program illustrates how approval regulation struggles to make tradeoffs between policy goals of safety and innovation and how to allocate risk across society in service of these goals.[332] Striking the right balance will be increasingly important as innovative devices like brain-computer interfaces approach the U.S. market, promising transformative new therapies but also containing vast risks to physical or mental health.[333] Approval regulation describes schemes where a regulatory body must provide some type of approval or license before a private actor can place their products or services on a market.[334] Any product or service comes with risks, which approval regulators must evaluate and seek to mitigate in performing their duties to protect patients or consumers.[335] An approval from a regulator amounts to a determination that enough risk mitigation has occurred and exposing the public to those risks can be justified. Yet, some level of risk will continue to manifest into harms, so tort liability plays an important role in complementing approval regulation since it provides mechanisms to resolve and reallocate risk following approval or to alert regulators or lawmakers to the need for reform.[336]

In this broader context of approval regulation, using expedited regulatory pathways like the Breakthrough Devices Program can seek to facilitate innovation. Regulatory authorization manages risk but takes time, potentially delaying the benefits of novel products to patients or consumers. The possibility of brain-computer interfaces to assist patients with paralysis with performing activities of

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[330] *See* Parts III, IV.

[331] *See* Parts I.D, IV. *See also* Gerke & Simon, *supra* note 117, at 1139-40 (examining openness in some lower courts to attach preemption to the De Novo Pathway).

[332] This discussion in the Conclusion returns to using the term "approval" in the broader sense, as opposed to the use of the term to specifically refer to authorization through the PMA pathway in the FDA law and policy context. *See supra* note 35 and accompanying text; *see also* Carpenter et al., *supra* note 33, at 383 (using "approval regulation" as a term for a broader model of regulation).

[333] *E.g.*, Chaudhary et al., *supra* note 11, at 513 (brain–computer interfaces may help patients with paralysis but also present safety concerns); García & Winickoff, *supra* note 12, at 17.

[334] *See generally* Carpenter et al., *supra* note 33, at 383 (conceptualizing approval regulation as a system where regulators act as gatekeepers to markets such that regulated actors must meet certain standards before they can access those markets).

[335] *See* Black & Baldwin, *supra* note 33, at 181.

[336] *See* Bastian A. de Mol, *Regulation of Risk Management of Medical Devices and the Role of Litigation*, 17 J. RISK RES. 735, 738-42 (2014).

daily living such as communicating and interacting with their environment offers an example of potential benefits that innovation promises.[337] Policymakers may therefore decide to use these kinds of expedited review mechanisms to accelerate access to innovative products, as Congress has done with the BDP in the Cures Act.[338] However, the BDP helps illustrate how that acceleration may come at the cost of reducing opportunities for regulators to manage risks in the premarket setting—which may instead manifest as potentially avoidable harms to patients after breakthrough devices enter the market.[339]

Tort liability, instead, creates a structural incentive for product developers to continuously monitor and manage risk even after market authorization from an approval regulator, such as the FDA.[340] In response to the threat of litigation, private actors who have products on the market feel pressures to develop and deploy meaningful systems of self-regulation to either prevent harms entirely or mitigate resulting liability.[341] In essence, the presence of tort liability encourages the developers of new products to continue to manage their risks, at least to an extent, even after regulatory approval. Particularly where innovation involves the use of new technologies such as AI or brain implants, some risks may be unknown or unknowable at the time of authorization, such as what types of injuries to the brain, cognition, or an individual's personality or identity could result. This reality further drives the importance of tort liability acting as a backstop for risk management.[342]

Immunizing the developers of innovative products from liability—through federal legal preemption or other tools—therefore reduces those structural incentives for developers to manage risks. At the same time, expedited regulatory review provides regulators with fewer tools and opportunities to detect and manage risk in the premarket context. These two trends intertwine in the FDA's Breakthrough Devices Program to produce a regulatory arrangement where risk management has been curtailed both before and after innovative medical devices, some using emerging technologies, are made widely available to patients. This article's analyses of the BDP stand for the argument that these two legal approaches should not be combined.

Even if expedited review or liability immunity can individually boost innovation as a policy goal, they together allocate too much risk onto individual patients rather than centering risk-based regulation on administrative agencies and

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[337] *E.g.*, Drew, *supra* note 11 (small scale brain-computer interface experiments are yielding some positive results for patients with paralysis).

[338] *See* 21 U.S.C. § 360e–3(a) (2024).

[339] *See supra* Parts II, III.

[340] *See also* de Mol, *supra* note 336, at 738-42 (noting that the absence of liability after approval regulation can prompt safety challenges).

[341] *E.g.*, Joseph Sanders, *Firm Risk Management in the Face of Product Liability Rules*, 11 LAW & POL'Y 253, 266-69 (1989) (arguing the potential for tort liability incentivizes firms to invest in defensive strategies); Simon, Shachar & Cohen, *supra* note 85, at 160-64.

[342] *See also* Elen Stokes, *Demand for Command: Responding to Technological Risks and Scientific Uncertainties*, 21 MED. L. REV. 11, 11-14 (2013) (illustrating the challenges of regulating risk in the setting of uncertainty).

private developers. For innovative and experimental technologies such as brain-computer interface implants, patients may have few meaningful ways of comprehensively identifying, anticipating, understanding, or responding to those risks. These normative issues of risk allocation in the BDP call for legal reforms, by either loosening liability preemption or raising regulatory supervision in both the pre- and postmarket settings.[343] These two pathways for legal reform mutually support one another in reallocating risk away from patients and promoting the public health and would ideally be implemented in tandem.

Notably, however, this argument to avoid mixing expedited regulatory review and liability immunity should only be applied in non-emergency contexts (such as the BDP). How to properly balance safety and innovation in approval regulation during emergencies may require a different analysis. Congress has provided separate mechanisms for facilitating rapid access to devices and other medical products during a declared public health emergency, such as the COVID-19 pandemic.[344] The FDA's Emergency Use Authorization (EUA) also facilitates innovation, similar to the BDP, and some medical products authorized through this route may receive immunity from some federal and state tort liability.[345] Even this preemption of tort liability during public health emergencies is controversial and may be paired with administrative compensation mechanisms for harmed patients,[346] but is clearly more justified than the preemption offered to breakthrough devices in non-emergency settings. During an emergency, certain kinds of guided innovation may be needed to protect the public's health on an urgent basis, such as delivering diagnostics, treatments, or preventative measures during a pandemic.

Innovation for its own sake, however, is not an emergency. For approval regulatory programs in non-emergency conditions such as the FDA's medical device regulation—including with the BDP initiative—innovation is not enough of an imperative to supersede safety as a preeminent policy goal. The BDP and other expedited regulatory review programs within approval regulatory schemes do not need liability immunity to achieve their objectives. Adding tort law immunity only threatens to shift the risks of innovation from the developers of new technologies to the patients who are supposed to benefit from them.

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[343] *See supra* Part VI.

[344] 21 U.S.C. §§ 360bbb–3 (2024); *see generally* U.S. FOOD & DRUG ADMIN., EMERGENCY USE AUTHORIZATION OF MEDICAL PRODUCTS AND RELATED AUTHORITIES: GUIDANCE FOR INDUSTRY AND OTHER STAKEHOLDERS (2017), https://www.fda.gov/media/97321/download [https://perma.cc/DH52-YKXW] (providing guidance on rapid authorizations during emergencies).

[345] 42 U.S.C. § 247d-6d (2024); *see* U.S. FOOD & DRUG ADMIN., *supra* note 344, at 41-42.

[346] *See generally* Peggy Binzer, *The PREP Act: Liability Protection for Medical Countermeasure Development, Distribution, and Administration*, 6 BIOSECURITY & BIOTERRORISM 293 (2008) (outlining the potential for liability preemption for medical products during a public health emergency).