Responses to Liability Immunization: Evidence from Medical Devices

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Responses to Liability Immunization: Evidence from Medical Devices

Elissa P. Gentry and Benjamin J. McMichael*

The Supreme Court’s decision in Riegel v. Medtronic immunized medical device manufacturers from certain types of state product liability claims. However, this immunization applies only when the devices underlying those claims have been approved through the Food and Drug Administration’s most rigorous—and costly—premarket approval (PMA). Exploiting this decision, we examine whether manufacturers strategically respond to this new immunity. We find evidence that, following Riegel, approvals for high-risk product categories increase relative to the comparable change for low-risk categories, suggesting that firms are sensitive to the newly immunized risk. We additionally find evidence that physician treatment patterns with respect to medical devices also change, consistent with Riegel shifting liability away from device manufacturers and toward physicians. The analysis provides evidence that sophisticated actors respond to changes in their expected legal liability and that technical legal decisions have important ramifications for the provision of healthcare.

I. INTRODUCTION

Medical devices are ubiquitous in U.S. medical care. From the use of intrauterine devices for contraception to stents for blocked arteries, medical devices pervade many everyday healthcare decisions. Until a few decades ago, however, the federal government did not regulate these devices. Instead, states regulated the safety of medical devices indirectly by allowing individuals harmed by these devices to assert tort claims against device manufacturers. Manufacturers would, in theory, create safer products to avoid this liability, fearing the large damages awards that could be imposed under tort law. Federal regulation began only in 1976, with the enactment of the Medical Device Amendments of 1976 (MDA).

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Rather than establish remedies for injured consumers, as tort law does, the MDA established ex ante standards for devices. The rigor of each standard varies by the risk each device class is likely to pose to consumers. Class I devices pose little risk to consumers and are subject to the lowest level of regulatory control by the Food and Drug Administration (FDA). Class II devices pose higher risks, and the FDA subjects these devices to more stringent regulation. Class III devices present the highest risk to patients and must undergo premarket approval (PMA), which includes the submission of valid clinical and scientific evidence demonstrating safety and efficacy, prior to being marketed to consumers. At the time the MDA was enacted, many devices that met the criteria for inclusion in Class III were already on the market. Rather than remove existing devices from the market until the FDA could review them under the PMA process, however, the MDA allowed existing Class III devices to remain on the market. New devices found to be “substantially equivalent” to those grandfathered devices can remain under a Section 510(k) license until the FDA requires their product category to go through PMA review.¹

In addition to creating a new federal regulatory scheme, the MDA curtailed state regulation of medical devices. Specifically, the MDA contained language that could be interpreted to preempt certain state laws, potentially including state tort law. The extent of this preemption was somewhat unclear until the Supreme Court clarified the MDA’s effect on state tort law in its 2008 decision Riegel v. Medtronic. In that case, the Court held that medical devices approved under the PMA process were immune from liability for certain state tort claims. In contrast, devices approved via the Section 510(k) process were not immune from state tort liability. With this decision, for a subset of complaints, the Supreme Court created a bifurcated liability scheme for the riskiest devices: PMA-approved devices are subject to only federal regulation, whereas Section 510(k)-approved devices are subject to federal regulation (albeit less rigorous) as well as indirect regulation under state tort law.

While the Supreme Court’s decision in Riegel was based on the interpretation of the language in the MDA—and not on furthering any theory of optimal liability or regulation—it nonetheless drastically changed the liability landscape for a number of medical actors. This article focuses on Riegel’s effect on two important entities—device manufacturers and physicians—and examines how these entities respond to a sudden and meaningful shift in their potential tort liability. This examination demonstrates that these sophisticated parties respond to the incentives created by tort liability and contributes to the ongoing—and often heated—debate over the salience of tort liability within the healthcare system.

Section II discusses the history and provisions of the MDA. It also details the Supreme Court’s evolving doctrine of preemption and how it led to Riegel. Based on the changes in expected liability effected by Riegel, Section III outlines our empirical strategy and data for analyzing the impact of Riegel on two related medical actors: device manufacturers and physicians.

Section IV focuses on quantifying the effect of Riegel on device manufacturer behavior. Prior work has found that firms respond strategically to shifting legal incentives. For example, Yin (2009) explores how drug manufacturers responded to the Orphan Drug

¹The FDA does not set deadlines for individual devices but for entire product categories.
Act (ODA), which introduced incentives for developing drugs for rare diseases. Yin finds that these incentives cause companies to strategically “develop drugs for ‘rare’ subdivisions of more prevalent diseases” (Yin 2009:950). With analogies to such strategic behavior, this section explores whether device manufacturers respond to changes in legal liability for PMA-approved devices by submitting more of their high-liability-risk devices for PMA review. Using data obtained from the FDA on medical device approvals, we find evidence consistent with manufacturers responding in this way. Following Riegel, the number of PMA approvals for devices with a high risk of tort liability increases relative to the change in approvals for devices with lower risks of liability.

Section V focuses on the other major actor in the medical device context: physicians. A large literature exists around the question of how physicians respond to changes in their expected legal liability. For example, prior work has examined whether physicians change their treatment decisions in response to tort reforms that are designed to reduce their expected liability (Kessler & McClellan 1996, 2002; Avraham & Schanzenbach 2015; Currie & MacLeod 2008; Cotet 2012; Frakes 2012). Other studies have analyzed how the supply of individual providers changes in response to tort reforms, suggesting that physicians are willing to relocate to states with lower liability risk (Helland & Seabury 2015; Lieber 2014; Klick & Stratmann 2007; Encinosa & Hellinger 2005; Kessler et al. 2005).

We extend this literature, offering evidence that physicians are sensitive to the Riegel decision in predictable ways. Of course, the effect of Riegel on physicians should be more muted than its effect on device manufacturers. However, this important group of healthcare actors should be affected to some extent, and our analysis of physicians serves as an important supplement to and check on our analysis of device manufacturers. Using a nationally representative dataset of individuals suffering from heart attacks and strokes, we examine whether physicians change the rate at which they use PMA-approved devices after Riegel. Because consumers can no longer sue device manufacturers for certain device-related injuries following Riegel, consumers on the margin may be more likely to sue their physicians if they are injured during a procedure involving a device. Accordingly, physicians may perceive an increase in their malpractice liability risk when using

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2On the manufacturer side, Galasso and Luo (2018) consider the upstream and downstream effects on innovation of an increase in manufacturer liability. They find that an increase in liability for polymer manufacturers led to a negative impact on downstream innovation but a negligible effect on upstream patenting.

3Related work has considered whether these changes in behavior in response to changes in liability reduce healthcare costs. Although no consensus exists on this question, some research suggests that reducing liability risk by reforming tort law can reduce healthcare costs (Mello & Kachalia 2016). Recently, Frakes and Gruber (2018) examined the role of tort liability by comparing the behavior of physicians when they are subject to tort liability and when they are not. Frakes and Gruber (2018) similarly rely on a doctrine of federal preemption of state tort law to estimate the effect of liability on physician decisions. They find that immunity from malpractice liability reduces inpatient spending by 5 percent.

4Some work suggests that the effect of tort reforms on physician supply may be limited (Paik et al. 2016; Yang et al. 2008).
PMA-approved devices after *Riegel*.

However, the degree of this increase is not equal across the country because some physicians practice in states with tort reforms, which can reduce liability risk. Consistent with this differential change in liability risk following *Riegel*, we find evidence that physicians in states without tort reform (i.e., those facing a relatively larger increase in liability risk) decrease their use of PMA-approved devices to a greater extent than physicians in states with tort reform. This suggests that physicians respond to changes in the liability risk associated with PMA devices by substituting away from these devices when their own malpractice risk is higher.

Overall, the evidence developed here suggests that sophisticated actors respond to changes in liability risk, either by exploiting new liability immunizations and submitting risky devices for approval or by proactively shielding themselves from perceived liability by using fewer devices in their medical practice.

## II. Federalism and Medical Device Regulation

### A. History of Medical Device Regulation

Prior to 1976, the federal government did not regulate medical devices. This regulation was left to individual states, which generally relied on tort law to discourage the manufacture and distribution of unsafe medical devices. Tort law, in this context, allows individuals harmed by medical devices to seek damages from manufacturers under several different theories: that the device was defectively manufactured (manufacturing defect), that the design of the device itself was defective (design defect), or that the device lacked an adequate warning (warning defect).

Federal passivity in medical device regulation came to an end in the 1970s. In 1970, a new intrauterine device, the Dalkon Shield, was introduced to the market. Positioned as an alternative to birth control pills, the Dalkon Shield was a semi-permanent form of contraception. Following its introduction, however, women began reporting miscarriages, infertility, and death. Numerous victims sued, resulting in a mass settlement, and the Dalkon Shield was withdrawn from the market in 1974. Following this highly public incident, Congress took action and passed the Medical Device Amendments (MDA) of 1976 to the Food, Drug, and Cosmetic Act (FDCA).

This statute created three classes of devices based on the procedures necessary to ensure safety and effectiveness of devices within each class. Class I devices only require

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5 In a similar vein, Galasso and Luo (2017) also explore the link between manufacturers and physicians. Galasso and Luo examine how changes in tort law affect the number of patents filed, under the hypothesis that physician demand for innovation changes with expected liability. Our article similarly acknowledges the interconnectedness of device manufacturers and physicians but considers the link between manufacturer liability and physician treatment.

6 These claims are generally brought as strict liability claims, although plaintiffs can also bring negligence claims.

general controls to ensure safety and effectiveness. Class II devices are those for which general controls are insufficient; these devices require "special controls" such as performance standards, post-market surveillance, patient registries, or development and dissemination of guidelines. Class III devices are those for which general or special controls are insufficient, given that they are used for supporting or sustaining human life. In light of these risks, Class III devices require some level of premarket approval.

Once designated as Class III, a device must complete the PMA process unless exempt. The Class III device process—the PMA process—was designed to be rigorous, involving individual inspection of the device and submission of clinical trial data. Given the rigor of this process and the number of devices that were required to complete it, devices already on the market when the MDA was enacted would have needed to be recalled pending approval or issued a temporary approval. Instead of pulling these devices from the market pending FDA approval, however, the FDA allowed them to remain on the market.

Given that such grandfathered products could bypass the PMA process for a period, immediately subjecting new entrants to the full PMA process could potentially produce anticompetitive effects. To prevent these advantages for grandfathered products, the FDA allowed devices that were "substantially equivalent" to any grandfathered devices to also delay the PMA process. They were allowed to apply through the Section 510(k) process and only complete the PMA process when the Secretary initiated a formal PMA process for the predicate grandfathered device. Thus, the FDA grandfathered entire product categories, instead of individual products. Although the Section 510(k) process was intended to be a temporary workaround, it has persisted until today. A number of product categories still have not reached their PMA deadline and continue to permit submissions through the Section 510(k) process.

Accordingly, Class III devices are subject to a bifurcated process: while all eventually go through the PMA approval process, the deadline after which completing the PMA process becomes mandatory varies. At any time, any Class III product can be submitted for the PMA process, including products that have completed the Section 510(k) process but have not yet been required to complete the PMA process.

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8A device is also designated as Class I when there is no evidence that such controls are sufficient but the device is not represented to be for a use "supporting or sustaining human life" or "of substantial importance in preventing impairment of human health" and does not involve a "potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(A)(ii).


10These devices either "purport[] or represent[] to be 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." 21 U.S.C. § 360c(a)(1)(C).

1121 U.S.C. § 360e(a). The exemption process is described in Section 360j(g).


B. The Preemptive Effect of the MDA

In enacting the MDA, Congress faced an important decision regarding how federal regulation of medical devices would interact with existing state regulation: Would it merely supplement state law or supersede it? In general, the Supremacy Clause of the Constitution gives Congress the authority to pass laws that supersede, or “preempt,” state laws, including state tort law. The principles of federalism and the desire to maintain a balance of power between the state and federal governments, however, weighs in favor of concurrent governance by state and federal governments. Accordingly, courts often read federal statutes with a “presumption against preemption.” Thus, federal law must be clear in its intent to supersede state law, even when express preemption is at issue.

To address this issue, Congress included the following provision in the MDA, stating that, with a few exceptions,

\[
\text{no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.}
\]

By including this language, Congress provided grounds for the MDA to preempt some state law. On its face, the MDA appears to preempt state requirements that are different from or in addition to the MDA’s requirements regarding safety and effectiveness. With a slight abuse of legal terminology, it is helpful to think of the preemption test for medical devices as involving three conditions. First, the state suit against the device manufacturer must be legally considered a “requirement.” Second, the federal process the device undergoes (i.e., PMA or § 510(k)) must be legally considered a “requirement.” Finally, these two “requirements” must be different. If all three conditions are satisfied, the device manufacturer is immunized from state tort liability. The definitions of “different” or “requirement,” however, are legally ambiguous. Decades later, in Medtronic v. Lohr, the Supreme Court provided some clarity.

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14 The doctrine of federal preemption is complex, and much of this complexity is beyond the scope of this article. In general, courts have recognized three types of preemption. “Express” preemption—which is relevant in the case of the MDA—occurs when the text of a federal statute explicitly provides that the federal statute supersedes state law. “Implied” preemption can occur in two different instances. In the case of “conflict” preemption, federal law preempts state law when an actor would find it impossible to comply with both federal and state law because the two laws conflict. “Field” preemption occurs when—even absent an express provision—Congress has indicated that it intended federal regulation of an entire field.


In *Lohr*, plaintiff Lora Lohr claimed that she was injured when her pacemaker, a device approved under the Section 510(k) process, failed. She sought to bring Florida tort law claims against the manufacturer, Medtronic. The questions before the Supreme Court included whether the MDA expressly preempted state tort claims against the manufacturer of the pacemaker.

*Medtronic v. Lohr* resulted in a narrow and divided opinion: Justice Stevens announced the opinion of the Court, which gained a majority in only five of the seven parts. Based on this fragmented opinion, there was one clear message: Lohr’s tort claims were not preempted because the Section 510(k) process did not constitute a “requirement.”

The Court found important that the Section 510(k) process did not mandate that the pacemaker take a particular form; instead, it merely examined whether the device was substantially equivalent to a predicate device.

Twelve years later, plaintiff Charles S. Riegel brought a claim against Medtronic for injuries caused by an Evergreen Balloon Catheter. This product was approved following the completion of the PMA process, unlike the Section 510(k) device in *Lohr*. As before, Riegel’s claims would be preempted only if the Court determined that both the PMA process and the state common-law claim were considered different “requirements.”

The Supreme Court answered both questions in the affirmative. In holding that the PMA process constitutes a federal requirement—unlike the Section 510(k) process—the *Riegel* Court found persuasive the difference in rigor and purpose of the review. “While § 510(k) is ‘focused on equivalence, not safety’... premarket approval is focused on safety, not equivalence.” More interestingly, the Court also formally held that negligence and strict liability tort claims constitute requirements, relying on the five justices in *Lohr* and two subsequent cases interpreting different statutes. In reaching this conclusion, the Court noted that a liability award “can be, indeed is designed to be, a potent method of governing conduct and controlling policy.” In doing so, an entire set of products were immediately granted immunity from certain state tort claims.

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18 Id. at 494.

19 In other words, the Court held that the second prong—whether the federal process undergone legally constitutes a requirement—was not satisfied.


21 552 U.S. at 323.

22 Id. at 323–25.

23 Id. at 324 (internal quotations and citation omitted).

24 *Riegel v. Medtronic* left open the possibility that state tort claims could impose requirements that were identical, or parallel, to federal requirements. In *Buckman Co. v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001), the Court noted that *Lohr* “can be read to allow certain state-law causes of actions that parallel federal safety requirements.” Id. at 353. The limits to this exception have been discussed thoroughly in legal scholarship (e.g., Prince 2013; Wartman 2009; Whitney 2010).
While both *Riegel* and *Lohr* addressed the preemption of state tort law claims, those decisions largely focused on design defect claims. For procedural reasons, the Supreme Court in *Riegel* did not consider whether manufacturing defect claims were preempted.\textsuperscript{25}

While interesting in demonstrating the narrow application of the legal doctrine of federal preemption, *Riegel* also has substantial practical implications for the medical device industry. Relevant for our purposes, it provides a clear change in the liability device manufacturers and others could expect to incur. We exploit this change in the analysis presented below, and it is important to emphasize that *Riegel* represents a clear departure from prior law from the perspective of manufacturers.

Prior to *Riegel*, lower courts had disagreed about whether the MDA preempted state tort claims against device manufacturers. The Second, Third, Fifth, Sixth, Seventh, and Eighth Circuits, along with the supreme courts of Pennsylvania, Rhode Island, and Texas concluded that the MDA preempted state tort claims, as the Supreme Court would eventually recognize in *Riegel*.\textsuperscript{26} The Eleventh Circuit and the Illinois Supreme Court held, however, that the MDA did not preempt state tort claims.\textsuperscript{27} While the fact that more lower courts ultimately supported the conclusion that *Riegel* would eventually reach may suggest some degree of predictability in *Riegel*’s outcome, a significant fraction of the Supreme Court had previously balked at the thought of such a complete bar to recovery. In *Lohr*, four justices pushed back against a sweeping notion of preemption of tort claims, noting that “it would take language much plainer than the text of § 360k” to convince them that Congress meant to “remove all means of judicial recourse for those injured by illegal conduct[.]”\textsuperscript{28} By *Riegel*, however, three of those four justices had joined with the majority, suggesting that the result in *Riegel* was uncertain ex ante.\textsuperscript{29}

In addition to the legal pivots in the substantive preemption conclusions, it is worth noting that *Riegel v. Medtronic* was the result of a technical legal analysis involving interpretation of a statute and the constitutional doctrine of preemption. Predicting the change in liability effected by *Riegel* would have necessitated predictions regarding the Court’s views on federal preemption—a prediction that is not generally aided by the outcomes of lower court decisions—rather than predictions about the best policies for

\textsuperscript{25}552 U.S. at 321, n. 2.

\textsuperscript{26}Riegel v. Medtronic, Inc., 451 F.3d 104 (2d Cir. 2006); Horn v. Thoratec Corp., 376 F.3d 163 (3d Cir. 2004); Martin v. Medtronic, Inc., 254 F.3d 573 (5th Cir. 2001); Kemp v. Medtronic, Inc., 231 F.3d 216 (6th Cir. 2000); McMullen v. Medtronic, Inc., 421 F.3d 482 (7th Cir. 2005); Brooks v. Howmedica, Inc., 273 F.3d 785 (8th Cir. 2001); Green v. Dolsky, 685 A.2d 110 (Pa. 1996); Fry v. Allergan Med. Optics, 695 A.2d 511 (R.I. 1997); Worthy v. Collagen Corp., 967 S.W.2d 360 (Tex.).

\textsuperscript{27}Goodlin v. Medtronic, Inc., 167 F.3d 1367 (11th Cir. 1999); Weiland v. Teletronics Pacing Sys., Inc., 721 N.E.2d 1149 (Ill. 1999).

\textsuperscript{28}518 U.S. at 487.

\textsuperscript{29}Stevens filed a concurrence, while only Ginsburg dissented from *Riegel*. Notably, a comparable case regarding preemption of tort claims for drugs was issued the following year and held that tort claims involving drugs were not preempted. *Wyeth v. Levin*, 555 U.S. 555 (2009).
medical devices. Moreover, the timing of the change provides a sharp discontinuity in expected liability. The Supreme Court exercises discretionary jurisdiction, so even the Court’s hearing of the case would be difficult to anticipate. And because Riegel was a Supreme Court case, it became binding on all courts across the country simultaneously as soon as it was handed down. Accordingly, we treat the Riegel decision as an exogenous shock to the expected liability faced by medical device manufacturers and others.

Treating Riegel as an exogenous shock is further justified by the nature of the market for medical devices. Device manufacturers do not sell their devices only in certain areas of the country and would find it exceedingly difficult to target only those jurisdictions where a lower court had concluded that the MDA preempted state tort liability. Thus, Riegel represents the relevant shock, not the lower court decisions. Methodologically, if we are incorrect in this, the results reported below would understate the effect of Riegel, suggesting that we would estimate a floor on the effect of this case.

In general, the legal changes effected by this case should impact both manufacturer behaviors in submitting devices for approval and physician treatment behavior using such devices. Section III details the empirical strategy for quantifying this impact. Section IV focuses on the effect of Riegel on device manufacturer behavior, using approval data from the FDA. Section V focuses on the effects of Riegel on physician treatment behavior.

III. EMPIRICAL STRATEGY AND DATA

Because the U.S. Supreme Court decided Riegel, the decision became binding on all lower courts simultaneously. Without different dates of adoption by different states (or other jurisdictions), we cannot employ a traditional difference-in-differences approach that relies on geographic variation as the source of identification. Instead, we rely on the differential effect Riegel would have on the decisions of medical device manufacturers and physicians facing different levels of liability risk. The economic intuition of our analysis for both manufacturers and physicians is straightforward.

With respect to device manufacturers, a firm will file an application to market a device when the expected profits exceed manufacturing costs, application costs, and expected liability associated with the device.30 Riegel eliminated a subset of expected liability costs for PMA-approved devices, lowering the requisite profits needed to enter the market and encouraging more applications for PMA review. Particularly, we should observe changes in product categories in which Riegel immunized a substantial level of expected liability.

With respect to physicians, a physician will, all else equal, choose a course of treatment that minimizes his or her liability risk. Prior to Riegel, a patient injured while

30For the sake of simplicity, expected liability refers to liability premised on state torts imposing specific, additional requirements to the FDCA.
undergoing treatment involving a PMA device—in a subset of circumstances—has the option of filing suit against the device manufacturer (under a products liability theory) or the physician (under a medical malpractice theory). Following Riegel, that same patient’s ability to successfully sue the device manufacturer is substantially curtailed. Left with little recourse, the patient may be marginally more likely to file suit against the physician. Although products liability claims and medical malpractice claims involve different elements and may not generally coexist within the same incident, clever attorneys may be able to credibly file either claim in some cases. Moreover, in situations that could serve as the basis for either type of claim, attorneys may be more inclined to sue manufacturers since they may be better able to pay a settlement or judgment. This may change following Riegel.

Even though success on a medical malpractice claim in a case that is better suited to a products liability claim may be rare, the threat of litigation alone is itself powerful and may be sufficient to induce behavioral changes in physicians (Dranove et al. 2012). Physicians, recognizing that their malpractice risk may increase in the absence of recourse against the device manufacturer, may choose to substitute alternative procedures not involving PMA devices in cases where they have some discretion. We should observe more substitutions of this type in areas where physicians face more liability risk in general because the incentives to shift (and avoid a malpractice suit) are greater in these areas.

This article focuses on the reaction of these two medical actors to Riegel. The empirical strategies for device manufacturers in Section IV and physicians in Section V are similar. Both exploit groups with different sensitivities to Riegel and document the changes in behavior before and after Riegel. Each analysis relies on a general model of the following form:

\[ \text{Outcome}_{rt} = \beta_1 \text{HighRisk}_{rt} \times \text{PostRiegel} + \beta_2 \text{HighRisk}_{rt} + \delta_t + \gamma_r + \epsilon, \]

where \( r \) is the relevant unit of aggregation and \( t \) is a function of time. \( \text{Outcome} \) is either the number of device approvals or an indicator for whether a physician chooses to employ a medical device when treating a given patient. \( \text{High Risk} \) is a category involving heightened sensitivity to Riegel. \( \text{High Risk} \) is operationalized differently in our analyses of medical device manufacturers and physicians. The following sections describe the data sources we use in our analysis, the definitions of \( \text{High Risk} \) based on those data sources, and the specific ways in which we incorporate those definitions of \( \text{High Risk} \) into our general model.

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3For a recent example of a case involving both medical malpractice and products liability (specifically design defect) claims, see Bigler-Engler v. Breg, Inc., 7 Cal. App. 5th 276 (Ct. App. 2017).

32This marginal effect need not occur within the same attorney. For example, an attorney who specializes in products liability may become more likely to refer clients to an attorney focusing on medical malpractice following Riegel.
A. Medical Device Data

1. Approval Data

To examine the effect of *Riegel* on firm decision making, we analyze a dataset of PMA approvals for 1997–2015 obtained from the FDA.\(^3\) The FDA, unfortunately, does not disclose the universe of applications submitted. There are three potential categories of submissions: those that are approved, denied, or “not approved in their current form.” Although the FDA publishes denials in the *Federal Register*, it will not disclose applications that have not yet been approved in their current form. Given that the total number of denials is very small, the undisclosed “not approved in their current form” presents an unobserved component of submissions.\(^4\) Our sample consists of PMA applications that are approved, rather than all submitted PMA applications. While this is a data limitation, as long as the probability that the FDA approves an application with a particular level of scientific evidence is constant over the study period, the analysis of the number of approvals will be informative of the effect of *Riegel* on the number of applications. This assumption does not require that the composition of aggregate applications remains constant; indeed, we hypothesize that after *Riegel*, firms are more likely to submit applications for products with substantial immunized tort liability. It merely means that the FDA will not be more or less likely to approve an application with a given level of scientific evidence after *Riegel* than it would if the application were submitted before *Riegel*.\(^5\)

While impossible to state with absolute certainty, there are several reasons to believe that this is the case. First, as noted above, because *Riegel* was a Supreme Court case, the immunization from tort liability occurred independently of the FDA’s authority. Second, statutory instructions to the FDA regarding the stringency of review do not change during the study period. Under the FDA Modernization Act of 1997, Congress established the “least burdensome” approach to PMA approval.\(^6\) Our review of the statutes passed in the interim suggests that this approach did not change during the study period.\(^7\) In December 2016, Congress passed the 21st Century Cures Act, which, while

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\(^{5}\)The assumptions necessary to validate this approach are further explained in Section VII.


\(^{7}\)We note here several statutes that were passed during the period that did not seem to change the stringency of FDA review. In 2007, Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA), which reauthorized the Medical Device User Fee Program (this program is reauthorized every five years). See https://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm109917.htm. The FDAAA also allowed for some changes to review of devices for pediatric purposes. Neither of these seem likely to affect the stringency of FDA review. See https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/ucm083161.htm. Similarly, in 2012, the Food and Drug Administration Safety and Innovation Act (“FDASIA”) was passed to again
nominally only reaffirming its commitment to the “least burdensome” approach to PMA approval, some critics suggested actually established less stringent standards. Our study period ends before this happened, however, ensuring that FDA policy remains constant over the time period we analyze.

However, even if—despite the lack of congressional action—the FDA took it upon itself to screen out PMA applications that would have immunized risk after Riegel, this would only bias against finding results supportive of our hypothesis. If firms submitted such applications and the FDA denied approval in light of the newly immunized liability, we may not find significant results despite the existence of a change in firm strategy. If we find results despite this type of change, it would only suggest that our results are stronger than they appear. Accordingly, we use number of approvals as a measure of device applications.

From the pool of all approvals, we restrict our analysis to only original device approvals. For each application, we observe the date the application was approved and the corresponding product category. Most importantly, we observe the date the application was received by the FDA. Although we see only applications that are eventually reauthorize medical device user fees and modify requirements for investigation device exemptions under 21 U.S.C. 360j. Our review of the provisions does not suggest that the statute appreciably changed the stringency of FDA review. Finally, since 1997, manufacturers were allowed to file a “de novo” application for products that do not have a predicate device but should be class I or II devices. In 2012, the FDASIA allowed manufacturers to directly file an application for “de novo” status rather than filing a § 510(k) application first.

Horvath (2017) offers one such argument.

While our time variable is quarter of receipt, we take the additional step of dropping any approvals with a decision date after December 13, 2016, to ensure that we do not observe approvals potentially issued under a less stringent standard. This potentially censors the number of approvals we see in later years. Insofar as review times are the same for high-risk products, this should not affect our results. Insofar as review times are longer for high-risk products, this biases against our hypothesis; if we still see a relative increase in approvals after Riegel, our results may be understated. Our results are qualitatively the same without this restriction, however.

We consider only original approvals in order to capture new device approvals rather than updates to existing devices, as this better reflects the relevant firm decision. We do this by only keeping approvals that do not list a supplement number.

Firms sometimes have a choice between filing an original application or a supplement to an existing application. As long as the choice between the two is stable throughout the policy period, our analysis will not suffer from any bias. During the period analyzed here, the FDA took several actions that could potentially impact a firm’s choice between an original application and a supplement to an existing application. The Medical Device User Fee and Modernization Act of 2002 (MDUFMA 2002) added specific definitions for three applications for supplemental approval, and the FDA updated its guidance on which modifications qualified for supplement paths between 2005 and 2008 (FDA 2008). These changes should not affect our analysis for the following reasons. First, the criteria relevant to supplemental application paths do not rely on the risk inherent in the device but on the types of changes made to the device (i.e., do the changes “result[] in a device design so different from the original version that the preclinical ... and clinical data you previously submitted on your original device are not applicable?”, p. 5). Second, even if the criteria for supplemental status had been correlated with riskiness of the device, our analysis would be affected only if firms reacted to the 2008 guidance rather than the 2002 Act that provided the definitions—an unlikely situation since firms should rationally respond to the definitions.

We only use this date to drop applications for which decisions were rendered after the Cures Act was passed.
approved, our unit of time is the quarter in which the application is received, which should be close to its submission date.

Our analysis examines the number of approvals in a given product category. We limit our analysis to PMA approvals in product categories designated as Class III. To do this, we supplement our data on approvals with other FDA data on product categories. This dataset includes unique product category codes that link to sections of the Code of Federal Regulations (CFR) and lists device class number.

To ensure we follow each product category for the appropriate number of periods, we drop any periods that precede the filing of the first PMA approval for a product category in our data. This ensures that we only consider as zero periods those periods where zero PMAs were actually approved for the product category, not merely periods preceding the establishment of the product category. We then restrict the entire sample to approvals received from January 1, 1997 to December 31, 2015. To address the potential concern that we might be capturing devices that simply become required to submit PMAs, we drop product codes that we identified as having PMA deadlines during our time period.

Throughout our analysis, we examine the number of approvals filed within a given product category. Each product category encompasses a group of devices with similar characteristics. For example, a product category may be labeled “electroanesthesia apparatus” or “intrauterine devices.” Product category is a natural aggregation unit, as the FDA itself uses these product category groups to impose the same PMA deadlines for a set of devices. This use of product categories is important for three reasons. First, by using product categories to aggregate device approvals, we ensure that comparable devices are grouped together. By including product category fixed effects, we are confident that our results are not driven by time-invariant unobservables across product categories. Second, we are able to measure growth in approvals by product category, rather than growth in approvals generally. Aggregate growth in approvals might be a function of more product categories entering the market; measuring by product category ensures our results are not driven by this. Third, we allow the risk data for other devices within the same product category to inform a firm’s expectation of liability risk for a new device application. This is a more realistic assumption about how firms assess risk for original applications than only allowing a specific device’s history to inform the firm of its own risk.

2. Analyzing the Risk Faced by Medical Device Manufacturers

Given the empirical strategy outlined above, our identification strategy relies on isolating product categories with a large change in expected liability after Riegel. We define High

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44Some of these classifications are merely tentative, however. The FDA notes that if there is no CFR section listed, the device classification is likely tentative.
Risk using data from voluntary complaints housed in the FDA’s Manufacturer and User Facility Device Experience Database (MAUDE).45

MAUDE data are available for a long time horizon,46 which allows us to incorporate more past history when determining High Risk status. We only keep records that indicate that the event involved a product problem and that the product was subsequently evaluated by the manufacturer.47 Data from MAUDE come from voluntarily submitted postmarket reports48 that do not fall within any reporting exemption. These data, accordingly, are not well suited to represent true safety risks associated with each product. For our purposes, however, MAUDE data are useful as a measure of the litigation risks perceived by companies. Mindful of the limitations of using nominal complaints as a measure of litigation risk, we focus on the percent of filed reports that allege serious injuries. A company may perceive its litigation risk as high if the percent of complaints it receives that allege serious injury is higher.

To examine the effect of Riegel on product categories with varying levels of risk, we create quintiles of the percent of adverse events reported as resulting in death, resulting in hospitalization, or deemed “life-threatening” for each year (collectively, “serious events”). These percentages are calculated as the cumulative sum of serious events divided by the cumulative sum of total events reported (by quarter). The quintiles are calculated by quarter, comparing the risk across product categories in a given quarter. Accordingly, not only can the composition of adverse events (serious or non-serious) reported change the quintile a product category falls in, but the relative riskiness of other products can do the same. We create quintiles of the nonzero risk and categorize zero risk products separately; these serve as our base (omitted) category. This construction allows us to see the effect of Riegel across the relative levels of risk for each product category over time.

Using this definition of High Risk, we estimate a series of ordinary least squares (OLS) difference-in-differences regressions with the following general specification to

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45We also ran a similar analysis using FDA recall data to characterize high-risk products. While the level of detail provided by the recall data, as well as the credible signal of risk provided by a manufacturer-initiated recall, is useful at targeting the type of liability that Riegel immunized, data availability is limited. Accordingly, we cannot draw too strong conclusions from this analysis and have omitted it from the main text. The results are qualitatively and quantitatively similar and are available upon request.


47The MAUDE database was downloaded from https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/manufacturer-and-user-facility-device-experience-database-maude in March 2019. We count unique MDR report keys as separate observations.

48There are mandatory reporters, including manufacturers. However, given that the mandatory report is triggered by a voluntary complaint, this does not help.
isolate the effect of *Riegel* on firms submitting applications in high-risk product categories:

\[
\text{Number PMA Approvals}_{pq} = \beta_1 \text{HighRisk}_{pq} \times \text{PostRiegel}_q + \beta_2 \text{HighRisk}_{pq} + \delta_p + \gamma_q + \epsilon.
\]

*Number PMA Approvals* \(_{pq}\) represents the number of approvals for given product category \(p\) and quarter of receipt \(q\).\(^{50}\) The variable of interest is the interaction term \(\text{HighRisk}_{pq} \times \text{PostRiegel}\), which captures the growth in approvals per product category considered *High Risk* after *Riegel* relative to the comparable growth for low-risk product categories. Product code and quarterly fixed effects, \(\delta\) and \(\gamma\) respectively, are also included to control for time-invariant unobservables occurring within product categories and quarters.\(^{51}\)

**C. Physician Data**

1. Data on Heart Attacks and Strokes

Given the somewhat messy reality of medical decision making, we must be careful in choosing the appropriate population on which to test our hypotheses about physician behavior following *Riegel*. To identify physicians’ volitional decisions in response to *Riegel*, we choose the following groups: (1) patients who have suffered an acute myocardial infarction (a heart attack) and (2) patients who have suffered from cerebrovascular problems (including strokes).\(^{52}\) There are several reasons why these patient populations provide a useful sample in which to test physicians’ responsiveness to *Riegel*.

First, the physicians treating this population are more likely than most to be sensitive to changes in liability pressure and to change their treatment choices accordingly. Heart surgeons, cardiologists, neurologists, and neurosurgeons all face significant liability pressure (Kachalia et al. 2016) and are accustomed to managing it. Second, both heart attack and stroke patients can be treated with or without the use of a device requiring PMA approval. Specifically, physicians have the option to employ cardiac stents when

\(^{49}\)As noted above, this is not a traditional difference-in-differences model, as there is no group of devices that is truly untreated. Given *Riegel*’s immediate, nationwide effect on manufacturers, all devices with any relevant expected liability were treated. Our strategy is to isolate the product categories with high levels of expected liability and compare them to categories with low levels of expected liability to estimate differential sensitivity to the passage of *Riegel*.

\(^{50}\)As explained below, we are unable to observe applications in the data and are forced to proxy with approvals instead. The assumptions necessary to validate this approach are further explained in Appendix A. However, for the approved applications we do observe the quarter that the application was received by the FDA; this gives us a better indication of firm behavior.

\(^{51}\)Because *Riegel* took effect across all states simultaneously and because we include a full set of time fixed effects, we do not include a separate *Riegel* indicator, which would not be identified.

\(^{52}\)We examine patients suffering from several different types of cerebrovascular conditions. However, we refer to these patients as “stroke patients” for ease of exposition.
treating heart attack patients and cranial stents when treating stroke patients. Both cardiac and cranial stents are PMA devices, so their manufacturers would be immune from state tort liability under Riegel. Third, physicians have some discretion in many cases with respect to whether to implant a stent or to employ other procedures that do not require the use of a stent. Fourth, the emergency nature of most heart attacks and strokes means that physicians have relatively little ability to schedule procedures far in advance, limiting factors that may impact our analysis of treatment decisions. Fifth, heart attack and stroke patients are almost always admitted to the hospital for non-elective procedures. This allows us to be confident that using only hospital data will not result in a biased sample.

Our sample of heart attack and stroke patients comes from the National Inpatient Sample (NIS), which is the largest all-payer dataset for inpatient care in the United States and contains a 20 percent sample of hospitals in the United States. Each year, approximately 1,000 hospitals are sampled, and between 5 and 8 million hospital stays are included in the dataset. When a hospital is chosen for inclusion, all the inpatient records from that hospital are gathered and coded into the dataset. In our analysis, we examine hospital stays occurring between 1999 and 2011, which provides sufficient time before and after the Court’s 2008 Riegel decision. While not all states’ hospitals are included in every year of the NIS dataset, we follow previous work and include all available data in our analysis (Avraham & Schanzenbach 2015).

Using information on hospital stays, we identify any stay that included a principal diagnosis of heart attack or stroke. Because the majority of individuals suffering from these conditions require a hospital visit—over 90 percent in the case of heart attacks—these data provide a clear picture of the relevant patient populations. Limiting our analysis to these individuals, we use the procedure codes associated with each patient to classify a patient as receiving care that involved the use of a cardiac or cranial stent. In our sample, approximately 30 percent of all heart attack patients and 0.3 percent of all stroke patients receive a course of treatment requiring the use of a cardiac and cranial stent, respectively. The disparity of stent use in heart attack patients and stroke patients—a difference of two orders of magnitude—allows us to examine the effect of Riegel in different contexts and confirm that our results are not unique to patients who regularly or rarely receive stents.

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53We are unable to extend our analysis beyond 2011 because the NIS stopped including information on the state in which each hospital was located in 2012. State information is required to determine whether a noneconomic damages cap was applicable to a given provider.

54Avraham and Schanzenbach (2015) provide an overview of which states’ hospitals are included in each year of the NIS.

55We identify patients suffering from heart attacks and strokes using codes provided by the Clinical Classifications Software (CCS), which maps groups of specific ICD-9 codes into general disease categories. We defined heart attack patients as those with a CCS code of 100 (acute myocardial infarction) listed as their primary diagnosis. We defined stroke patients as those with the following CCS codes listed as their principal diagnosis: 109 (acute cerebrovascular disease), 110 (occlusion or stenosis of precerebral arteries), 111 (other and ill-defined cerebrovascular disease), and 112 (transient cerebral ischemia).

56Because of a change in ICD-9 coding, stent information is not available for stroke patients prior to 2004. Accordingly, we limit our analysis of these patients to 2004–2011.
In addition to these outcome variables, we use other information provided in the NIS to construct a series of control variables. In particular, we collect information on the patient’s sex, age, and payer (Medicare, Medicaid, private insurance, or other payer). Both sex and age may be medical indicators for certain treatments, and payer information allows us to control for potential financial incentives physicians face when making treatment decisions (Avraham & Schanzenbach 2015). Beyond this demographic information, each observation includes up to 15 separate diagnoses that were entered into each patient’s record. We use this information to construct the constituent parts of the Charlson Comorbidity Index, which control for various comorbidities that may influence treatment choices.57 Finally, because the type of hospital may influence the availability of different procedures and physician preferences for those procedures, we construct control variables for the type of hospital where the patient was treated.58

D. Analyzing the Risk Faced by Physicians

To construct groups of physicians who vary in their sensitivity to Riegel, we examine physicians facing different levels of malpractice liability risk. Specifically, physicians in areas with relatively high malpractice liability risk will be more sensitive to Riegel than physicians in areas with relatively low malpractice liability risk because the increase in expected malpractice costs for physicians in high-risk areas will be larger than the expected increase for physicians in low-risk areas. To distinguish between physicians in low- and high-risk areas, we focus on states with and without noneconomic damages caps in place. Prior work has shown that, among all tort reforms, noneconomic damages caps are the most likely to reduce malpractice risk (Kachalia et al. 2016), so we use information on whether a state has such a cap in place to distinguish between low- and high-malpractice-risk areas. With information on noneconomic damages caps, we estimate a series of difference-in-differences models that isolate the effect of Riegel in high-risk areas relative to low-risk areas.

Because our analysis relies on the presence of noneconomic damages caps in different states over time, we gather information on which states had these caps in place from Avraham’s (2014) Database of State Tort Law Reforms (5th). In general, individual noneconomic damages caps vary in both the threshold at which damages are capped and in the permissiveness of the exceptions to the cap amount. To address this issue, we employ Avraham’s (2014) definition of “clever” noneconomic damages caps, which are set low enough and contain sufficiently few exceptions to be generally binding on damages awards. We match these “clever” caps to the NIS data based on the year of the hospital

57The Charlson Comorbidity Index is used to predict the one-year mortality for patients. A number of different comorbid conditions (e.g., AIDS or cancer) are assigned a score to arrive at a final index that measures the patient’s overall condition. By including scores for the constituent parts of the index instead of the index itself, we avoid imposing specific functional form assumptions on the index. The same procedure was used by Avraham and Schanzenbach (2015) in their analysis of the same dataset examined here.

58The NIS provides the following information about hospitals: whether the hospital is a teaching hospital; whether the hospital is large, medium, or small; whether the hospital is public or private; whether the hospital is for-profit; and whether the hospital is in a rural area.
visit and the state in which the visit occurred.\textsuperscript{59} Using these cap data, we estimate a series of linear probability models with the following general specification:

\[ I(\text{stent})_{ist} = \beta_1 \text{PostRiegel}_i \times \text{No Noneconomic Cap}_{st} + \beta_2 \text{No Noneconomic Cap}_{st} + \text{Patient Characteristics}_{ist} \gamma + \text{Hospital Characteristics}_{ist} \delta + \tau_t + \phi_h + \epsilon. \]

Here, \( i, h, s, \) and \( t \) index individual patients, hospitals, states, and years, respectively. The dependent variable is an indicator for whether the patient received a cardiac stent (when the model is limited to heart attack patients) or cranial stent (when the model is limited to stroke patients). As before, \text{PostRiegel} is an indicator variable for whether the patient was treated after the \textit{Riegel} case had been decided by the Supreme Court.\textsuperscript{60} Because Supreme Court decisions are binding on all lower courts, \text{PostRiegel} equals 1 in all states and years after 2008. The variable \text{No Noneconomic Cap} equals 1 in states that did \textit{not} have a noneconomic damages cap in place, based on Avraham’s (2014) definition of these clever caps.\textsuperscript{61}

The variable of interest is the interaction term \( \text{PostRiegel}_i \times \text{No Noneconomic Cap}_{st} \) and \( \beta_1 \) captures the differential effect of \textit{Riegel} in states that did not have a cap in place (i.e., high-malpractice-risk states). For identification of this interaction term, we rely on the exogenous shock provided by \textit{Riegel}. Based on the theory noted above, we expect \( \beta_1 < 0 \).

The vectors \textit{Patient Characteristics} and \textit{Hospital Characteristics} include indicators for the patient characteristics and hospital characteristics discussed above. The vectors \( \phi_h \) and \( \tau_t \) include a series of hospital and year fixed effects, respectively. These fixed effects control for unobserved characteristics of individual hospitals and unobserved changes over time, allowing the models to provide estimates of the change in stent use independently of these other factors. Throughout the analysis, standard errors are clustered at the state level. Because the size of the clusters differs and only 46 clusters are included (based on the inclusion of states in the NIS), we also estimate wild bootstrapped clustered standard errors. Additionally, we re-estimate all the primary models with standard errors clustered at the hospital level, and these results are reported in Table B4.

\section*{IV. \textit{Riegel} and Device Manufacturer Behavior}

Under \textit{Riegel}, device manufacturers were immunized from certain types of tort liability if they submitted their Class III device for PMA review. This section focuses on the effect of \textit{Riegel} on manufacturers’ incentives to complete the PMA process. Table 1 reports the results of our primary model. The magnitudes and significance of these results are in line

\textsuperscript{59}A complete overview of the states that adopted and maintained a clever cap during our data period is provided in Table B5.

\textsuperscript{60}As before, since \textit{Riegel} took effect across all states simultaneously and because we include a full set of year fixed effects, we do not include a separate \textit{Riegel} indicator, which would not be identified.

\textsuperscript{61}For ease of interpretation, we define this variable based on the absence of caps.
Table 1: Ordinary Least Squares—Number of Applications Approved

<table>
<thead>
<tr>
<th>Quintile</th>
<th>Coefficient</th>
<th>Standard Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>First quintile</td>
<td>0.011</td>
<td>(0.030)</td>
</tr>
<tr>
<td>Second quintile</td>
<td>-0.063***</td>
<td>(0.023)</td>
</tr>
<tr>
<td>Third quintile</td>
<td>-0.037</td>
<td>(0.023)</td>
</tr>
<tr>
<td>Fourth quintile</td>
<td>-0.059***</td>
<td>(0.019)</td>
</tr>
<tr>
<td>Fifth quintile</td>
<td>-0.070***</td>
<td>(0.015)</td>
</tr>
<tr>
<td>PostRiegel x First quintile</td>
<td>-0.030</td>
<td>(0.029)</td>
</tr>
<tr>
<td>PostRiegel x Second quintile</td>
<td>0.035</td>
<td>(0.030)</td>
</tr>
<tr>
<td>PostRiegel x Third quintile</td>
<td>-0.015</td>
<td>(0.023)</td>
</tr>
<tr>
<td>PostRiegel x Fourth quintile</td>
<td>0.033*</td>
<td>(0.018)</td>
</tr>
<tr>
<td>PostRiegel x Fifth quintile</td>
<td>0.028**</td>
<td>(0.012)</td>
</tr>
<tr>
<td>Observations</td>
<td>14,645</td>
<td></td>
</tr>
<tr>
<td>$R^2$</td>
<td>0.107</td>
<td></td>
</tr>
</tbody>
</table>

Notes: Variables included but not reported include indicator variables for quarters and product categories. Standard errors are clustered by product category. The quintiles refer to nonzero levels of the percent of adverse events classified as serious events, by quarter. The base category is product categories with zero serious risk. ***p < 0.01.; **p < 0.05.; *p < 0.1.

Relative to product categories with zero serious risk, there is no significant effect on the number of approvals after *Riegel* for low quintiles of serious risk. However, for the fourth and fifth quintiles, the coefficients are positive and statistically significant.62 Given that the dependent variable is the number of applications approved, the relative increase in number of approvals for product categories with higher quintiles of risk corresponds to roughly 0.03 applications. While this may seem small, the average number of applications approved per product category and quarter is 0.04. Accordingly, this effect is both statistically and practically significant. These results confirm that product categories associated with higher levels of risk in a given quarter see greater growth in approvals after *Riegel*, relative to product categories with zero serious risk. Subject to the aforementioned assumptions, this implies that manufacturers pursue PMA approvals at higher rates for higher-risk products following *Riegel*.

As noted above, this analysis classifies serious risks by quarter, allowing product categories to change quintiles each quarter. This allows for a flexible definition of high risk that allows for

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62 The Appendix lists the same results using a negative binomial model in Table B1. We have more concerns about the negative binomial model given the number of fixed effects, but the results are qualitatively similar, though proportional increases are significant for lower quintiles as well.
changes in status based on quarters with relatively few serious complaints. Below, we extend this analysis to allow for lagged effects of high-risk categories. Using the quintiles already established, we create a dichotomous treatment variable, High Risk, which takes the value of 1 for a product category in any quarter after that product category is classified in the fourth or fifth quintile of risk. Accordingly, if a product category ranks within the fourth or fifth quintile of risk in a given quarter, High Risk will take the value of 1 in that quarter and every quarter afterward. This is consistent with a world in which product manufacturers receive information shocks about the dangerousness of their device, which do not disappear in periods following the shock. This allows us to see the average effect of the riskier product codes and include some reputational effects following such a negative signal of risk. Moreover, the binary measure allows us to perform a clean event study, which is reported below.

Table 2 reports results from models employing this new definition of High Risk. As before, the variable of interest is the interaction between High Risk and PostRiegel. The results in Table 2 are consistent with those in Table 1 in both sign and magnitude.

To further test the pre-trends for High Risk categories, we conduct an event study in which the PostRiegel indicator variable is replaced by a set of broad period indicators. We include an indicator for four or more years prior to Riegel, a three-year lead, a two-year lead, an indicator for the year Riegel took effect, a one-year lag, and a two-year lag. We exclude the four quarters preceding the Riegel decision as our baseline period. Displayed in Figure 1 are the comparable treatment effects resulting from the interactions between High Risk and each period. Relative to the baseline of a year prior to Riegel, the prior periods are not significantly different. The point estimates on these periods are small and imprecise. For Enactment Year, the year of Riegel, the point estimate is larger, though barely not significantly greater than the baseline year. The remaining coefficients on the two years following Riegel are positive, and the coefficient for the period more than two years after Riegel is positive and significant. This trend in treatment effect suggests that the results are not driven by a negative pre-trend; instead, the pattern is consistent with the lagged effect of a legal change. Overall, these results suggest that device manufacturers strategically respond to the immunization from liability effected by Riegel in economically predictable ways.

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We run a negative binomial model as well, as shown in Table B2. The results there are consistent with the OLS results in Table 2.
**Figure 1:** Difference in number of approvals for high- and low-risk products, relative to difference in year before enactment.

![Graph showing the difference in number of approvals](image)

**V. Riegel and Physician Treatment Decisions**

As detailed above, physicians should respond differently to *Riegel* depending on whether they face high or low malpractice risk. Table 3 reports results from a series of linear probability models that examine the effect of *Riegel* on physicians’ decisions to employ stents in treating heart attack and stroke patients. The first two columns report results for patients suffering from heart attacks. The results suggest that physicians in high-malpractice-risk areas choose to use stents less often following the *Riegel* decision, relative to physicians in low-malpractice-risk areas. Because all the models are linear probability models and the variable of interest is an interaction between indicator variables, the reported coefficients can be interpreted as percentage point changes. Thus, the coefficient on the interaction term in Column (1) implies that physicians in high-malpractice-risk areas are 2 percentage points less likely to employ PMA devices following *Riegel*, relative to physicians in low-malpractice-risk areas. This represents an approximately 7 percent decrease overall relative to the national average of stent use. Adding a full set of controls for demographic and medical factors, as well as the type of treating hospital, in Column (2) results in almost no change in the estimated effect.

We estimate a similar pattern of results with respect to the use of cranial stents in Columns (3) and (4) of Table 3. In the specifications with and without additional control variables, *Riegel* results in a 0.1 percentage point decrease in stent use by physicians in high-malpractice-risk areas, relative to physicians in low-malpractice-risk areas. Although the magnitude of the effect is smaller, this result is consistent with that of cardiac stent use.
To further test whether Riegel changed physician practice patterns consistent with a decrease in the risk of products liability claims, as in Section IV, we estimate a series of event study models. As before in these models, we replace the interaction between the PostRiegel and No Noneconomic Cap variables with a series of interactions between leads and lags of the PostRiegel variable and the No Noneconomic Cap variable. We include an indicator for four or more years prior to Riegel, a three-year lead, a two-year lead, an indicator for the year Riegel took effect, a one-year lag, and a two-year lag. As before, we exclude the year preceding the Riegel decision as our baseline period. Otherwise, the event study models are identical to general models (with a full suite of control variables). Figure 2a reports results for the cardiac stent model, and Figure 2b reports results for the cranial stent model. Both figures demonstrate that Riegel had a greater negative effect on stent use in high-malpractice-pressure states than in low-malpractice-pressure states. The event studies indicate that the difference in changes between high-malpractice-pressure states and low-malpractice-pressure states in each period follows the expected pattern of a policy change. There is no significant pre-trend that is driving the results, and the larger negative effects are seen after the policy is implemented. Although the results, particularly for cardiac stents, are not very precise, this does follow the pattern we would expect after a legal change.

Given that, unlike device manufacturers, our physician analysis relies on geographical differences in liability exposure, we turn back to the issue of lower court rulings prior to the Supreme Court’s decision in Riegel. Even though the potential that physicians would react to a lower court ruling rather than to the Supreme Court’s ruling would merely understate our findings, we perform the following robustness check. To test whether the lower court decisions had an effect, we adopt the methodology outlined in Section V and

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**Table 3: Linear Probability Model—Effect of Riegel on Physician Decisions to Use Stents**

<table>
<thead>
<tr>
<th></th>
<th>Cardiac</th>
<th>Cardiac</th>
<th>Cranial</th>
<th>Cranial</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No cap x Post-Riegel</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(1)</td>
<td>(2)</td>
<td>(3)</td>
<td>(4)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No cap</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
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<td></td>
<td></td>
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</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Observations</td>
<td>989,728</td>
<td>989,678</td>
<td>803,232</td>
<td>803,185</td>
</tr>
<tr>
<td></td>
<td></td>
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</tr>
<tr>
<td>Additional controls</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
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</tbody>
</table>

*Notes: The dependent variable in all specifications is an indicator for whether a stent was used in the treatment of a patient. The sample in the first two columns is limited to heart attack patients, and the dependent variable equals 1 if a cardiac stent was used in treating a given patient. The sample in the final two columns is limited to stroke patients, and the dependent variable equals 1 if a cranial stent was used in treating a given patient. All specifications include full sets of hospital and year fixed effects. The specifications in Columns (2) and (4) also include a full set of controls for patient and hospital characteristics. Standard errors clustered at the state level are reported in parentheses (and significance stars are based on these standard errors). P-values based on wild clustered bootstrapped standard errors are reported in brackets. ***p < 0.01; **p < 0.05; *p < 0.1.*
Figure 2: Event studies—difference in prevalence of stent use in high- and low-malpractice states, relative to difference in baseline year. (a) Cardiac Stents (b) Cranial Stents

estimate a series of models that include an indicator for whether a given state was located in a jurisdiction that adopted the conclusion in Riegel prior to the Supreme Court’s 2008 decision. As reported in Table B3, we find no evidence that a lower court’s adoption of the
Riegel conclusion affected our outcomes of interest. This provides useful evidence that Riegel itself, and not lower court decisions to the same effect, is the relevant change in liability.

The pattern of effects in Figures 2a and 2b, combined with the results reported above, suggest that Riegel changed how physicians treat patients in a manner consistent with their malpractice risk increasing following Riegel. Recognizing that Riegel's immunization of tort liability for device manufacturers might make patients more likely to sue physicians, physicians substitute away from using these devices. While we cannot directly estimate the effect of Riegel, the results demonstrate that this decision had a stronger effect on physicians in states with high malpractice risk relative to physicians in states with low malpractice risk. This differential effect is consistent with physicians responding to an increase in malpractice risk following Riegel.

In addition to providing evidence of physician sensitivity to changes in legal liability, these results provide an important check on the earlier medical device results. The results in this section are derived from a separate dataset and document the decisions of independent medical actors. Despite this, the results are consistent with our expectations: Riegel's immunization of certain legal liability has practical, and potentially perverse, consequences for sophisticated entities interacting with devices.

VI. THE PRACTICAL CONSEQUENCES OF Riegel

The evidence presented here extends the existing literature on the role of liability in the regulation of healthcare. The two separate empirical analyses provide evidence of the same underlying principle: sophisticated actors respond predictably to changes in expected legal liability. Even though Riegel v. Medtronic involved close statutory interpretation regarding the technical doctrine of preemption, the decision had lasting impacts on the practical incentives of device manufacturers and other entities interacting with medical devices.

For device manufacturers, eliminating the availability of certain products liability claims results in a relative increase in marginally riskier—presumably previously less profitable—devices coming to market. This result is consistent with the strategic behavior of a profit-maximizing firm aware of its expected liability costs. For physicians, the limitation of plaintiffs' options for pursuing device manufacturers should lead to an increased expected malpractice liability risk. Our results show that physicians in high-malpractice-pressure states change their treatment plans to reduce the use of medical devices, relative to physicians in low-malpractice-pressure states. This change is consistent with Riegel shifting liability away from manufacturers and toward physicians.

We do not draw any normative conclusions from our results about the optimality of the changes in liability induced by Riegel. It is possible that, absent Riegel, subjecting device manufacturers to both federal regulation and state tort law would result in reduced innovation or suboptimal medical devices. It is also possible that physicians took too little care in employing devices in the treatment of patients, knowing that patients would be drawn to device manufacturers' deeper pockets. Our results, however, emphasize that these practical effects exist, despite the Supreme Court's perhaps principled choice not to consider them. More generally, our results demonstrate that sophisticated actors—device manufacturers and physicians—respond to changes in their expected liability. In other words, liability matters. As
policymakers continue to address the incentives created by legal liability, our results highlight the importance of anticipating changes in the behavior of those affected by liability.

REFERENCES


APPENDIX A

In view of the data limitations, the empirical analysis in Section IV focuses on the population of approvals, not the population of submissions. An approval is a function of a firm’s decision to submit an application and whether the submission satisfies a standard of approval. A change in approvals without a corresponding change in submission quantity or quality can result if the FDA standard changes. Conversely, if the FDA standard is

*Figure A1: Percent of PMAs
Quarterly Update on Medical Device Performance Goals (FDA 2015:23).

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*Based on original PMAs that were accepted for filing as of 06/30/2015; percentages may not add to 100% due to rounding
Table A1: Ordinary Least Squares: Number of Applications Approved, 1997–2012

<table>
<thead>
<tr>
<th>Quintile</th>
<th>(1)</th>
<th>(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>First quintile</td>
<td>-0.011</td>
<td>(0.029)</td>
</tr>
<tr>
<td>Second quintile</td>
<td>-0.078***</td>
<td>(0.027)</td>
</tr>
<tr>
<td>Third quintile</td>
<td>-0.039</td>
<td>(0.024)</td>
</tr>
<tr>
<td>Fourth quintile</td>
<td>-0.067***</td>
<td>(0.020)</td>
</tr>
<tr>
<td>Fifth quintile</td>
<td>-0.084***</td>
<td>(0.019)</td>
</tr>
</tbody>
</table>

PostRiegel $\times$ First quintile  
0.003  
(0.026)

PostRiegel $\times$ Second quintile 
-0.001 
(0.033)

PostRiegel $\times$ Third quintile  
-0.011  
(0.022)

PostRiegel $\times$ Fourth quintile 
0.049** 
(0.022)

PostRiegel $\times$ Fifth quintile  
0.030**  
(0.014)

Observations  
11,723

$R^2$  
0.114

NOTES: Variables included but not reported include indicator variables for quarters and product categories. Standard errors are clustered by product category. The quintiles refer to nonzero levels of the percent of adverse events classified as serious events, by quarter. The base category is product categories with zero serious risk. The data only include applications received from 1997–2012. ***p < 0.01; **p < 0.05; *p < 0.1.

Table A2: Ordinary Least Squares: Number of Applications Approved, 1997–2012

<table>
<thead>
<tr>
<th>High Risk</th>
<th>(1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Risk $\times$</td>
<td>-0.041**</td>
</tr>
<tr>
<td></td>
<td>(0.017)</td>
</tr>
</tbody>
</table>

PostRiegel $\times$ High Risk  
0.024**  
(0.011)

Observations  
11,723

$R^2$  
0.112

NOTES: Variables included but not reported include indicator variables for quarters and product categories. Standard errors are clustered by product category. High Risk takes the value of 1 in quarters during and after a product category ranks within the fourth or fifth quintiles of serious risk. The data only include applications received from 1997–2012. ***p < 0.01; **p < 0.05; *p < 0.1.

constant (i.e., such that the likelihood that the FDA approves an application with a given level of scientific evidence stays the same before and after Riegel), a change in approvals can tell us about the change in submissions.
Figure A2: Difference in number of approvals for high- and low-risk products, relative to difference in year before enactment, 1997–2012.

While our analysis relies on the actual FDA standard, which may result in different approval rates depending on composition of incoming submissions, we can also look at documented approval rates. Although the FDA does not disclose PMAs that are not approved in their current form, it published a chart of PMA approval rates by year.  

Figure AI indicates that the nominal approval rate declined from 2005 onward and reached a low in 2010. From there, the approval rate reverted back to its previous levels before reaching its highest point in 2015. Notably, most applications that were not approved are listed as “withdrawn,” rather than denied, as the denial rate is quite low (consistently below 5 percent over time).

As noted above, the nominal approval rates can reflect different compositions of applications (e.g., good-quality and bad-quality applications). With a uniform FDA standard, we essentially observe only good-quality applications for high- and low-risk devices. An approval rate can reflect a fluctuating proportion of bad-quality applications in aggregate. So long as there is a parallel trend in the number of bad-quality applications for high- and low-risk products (i.e., the change in number of bad-quality applications after Riegel is the  

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64Quarterly Update on Medical Device Performance Goals (FDA 2015:23), available at https://www.fda.gov/media/93353/download.
same for high- and low-risk products), the effect calculated using the sample of good applications will be the same effect from all submitted applications.\textsuperscript{65}

If instead the change in bad applications is more negative for high-risk products than for low-risk products, this itself is informative. Although overall submission for high-risk products may not have actually increased, firms spending more time to submit high-quality high-risk applications is consistent with a rational response to \textit{Riegel}.

Out of an abundance of caution, however, we also run our specification on a subsample of the data (1997–2012), before the change in nominal approval rates from 70 percent to 85 percent. We find no significant difference in our findings (Table A1, Table A2, and Figure A2), which leaves us confident that our results are not driven by a change in FDA approval standard.

\section*{APPENDIX B}

\begin{table}[h]
\centering
\caption{Negative Binomial Model—Number of Applications Approved}
\begin{tabular}{ll}
\hline
(1) & \\
\hline
First quintile & $-0.245$ \\
 & (0.226) \\
Second quintile & $-0.772^{***}$ \\
 & (0.295) \\
Third quintile & $-0.375$ \\
 & (0.336) \\
Fourth quintile & $-1.113^{**}$ \\
 & (0.491) \\
Fifth quintile & $-2.127^{*}$ \\
 & (1.105) \\
Post\textit{Riegel} $\times$ First quintile & $1.132^{***}$ \\
 & (0.329) \\
Post\textit{Riegel} $\times$ Second quintile & $1.226^{**}$ \\
 & (0.494) \\
Post\textit{Riegel} $\times$ Third quintile & $0.286$ \\
 & (0.418) \\
Post\textit{Riegel} $\times$ Fourth quintile & $1.527^{***}$ \\
 & (0.591) \\
Post\textit{Riegel} $\times$ Fifth quintile & $0.341$ \\
 & (1.741) \\
\hline
Observations & 14,645 \\
\end{tabular}
\end{table}

\textbf{NOTES:} Variables included but not reported include indicator variables for quarters and product categories. Standard errors are clustered by product category. The quintiles refer to nonzero levels of the percent of adverse events classified as serious events, by quarter. The base category is product categories with zero serious risk. $^{***}p < 0.01$; $^{**}p < 0.05$; $^{*}p < 0.1$.

\textsuperscript{65}Similarly, if the change in bad applications is more negative for low-risk products than for high-risk products, the effect calculated for good applications will only be an understatement of the effect on total applications.
Table B2: Negative Binomial Model—Number of Applications Approved

<table>
<thead>
<tr>
<th></th>
<th>High Risk</th>
<th>PostRiegel × High Risk</th>
<th>Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>14,645</td>
</tr>
<tr>
<td>Notes: Variables included but not reported include indicator variables for quarters and product categories. Standard errors are clustered by product category. High Risk takes the value of 1 in quarters during and after a product category ranks within the fourth or fifth quintiles of serious risk. ***p &lt; 0.01; **p &lt; 0.05; *p &lt; 0.1.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table B3: Linear Probability Model—Effect of Lower Court Rulings on Physician Decisions to Use Stents

<table>
<thead>
<tr>
<th></th>
<th>(1)</th>
<th>(2)</th>
<th>(3)</th>
<th>(4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower court adopted</td>
<td>Cardiac</td>
<td>Cardiac</td>
<td>Cranial</td>
<td>Cranial</td>
</tr>
<tr>
<td>Observations</td>
<td>781,776</td>
<td>781,733</td>
<td>498,622</td>
<td>498,587</td>
</tr>
<tr>
<td>R²</td>
<td>0.217</td>
<td>0.288</td>
<td>0.020</td>
<td>0.021</td>
</tr>
<tr>
<td>Additional controls</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Notes: The dependent variable in all specifications is an indicator for whether a stent was used in the treatment of a patient. The sample in the first two columns is limited to heart attack patients, and the dependent variable equals 1 if a cardiac stent was used in treating a given patient. The sample in the final two columns is limited to stroke patients, and the dependent variable equals 1 if a cranial stent was used in treating a given patient. All specifications include full sets of hospital and year fixed effects. The specifications in Columns (2) and (4) also include a full set of controls for patient and hospital characteristics. Standard errors clustered at the state level are reported in parentheses. ***p < 0.01; **p < 0.05; *p < 0.1.

Table B4: Linear Probability Model—Effect of Riegel on Physician Decisions to Use Stents

<table>
<thead>
<tr>
<th></th>
<th>(1)</th>
<th>(2)</th>
<th>(3)</th>
<th>(4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No cap × Post-Riegel</td>
<td>Cardiac</td>
<td>Cardiac</td>
<td>Cranial</td>
<td>Cranial</td>
</tr>
<tr>
<td>Observations</td>
<td>989,728</td>
<td>989,678</td>
<td>803,232</td>
<td>803,185</td>
</tr>
<tr>
<td>R²</td>
<td>0.204</td>
<td>0.280</td>
<td>0.020</td>
<td>0.021</td>
</tr>
<tr>
<td>Additional controls</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Notes: The dependent variable in all specifications is an indicator for whether a stent was used in the treatment of a patient. The sample in the first two columns is limited to heart attack patients, and the dependent variable equals 1 if a cardiac stent was used in treating a given patient. The sample in the final two columns is limited to stroke patients, and the dependent variable equals 1 if a cranial stent was used in treating a given patient. All specifications include full sets of hospital and year fixed effects. The specifications in Columns (2) and (4) also include a full set of controls for patient and hospital characteristics. Standard errors clustered at the hospital level are reported in parentheses (and significance stars are based on these standard errors). P values based on wild clustered bootstrapped standard errors are reported in brackets. ***p < 0.01; **p < 0.05; *p < 0.1.
Table B5: Clever Noneconomic Damages Caps 1999–2011

<table>
<thead>
<tr>
<th>Category</th>
<th>States/Year(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Always had cap</td>
<td>AK, CA, CO, HI, ID, KS, MD, MA, MI, MO, MT, ND, SD, UT, WV, WI</td>
</tr>
<tr>
<td>Repealed cap between 1999 and 2011</td>
<td>OR (2000)</td>
</tr>
<tr>
<td>Never had cap</td>
<td>AL, AZ, AR, CT, DE, DC, IN, IA, KY, LA, ME, MN, NE, NH, NJ, NM, NY, NC, PA, RI, TN, VT, VA, WA, WY</td>
</tr>
</tbody>
</table>