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# Responses to Liability Immunization: Evidence from Medical Devices

Elissa Philip Gentry\*      Benjamin J. McMichael†

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## Abstract

The Supreme Court’s decision in *Riegel v. Medtronic* unexpectedly and immediately immunized medical device manufacturers from certain types of state tort liability. *Riegel* immunized manufacturers from liability if their devices had been approved through the Food and Drug Administration’s most rigorous—and costly—review process, premarket approval (“PMA”). Exploiting this unanticipated decision, we examine whether manufacturers strategically respond to this new immunity. We find evidence that, following the *Riegel* decision, device manufacturers file more PMA applications for high risk product categories (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 towards 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 health care.

Keywords: Medical Device, Liability, FDA, Regulation

JEL Codes: I18, K13, K23

## 1 Introduction

Medical devices are ubiquitous in U.S. healthcare. From the use of intrauterine devices for contraception to stents for blocked arteries, medical devices pervade many everyday health

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care 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 only began in 1976, with the enactment of the Medical Device Amendments of 1976 (“MDA”).

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 under a less rigorous review, the § 510(k) process. These devices, and new devices found to be “substantially equivalent” to those devices, could remain under a § 510(k) license until the FDA requires their product category to go through PMA review.<sup>1</sup>

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

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<sup>1</sup>The FDA does not set deadlines for individual device but rather for entire product categories.

devices approved under the PMA process were immune from liability for certain state tort claims. In contrast, devices approved via the § 510(k) process were not immune from state tort liability. With this decision, the Supreme Court created a bifurcated liability scheme for the riskiest devices: PMA-approved devices are subject only to federal regulation, while § 510(k)-approved devices are subject to both 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 paper 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 2.2 discusses the nuances of the Supreme Court's evolving doctrine of preemption and how it led to *Riegel*. Section 3 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 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.” With analogies to such strategic behavior, this project 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 that manufacturers do respond in this way. Following *Riegel*, the number of PMA approvals for devices with a high risk of tort liability increases after *Riegel* relative to the change for devices with lower risks of liability.

In addition to examining medical device manufacturers' response to *Riegel*, section 4 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, which are designed to reduce their expected liability (Kessler and McClellan (1996); Kessler and McClellan (2002); Avraham and Schanzenbach (2015); Currie and MacLeod (2008); Cotet (2012); Frakes (2012)).<sup>2</sup> Other studies have analyzed how supply of individual providers changes in response to tort reforms, suggesting physicians are willing to relocate to states with lower liability risk (Helland and Seabury (2015); Lieber (2014); Klick and Stratmann (2007); Encinosa and Hellinger (2005); Kessler, Sage, and Becker (2005)).<sup>3</sup>

We extend this literature, offering evidence that physicians are sensitive to the *Riegel* ruling in predictable ways. 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 face an increase in their malpractice liability risk when using PMA-approved devices after *Riegel*.<sup>4</sup> However, the degree of this increase is not equal across the country because some physicians practice in states with tort reforms, which can

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<sup>2</sup>Related work has considered whether these changes in behavior in response to changes in liability reduce healthcare costs. While no consensus exists on this question, some research suggests that reducing the liability risk by reforming tort law can reduce healthcare costs (Mello and 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.

<sup>3</sup>Some work suggests that the effect of tort reforms on physician supply may be limited (Paik et al. (2016); Yang et al. (2008)).

<sup>4</sup>Galasso and Luo (2017) explore the link between manufacturers and physicians in a slightly different way. They 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 paper instead considers the link between manufacturer liability and physician treatment.

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 riskier devices for approval or by proactively shielding themselves from perceived liability by using fewer devices in their medical practice. Before detailing that evidence, the next Section discusses the regulatory backdrop surrounding *Riegel*, starting with the original medical device statute and the more recent Supreme Court interpretation of that statute to preempt state tort liability in certain cases.

## 2 Federalism and Medical Device Regulation

### 2.1 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”).<sup>5</sup>

Federal passivity in medical device regulation came to an end in the 1970s. In 1970,

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<sup>5</sup>These claims are generally brought as strict liability claims, although plaintiffs can also bring negligence claims.

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.<sup>6</sup> 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 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 general controls in order to ensure safety and effectiveness.<sup>7</sup> 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.<sup>8</sup> Class III devices are those for which general or special controls are insufficient, given that they are used for supporting or sustaining human life.<sup>9</sup> In light of these risks, class III devices require some level of premarket approval.

Once designated as class III, a device must complete the premarket approval unless exempt.<sup>10</sup> The class III device process—the premarket approval (“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 which were required to complete it, devices already on the market at the time the MDA was enacted would have needed to be recalled pending approval or the grant of a temporary approval.

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<sup>6</sup>[https://www.washingtonpost.com/archive/entertainment/books/1985/11/17/the-dalkon-shield-disaster/6c58f354-fa50-46e5-877a-10d96e1de610/?utm\\_term=.4f61c04da319](https://www.washingtonpost.com/archive/entertainment/books/1985/11/17/the-dalkon-shield-disaster/6c58f354-fa50-46e5-877a-10d96e1de610/?utm_term=.4f61c04da319)

<sup>7</sup>A 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).

<sup>8</sup>21 U.S.C. § 360c (a)(1)(B).

<sup>9</sup>These 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).

<sup>10</sup>21 U.S.C. § 360e(a). The exemption process is described in § 360j(g).

Instead of pulling these devices from the market pending FDA approval, however, the FDA allowed to them to remain on the market after completing the “§ 510(k) approval process.” These “grandfathered” devices would eventually be required to complete the PMA process but were allowed to remain on the market under a § 510(k) approval.

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 § 510(k) process and only complete the PMA process when the Secretary initiated a formal PMA process for the predicate grandfathered device.<sup>11</sup> Thus, the FDA grandfathered entire classes of products, instead of individual products. While the § 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 § 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.<sup>12</sup> At any time, any class III product can be submitted for the PMA process, including products that have completed the § 510(k) process but have not yet been required to complete the PMA process. However, any product that is neither grandfathered nor substantially equivalent to a grandfathered product must immediately complete the PMA process.

## 2.2 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 Constitu-

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<sup>11</sup>21 U.S.C. § 360e(b)(1)(B).

<sup>12</sup>§ 360e(b)(1).



tion gives Congress the authority to pass laws that supersede, or “preempt,” state laws,<sup>13</sup> 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 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<sup>14</sup>

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.<sup>15</sup>

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,” how-

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<sup>13</sup>The doctrine of federal preemption is complex, and much of this complexity is beyond the scope of this paper. 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.

<sup>14</sup>21 U.S.C. § 360k(b)

<sup>15</sup>21 U.S.C. § 360k(a).

ever, are legally ambiguous. Decades later, in *Medtronic v. Lohr*,<sup>16</sup> the Supreme Court provided some clarity.

In *Lohr*, plaintiff Lora Lohr claimed that she was injured when her pacemaker, a device approved under the § 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 § 510(k) process did not constitute a “requirement.”<sup>17</sup> The Court found important that the § 510(k) process did not mandate that the pacemaker take a particular form but merely be substantially equivalent to a predicate device.<sup>18</sup>

Twelve years later,<sup>19</sup> plaintiff Charles S. Riegel brought a claim against Medtronic for injuries caused by an Evergreen Balloon Catheter. This product was approved by a PMA process, unlike the § 510(k) device in *Lohr*. As before, Riegel’s claims would only be preempted if the Court determined that both the PMA process and the state common law claim were considered “requirements.”

The Supreme Court answered both questions in the affirmative. In holding that the PMA process is a federal requirement, unlike the § 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.”<sup>20</sup> The Court also formally held that negligence and strict liability tort claims impose requirements,

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<sup>16</sup>518 U.S. 470 (1996).

<sup>17</sup>*Id.* at 492.

<sup>18</sup>In other words, the Court held that the second prong—whether the federal process undergone legally constitutes a requirement—was not satisfied.

<sup>19</sup>552 U.S. 312 (2008).

<sup>20</sup>552 U.S. at 323.

relying on the five justices in *Lohr* and two subsequent cases interpreting different statutes.<sup>21</sup> 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.”<sup>22</sup>

*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*,<sup>23</sup> the Court noted that *Lohr* “can be read to allow certain state-law causes of actions that parallel federal safety requirements.”<sup>24</sup> However, there are limits to this exception as well.<sup>25</sup> 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.<sup>26</sup> Some language in *Riegel* and *Lohr* suggests that manufacturing defect claims might escape preemption insofar as they impose generally applicable requirements.

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 provided a sharp 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 this change in liability was unanticipated and, for our purposes, an exogenous shock.

While the benefit of hindsight might suggest the *Riegel* holding was unsurprising, it was by no means a foregone conclusion after *Lohr*. Four justices in *Lohr* suggested that the preemption provision, § 360k, was mainly concerned with state statutes<sup>27</sup>. Moreover, those 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

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<sup>21</sup> *Id.* at 323-325.

<sup>22</sup> *Id.* at 324 (internal quotations and citation omitted).

<sup>23</sup> 531 U.S. 341 (2001).

<sup>24</sup> *Id.* at 353.

<sup>25</sup> This exception has been discussed thoroughly in legal scholarship (e.g., Prince (2013); Wartman (2009); Whitney (2010)).

<sup>26</sup> 552 U.S. at 321, n. 2.

<sup>27</sup> *Id.* at 489

meant to “remove all means of judicial recourse for those injured by illegal conduct[.]”<sup>28</sup> By *Riegel*, however, three of those four justices had joined with the majority.<sup>29</sup>

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 rather than predictions about the best policies for 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.

In general, the legal changes effected by this case should impact both manufacturers’ behaviors in submitting devices for approval and physicians’ treatment behavior using such devices. Section 3 focuses on the effect of *Riegel* on device manufacturer behavior, using approval data from the FDA. Section 4 focuses on the effects of *Riegel* on physician treatment behavior.

### **3 *Riegel* and Device Manufacturer Application Behavior**

Given the Supreme Court’s ruling in *Riegel*, device manufacturers were immunized from certain types of tort liability if they submitted their class III device for PMA review. This

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<sup>28</sup>*Id.* at 487.

<sup>29</sup>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 for drugs were not preempted, *Wyeth v. Levin*, 555 U.S. 555 (2009).

Section focuses on the effect of *Riegel* on manufacturers' incentives to complete the PMA process. We begin by describing our general empirical strategy before discussing the data used in executing that strategy.

### 3.1 Empirical Strategy

The economic intuition of our analysis is straightforward. 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.<sup>30</sup> *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.

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, and relatedly, 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

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<sup>30</sup>For the sake of simplicity, expected liability refers to liability premised on state torts imposing specific, additional requirements to the FDCA.

realistic assumption of how firms assess risk for original applications than only allowing a specific device's history to inform the firm of its own risk.

To isolate the effect of *Riegel* on firms submitting applications in high risk product categories, we estimate a series of differences-in-differences regressions with the following general specification:

$$NumberPMAApplications_{pq} = \beta_1 HighRisk_{pq} \times PostRiegel + \beta_2 HighRisk_{pq} + \delta_p + \gamma_q + \epsilon. \quad (1)$$

$NumberPMAApplications_{pq}$  represents the number of applications filed in a given product category  $p$  and quarter  $q$ .<sup>31</sup>  $HighRisk_{pq}$ , defined multiple ways below, indicates that a product category is associated with significant expected liability later immunized by *Riegel*. 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.<sup>32</sup>

The variable of interest is the interaction term  $HighRisk \times PostRiegel$  which captures the growth in approvals per product category considered *HighRisk* after *Riegel*. Notably, 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 low levels of expected liability to estimate differential sensitivity to the passage of *Riegel*.

## 3.2 Approval Data

In order to examine the effect of *Riegel* on firm decision-making, we analyze a dataset of device approvals for 1997-2015 obtained from the FDA. We downloaded these data from the

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<sup>31</sup>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 Section 3.1.

<sup>32</sup>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.

FDA website, and the dataset contains approvals from the PMA<sup>33</sup> and § 510(k) processes.<sup>34</sup> From the pool of all approvals, we restrict our analysis to only original device approvals.<sup>35</sup>

The FDA, unfortunately, does not disclose the universe of applications submitted, merely the universe of releasable applications approved. While this is a data limitation, our results are unaffected as long as the probability of the FDA approving an application with a particular level of scientific evidence is constant over the study period, the number of approvals should be an unbiased estimate of the number of applications. This assumption does not require that the composition of aggregate applications remains constant; indeed, we hypothesize that firms are more likely to submit riskier applications after *Riegel*. 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*.

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.<sup>36</sup> We have found no evidence that this approach changed within the study period.<sup>37</sup> Only in December 2016, did Congress pass the

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<sup>33</sup><https://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/pmaapprovals/default.htm#pma>, accessed on May 29, 2018

<sup>34</sup>[https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510\(k\)Clearances/ucm089428.htm](https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510(k)Clearances/ucm089428.htm), accessed on May 29, 2018.

<sup>35</sup>We only consider 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 dropping approvals that list a supplement number.

<sup>36</sup>21 U.S.C. 360c(a)(3)(D)(ii), 360c(i)(1)(D).

<sup>37</sup>We note here several statutes that were passed in the intermediate period which did not 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). <https://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm109317.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. <https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentsstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/ucm083161.htm> Similarly, in 2012, the Food and Drug Administration Safety and Innovation Act (“FDASIA”) was passed to again reauthorize medical device user fees and modify requirements for investigation device exemptions under 21 U.S.C. 360j. Our

21st Century Cures Act. While this nominally only reaffirmed its commitment to the “least burdensome” approach to PMA approval, some critics suggested it actually established less stringent standards.<sup>38</sup> 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 PMA applications more stringently after *Riegel*, this would only produce a bias against our hypothesis. If firms submitted applications for riskier devices and the FDA denied approval based on its more stringent regulations, we may not find significant results despite the existence of a change in firm strategy. Conversely, 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.

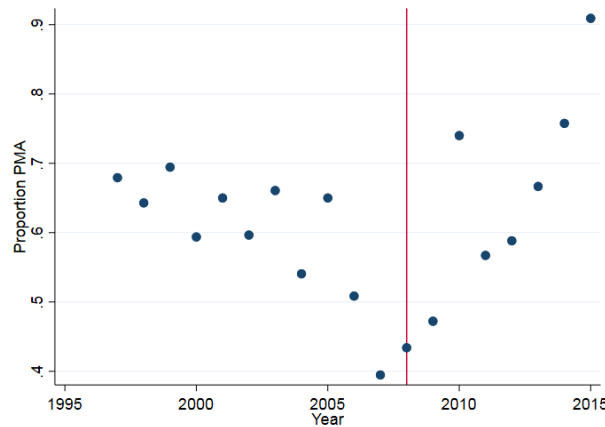


Figure 1: Proportion of Class III Devices Filed as PMAs over Time

Figure 1 presents the raw approval counts filed by year. The data are presented as the proportion of class III device approvals filed as PMAs (as opposed to as § 510(k)s). The vertical line 2008 indicates the year that *Riegel* was decided. The raw data in Figure 1 are certainly suggestive. In 1997, PMAs made up around 70% of all class III approvals

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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.

<sup>38</sup>Horvath (2017) offers one such argument.



filed. This proportion declined until 2008, when PMAs constituted around 40% of class III approvals. Notably, *Medtronic v. Lohr* was decided in 1996. Given that *Medtronic v. Lohr* held that devices approved under the § 510(k) process are not exempt from state tort liability, if manufacturers anticipated that PMAs would not be treated any differently, there would be no additional incentive to pursue the more rigorous PMA process. After 2008, however, the trend reverses and the proportion of PMAs steadily increase.

Though Figure 1 lists both PMA and § 510(k) approvals, we limit our analysis to the number of PMA approvals. Additionally, as noted above, instead of counting the number of approvals by each device, we aggregate the number of approvals by product category. In order to do this, we supplement our data on approvals with other FDA data on product categories.<sup>39</sup> This dataset includes unique product category codes which link to sections of the Code of Federal Regulations (“C.F.R.”) and lists device class number.<sup>40</sup>

In order 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 zeros periods where zero PMAs were actually approved for the product category, not merely periods preceding the establishment of the product category. We subsequently restrict the entire sample to 1997-2015. 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.

### 3.3 High Risk Data and Results

Given the empirical strategy outlined in section 3.1, our identification strategy relies on isolating product categories with a large change in expected liability after *Riegel*. Accordingly, the definition of *HighRisk* is particularly important. This section outlines multiple,

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<sup>39</sup><https://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/ucm051668.htm>, accessed on May 14, 2018.

<sup>40</sup>Some of these classifications are merely tentative, however. The FDA notes that if there is no CFR section listed, the device classification is likely tentative.

potential definitions of *HighRisk*: The first relies FDA recall data to characterize high risk products. Given the level of detail provided by the recall data, as well as the credible signal of risk provided by a manufacturer-initiated recall, this data is most targeted to the type of liability that *Riegel* immunized. Data availability on recalls, however, is limited. To ensure that the results using this definition of *HighRisk* are robust to a longer time period, we employ a second definition that relies on data from voluntary complaints housed in the FDA’s Manufacturer and User Facility Device Experience Database (“MAUDE”). Under both definitions of *HighRisk*, we find that, consistent with our predictions, the change in the number of approvals for *HighRisk* product categories is significantly positive, relative to the change in approvals for low risk categories.

### 3.3.1 High Risk: FDA Recall Data

In order to construct our *HighRisk* variable, we rely on recall data from the FDA.<sup>41</sup> We downloaded recalls by searching for recalls by month. These downloaded files include the following information: recall class, recall number, product description, and date that the recall was posted online. We link this to more detailed information available on the FDA website, including the date on which the firm initiated the recall and the larger product code of the recalled product.<sup>42</sup> Recalls are available on the FDA website from November 2002. These recalls can be either FDA-initiated or firm-initiated and are categorized into three types based on the severity of the risk posed.<sup>43</sup> Type 1 recalls involve “a reasonable chance that a product will cause serious health problems or death,” while Type 2 recalls involve “a temporary or reversible health problem or where there is a slight chance that it will cause serious health problems or death.”<sup>44</sup>

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<sup>41</sup><https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm>. This data was accessed in August 2018.

<sup>42</sup>In order to get this detailed information, which allows us to link the recall data to larger product categories, we use an algorithm to collect product codes.

<sup>43</sup>The FDA separate these into “classes”, but in order to distinguish recall classes from device classes we will refer to recall classes as “types.”

<sup>44</sup>Not considered are Type 3 recalls in which “a product is not likely to cause any health problem or injury.” <https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall>.

In order to capture firms' dynamic expectations of liability, we allow *HighRisk* to vary by time depending on whether the product category is subject to a relevant recall in the current or any previous quarter. We match the recall data to the approval data by product code. Because recall information is only available from late 2002, we limit our analysis of approval data to 2003-2015.

In order to only isolate significant expected liability concerns, we further limit the recalls considered to those in which “there is a reasonable chance that a product will cause serious health problems or death” or when “a product may cause a temporary or reversible health problem or where there is a slight chance that it will cause serious health problems or death.”<sup>45</sup>

To create a *HighRisk* variable that only captures liability risk that would be preempted by *Riegel*, we drop recalls that appear to involve manufacturing defects. We do not want to consider manufacturing defects for two reasons: First, *Riegel* did not address manufacturing defects, so it is less clear that liability for such defects would be affected. Second, unlike design defects, manufacturing defects do not implicate products throughout the whole product type; instead, manufacturing defects represent singular deviations from manufacturing standards. In order to implement this screen, we drop recalls that mention “sterility” as the manufacturer reason for recall, as this generally is indicative of a recall due to a manufacturing defect. In addition to dropping recalls mentioning “sterility” as the manufacturer reason, we only consider a recall if it mentions “design” as the FDA-determined cause for the recall.<sup>46</sup> We designate this the “narrow” *HighRisk* definition.

The results for the above analyses are reported in Table 1. As previously noted, if *Riegel* incentivized manufacturers of high-risk devices to seek PMA approval and gain immunity from many state tort claims, the interaction term  $HighRisk \times PostRiegel$  should be positive. The results in Table 1 support this hypothesis. Columns (1) and (2) use the narrow

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<sup>45</sup>These are considered class III or class II recalls, as designated by the FDA. <https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall>.

<sup>46</sup>As noted above, *Riegel* focuses on design defects.

Table 1: OLS for Number of Applications Approved

	(1)	(2)	(3)	(4)
High Risk x PostRiegel	0.037** (0.016)	0.045*** (0.016)	0.038*** (0.013)	0.037 (0.023)
High Risk	-0.028 (0.029)	-0.052** (0.020)	-0.026 (0.021)	-0.049* (0.028)
Recalls Used	Type1	Type1&2	Type1	Type1&2
Definition of High Risk	Narrow	Narrow	Broad	Broad
Observations	11,077	11,077	11,077	11,077
R-squared	0.125	0.125	0.125	0.126

**Notes:** Variables included but not reported include indicator variables for periods and product categories. Standard errors are clustered by product categories. In columns (1) and (2), *HighRisk* takes the value of one when there is at least recall that mentions “design” but does not mention “sterility” as the manufacturer reason for recall. In columns (3) and (4), *HighRisk* takes the value of one when there is at least one recall that does not mention “sterility” as the manufacturer reason for recall and does not list as the FDA determined cause “Contamination,” “No Marketing Application,” “PMA,” “Pending,” “Other,” “Radiation Control,” “Under Investigation,” or “Unknown.” Significance levels: \*\*\*  $p < 0.01$ , \*\*  $p < 0.05$ , \*  $p < 0.1$ .

definition of *HighRisk*. Column (1) only includes Type 1 recalls, while column (2) includes both Type 1 and 2 recalls. The interaction effect captures the difference in number of PMA-process approvals for high risk products before and after *Riegel*, relative to low risk products. In column (1), this effect is positive and significant, resulting in roughly 0.037 additional approvals per product category in a given quarter. Given that the average number of approvals per product category in a given quarter is 0.034,<sup>47</sup> this is a meaningful increase. The effect incorporating Type 2 recalls, shown in column (2), is similar.

While this level of detail is helpful in isolating the relevant type of risk, we face some data limitations with the recall data. Given that recall data only begins in 2002, and that recalls for class III devices are relatively rare, it is possible that the definition of *HighRisk* is underinclusive. In order for a product to be considered *HighRisk* before *Riegel*, a recall would need to be listed after 2002 but before 2008. And while several product categories

<sup>47</sup>This is the average over 2003-2015.

are still considered *HighRisk* before *Riegel*, the first period in which a *HighRisk* product category has a nonzero number of approvals is after *Riegel*. This is not unusual, given the relatively rare event of a class III device approval in any period. This does not affect our difference-in-difference model, as there are treated observations both before and after *Riegel*; however, the fact that our pre-*Riegel* treated observations have the value of zero introduces the concern that a negative binomial model may not produce accurate hypothesis test results. Accordingly, we estimate our difference-in-difference regression using ordinary least squares.

Given the potential scarcity of approvals defined as *HighRisk*, we also experiment with a broader definition of this designation. In doing so, we still need to ensure that manufacturing defects are not included, as this liability likely did not change after *Riegel*. To do this, we continue to drop recalls that mention “sterility” in the manufacturer recall reason but only drop recalls that list as the FDA-determined cause of the recall “Contamination,” “No Marketing Application,” “PMA,” “Pending,” “Other,” “Radiation Control,” “Under Investigation,” or “Unknown.” While this is less restrictive than only considering recalls involving “Design” as a cause, it still drops recall causes that are either inherently unknown (i.e., “Under Investigation” or “Unknown”), likely to involve manufacturing defects (i.e., “Contamination”), or involve technical violations (i.e., “PMA” or “No Marketing Application”). We designate this the “broad” *HighRisk* definition. Despite these restrictions, this broader definition might include more recall circumstances than those that imply risk immunized by *Riegel*; accordingly, we expect that this effect may be weaker than the results derived from the more narrowly defined *HighRisk* category. Examining this broader classification of *HighRisk* products nevertheless provides a useful robustness test of our results.

Columns (3) and (4) use the broad definition and produce qualitatively similar results. The coefficient on the interaction term  $HighRisk \times PostRiegel$  remains positive, though it loses statistical significance upon incorporating Type 2 recalls in column (4).

By using data from the FDA Recall Database, the risk variable is tailored to the type of risk *Riegel* exempted from state tort liability. However, as noted above, there limits to these

data. Even in its broadest definition, the number of product classes classified as *HighRisk* with nonzero approvals before *Riegel* is small. Accordingly, we supplement the analysis using these definitions and data with additional results in the next section.

### 3.3.2 High Risk: FDA MAUDE Data

In this section, we use data from Manufacturer and User Facility Device Experience Database (MAUDE) to replicate the previous section’s results. MAUDE data is available for a longer time horizon than the FDA recall data,<sup>48</sup> which allows us to incorporate more past history when determining *HighRisk* status.

Data from MAUDE come from voluntarily submitted postmarket reports<sup>49</sup> that do not fall within any reporting exemption. These data, accordingly, provide a noisy signal of the true underlying risk. However, MAUDE data are useful as a measure of the litigation risks perceived by companies. We only keep event records that indicate that the event involved a product problem and that the product was subsequently evaluated by the manufacturer.<sup>50</sup>

In order to capture the highest liability costs, we consider a product category to be *HighRisk* when the percent of adverse events reported resulting in either death, hospitalization, or deemed “life-threatening” rises above the median percent over all product categories and time periods.<sup>51</sup> Intuitively, when the percent of serious adverse events is higher than the median product category over time, manufacturers consider product applications submitted to such a product category to have a high level of liability risk. As before, *HighRisk* is a dynamic measure, reflective of the idea that device manufacturers learn about the risks

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<sup>48</sup>The FDA notes that “voluntary reports [were collected] since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996.”

<sup>49</sup>There are mandatory reporters, including manufacturers. However, given that the mandatory report is triggered by a voluntary complaint, this does not help.

<sup>50</sup>The MAUDE database was downloaded from <https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/manufacture-and-user-facility-device-experience-database-maude> in March 2019. We count unique MDR codes as separate observations. New data, including previously unreleased reports became available on June 21, 2019. Results incorporating this new data are listed in Appendix 5

<sup>51</sup>After the percent of serious adverse events rises above this level, the category is considered *HighRisk* for the rest of the sample. This is consistent with a world in which product manufacturers receive information shocks about the dangerousness of their device, which does not disappear in periods following the shock.

associated with their product over time. Though this definition of *HighRisk* is less well calibrated to true liability risk, it does allow us to examine our full time period, 1997-2015.

Table 2: OLS for Number of Applications Approved

	(1)
High Risk x PostRiegel	0.040*** (0.010)
High Risk	-0.064*** (0.016)
Observations	14,648
R-squared	0.106

**Notes:** Variables included but not reported include indicator variables for quarters and product category. Standard errors are clustered by product category. *HighRisk* takes the value of one when the percent of MAUDE complaints involving death, hospitalization or deemed “life-threatening” rises above the median percent over all product categories over time. Significance levels: \*\*\*  $p < 0.01$ , \*\*  $p < 0.05$ , \*  $p < 0.1$ .

Table 2 reports results from models employing this new definition of *HighRisk*. As before, the variable of interest is the interaction between *HighRisk* and *Post – Riegel*. The results in Table 2 are consistent with those in Table 1 in both sign and magnitude.<sup>52</sup>

Moreover, given the greater availability of MAUDE data, we can test the pre-trends for *HighRisk* categories. To this end, we conduct an event study in which the *Post – Riegel* indicator variable is replaced by a set of broad period indicators. We exclude the four quarters preceding the *Riegel* decision as our baseline period. Displayed in Figure 2 are the comparable treatment effects resulting from the interactions between *HighRisk* and each period. Relative to the baseline of a year prior to *Riegel*, the periods prior are not significantly different.  $> 2YearsPrior$  includes all years more than 2 years before *Riegel*, while *2YearsPrior* is a dummy variable for the year prior to the baseline. The point estimates on these periods are small and imprecise. For *EnactYear*, the year of *Riegel*, the point estimate is larger, though barely not significantly greater than the baseline year.

<sup>52</sup>Given the better availability of MAUDE data, we are able to run a negative binomial model as well, as shown in Table B1. The results there are consistent with the OLS results in Table 2.

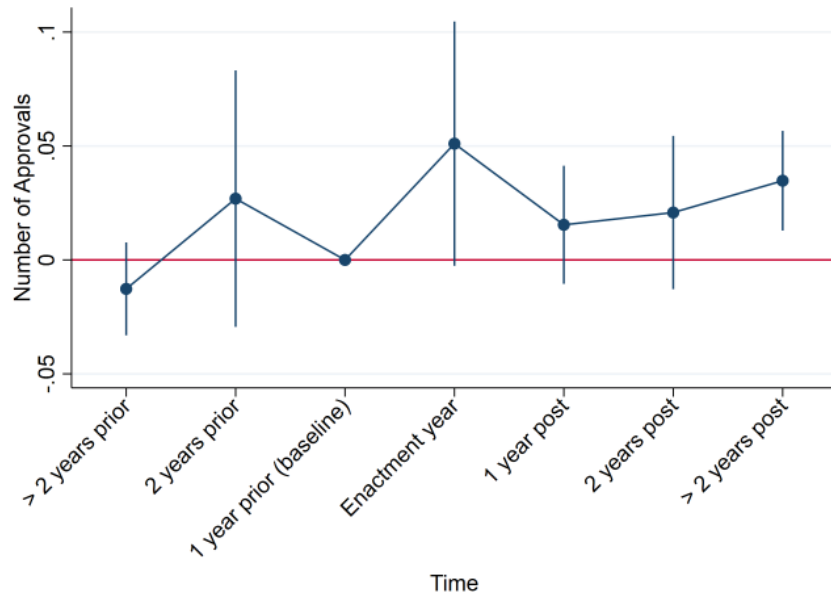


Figure 2: Difference in Number of Approvals for High and Low Risk Products, Relative to Difference in Year Before Enactment

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 suggest that the results are not driven by a negative pre-trend; instead, the pattern is consistent with the lagged effect of a policy change.

Since *Riegel* provided device manufacturers immunity from state tort claims imposing different requirements than PMA approval, if device manufacturers are sensitive to liability risk, we expect to see marginal increases in the number of risky PMAs filed. In this section, we find evidence that device categories with the biggest change in expected legal liability experienced a significant increase in the number of PMA applications approved. By using data from both the FDA Recall and MAUDE databases, we construct *HighRisk* categories and find that these categories predictably are more likely to have additional PMA approvals filed after *Riegel*. While these results are subject to data limitations, the consistency of these results across multiple definitions of *HighRisk* is comforting and support the suggestion that device manufacturers strategically respond to the immediate—and unexpected—immunization of liability in economically predictable ways.



## 4 *Riegel* and Physician Treatment Decisions

While *Riegel* directly changed the incentives of manufacturers in bringing devices to market, it also potentially influenced the perceived liability of a related entity: physicians. This Section explores *Riegel's* effect on physicians, a group of sophisticated actors who routinely decide whether to incorporate medical devices into their treatment plans. Given the potential liability device use triggers for both physicians and device manufacturers, this Section examines whether liability immunization for device manufacturers actually lead physicians to choose to employ PMA devices less often following *Riegel*.

The theory underlying this potential change in behavior is straightforward. Prior to *Riegel*, a patient injured while 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 liability 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. While products liability claims and medical malpractice claims involve different elements and may not generally co-exist within the same incident, clever attorneys may be able to credibly file either claim in some cases.<sup>53</sup> Moreover, in cases that could involve both types of claims, attorneys may be more inclined to sue manufacturers since they may be better able to pay a settlement or judgment.<sup>54</sup> 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

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<sup>53</sup>For 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).

<sup>54</sup>This 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*

substitute alternative procedures not involving PMA devices in marginal cases where they have some discretion.

Given the somewhat messy reality of medical decisionmaking, we must be careful in choosing the appropriate population on which to test the above hypothesis. In order 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).<sup>55</sup> These patient populations provide a useful sample in which to test the question of whether physicians respond to *Riegel* as described above for several reasons.

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 used to understanding how to manage 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 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.

While these patient populations provide a useful context in which to test the effects of *Riegel*, as above, we cannot estimate the causal effect of this case in a traditional difference-

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<sup>55</sup>As described in detail below, we examine patients suffering from several different types of cerebrovascular conditions. However, we refer to these patients as “stroke patients” for ease of exposition.

in-differences model. *Riegel*, as a decision of the United States Supreme Court, became binding law in all states as soon as it was decided, meaning there was no phase-in period or a subset of physicians who were not subject to *Riegel*. Because of the obvious limitations in simply comparing physician treatment decisions before and after *Riegel*, we construct groups of physicians who vary in their sensitivity to *Riegel*. Specifically, physicians in areas with relatively high malpractice risk will be more sensitive to *Riegel* than physicians in areas with relatively low malpractice 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 differentiate 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-difference models that isolate the effect of *Riegel* in high-risk areas relative to low-risk areas.

## 4.1 Data and Empirical Specification

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% sample of hospitals in the United States. Each year, approximately one-thousand hospitals are sampled, and between five and eight million hospital stays are included in the dataset. When a hospital is chosen for inclusion, all of 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.<sup>56</sup> While not all states’ hospitals are included in every year of the NIS

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<sup>56</sup>We 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

dataset, we follow previous work and include all available data in our analysis (Avraham and Schanzenbach, 2015).<sup>57</sup>

Using information on hospital stays, we identify any stay that included a principal diagnosis of heart attack or stroke.<sup>58</sup> Because the majority of individuals suffering from these conditions require a hospital visit—over 90% 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.<sup>59</sup> In our sample, approximately 30% of all heart attack patients and 0.3% 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.

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 and Schanzenbach, 2015). Beyond this demographic information, each observation includes up to fifteen 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

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noneconomic damages cap was applicable to a given provider.

<sup>57</sup>Avraham and Schanzenbach (2015) provide an overview of which states's hospitals are included in each year of the NIS.

<sup>58</sup>We 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).

<sup>59</sup>Because 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.

control for various comorbidities that may influence treatment choices.<sup>60</sup> 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.<sup>61</sup>

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 visit and the state in which the visit occurred. A complete overview of the states that adopted and maintained a clever cap during our data period is provided in Table B3. Using these cap data, we estimate a series of ordinary least squares models with the following general specification:

$$I(stent)_{ihst} = \beta_1 PostRiegel_t \times NoNoneconomicCap_{st} + \beta_2 NoNoneconomicCap_{st} + PatientCharacteristics'_{hsi} \lambda + HospitalCharacteristics_{hst} \theta + \tau_t + \phi_h + \epsilon. \quad (2)$$

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, *PostRiegel* is an indicator variable for whether the patient was

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<sup>60</sup>The 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.

<sup>61</sup>The 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.

treated after the *Riegel* case had been decided by the Supreme Court.<sup>62</sup> Because Supreme Court decisions are binding on all lower courts, *PostRiegel* equals one in all states and years after 2008. The variable *NoNoneconomicCap* equals one in states that did *not* have a noneconomic damages cap in place, based on Avraham's 2014 clever definition of these caps.<sup>63</sup>

The vectors *PatientCharacteristics* and *HospitalCharacteristics* include indicators for the patient characteristics and hospital characteristics discussed above. The vectors  $\phi$  and  $\tau$  include a series of hospital and year fixed effects, respectively. These fixed effects control for unobserved characteristics of individual hospitals and unobserved linear and non-linear trends 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 of the primary models with standard errors clustered at the hospital level, and these results are reported in Table B2.

The variable of interest is the interaction term  $PostRiegel_t \times NoNoneconomicCap_{st}$ , and  $\beta_1$  captures the differential effect of *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 *Riegel*. Based on the theory noted above, we expect  $\beta_1 < 0$ .

## 4.2 Treatment Decisions for Heart Attack and Stroke Patients

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

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<sup>62</sup>As before, since *Riegel* took effect across all states simultaneously and because we include a full set of year fixed effects, we do not include a separate *Riegel* indicator, which would not be identified.

<sup>63</sup>We define this variable based on the absence of caps for ease of interpretation.

following the *Riegel* decision, relative to physicians in low-malpractice-risk areas. Because all of 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 the change in likelihood of device use for physicians in high-malpractice-risk areas is 2 percentage points less following *Riegel* relative to the comparable change for physicians in low-malpractice risk areas. This represents an approximately 7% 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.

Table 3: Effect of Riegel on Physician Decisions to Use Stents

	(1) Cardiac	(2) Cardiac	(3) Cranial	(4) Cranial
No Cap x Post-Riegel	-0.021* (0.011) [0.126]	-0.018* (0.011) [0.166]	-0.001** (0.001) [0.057]	-0.001** (0.001) [0.059]
No Cap	0.006 (0.006) [0.316]	0.008 (0.006) [0.178]	0.002*** (0.001) [0.061]	0.002*** (0.001) [0.061]
Observations	989,728	989,678	803,232	803,185
R-squared	0.204	0.280	0.020	0.021
Additional Controls	No	Yes	No	Yes

**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 one 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 one 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. Significance levels: \*\*\*  $p < 0.01$ , \*\*  $p < 0.05$ , \*  $p < 0.1$

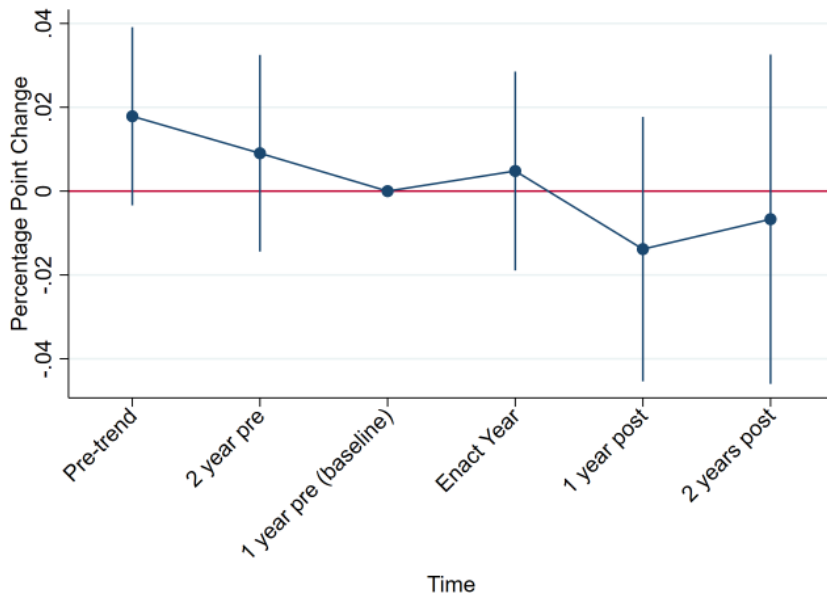
We estimate a similar pattern of results with respect to the use of cranial stents in columns

(3) and (4). In the specifications with and without additional control variables, *PostRiegel* 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. While the magnitude of the effect is smaller, this result is consistent with that of cardiac stent use.

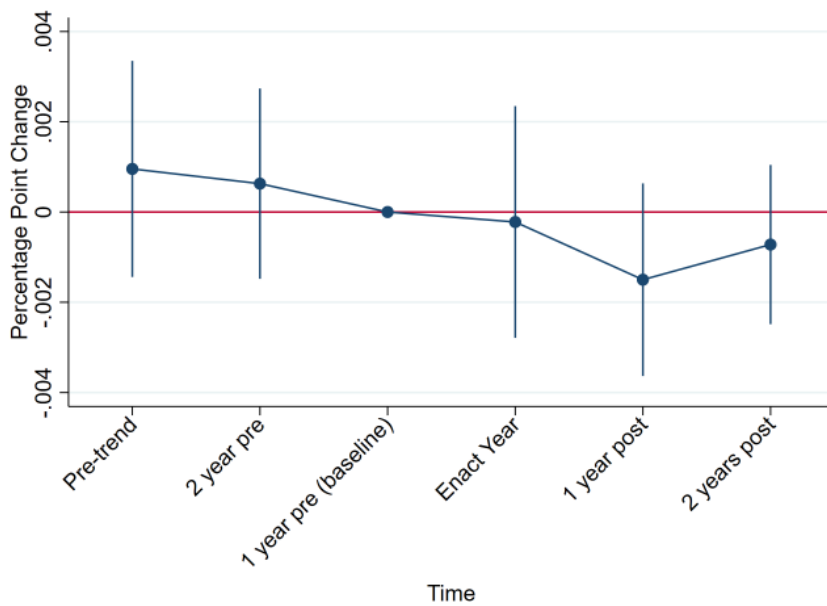
To further test whether *Riegel* changed physician practice patterns consistent with a decrease in the risk of products liability claims, we estimate a series of event studies. As before, in these models, we replace the interaction between the *PostRiegel* and *NoNoneconomicCap* variables with a series of interactions between leads and lags of the *PostRiegel* variable and the *NoNoneconomicCap* variable. We include an indicator for whether the treatment occurred three or more years prior to *Riegel* (the "pre-trend"), a two-year lead, an indicator for the year *Riegel* took effect, a one-year lag, and a two-year lag (one-year prior to *Riegel* is the baseline). Otherwise, the event study models are identical to general models (with a full suite of control variables). Figure 3a reports results for the cardiac stent model, and Figure 3b 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 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. While the results, particularly for cardiac stents, are not very precise, this does follow the pattern we would expect after a legal change.

The pattern of effects in Figures 3a and 3b as well as the results reported above suggest that *Riegel* changed how physicians treat patients 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





(a) Cardiac Stents



(b) Cranial Stents

Figure 3: Event Studies: Difference in Prevalence of Stent Use in High and Low Malpractice States, Relative to Difference in Baseline Year

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*.

This Section examines a set of independent medical actors and documents evidence of decisions consistent with awareness of shifting liability. In addition to providing evidence of physician sensitivity to changes in legal liability, these results provide an important check on the earlier medical device regulation results. The two separate hypotheses, borne from the underlying principle that sophisticated actors respond predictably to changes in expected legal liability, are consistent with the results from two separate empirical analyses. through 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 the narrative above: *Riegel*'s change to legal liability has practical, and potentially perverse, consequences for sophisticated entities interacting with devices.

## 5 The Practical Consequences of *Riegel*

The evidence presented here extends the existing literature on the role of liability in the regulation of healthcare. The results suggest that even technical Supreme Court decisions, which may focus on arcane doctrines, still have salient—if unanticipated—impacts on many related entities. 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.

In this paper, we present results from two separate populations, each of which should be theoretically impacted by *Riegel* in different ways. Although we are subject to data limitations inherent to the FDA's policies and the way the legal change was actually implemented, the consistency of the results for these separate population tells a suggestive story.

For device manufacturers, immunizing a subset of medical device manufacturers' liability results in the arrival of marginally riskier—presumably previously less profitable—devices coming to market. This result is robust to several definitions of high-risk and are consistent with the strategic behavior of a profit-maximizing firm aware of their expected liability costs.

For physicians, the curtailment of plaintiffs' options for legally pursuing device manufacturers should lead to an increased expected malpractice liability risk. Our results show that physicians in high-malpractice-pressure states marginally change their treatment plans to reduce the use of medical devices, relative to changes for physicians in low-malpractice-pressure states. This protective measure is similarly entirely predictable considering the potential substitutability of liability between physicians and device manufacturers, and the evidence is consistent with sophisticated action on physicians' parts.

Ironically, in interpreting the literal text of the MDA, the Supreme Court's decision in *Riegel* ran the risk of undermining the original purpose of the MDA: to provide patients with safe, effective devices. Relative to the pre-*Riegel* baseline, relatively more device approvals are associated with higher liability—and by correlation, injury—risk after *Riegel*. Moreover, while *Riegel* was concerned with preventing tort law from overly reducing access to medical devices, the shifting liability caused seems to result in patients having less access to devices operated by physicians.

Our results are not designed to draw any normative conclusions regarding the optimality of such changes. It is possible that, absent *Riegel*, subjecting device manufacturers to both federal regulation and state tort law would result in reduced innovation or sub-optimal 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 more drawn to device manufacturers' deeper pockets. Our results, however, merely emphasize that these practical effects exist, despite the Supreme Court's perhaps principled choice not to consider them. Moreover, these results are entirely predictable assuming that device manufacturers and physicians are sophisticated actors acting strategically to systematically maximize profits. We suggest that

in constructing new legal incentives, it is important to anticipate such strategic behavior, especially in relationship to the potentially less sophisticated actions of consumers.

## Appendix A

The following analysis incorporates data from the newly released Alternate Summary Report (ASR) data, which had previously been considered confidential.<sup>64</sup> These adverse events were released separately from the MAUDE data and have slightly different fields, so we have to make a few adjustments to combine these two types of data. First, and most restrictively, the ASR data have only four types of outcomes: malfunction, malfunction in which a patient death was reported, injury, and injury in which a patient death is reported. We accordingly miss nuanced information about how serious the injury was if it did not end in death. To do the best we can, we count any adverse events in which a patient death is reported. This number, however, is relatively low compared to the number of reports made. Less than two hundred out of the roughly 6 million new events released involve death. In contrast, out of the roughly 1.5 million MAUDE reports which were related to product problems and were evaluated by manufacturers, around 3,800 involved death. Because of these discrepancies, while inclusion of the ASR data provides a more complete picture of expected manufacturer liability than before, it may introduce a bit of noise as well. We may be capturing a more serious subsample of cases from the ASR data than the MAUDE data; however, this is more workable than counting any injury or malfunction as a serious case (since almost every adverse event report is labeled either an injury or malfunction and would accordingly with every product category being considered high risk). Despite these difficulties, we include these results for completeness.

The results in Table A1 are very similar to those in Table 2. Given the fact that once a product category is considered high risk, it does not return to being low risk, it is possible that the new ASR observations merely contributed to the high risk percent in periods after

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<sup>64</sup>We accessed this data on June 24, 2019.

becoming high risk. Looking through the data, the ASR data is definitely clustered around a couple of product categories, many of which were never considered high risk. This would explain why the results look so similar to the previous results.

Table A1: OLS for Number of Applications Approved

	(1)
High Risk x PostRiegel	0.031*** (0.011)
High Risk	-0.044** (0.017)
Observations	14,648
R-squared	0.106

**Notes:** Variables included but not reported include indicator variables for quarters and product category. Standard errors are clustered by product category. *HighRisk* takes the value of one when the percent of MAUDE complaints involving death, hospitalization or deemed “life-threatening” rises above the median percent over all product categories over time. Significance levels: \*\*\*  $p < 0.01$ , \*\*  $p < 0.05$ , \*  $p < 0.1$ .

Similarly, we perform the same event study as in Figure 2. This has a bit more noise in the estimates, as most are not actually significant, but follows the same general pattern.

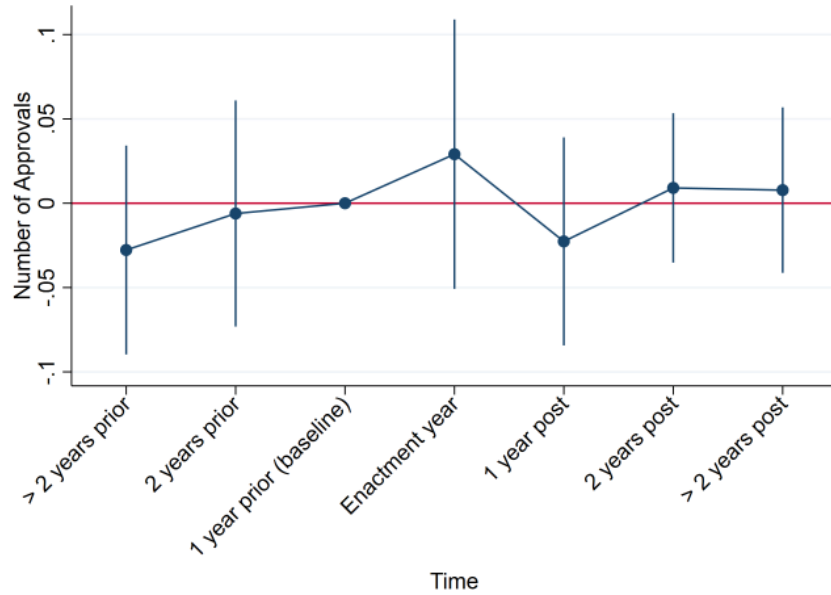


Figure 4: Difference in Number of Approvals for High and Low Risk Products, Relative to Difference in Year Before Enactment

## 6 Appendix B

Table B1: Negative Binomial Model for Number of Applications Approved

	(1)	(2)
High Risk x PostRiegel	1.109*** (0.328)	1.109*** (0.328)
High Risk	-1.288*** (0.289)	-1.288*** (0.289)
Observations	14,648	14,648

**Notes:** Variables included but not reported include indicator variables for quarters and product categories. Standard errors are clustered by product categories. *HighRisk* takes the value of one when the percent of MAUDE complaints involving death, hospitalization or deemed “life-threatening” rises above the median percent over all product categories over time. Significance levels: \*\*\*  $p < 0.01$ , \*\*  $p < 0.05$ , \*  $p < 0.1$ .

Table B2: Effect of Riegel on Physician Decisions to Use Stents

	(1) Cardiac	(2) Cardiac	(3) Cranial	(4) Cranial
No Cap x Post-Riegel	-0.021** (0.011) [0.058]	-0.018* (0.010) [0.063]	-0.001** (0.001) [0.057]	-0.001** (0.001) [0.046]
No Cap	0.006 (0.008) [0.412]	0.008 (0.007) [0.264]	0.002*** (0.001) [0.004]	0.002*** (0.001) [0.001]
Observations	989,728	989,678	803,232	803,185
R-squared	0.204	0.280	0.020	0.021
Additional Controls	No	Yes	No	Yes

**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 one 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 one 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 B3: Clever Noneconomic Damages Caps 1999-2011

Always Had Cap	AK, CA, CO, HI, ID, KS, MD, MA, MI, MO, MT, ND, SD, UT, WV, WI
Enacted Cap Between 1999 and 2011	FL (2003), GA (2005 - 2009), IL (2006 - 2009), MS (2003), NV (2003), OH (2003), OK (2004), SC (2006), TX (2004)
Repealed Cap Between 1999 and 2011	OR (2000)
Never Had Cap	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

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