Regulating the Innovators:

Approval Costs and Innovation in Medical Technologies

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Abstract

How does regulation affect innovation and market competition? I examine this question by exploiting FDA deregulation events that affected certain medical device types but not others. I gather new, comprehensive data on medical device innovation, prices, and regulation changes from eight different sources. The analysis of this data yields three core results. First, deregulation significantly increases the quantity and quality of innovation in treated device types relative to controls. These effects are especially large among small and inexperienced firms. Second, deregulation increases firm entry and lowers the prices of medical procedures that use treated medical device types. Third, rates of serious injuries and deaths caused by defective devices do not measurably increase after deregulation. In fact, deregulating some device types lowered these adverse events rates significantly—consistent with firms increasing their emphasis on product safety as deregulation exposed firms to more liability risk.

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While most innovators create new products with the intention to make them safe and reliable, there is some chance that these products will harm consumers. One approach to mitigating this uncertainty is to regulate new products through mandatory pre-market testing. Critics of this approach claim that regulations reduce innovation and shield established firms from competition due to higher entry costs and approval delays (Peltzman, 1973). Proponents counter that regulations bolster innovation by allowing new firms to signal their quality without a longstanding reputation and that competition erodes incentives to innovate (**?**Carpenter, 2017). Clear evidence testing these claims has been modest.

Emblematic of this debate is the U.S. Food & Drug Administration (FDA), which regulates $2.8 trillion worth of products each year (FDA, 2020b). The FDA tests medical devices before they can be purchased on the U.S. market. Testing requirements differ by broad device types (e.g., X-ray machines or COVID-19 tests) according to a three-tier classification system. On average, the strictest Class III testing costs firms $75 million, and firms await a 54-month review process (Makower et al., 2010). Class II testing imposes $24 million in costs and creates 10-month delays. Class I device types carry no testing requirements. The FDA can move device types into different classes while monitoring the safety outcomes of marketed devices within the same type.

In this paper, I measure the impact of FDA regulation on innovation and market competition by examining deregulation events that affect certain types of medical devices. These events moved device types from Class III to II or II to I. As testing requirements are lifted, the returns to investments in new technologies are clearly and immediately changed. I show that deregulation leads to substantial increases in the flow and quality of new technologies, especially among small and inexperienced firms. Deregulation also leads to a significant influx of new firms. As firms enter, healthcare procedures that use deregulated device types exhibit decreased prices. Lastly, deregulating some devices can lead to *fewer* injuries related to device flaws or "adverse events."

My empirical analysis relies on a combination of eight data sources that provide an

expansive view of the costs and benefits of medical device regulations.[1] First, a collection of all FDA policymaking across the last 40 years allows a comprehensive analysis of device regulations. Second, I draw from various measures of innovation, innovation quality, and firm participation to provide a fuller view of new technologies and market dynamics. Third, I detail trends in the safety of new devices using data from FDA adverse event reports and patent texts. Linking these data with information on firm asset holdings uncovers how regulation affects small and large firms differently. Lastly, insurance claims data allow for a suggestive look into how regulation affects healthcare prices.

I infer the causal effect of deregulation by comparing deregulated device types to a carefully selected set of control groups. These groups include device types matched on baseline means, intuitively similar devices, later-deregulated devices, and a broad set of unaffected devices. I find that my results are stable across these control groups. Furthermore, a comparison of deregulated device types to control groups reveals no divergent pre-existing trends in the outcomes of interest, consistent with the characterization of these events as "unpredictable" (Powell, 2018). Together, these insights reinforce the credibility of my empirical strategy.

My first result quantifies the effects of deregulation on the flow and quality of innovation. After moving from Class III (high regulation) to II (moderate), device types exhibited a 200% increase in patenting and FDA approvals relative to control groups. Patents filed after these events were also of significantly higher quality, as measured by a 200% increase in received citations and market valuations. For Class II to I deregulations, the rate of patent filings increased by 50%, though insignificantly, and the quality of patent filings exhibited a significant 10-fold improvement. There is substantial heterogeneity in how firms respond to deregulation. Increases in innovation are strongest among relatively small firms and those with the least regulatory experience.

Second, I explore how deregulation affected the safety of new devices. After Class III

[1]FDA's MAUDE, 510(K), and PMA databases, UPSTO patents database, UC San Diego Health claims, CRSP/Compustat, Federal Register, and private patent valuations from Kogan et al. (2017).

to II events, some adverse event rates increase. For Class II to I events, however, adverse event rates *dropped* significantly. This surprising improvement in the safety of new devices is plausibly driven by heightened liability risk after deregulation. Deregulated Class I devices no longer experience litigation protection afforded to Class III and II devices (Riegel v. Medtronic Inc. (2008)). To avoid liability from injury, inventors must lower the likelihood that injuries occur instead of meeting Class II requirements deemed by the National Institute of Medicine as insufficient for establishing device safety (IOM, 2011). Indeed, an analysis of patent texts also reveals that inventors focus more on product safety after deregulation. These safety improvements are concentrated at larger firms that cannot use bankruptcy to avert worst-case liability payouts (see Boomhower (2019)). Together, these results suggest that Class II regulations may *decrease* device safety.

Lastly, deregulation led to significant changes in market forces. First, Class III to II events led to a ten-fold increase in entry of firms without prior device approvals ("new entry"). Firms with prior FDA device approvals exhibited a four-fold increase in entry into treated device types ("incumbent entry"). Correspondingly, Class III to II events significantly decreased the amount paid by insurers for medical procedures that use deregulated device types by as much as 40% compared to control groups. Lastly, Class II to I events were associated with a significant doubling of new firms entering treated device types, with no effect on incumbent firm entry.

A back-of-the-envelope calculation uses these three core results and suggests that the benefits of deregulation outweigh the costs. The unmeasured costs of deregulation (e.g., the political risk of misguided deregulation) would need to be larger than the measured costs to justify the FDA's timing for Class III to II events. For Class II to I events, there are virtually no measurable costs of down-classifications as adverse events *decline*. By contrast, the benefit of Class II to I deregulation amounts to more than $24 million a year. Although these benefits may not generalize to Class II devices not chosen for deregulation, I find that the safety benefits are higher among more dangerous, marginal deregulated device types. If

this relationship holds, the yearly forgone benefits could amount to as much as $60 billion across 2,500 current Class II device types, or nearly 34% of the annual value of medical devices consumed.

I build a model that captures the incentives that drive firm investments in new devices, which generates predictions that are consistent with my empirical results. The model incorporates the central concerns of medical device innovators. First, stricter regulation imposes longer FDA approval delays, but firms shorten delays as they gain more experience navigating FDA approval requirements (e.g., "learning by doing"). Firms also face fundraising costs if approval costs exceed their assets. Lastly, when regulations are lifted (Class I), firms are exposed to legal liability risk from product defects and may profit by exerting efforts to improve product safety. Small firms, however, do not fully bear this increased risk as they can use bankruptcy to avoid damages that exceed their assets. This characterization of the firm's decision shapes the benefits of deregulation and generates the following insights. Firms with less experience navigating FDA requirements and firms with fewer asset holdings disproportionately benefit from deregulation.

My findings connect to several literatures. First, I add to a growing literature on the effects of market forces on medical innovation (Grennan and Town, 2020; Clemens and Rogers, 2020; Clemens and Olsen, 2021; Stern, 2017; Budish et al., 2015; Acemoglu and Linn, 2004; Finkelstein, 2004; Peltzman, 1973). Despite the size and growth of the industry, the literature on medical devices is small and only partly confronts how regulation affects medical device innovation.[2] I address this gap by providing the first evidence of the effect of deregulation on medical innovation. I analyze these effects across many device types and degrees of regulatory scrutiny, adding to existing studies that exclusively examine cardiovascular device innovation under Class III regulations. These results also give a suggestive first look at the safety benefits of FDA regulation, a topic that is under-explored (Grennan and Town, 2020).

[2]Stern (2017) analyzes how uncertainty in the Class III approval process can lead to less cardiovascular device innovation. Grennan and Town (2020) find that Class III cardiovascular device regulations can reduce consumer uncertainty and improve welfare, but these regulations also lower access to existing coronary stent technologies.

I also add to a longstanding literature on the tradeoffs between regulation and litigation (Coase, 1960; Ehrlich and Posner, 1974; Kolstad et al., 1990; Shavell, 2013, 2018). Regulation, a preventive strategy, can impose a lower bar on product safety, whereas litigation, a deterrence strategy, punishes those who violate standards through the courts (Kessler, 2010). A related study by Philipson et al. (2010) finds that FDA drug regulation alone is more efficient than a hybrid of both regulation and litigation. In another study, Galasso and Luo (2018) find that increased product liability risk chills innovation. I add to this literature by analyzing the effects of moving from regulation (Class II) to litigation only (Class I) and find that, in my context, litigation can best prevent adverse events while better promoting innovation and competition.

Lastly, my findings relate to the literature on endogenous growth (Romer, 1990; Aghion and Howitt, 1992). Specifically, this paper is closely related to studies on the impact of regulation on economic growth. Some studies suggest that certain kinds of labor market regulations increase innovation (Acharya et al., 2014, 2013), while others reduce innovation (Aghion et al., 2019). Others broadly show that regulation can reduce competition and create long-run inefficiencies by stunting innovation and technological change (Buettner, 2006; Aghion et al., 2009, 2005; Djankov et al., 2006; Hahn and Hird, 1991). My findings build on this literature and suggest that regulatory knowledge does not smoothly flow across firms. Instead, regulatory proficiency stays with the firms that acquire it (akin to Azoulay et al. (2011)). Conceptually, my paper relates to models of productivity growth through learning by doing (Arrow, 1971; Auerswald et al., 2000) and models of productivity losses through capital frictions (Buera and Shin, 2013; Midrigan and Xu, 2014; Moll, 2014).

This paper is organized as follows. Section 1 provides background on the FDA regulatory process, section 2 provides the conceptual framework, section 3 discusses my data, section 4 describes my empirical strategy, section 5 presents my empirical results, section 6 presents a back-of-the-envelope welfare calculation, and section 7 concludes.

1 Background

1.1 Enactment of FDA and Medical Device Regulations

At the turn of the 19th century, "corruption in the food and drug trade was unlike anything seen at any time in history" (Hilts, 2003, p.21). In response, the U.S. Progressive Era ushered in the 1906 Pure Food and Drugs Act, establishing consumer protection laws that led to the creation of the FDA. In 1976, the U.S. Congress expanded the FDA's oversight to include medical devices through the Medical Device Amendments (MDA). Today, the FDA regulates products like drugs, medical devices, and food. This paper focuses exclusively on its regulation of medical devices, which includes products like pacemakers, X-ray machines, and tongue depressors.

The MDA established a framework consisting of 17 expert advisory committees responsible for regulating medical devices within their purview. These committees grouped medical devices into generic types to deliver targeted regulation. "Daily-wear soft contact lenses," for example, is a device type that is regulated differently than "extended-wear soft contact lenses." The policy variation that I study occurs at the level of these generic device types, and I refer to them as "medical device types." In addition, these device types are organized into broad medical categories, like "therapeutic ophthalmic devices." These categories define the device type's indications and its target medical specialty. Figure C.1 describes the hierarchy of medical device types and categories.

With medical device types organized, the MDA mandated each FDA advisory committee to classify these device types according to three classes of perceived risk. Manufacturers of Class I, low-risk devices must simply register their facility with the FDA, which carries a small fee and takes less than one month to process. The FDA requires Class II, moderate risk device manufacturers to file a "510(k)" to prove their device is similar enough to an already marketed device.[3] This process of proving "substantial equivalence" has been criticized by

[3]Manufacturers must also follow best-practice protocols (called "special controls.")

many, including the National Institute of Medicine, as being insufficient for establishing safety (IOM, 2011) and can impose substantial costs. The 510(k) process costs an average of $24 million (Makower et al., 2010), including approval timelines of up to a year. Class III, high-risk device manufacturers must perform clinical trials through the "premarket approval" (PMA) process to ensure their new device is safe and effective before commercialization. The PMA process takes much longer than the 510(k) process and costs, on average, $75 million (Makower et al., 2010). The average costs of these different levels of regulation are shown in figure 1. Appendix C.2 provides more details.

The structure of FDA medical device regulations is designed to accommodate learning. The FDA does not integrate new devices with markedly novel attributes into existing device types as novelty creates unknown risks. Instead, these new devices are classified as Class III to allow learning and ensure safety through stringent testing protocols.[4]

1.2 Deregulation of Medical Device Types

While learning about a device type's inherent risk, the FDA can deregulate or "down-classify" a Class III medical device type when the current body of evidence (e.g., adverse event reports) suggests that discovered risks are mild enough for Class II regulations (see figure 1). On the other hand, manufacturers can file a petition for down-classification, bringing the FDA's attention to particular device types for further investigation. My analysis, however, focuses on down-classification events explicitly enacted by the FDA's initiative (rather than a petition). Class III to II events are described by onlookers as "unpredictable," suggesting the difficulty of anticipating such policy changes (Powell, 2018). My empirical analysis supports this assessment as I do not find evidence of divergent pre-existing trends when comparing down-classified device types to control groups.

[4]In 1997, the FDA allowed manufacturers of markedly novel devices to petition for a direct Class II or I classification. To be deemed eligible, firms must show that best practices assure the safety and efficacy of their device. All the device types I consider, however, existed before 1997, thus were either automatically or intentionally classified into Class III, or were device types that existed before 1976 and were classified into Class II.

As an example of a Class III to II event, the FDA moved spinal fusion devices from Class III to Class II in 2007. Spinal screw systems—a Class II device type often implanted with spinal fusion devices—serve as a useful comparison group. This event led to a sharp rise in the number of new spinal fusion devices submitted for approval, while the number of new spinal screw systems remained relatively steady (see figure 2). The rate of serious adverse events was similar for both device types after the event.

Complete deregulation of medical device types (Class II to I) typically results from Congressional orders. Many of the events I analyze, for example, were spurred by the FDA Modernization Act (FDAMA; FDA (1995)). The FDAMA mandated the FDA to establish a list of Class II devices for deregulation, which ultimately included 158 device types. Device types were chosen for down-classification based on the score calculated in the FDA's Device Priority Model (DPM) (FDA, 1995). DPM scores were primarily determined by annual baseline adverse event counts. Down-classified device types were those that fell below a previously unknown DPM score threshold (see appendix C.1). The publication of the DPM and the down-classification rulings occurred contemporaneously, suggesting that firms could not have expected a given device type's down-classification. This evaluation is strengthened by the similar pre-trends of deregulated devices and control groups.

It is worth noting that these down-classifications only affect established medical device types. Thus, rather than measuring the effect of regulation on radical innovation, this paper measures how regulation affects the development and improvement of existing medical device types. Improving medical devices may require fundamental scientific advances and bring substantial health benefits through increased efficacy or reduced side effects and adverse events.

1.3 Regulation versus Litigation: Federal Preemption

Medical devices that undergo FDA approval are shielded from product design defect lawsuits, creating a stark tradeoff between regulation and litigation. The doctrine of federal

preemption, found in the Supremacy Clause of the U.S. Constitution, establishes that federal approvals preempt state law tort suits (Riegel v. Medtronic Inc. (2008)). The supreme court case Riegel v. Medtronic Inc. (2008) offers manufacturers of Class III devices strong liability protection, but manufacturers of Class II devices are protected to a lesser extent. When device types are fully deregulated (Class I), manufacturers no longer receive FDA approval, completely exposing them to litigation.

A recent example of Class II approval barring product defect torts through preemption is Kelsey v. Alcon Laboratories Inc. (2019). In this case, the plaintiff claimed that a contact lens disinfectant manufactured by Alcon Laboratories did not prevent a severe eye infection due to a design flaw. This product, however, was approved by the FDA as a Class II regulated device. The court deemed that this type of federal approval covered product design and labeling, thus forcing preemption to bar the design claims.

2 Conceptual Framework

In this section, I model a firm's decision to create a new medical device in a given medical device type. This decision yields a payoff from medical device sales but incurs costs associated with regulatory compliance. These costs include delay costs, capital costs (for small or new firms), costs from exerting effort to make the product safer, and expected legal damages from product design flaws. Firms determine an optimal level of safety effort before choosing to create their new device by equating the marginal benefit of safety effort (reducing expected damages) to the marginal cost.

Although many factors influence a firm's decision to invest in a new medical device, I consider these associated costs since firms view them as central concerns. According to industry-wide surveys, a few specific concerns about regulation are strikingly prevalent. First, inexperienced firms face approval delays that are almost twice as long as experienced firms due to "opaque" and "unpredictable" requirements (Makower et al., 2010; Y Combi-

nator, 2016; Pietzsch et al., 2012). Indeed, new firms with founders from incumbent firms ("spawns") perform better than those without largely due to their regulatory knowledge (Chatterji, 2009). Second, 56% of small firms cite funding and capital as a central challenge (Emergo, 2019). These firms traverse a "funding chasm," a period of capital scarcity carved from long approval delays and uncertainty (Gaglani, 2014; Propel, 2017). Lastly, firms spend as much as 3.8% of annual revenue on lawsuits and other events associated with product defects (Fuhr et al., 2018). I integrate these costs into the model to simulate how the flow of new technologies responds to regulatory changes and to motivate my empirical analysis.

2.1 Model Setup

Idea Payout. I first model the payout for creating a new device. To simplify the model, I assume firm f exogenously draws an idea for device j with value $v_{f,j}$, abstracting away from the firm's decision of how intensely to innovate and associated R&D costs. Firm f inelastically produces quantity $q_{f,j}$ of device j.[5] The firm faces an average production cost per unit of $AC_{f,j}$. Hospitals pay an exogenously bargained price to device manufacturers, $p(v_{f,j}, R_c)$, which increases in the product's value. The regulatory environment R_c of Class c may also affect prices through its effect on competition. Thus, firm f receives approval payoff $\alpha_{f,j} = q_{f,j}[p(v_{f,j}, R_c) - AC_{f,j}]$ if it chooses to create a new device in type j.

Delay Costs and Learning by Doing. I then model how experience with FDA regulations can shrink approval delays through "learning by doing" (Arrow, 1971; Auerswald et al., 2000).[6] Firm f, with N previously approved devices, faces $T_{N,f}$ days of approval delay,

[5]This quantity, instead, could be determined by a firm's acquired market share, which itself could be determined by its product value. Since market share and price would likely move in the same direction, however, the qualitative insights of the model would remain unchanged.

[6]There are several reasons why markets cannot remedy a firm's lack of regulatory proficiency. First, inexperienced firms lament paying "sky-high prices" when hiring FDA regulation consultants (Y Combinator, 2016). In addition, hired consultants may not accommodate their expertise to the needs of inexperienced firms, as they are "focused on working with large medical device companies, not upstart firms," and employ "convoluted practices" (Y Combinator, 2016). On the other hand, learning could occur on the part of the regulator. A regulator may learn about a firm's tendency to produce safe technologies in regulatory interactions (Carpenter, 2004b). If a firm has little experience with the FDA, its carefulness is uncertain, leading the FDA to exercise caution. Whether this is a supply-side phenomenon or a regulator-driven

which is increasing in regulation and decreasing in prior FDA experience. Given a history of days spent with FDA regulation across N devices, $(t_{s,f})_{s=1}^{N}$, FDA experience is the summation of that history, or $T_{Sum,N,f} = \sum_{s=1}^{N} t_{s,f}$. In the regulatory environment R_c of Class c, the baseline delay is given by $\beta(R_c)$, which is increasing in R_c. Finally, the approval delay, $T_{N,f}$, is determined by the product of the baseline delay, $\beta(R_c)$, and a monotonically decreasing transformation of total FDA experience, $T_{Sum,N,f}^{-\gamma}$ with $\gamma > 0$. Thus, $T_{N,f} = \beta(R_c)T_{Sum,N,f}^{-\gamma}$. The daily cost of approval delays is χ_j, yielding a total approval delay cost of $\chi_j T_{N,f}$.

Capital Costs. Firm f, with capital stock K_f, also faces capital costs during the approval process (e.g., fundraising and/or startup costs), given by $F(R_c, K_f)$. Since larger firms need less external capital, I assume that $F(R_c, K_f)$ is decreasing in own capital ($\frac{dF(R_c,K_f)}{dK_f} < 0$). With stricter regulation, firms face more approval uncertainty and need more capital to cover delays and testing. Thus, I assume $F(R_c, K_f)$ is increasing in regulation ($\frac{dF(R_c,K_f)}{dR_c} > 0$).

Damages and Safety Effort Costs. Each new medical device generates stochastic adverse events. Firms can reduce expected legal damages from these events by exerting effort to make new devices safer, denoted by x, at a cost of ψx. The damages from new devices of type j are $\phi_j(R_c, x)$, a random variable with expected value of $\mu_j(R_c, x)$ and upper bound $\bar{\phi}_j$ (j subscript supressed hereafter). I assume that damages are decreasing in regulatory stringency, with $\phi_{R_c}(R_c, x) < 0$, due to the doctrine of federal preemption (e.g., stricter federal regulation preempts more liability torts). I also assume that damages are decreasing in safety effort, or $\phi_x(R_c, x) < 0$, and that there are diminishing returns from those efforts ($\phi_{xx}(R_c, x) > 0$). Assume also that the marginal benefit of safety effort increases as regulation decreases since fewer damages are prevented by federal preemption ($\phi_x(R, x) < \phi_x(R', x)$, when $R < R'$). Exerted safety effort is not visible to the buyer (asymmetric information) and thus does not influence the device payout. Instead, safety effort is only visible to the regulator through the approval process. The regulating agency imposes a lower bound on safety effort $\underline{x}^R = g(R_c)$, which is increasing in regulation, or $g'(R_c) > 0$ with $g(0) = 0$.

outcome, the policy levers and the implications remain unchanged (see section 7).

Profit Function. The profitability of developing a new medical device within regulatory environment R_c depends on the device payoff, the firm's cumulative experience with the FDA, the firm's optimal safety effort, and the firm's capital stock. The expected profit from deciding to create a new medical device is given by

$$\underbrace{\alpha_{f,j}(R_c,\cdot)}_{\text{Payout}} - \underbrace{\chi_j T_{N,f}(R_c)}_{\text{Delay Cost}} - \underbrace{(\psi x^* + \mu(R_c, x^*))}_{\text{Damages \& Effort Costs}} - \underbrace{F(R_c, K_f)}_{\text{Capital Costs}}. \tag{1}$$

Note that firms solve a two-step optimization problem. First, they determine the optimal level of safety effort x^*. Then, they decide whether or not to create the device, given the expected profit. When firms are fully liable for damages, the optimal level of effort to ensure product safety is given by $-\phi_x(R_c, x^*) = \psi$, if x^* is above the FDA-mandated minimum ($x^* = \underline{x}^R$ otherwise). This value equates the marginal reduction in damages to the marginal cost of ensuring product safety. The firm chooses to invent a new device in j if $\alpha_{f,j} > \chi_j T_{N,f} + (\psi x^* + \mu(R_c, x^*)) + F(R_c, K_f)$. Assume distributions of product values, capital stock, and accumulated FDA experience such that there is a range of potential profits.

Extension: Bankruptcy Protection. Following insights from literature on the "judgement proof problem" (see Shavell (1986); Boomhower (2019)), when damages exceed the value of a firm's seizable assets, the difference can be discharged through bankruptcy. Thus, I augment the model above to include expected damages that differ by firm asset values. Let ν represent the total realized damages from product defects, with probability distribution function $f(\nu; R_c, x^*)$. In the presence of bankruptcy, the expected profit is given by

$$\underbrace{\alpha_{f,j}}_{\text{Payout}} - \underbrace{\chi_j T_{N,f}}_{\text{Delay}} - \underbrace{\psi x^*}_{\text{Effort}} - \underbrace{F}_{\text{Capital}} - \underbrace{\begin{cases} \mu(R_c, x^*) & K_f \geq \bar{\phi} \\ \left[\int_0^{K_f} \nu f(\nu, R_c) d\nu + \int_{K_f}^{\bar{\phi}} K_f f(\nu, R_c) d\nu\right] & K_f < \bar{\phi} \end{cases}}_{\text{Damages}}. \tag{2}$$

When asset values are higher than worst-case damages, $\bar{\phi}$, the profit function does not

change. However, if asset values are smaller than $\bar{\phi}$, the firm considers a truncated damages distribution. For all possible damages above asset values, the firm declares bankruptcy and contributes the value of its total assets to partially cover its damages. In this case, expected damages are replaced in equation 2 by the probability-weighted sum of damages from 0 to K_f, plus K_f for all damages higher than K_f. Thus, the expected damages for small firms are lower than that of large firms as small firms do not fully internalize worst-case damages. This difference drives smaller firms to choose a lower effort level if the optimal level of effort is higher than the lower bound induced by regulation.

2.2 Comparative Statics

This set-up yields the following expected effect of the change in regulatory stringency,

$$\underbrace{\frac{d\pi_{f,j}}{dR_c}}_{\Delta\text{Profit}} = \underbrace{q_{f,j}\left(\frac{dp(R_c,\cdot)}{dR_c}\right)}_{\Delta\text{Payout}} - \underbrace{\chi_j \frac{d\beta(R_c)}{dR_c}(T_{Sum,f})^{-\gamma}}_{\Delta\text{Delay Cost}} - \underbrace{\frac{F(R_c,K_f)}{dR_c}}_{\Delta\text{Capital Cost}}$$
$$- \begin{cases} \frac{d\mu(R_c,x^*)}{dR_c} & K_f \geq \bar{\phi} \\ \underbrace{\left[\int_0^{K_f} \nu \frac{df(\nu,R_c)}{dR_c} d\nu + \int_{K_f}^{\bar{\phi}} K_f \frac{df(\nu,R_c)}{dR_c} d\nu\right]}_{\Delta\text{Damages}} & K_f < \bar{\phi} \end{cases} . \tag{3}$$

This expression describes how regulatory changes affect a firm's decision to innovate and how smaller and less regulation-proficient firms experience these changes differently. This expression generates the following insights.

The Change in Innovation after Deregulation. First, provided that price elasticities and product quantities are sufficiently low, deregulation leads to increased innovation from lower approval and capital costs. Second, deregulation will differentially induce innovation from the firms with the least regulatory proficiency since the change in profits is most dramatic for firms with the lowest FDA experience ($T_{Sum,f}$). Lastly, since deregulation reduces approval delays, small firms could rely less on external capital, lowering fundraising costs and leading

to outsized small firm entry. Similarly, small firms experience smaller increases in expected damages after deregulation as these firms do not bear the entire distribution of increased damages.

Change in Safety Effort after Deregulation. In practice, FDA regulations do not change differentially, thus firms must reoptimize their safety effort x after deregulation. Suppose regulated firms in Class II ($R_{II} > 0$) exert the FDA's lower bound of safety effort $g(R_{II}) > 0$, as additional effort yields greater costs than benefits ($-\mu_x(R_c, x) < \psi$ for all $x > g(R_{II})$). Deregulation (Class II to I) moves a device type from R_{II} to $R_I = 0$ and removes the FDA-mandated minimum ($g(0) = 0$). Now that federal preemption no longer protects manufacturers from legal liability, safety efforts above x^*_{II} may yield marginal benefits that are greater than marginal costs if the shift in the marginal benefit curve is strong enough (see figure C.2).[7]

Bankruptcy options can also affect how dramatically the marginal benefit curve shifts after deregulation. Smaller firms do not bear the entire distribution of increased damages after deregulation, dampening the shift in the marginal benefit curve. This dampening would lead small firms to increase their efforts less than large firms (if at all).

The safety effort response to deregulation, however, is theoretically ambiguous. On the one hand, deregulation could also spur more safety effort if x^*_{II} is higher than government-mandated levels (e.g., outsized damages even with preemption). By contrast, if the FDA minimum is binding and the marginal damage curve shifts less dramatically (e.g., marginal benefits of effort are not greatly influenced by preemption), firms could decrease safety efforts.

It is worth noting that this framework does not address whether outcomes are socially optimal. Consumer welfare, for example, is not considered. However, if deregulation increases the flow and quality of innovation, increases competition, and increases safety efforts, social welfare could improve. Such an outcome would indicate that firms have more profitable

[7] As another illustrative example, figure C.3 presents deregulation from Class III to II. Since Class III approved devices are fully shielded from liability torts, there are no marginal benefits from exerting safety effort above mandated levels ($\phi_x(R_{III}, x) = 0$).

opportunities for innovation, and consumers can choose from more high-quality products at potentially better prices.

The Social Planner's Problem. In appendix A.1, I conceptualize the social planner's decision to regulate a medical device type within this framework as an optimal stopping problem in which the regulator learns about a device type's inherent risk. This characterization is consistent with the FDA's current framework for regulating medical devices: Radical new devices are automatically regulated heavily in Class III to accommodate learning. Then, the FDA chooses when (if ever) to deregulate, given a history of information on device risk.

This model helps characterize the optimal approach to medical device regulation. Several intuitive insights arise from this model. First, the optimal time to down-classification is decreasing in the net flow of innovation. For example, if a high regulation environment dampens the flow of innovation relative to a low (or no) regulation environment, the agency should down-classify sooner (if ever). Second, the optimal time to down-classification is increasing in the net flow of harm. Intuitively, if loose regulation prevents harm almost as well as strict regulation, then down-classification should occur sooner. Third, if there is a high degree of uncertainty regarding a device type's inherent risk, it is valuable to wait and continue learning. Lastly, if innovation itself prevents harm (e.g., through more durable materials) and flows of innovation increase in a low-regulation environment, the agency should down-classify sooner. My empirical analyses identify the parameters that drive these decisions, namely, the net flow of innovation and harm that results from down-classifications.

3 Data

To conduct my empirical analysis, I compile data from eight different sources to provide an expansive view of the costs and benefits of medical device regulations. Summary statistics for these data are provided in table 1.

FDA Device Submissions (PMA and 510(k) Databases). The primary dataset used in this

study is derived from FDA administrative data on the universe of medical devices submitted for FDA approval. These data combine the FDA's PMA and 510(k) databases to cover both Class III and II devices. Submissions include the submitting company name, device brand name, medical device type, and submission and approval dates. I use fuzzy matching to form three measures of market dynamics and innovation. First, I measure "new entry" by identifying firms submitting approval documents for the first time. Second, I also form a measure of "incumbent entry," by locating firms that have filed prior approval documents but are starting to submit for approval in a given device type. Third, I isolate the first occurrence of unique device brand names within a device type to form the "unique devices approved" measure. These variables are aggregated to the device type-year level. To measure each firm's regulatory proficiency, I calculate the total approval delays (in days) the submitting firm has experienced up to the given point in time.

FDA Deregulation Events. To provide a comprehensive analysis of FDA deregulation events, I collect all down-classifications from 1980 to 2015. For Class III to II events, I also indicate whether the event was motivated by the FDA's "own initiative" or by industry petition. This distinction is empirically important. Figure C.4 shows that device types that experience a petitioned down-classification exhibit divergent pre-trends in patenting rates in the five years before the event. Table C.2 shows the number of events collected by event type. The Class III to II events I consider are those enacted by the FDA's own initiative and for which down-classified device types experienced at least one PMA document submission beforehand.[8] For Class II to I events, I consider affected device types that experienced at least one 510(k) document submission beforehand.

FDA Adverse Event Reports (MAUDE). The FDA's Manufacturer and User Facility Device Experience (MAUDE) database contains adverse event reports related to medical devices. Using this data, I create measures of device safety by forming a panel of deaths, hospitalizations, and life-threatening events for each device type from 1992–2019. I follow

[8]Many Class III "preamendment" devices were never officially required to submit PMA documentation.

Ensign and Cohen (2017) to account for data and coding idiosyncrasies in the MAUDE data. Adverse events are aggregated to the device-type-year level. Adverse event rates (e.g., deaths per year) of down-classified device types are similar to those of device types in the prospective class (see figure C.6). To perform a heterogeneity analysis of device safety by firm size, I hand-linked the offending firms listed in adverse event reports to data on firm assets for the top 300 firms by report volume. Asset totals are derived for public firms using data from CRSP/Compustat.

USPTO Patent Grants Extract. Patents offer an additional measure of innovation to support my "unique devices approved" measure. I follow a three-step procedure to form a patent-based measure of innovation within each device type. First, I gather a list of keywords from each FDA device type description. Second, I programmatically collect all patents granted by USPTO that contain those keywords in their text. Third, I then compute the annual number of patents filed within each device type according to the date the patent was first filed. The resulting dataset is a panel of yearly patent counts across 5,000 FDA-defined medical device types from 1976–2019. Patents are a useful complement to FDA device data for several reasons. First, patents allow me to analyze how Class II to I events affect innovation as I only observe my "unique devices approved" measure for Class III and II devices. For this same reason, patents also enable comparisons of effect sizes across down-classification types. Lastly, an analysis of two different measures of innovation is corroborative if the results are consistent. In section 5, I show that the estimates of changes in patent filing rates and device approval rates are quite similar for Class III to II events.

Patent and Patent Applicant Characteristics. I enrich the patent data with measures of innovation quality and applicant characteristics. A patent's quality is measured using the number of citations received from other patents and its market value.[9] Patent market values (in millions USD) are derived from Kogan et al. (2017). These values are based on the increase in the patent assignee's stock price resulting from a USPTO announcement of patent

[9]I omit examiner citations and set patent citations and market values to zero when no patents were filed in a given device-type-year.

issuance and are only available for publicly traded firms. I also generate a quality-related measure of device safety using patent texts. Following a procedure used in Clemens and Rogers (2020), I calculate the annual share of patents within a device type that mention keywords related to safety.[10] This variable allows me to analyze how deregulation affects inventors' emphases on improving device safety and to corroborate resulting changes in adverse events. Lastly, to analyze how deregulation affects innovation from firms of different sizes, I link total firm asset holdings from the CRSP/Compustat database to patent applicants.

UCSD Health Insurance Claims Extract. Insurance claims data from UCSD Health provide information on how health care prices respond to deregulation. The direct prices paid for medical devices are difficult to obtain as they result from proprietary hospital–supplier negotiations. Moreover, survey data (like ECRI) do not cover the years that down-classification events occurred (pre-2011). Thus, I instead focus on the downstream prices of procedures that use medical devices contained in more readily available insurance claims data, centering my analysis on the price that the consumer ultimately pays (via increased premiums or out-of-pocket costs).[11] Procedures are defined by the Current Procedural Terminology (CPT).

Using claims data, however, presents another challenge. The leading private health insurance claims databases (e.g., MarketScan and Optum) only provide estimates of procedure prices. Exact paid amounts are only available at the encounter level, which would include expenses from other procedures unrelated to a given medical device. Thus, I acquire claims data from UC San Diego Health that breakdown prices at the procedure level. These data

[10]To construct a comprehensive list of keywords related to medical device safety, I use Word2Vec, an algorithm that maps text to a vector space, with proximity indicating semantic similarity. After gathering semantically similar keywords, I search patent claims to identify whether a patent contained any of the keywords of interest and calculate the fraction of patents that mention these keywords in a given device-type-year. If no patents were filed in a given year, I set the fraction of patents mentioning safety to zero (e.g., no scientific advancements in product safety).

[11]The connection between procedure prices and medical device prices is natural in some cases and less so in others. The price of a COVID-19 diagnostic test, for example, is driven by the test's unit cost, as test administration is relatively cheap. By contrast, a spinal fusion procedure requires a great deal of skilled labor, overshadowing device-related input costs. However, to the extent that changes in input costs are felt by the consumer (and not entirely by the hospital), changes to medical device input costs would plausibly change procedure costs.

contain nearly 500,000 unique patient claims from 2005–2020. I then identify claims with procedures that use medical device types that were down-classified since 2006.[12] I also gather a set of procedures that use matched control device types and a set of 100 randomly selected procedures to form control groups. I then take the average amount paid for a given procedure in a given year, forming a panel of procedure-year prices.[13]

4 Empirical Strategy

I now present my strategy for estimating the effects of deregulation. This strategy includes estimates from staggered difference-in-differences and event-study designs. After describing each design, I underscore how I address potential issues when generating causal estimates in my context.

The first regression specification uses a staggered difference-in-differences design. I use a "stacked" regression, similar to Cengiz et al. (2019), which confronts issues that might arise from using staggered treatment designs in the presence of heterogeneous treatment effects within-unit over time (Goodman-Bacon, 2018; de Chaisemartin and d'Haultfoeuille, 2019).[14] This approach assembles event-specific panel data using each treated group $r \in \{1, \ldots, N^1\}$ and all admissible controls. Then, all event-specific panels are stacked while allowing unique time and group fixed effects for each panel. Thus, the estimating equation is given by

$$Y_{t,c,r} = \gamma_{c,r} + \gamma_{t,r} + \beta_1 1\{\text{reclass}\}_{t,c,r} + \varepsilon_{t,c,r}. \tag{4}$$

In equation 4, c denotes the medical device type, t denotes time, r denotes the event, and $1\{\text{reclass}\}_{t,c,r}$ is an indicator equal to one when down-classification has ocurred in device type c. The outcomes of interest are denoted by $Y_{t,c,r}$. Event-by-time fixed effects ($\gamma_{t,r}$) and

[12] In total, five Class III to II down-classified medical device types fit this criterion. All Class II to I down-classifications that I analyze are outside the time coverage of the claims database.

[13] Although the average UCSDH procedure amount paid is close to the average procedure amount paid by Medicare, using only UCSDH claims data is a limitation of my study.

[14] I find that my results do not change meaningfully when I consider another estimator in the heterogeneous treatment effects literature from Borusyak et al. (2021) (see tables C.3, C.4, and C.5).

event-by-device type fixed effects ($\gamma_{c,r}$) are included. The coefficient of interest, β_1, estimates the differential change in the outcome variable for treated device types relative to control device types after down-classification. I estimate equation 4 separately for Class III to II events and Class II to I events.

The number of FDA-initiated Class III to II events is relatively low ($N^1 = 13$). Thus, I follow Conley and Taber (2011), who provide a method of constructing reliable confidence intervals for differences-in-differences estimates in the presence of a small number of policy changes. This approach uses information from control group residuals to form confidence intervals.

Like all difference-in-differences designs, I face the question of whether my estimates are biased due to differential trends in the outcomes of interest that pre-date the down-classification events. To this end, I estimate a stacked event-study design using OLS to test for pre-trends, given by

$$Y_{t,c,r} = \gamma_{c,r} + \gamma_{t,r} + \sum_{t \neq 0} \beta_t 1\{\text{Treated}\}_{c,r} \times 1\{\text{Years from Reclass}\}_{t,r} + \varepsilon_{t,c,r}. \tag{5}$$

In equation 5, the omitted interaction between the treated group indicators ($1\{\text{Treated}\}_{c,r}$) and the time dummy variables ($1\{\text{Years from Reclass}\}_{t,r}$) aligns with the year the event occurred. Thus, each parameter β_t represents the difference-in-differences estimate of the change in the outcome relative to that reference period. Standard errors for each β_t are calculated using Conley and Taber (2011).

Down-classification rulings are typically announced a year before enactment. Since innovators could respond to a down-classification announcement, $1\{\text{reclass}\}_{t,c}$ is equal to one for all device-type-years after an announcement occurs in device type c. However, FDA administrative data will not reflect changes until the year of enactment since firms cannot market devices under new regulations before then. Thus, for FDA-derived outcomes data, the indicator $1\{\text{reclass}\}_{t,c}$ is equal to one for all device-type-years after a down-classification is enacted in device type c. For the event-study, the event-time $t = 0$ follows accordingly.

Identifying control device types that track the counterfactual development of the outcome variables is a central challenge in my empirical context. Controls could be unsuitable for several reasons. Control device types, for example, could be affected by unique scientific developments, have lower scientific potential, or face different market forces. Alternatively, some device types could be affected by spillovers from treated device types. Lastly, the FDA selects device types for down-classification based on inherent risk. Thus, down-classified devices may be different from those not chosen.

I provide four control groups, each addressing aspects of these concerns, and find that my results are robust across these groups. The first control group is broadly comprised of all Class III and II devices (for III to II events) and all Class II and I devices (for II to I events) that have not been down-classified. This group provides baseline DID estimates. Second, I construct a group of "later treated" control device types that were down-classified after treated device types and after the latest sample year.[15] This "later treated" group allows me to compare only device types which the FDA deemed appropriate for the same kind of down-classification.

Third, if later-treated device types are different from those treated earlier, the later-treated group may produce biased estimates. To this end, I compute a data-driven "matched" control group using nearest neighbor matching on baseline adverse events and innovation rates. Although I do not find evidence for spillovers in my context, I ensure that matched control device types do not treat the same medical ailments as treated device types.[16] Lastly, I provide a set of "intuitive" controls. This set of controls includes medical device types that test for or target similar diseases. I also ensure that device risk is intuitively and empirically comparable. For example, I avoid inappropriate comparisons between external-use devices and implantable or life-sustaining devices (e.g., contact lenses versus pacemakers), as these

[15]Specifically, for Class III to II events, I gather controls from all Class III to II events that occurred after 2015, censoring the outcome data after 2015. For Class II to I events, all device types moved from Class II to I in late 2019 constitute the control group. The 21st Century Cures Act drove this Class II to I event and was the first time FDA-initiated down-classifications of Class II devices occurred since 1998 (the year of the event I analyze). Importantly, the FDA used the same explicit down-classification criteria in both events.

[16]See table C.6 for spillover estimates.

devices would have drastically different safety profiles. Instead, I compare like with like (e.g., daily- vs. extended-wear soft contact lenses). Profiles of the treatment and intuitive control groups are given in table C.7 for Class III to II down-classifications, and in tables C.8 and C.9 for Class II to I down-classifications. Although the estimates are similar across control groups, the matched control groups constitute my preferred specification.

Additionally, some medical device types may never exhibit adverse events or innovative activity and thus would be incomparable to those that do. Thus, I also provide results from analyses that consider only treated and control device types with positive counts of a given outcome, in the appendix tables C.10, C.11, and C.12. My findings are robust to these restrictions.

As with every non-experimental research design, selection into treatment is a primary concern. Since the FDA selects medical device types to down-classify based on baseline adverse event rates, down-classification is endogenous to changes in adverse event rates.[17] Thus, I cannot ascertain how deregulation would affect the adverse event rates for a randomly chosen device type. However, I can speak to the optimality of the FDA's decisions on the margin of their rule (e.g., the most dangerous down-classified devices).

5 Results

In this section, I present the results from estimating equations 4 and 5. I first present changes in innovation. I then provide results for changes in market composition. I also explore the types of firms that drive these changes in innovation and market composition. Lastly, I detail results on changes in adverse event rates.

[17] See appendix C.1 for more details.

5.1 Changes in Innovation

Here I present changes in the flow and quality of innovation, as measured by the rate of unique devices approved, patents filed, citations-per-patent, and average patent values, for Class III (high reg.) to II (moderate) and II to I (low) down-classifications.

Table 2 presents the difference-in-differences estimates of equation 4 for the innovation outcomes.[18] Panel A provides estimates for Class III to II events, and panel B provides estimates for Class II to I events. Column (1) provides the baseline 5-year average of the treated groups, and columns (2)–(5) report the estimates of equation 4 when comparing treated groups to a matched control group, intuitive controls, "later treated" device types, and all untreated device types, respectively. Conley-Taber standard errors are reported below the estimates.

Panel A, columns (2)–(5) reveal significant and consistent increases in patenting rates, unique device approvals, citations-per-patent, and average patent values across control groups. Patenting rates and device approval rates increase 2- and 6-fold from down-classification, respectively. Panel B, columns (2)–(5) also reveal increases in patenting rates, citations-per-patent, and average patent values, though the patenting rate estimate is not significant using my preferred specification.

To assess whether differential trends in innovation rates pre-date down-classification events, I present event-study estimates of equation 5 in figures 3 and 4. The event-study estimates suggest quite strongly that there are no pre-existing trends in the ten years before down-classification for both event types.

Notably, the event-study estimates suggest that the rate of unique device approvals increases immediately, whereas patenting rates increase slowly over time. Several factors could drive this distinction. First, medical devices awaiting FDA approval in the prior regulatory framework are fast-tracked in the new framework. Second, many existing medical technologies are marketed in Europe where regulations are more lenient, but not in the U.S. (Grennan

[18] Table C.10 presents the results from only including device types with some positive outcome counts.

and Town, 2020). After deregulation, firms may take advantage of looser regulations and quickly market existing technologies in the U.S. market. Third, firms may promptly repurpose existing technologies for new indications in response to the policy change. Lastly, although the FDA approves most Class III and II devices (80% and 90%, respectively), a slight drop in denials after deregulation could lead to a small but sharp increase in the number of new devices approved (GAO, 2009).

By contrast, the event-study estimates for patenting rates reflect a more intuitive, gradual increase after deregulation, consistent with the time-intensive R&D process. U.S. patenting rates, unlike device approvals, are not affected by sudden influxes of technologies that were previously only marketed abroad. Those technologies are either already patented or are not patentable. In particular, if a firm files a patent in one country, it must file patents in other countries in which it desires protection within one year to receive protection in those countries (Popp, 2005). Applying for patents in multiple countries is inexpensive as firms can concurrently file patents in up to 153 countries through the Patent Cooperation Treaty (WIPO, 2020).

5.2 Changes in Market Composition (Firm Entrants and Prices)

Here I present changes in market composition after down-classification events as measured by firm entry, incumbent entry, and procedure prices. I estimate changes in firm entry and incumbent entry separately using both FDA and patent data.

Table 3 presents the difference-in-differences estimates from equation 4 of the changes in market composition from down-classification events.[19] Panel A provides estimates for Class III to II events, and panel B provides estimates for Class II to I events. Column (1) provides the baseline 5-year average of the treated groups. Columns (2)–(6) provide estimates of equation 4 when comparing treated groups to a matched control group based on baseline prices, a matched control group based on baseline rates of innovation and adverse event

[19]Table C.11 presents results from including only device types with some positive outcome counts.

rates, intuitive control groups, later treated device types, and all untreated device types, respectively. Panel A reveals significant increases in incumbent entry and new firm entry into treated device types across control groups and data sources. Strikingly, the rate of new firm entry measured using FDA device data exhibits a ten-fold increase.[20]

Consistent with an increase in firm entry, prices of procedures that use treated device types significantly fell. Columns (1) and (2) of panel A show a 33–40% drop in prices, respectively. A few caveats should be considered when interpreting these price results. First, data limitations restrict the number of treated device types I study to five. Further limiting generalizability, UCSD healthcare claims data cover only one regional hospital system. Thus, these results offer only a suggestive look into how regulation affects healthcare prices.

Panel B shows that firm entry also increased after Class II to I events. Columns (3), (5), and (6) document that these events increased the rate of new firms patenting within treated device types by 53%. By contrast, incumbent firms are relatively unaffected; The estimate of incumbent firm entry is statistically and economically insignificant under my preferred specification. The distinction between these two estimates suggests that Class II regulations lower the profitability of new investments for inexperienced firms. On the other hand, Class II regulations may be less burdensome for experienced firms that know how to efficiently meet FDA requirements.

To address concerns of differential trends in market composition that pre-date down-classification events, I present event-study estimates of equation 5 in figures 5 and C.7 for Class III to II events and figure C.8 for Class II to I events. The event-study estimates suggest quite strongly that there are no pre-existing trends in the market composition variables in the ten years before down-classification across both event types.[21]

[20]Supply-side factors may not be the sole driver of these dramatic changes in market composition. As shown in figure C.5, there were considerable equilibrium forces at play: After the number of suppliers of treated device types increased, demand increased for procedures that use treated devices three years after deregulation, plausibly driven by lower prices. No significant pre-trends are measured.

[21]Firm entry exhibits a discontinuous jump for the same reasons as device approvals. Thus, firm entry measured using patent data gives a better sense of firms entering to innovate entirely new technologies at a given period. Even if firms are shifting existing technologies to the U.S., there are still substantive benefits of these actions, including job creation (Makower et al., 2010) and improved access to life-saving technologies.

5.3 Drivers of Changes in Innovation and Market Composition

I explore how firm characteristics drive changes in innovation and market composition and compare my findings to results from simulation exercises detailed in appendix B. I also highlight potential ways to reduce frictions that U.S. firms currently face. Since I cannot directly measure fundraising costs, and firm experience and size are not exogenous, these results should be interpreted with some caution.

Firm Experience. How does experience with FDA regulations affect a firm's decision to invest in new devices? I explore this question by estimating the change in device approval rates, using equation 4, for firms within different experience quartiles. I center this analysis on Class III to II events.[22] Panel A of figure 6 presents these changes expressed as percent changes relative to baseline rates. The estimated percent changes across experience quartiles are positive and significant, but less experienced firms exhibit outsized increases. Firms in the bottom quartile of cumulative FDA experience exhibit a 1,000% increase in new device rates, but these effects quickly taper off when moving up the experience distribution, with firms in the top quartile bringing 50% more devices to market.

I present results from Monte Carlo simulations of the theoretical model that mirror those from the empirical analysis. To run this simulation exercise, I calibrate the parameters of the firm's strategy described in section 1 and create a distribution of firms using moments in the data (see appendix B for details). Panel C of figure 6 presents simulations of the effects of down-classification on the number of new devices brought to market across firm experience quartiles. The simulation results show striking similarities to the empirical estimates shown in panel A, as firms with the least regulatory proficiency exhibit the largest gains from down-classifications. Panel B of figure 6 shows why Class III to II events lead inexperienced firms to innovate the most. These events flatten the learning curve, which dramatically shortens approval delays for inexperienced firms. Together, these results strongly suggest

[22] I focus on Class III to II events as the learning curve is much flatter for Class II devices. Thus, Class II to I events would not allow me to identify the effect of differential changes in approval delays.

that regulatory proficiency can affect a firm's decision to innovate.[23]

The FDA could simplify and standardize approval protocols to help less regulation-proficient firms. These measures could help these firms receive FDA approval quicker by removing the need to learn to navigate complicated protocols.

To this end, I simulate the effects of these measures on the rate of unique devices brought to market. I iteratively lower the learning curve parameter γ, which determines the approval delay disparity between firms with more or less experience, and perform a Monte Carlo simulation of the innovation response, taking repeated draws from the parameter distributions. As γ falls, the learning curve is flattened, equalizing approval delays across firms' levels of experience (see figure C.10). Table C.14 shows how a flatter learning curve can increase innovation across FDA experience quartiles. The results suggest that a simpler approval process could increase the number of unique devices approved by as much as 63%, with the most inexperienced firms exhibiting the largest gains.

Since deregulation does not exogenously change a firm regulatory proficiency, other factors correlated with FDA experience may be driving the results of my analysis. However, the striking similarity between the empirical results and the model simulations suggests that a firm's regulatory proficiency is central to R&D decisions and highlights the frictions inexperienced firms face.[24]

Firm Size. Figure 7, panels A and B, illustrate the effects of down-classifications on patenting rates across down-classification type and firm asset terciles.[25] Across both event

[23]Table C.13 shows the estimated parameters of the learning curve in equation B.1. I estimate these parameters for both Class III and Class II device documentation submissions. By restricting my analysis to original PMA document submissions for Class III devices, I ensure that device novelty is not driving longer/shorter approval delays. For Class II devices, I ensure consistent novelty across devices by only considering documentation submissions for devices with unique brand names. The estimates of the learning curve parameters are significant for both Class III and II documentation submissions. Figure C.9 shows that the fit of the log-linear regression line that estimates equation B.1 is quite close after accounting for firm and device-type fixed effects.

[24]Firm size, the most obvious potential confounder, is uncorrelated with a firm's FDA experience (see table C.15). This lack of correlation may result from publicly traded companies having high baseline assets relative to the average MedTech firm.

[25]Since I use firm asset holdings of publicly traded companies as a proxy for firm size, this analysis excludes roughly 3/4 of all patenting activity in the data that comes from private companies.

types, firms in the bottom tercile of asset holdings exhibit the largest increases in patenting rates, plausibly driven by smaller firms facing higher capital costs (e.g., fundraising costs).

In figure 7, panels C and D, I pair my empirical results with Monte Carlo simulations of the effects of deregulation on patenting activity across firm asset terciles. These simulations show increases in patenting activity across firm asset terciles similar to the empirical estimates shown in figure 7, with small firms exhibiting the highest gains from down-classifications.

These heterogeneous effects of deregulation across firm characteristics add intuition to the increases in innovativeness presented earlier. Standard economic theory would suggest that lowering barriers to innovation would induce those with lower-quality ideas to innovate. However, when small firms face relatively strong capital frictions, they cannot enter even with high-quality ideas. When regulations are lifted, both highly innovative and less innovative firms enter. Depending on the distribution of small and large firms, increases in innovative technologies from small firms could outweigh increases in less innovative technologies from larger firms, leading to an average increase in innovativeness (as in my context).

5.4 Changes in Adverse Event Rates

Here I present changes in yearly injuries related to device flaws (adverse event rates) resulting from deregulation. The adverse events I measure are deaths, hospitalizations, and life-threatening events. As a potential mechanism for these changes, I also supplement these results with changes in the rate at which inventors emphasize device safety in patent texts.

Table 4 presents the difference-in-differences estimates from equation 4 of the changes in adverse events and inventor emphasis on safety after down-classification.[26] Panel A provides the estimates for Class III to II events, while panel B provides estimates for Class II to I events. Column (1) provides the baseline 5-year average of the treated groups, and columns (2)–(5) provide estimates of equation 4 when comparing treated groups to a control group

[26]Table C.12 presents the results from including only device types with some postive outcome counts.

matched on baseline adverse events, intuitive controls, later treated device types, and all untreated device types, respectively.

Panel A, columns (2)–(5) reveal insignificant, mixed movement in adverse events and the safety of new technologies across control groups. As an exception, hospitalizations increased 10-fold after deregulation under my preferred specification. This result, however, is only marginally significant and is not robust to alternative control strategies. For example, when using the broadest control group (column (5)), the estimate indicates that hospitalizations decrease as treated devices are compared to some of the most dangerous device types. By contrast, the comparison groups used in columns (2)–(4) have similar safety profiles to treated types, suggesting a more appropriate comparison.

The estimates for Class II to I events, shown in panel B columns (2)–(5), reveal significant *declines* in the rate of hospitalizations and deaths. The drop in hospitalizations is consistent across all control groups. In addition, all estimates of changes in deaths and life-threatening events are negative and large relative to baseline, with most estimates significant at the 10% level. These reductions in adverse events are plausibly driven by a significant 100% *increase* in the share of patents emphasizing an advancement in product safety.

Why do adverse event rates fall and inventors focus more on product safety after safety regulations are removed? As described above, firms marketing deregulated devices (Class I) are not shielded from legal liability. In this environment, it may be cost-effective for firms to exert more effort to improve product safety. However, small firms may not face the same risks that large firms do after down-classification: Small firms can avoid worst-case damages through bankruptcy (see Boomhower (2019)). Indeed, as shown in figure 8, firms in the top tercile of asset holdings exhibit a significant 100% increase in the likelihood of demonstrating at least one safety innovation in a given year. By contrast, smaller firms respond much less dramatically. Figure 8 also shows a drop in serious events that mirrors these safety efforts, with the sharpest declines coming from devices manufactured by the largest firms.

To address the concern of differential trends in adverse events before down-classification,

I present event-study estimates of equation 5. Figures C.11, C.12, and C.13 present these estimates for both event types. The event-study estimates suggest no pre-existing trends in the adverse events in the ten years before down-classification.

A few caveats arise when analyzing adverse event rates. First, the FDA does not normalize adverse event rates by device utilization due to a lack of available data. Thus, changes in adverse event rates could reflect changes in utilization rather than changes in the safety of underlying technologies. Figure C.5 shows that, although no pre-trends are present, utilization rates of treated medical device types significantly increase three years after Class III to II deregulations due to increased supply and decreased prices. Increased utilization in treated groups would bias upward the changes in adverse event rates. My use of raw adverse event rates, thus, provides a conservative estimate of the net benefit of deregulation by overstating the associated costs of decreased product safety. These costs are overstated since estimates using normalized rates would be smaller for Class III to II events and even more negative for Class II to I events. Although I do not have similar utilization data for Class II to I events, treated device types also exhibit increased supply after deregulation. If the demand curve slopes downward, utilization would also increase.

Second, the FDA explicitly down-classifies device types for which prospective regulation adequately mitigates harm. Thus, the insignificant adverse event results from Class III to II events should not be surprising and should not be interpreted as the causal effect of fewer regulations on adverse events. For Class II to I events, however, I can use the FDA decision rule described in appendix C.1 to assess whether the FDA's decisions are optimal on the margin (at higher DPM scores). Accordingly, I separately generate DID estimates from equation 4 for each treated device type, relative to a matched control (matched based on DPM score), and plot the relationship between the effect size and the decision rule. Figure C.14 shows that marginal device types exhibit *fewer* deaths after down-classifications when compared to control groups, relative to less dangerous treated device types, suggesting the down-classification rule was too conservative. Although device types may differ on several

dimensions, roughly 95% of current Class II device types exhibit fewer adverse events than the marginal Class II to I down-classified device type.

Lastly, media and regulatory decisions may directly influence adverse event reports. However, the FDA requires device manufacturers and hospitals to report deaths or severe injuries related to their devices (FDA, 2020c). Thus, I center my analysis on reports of deaths and severe injuries from these sources. This strategy excludes voluntary consumer reports and reports of less severe injuries or device malfunctions, as these may be more sensitive to regulatory decisions. As an added layer of validation, I also analyze the intensity with which inventors emphasize safety improvements in their patent documents and find that the results from both data sources are consistent.

6 Back-of-the-Envelope Calculation: Costs & Benefits

This section presents the costs and benefits of deregulation measured by the three core results derived in section 5. First, deregulation increases patenting rates. The value of this increase is determined by the sum of each additional patent's market value (accounting for creative destruction and increases in innovativeness). Second, deregulation decreases market concentration and healthcare prices. To value lower healthcare prices, I convert price changes to changes in expenditures by assuming constant utilization. Lastly, complete deregulation reduced adverse event rates. The resulting drop in deaths is appraised at the statistical value of all lives saved, while prevented hospitalizations are valued according to Moses et al. (2019). The assumptions and math underlying these calculations are detailed in table 5.

Figure 9 presents the measured costs and benefits of down-classification decisions. To justify the FDA's decision rule for Class III to II down-classifications, the unmeasured costs (e.g., political risks) associated with these events would have to be larger than the measured costs. Class II to I down-classifications do not exhibit any measurable costs, bringing *fewer* adverse events relative to control groups and inducing more innovative activity. The benefits

of these down-classifications, including fewer adverse events, amount to roughly $24 million a year per device type, even at the margin of the most dangerous devices at baseline. Since 2,500 devices are currently regulated in Class II, the yearly forgone benefits could amount to as much as $60 billion, or nearly 34% of the value of medical devices consumed each year.

There are several unmeasured costs and benefits of deregulation not considered in these calculations. For unmeasured costs, I do not measure the value of efficacy assurances provided by the FDA, which are lost after down-classification (see Grennan and Town (2020)). However, one criterion for down-classification is whether device efficacy is easily verifiable and maintained after deregulation, so these costs are likely small. Second, waiting to deregulate to learn more about a device type's inherent risk is valuable if deregulation could lead to increased adverse events (e.g., the option value of waiting). However, Class II regulations increase adverse event rates relative to Class I, so waiting to deregulate is costly—irrespective of a device's risk of inducing harm. Lastly, there are potential political costs of misguided deregulation that I do not measure.

The unmeasured benefits of deregulation include reductions in FDA administrative costs, price reductions (for Class II to I events), the value of new jobs created with firm entry, the benefits of innovation from private firms, and the scientific value of innovation.

7 Discussion and Conclusion

I analyze how regulation affects medical device innovation, market composition, and adverse events. I find that deregulation benefited small and inexperienced firms most and accelerated technological progress and firm entry. Firm entry increased competition, which subsequently reduced related health care prices. I show that some adverse events increase after moving from high to moderate regulation (Class III to II)—although insignificantly. By contrast, I show that adverse events decrease significantly after complete deregulation (Class II to I). These reductions in harm are plausibly driven by increased legal liability.

Back-of-the-envelope calculations suggest that deregulation exhibited higher measured benefits than costs. For Class II device types, there is likely room for policy improvements. The benefits of deregulation are higher for marginal, higher-risk device types, suggesting my results would extend to devices still in Class II.[27] Further, physicians and the National Institute of Medicine have criticized Class II regulations as being insufficient and have advocated for an alternative that ensures safety and efficacy while encouraging innovation. My results suggest that deregulating Class II devices is one such alternative: An approach that allows the courts to intermediate, improving the rate of innovation and product safety while lowering administrative costs.

For Class III devices, however, it is difficult to make substantive claims about the FDA's current down-classification rule without considering the political benefits of preventing the increase in adverse events that occurs after deregulation (see Carpenter (2004a,b) and Wilson (1984)). Class III to II events could lead to salient device-related deaths that degrade the regulator's reputation and undermine its more cost-effective efforts elsewhere. In contrast, the technological benefits that come from deregulation are more abstract. For example, an appraisal of the number of lives saved from future innovation is less likely to influence public opinion than deaths from device flaws. This asymmetry is evident in the FDA's decision-making: According to documents outlining the decision process for down-classification, the value of forgone innovation is not directly considered. This study seeks to bridge this gap by quantifying the technological benefits of less stringent regulation. Ultimately, more empirical research is needed to determine the precise reputational effects of regulatory mistakes and the corresponding benefits of that reputation.

Even if the costs of Class III to II events outweigh the benefits, my analysis also sheds light on the types of firms that could benefit from other business-friendly policies. Small and inexperienced firms, for example, exhibited higher increases in innovation after deregulation, suggesting that these firms are disadvantaged in the current regulatory framework. Policy-

[27]Moreover, 95% of current Class II devices have lower adverse event rates than the most dangerous deregulated device type before deregulation.

makers could address these inequities by providing relief. Some European governments, for example, provide financial assistance during the early phases of medical device approvals, blunting the burn rate of new MedTech firms (Propel, 2017). Also, establishing a simplified and standardized set of approval protocols could lower the barriers inexperienced firms face.[28] These measures, among others, could prove to be cost-effective ways to make FDA regulations more amenable, particularly to disadvantaged firms.

Lastly, deregulating when the benefits of such actions outweigh the costs could improve the dynamism of medical device markets. Firm creation brings job creation. Descriptive evidence suggests that new high-paying MedTech jobs create ripple effects: For every 100 MedTech jobs created, 447 indirect jobs are also created (Makower et al., 2010). Increased competition in device markets could lower the prices of procedures that use medical devices and combat rising health care costs (Cutler, 2005; Smith et al., 2009).

I reiterate a few caveats with this evidence. The FDA's decision to down-classify is endogenous to changes in adverse event rates. Thus, I cannot causally identify the effects of looser regulations on product safety, though I provide evidence of these effects on the margin of the FDA's decision rule. In addition, the adverse event results should be interpreted with some caution. Lastly, the exploration into how firm characteristics drive the core results is suggestive, as I do not exploit exogenous variation in firm capital stock and regulatory proficiency.

[28] If learning by doing is primarily on the part of the FDA, as it seeks to learn which firms conduct reliable device testing, then these same standards would provide additional assurance that the evidence provided by new firms is reliable.

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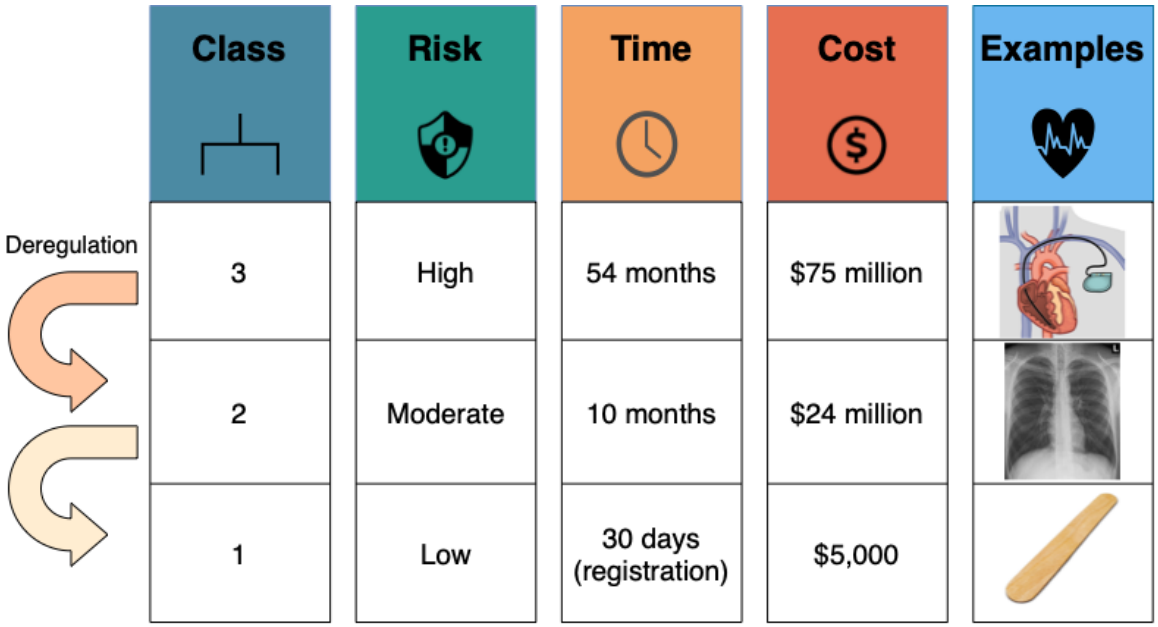
Figures and Tables

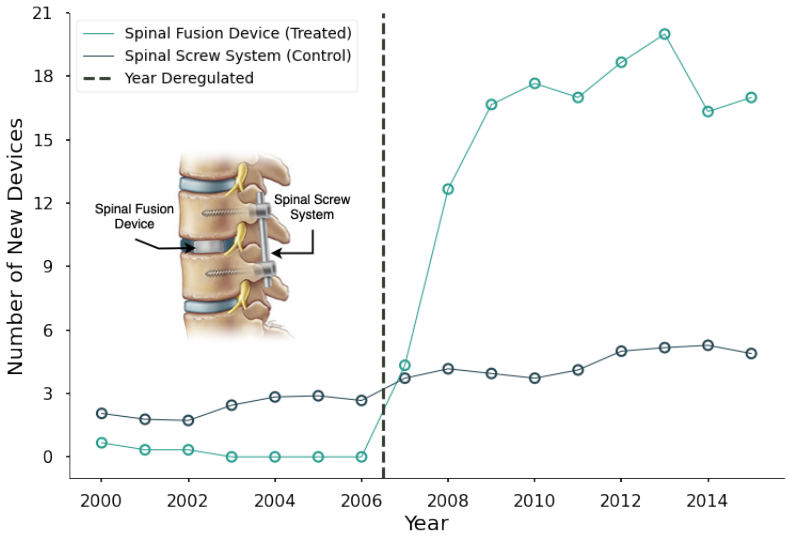
Figure 1: Background on Medical Device Regulations



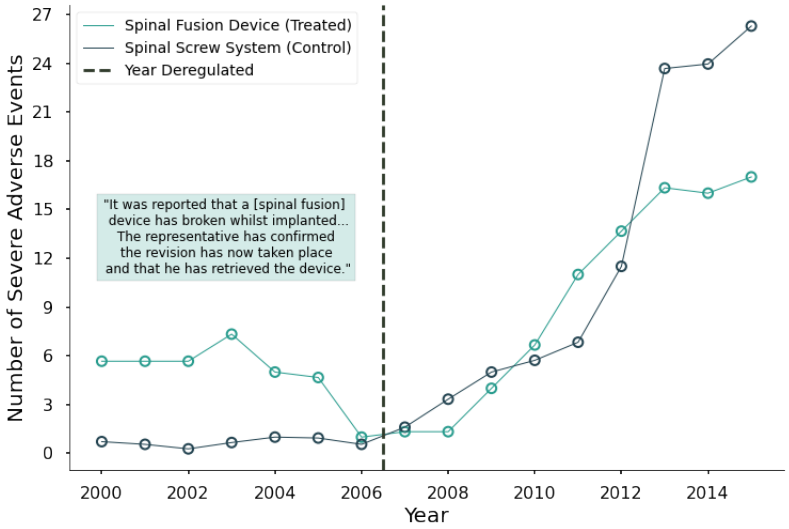
Note: This figure presents background on FDA Medical device regulations and the deregulation policy changes I leverage in my analysis. Device types are placed into one of three classes, each corresponding to a level of perceived risk. Higher perceived risk requires a longer approval process and additional costs to conduct testing and to maintain business operations before a product is approved. The time and cost values are averages within the given class and are derived from Makower et al. (2010). While learning about a device type's underlying risk, the FDA can choose to deregulate a device type by moving it from a higher risk class to a lower risk class (called "down-classification"). This decision dramatically reduces the approval delays and costs that device manufacturers confront. Rarely are device types reclassified to a higher risk class. The last column includes examples of Class III, II, and I devices, namely, pacemakers, x-ray machines, and a tongue depressors, respectively.

Figure 2: Spinal Implant Use Case—III to II Down-Classification

(a) Panel A: Number of New Devices Submitted for Approval

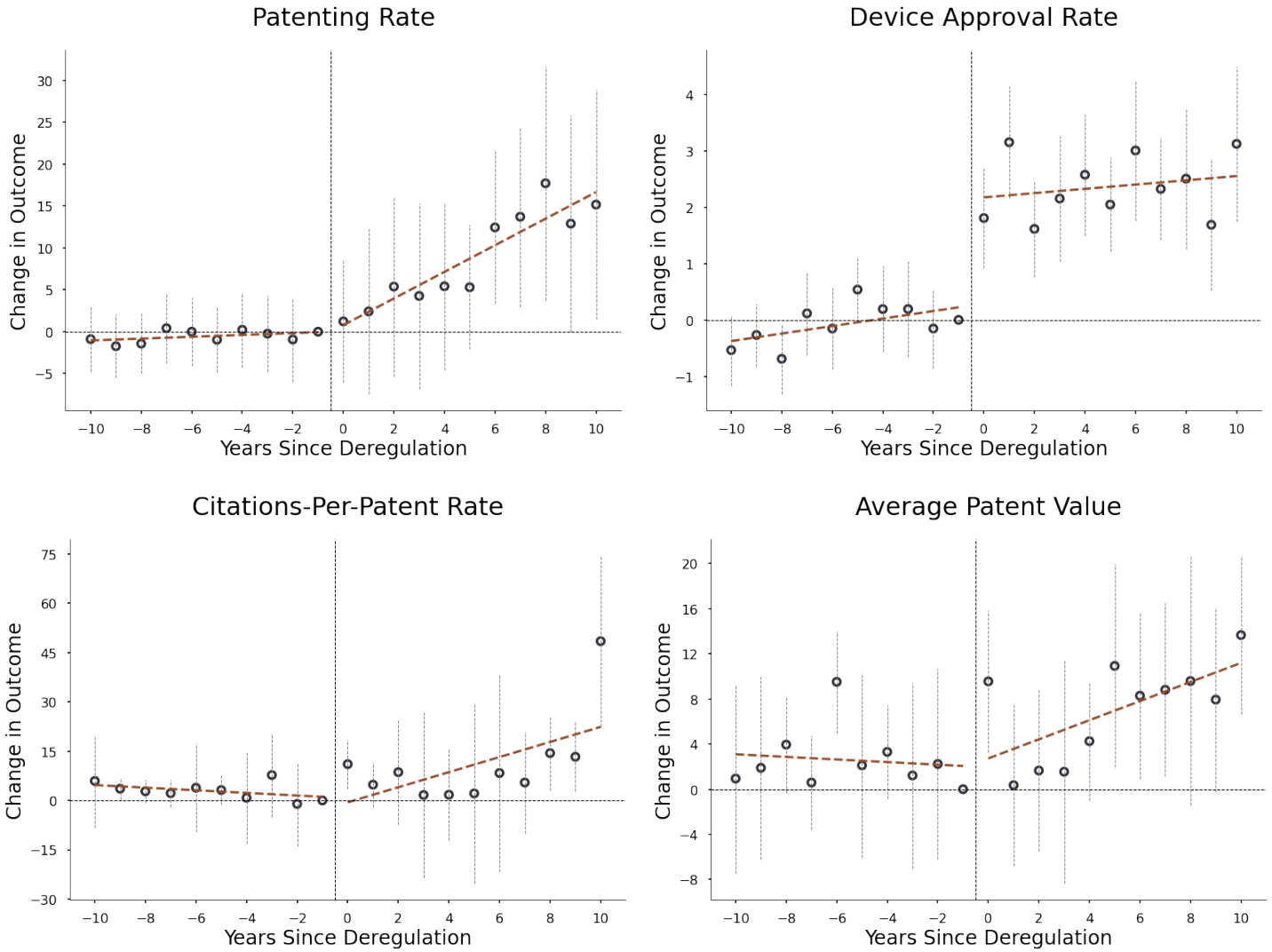


(b) Panel B: Annual Count of Serious Adverse Events



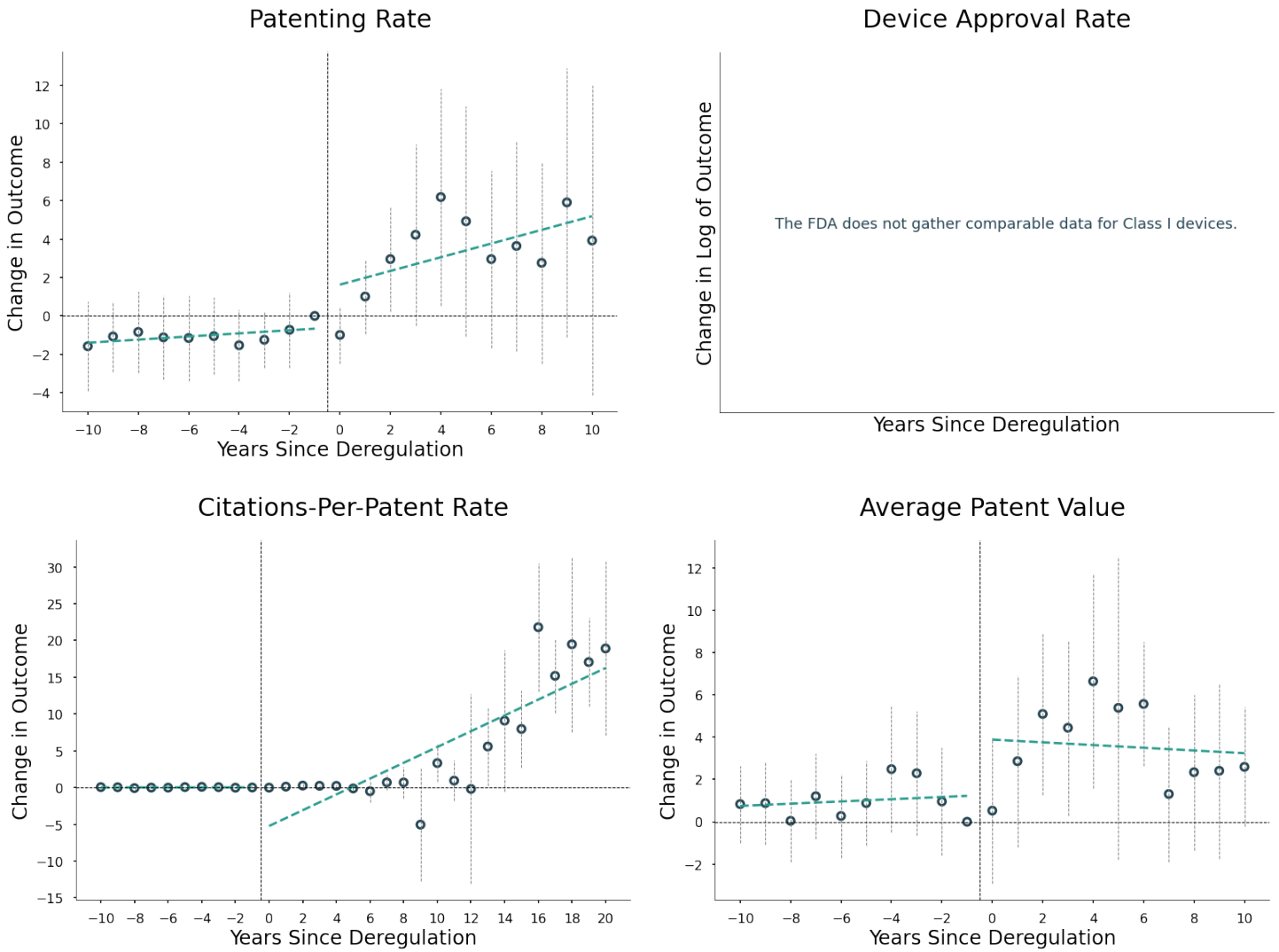
Note: This figure presents an example of a Class III to II down-classification event. In 2007, the FDA down-classified "intervertebral body fusion devices" to Class II. As a control case, "thoracolumbosacral pedicle screw systems" remained in Class II. Panel A measures the number of unique contact lens devices submitted to the FDA for approval in a given year, and panel B measures the annual count of serious adverse events. The teal line represents the outcome for spinal fusion devices, and the dark blue line represents the same for spinal screw systems. The vertical black line represents the year of reclassification. The imposed picture on panel A shows both device types implanted into the spine in the same spinal fusion procedure. The text on panel B gives an example of a serious adverse event report that resulted in an injury.

Figure 3: Innovation Event-Study Class III to II



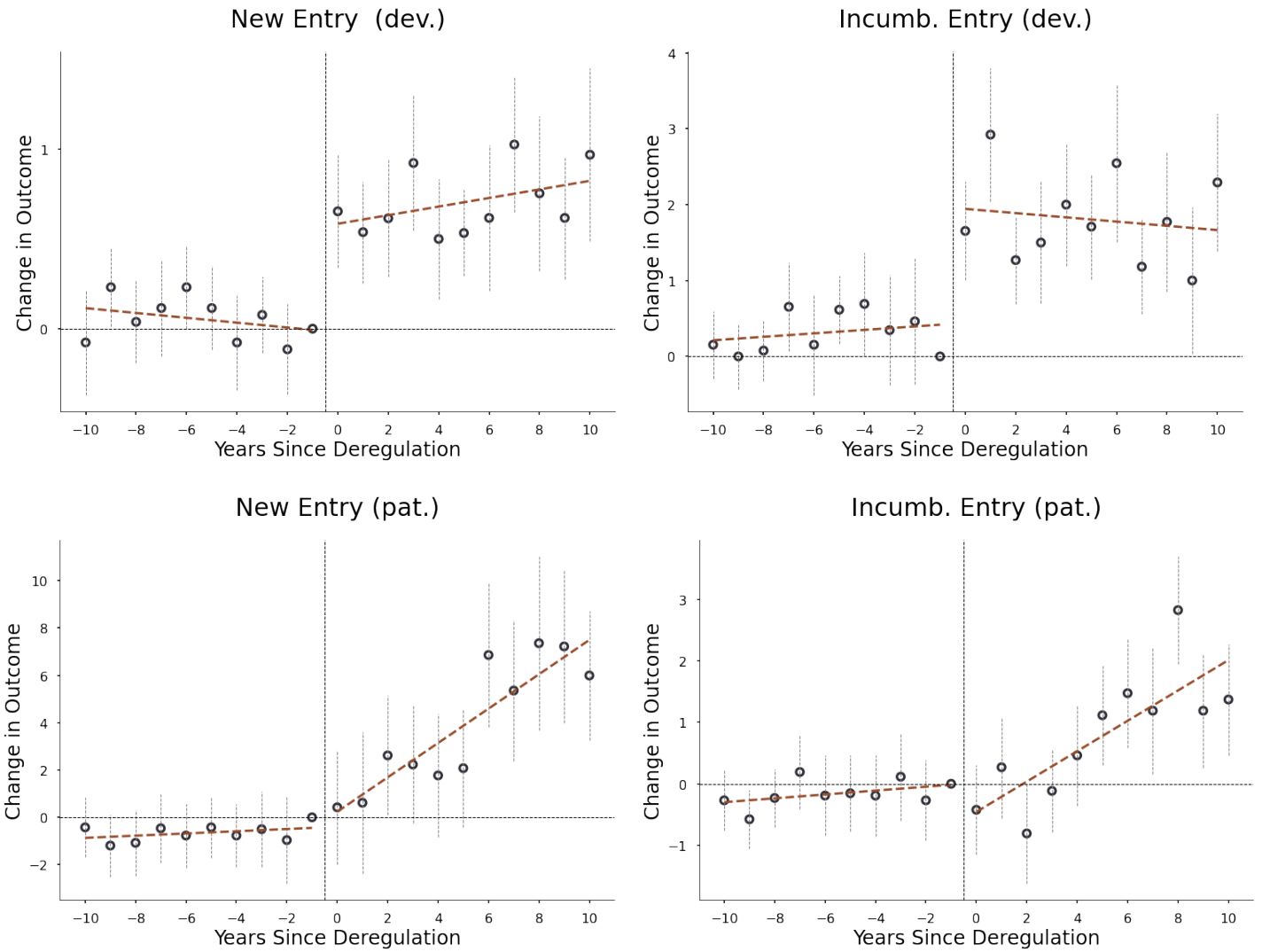
Note: This figure presents the estimates of the β_t coefficients from the event-study equation 5 for the innovation outcomes. Only Class III to II down-classification events are considered. Controls are device types matched on baseline averages of the outcome. The coefficient β_{-1} is omitted and serves as the reference period. Data are analyzed at an annual frequency. The top-left subfigure illustrates the evolution of the patenting rate of treated device types relative to matched control groups. The top-right subfigure describes the evolution of unique devices approved by the FDA for treated device types relative to control groups. The bottom-left subfigure describes the evolution of the average citations-per-patent rate. When no patents are filed in a given year, the citations-per-patent rate is set to zero. The bottom-right subfigure presents the evolution of the average patent value in treated device types relative to controls. Patent values are derived from Kogan et al. (2017), who calculate the change in a firm's stock market valuation upon patent grant announcements to measure patent value. Standard errors are calulcated following Conley and Taber (2011).

Figure 4: Innovation Event-Study Class II to I



Note: This figure presents the estimates of the β_t coefficients from event-study equation 5 for my innovation measures. Only Class II to I down-classification events are considered. Controls are device types matched on baseline averages of the outcome. The coefficient β_{-1} is omitted and serves as the reference period. Data are analyzed at an annual frequency. The top-left subfigure illustrates the evolution of the patenting rate of treated device types relative to matched control groups. The top-right subfigure is blank as there is no comparable data for Class I approved devices. The bottom-left subfigure describes the evolution of the average citations-per-patent rate. When no patents are filed in a given year, the citations-per-patent rate is set to zero. The bottom-right subfigure presents the evolution of the average patent value in treated device types relative to controls. Patent values are derived from Kogan et al. (2017), who calculate the change in a firm's stock market valuation upon patent grant announcements to measure patent value.

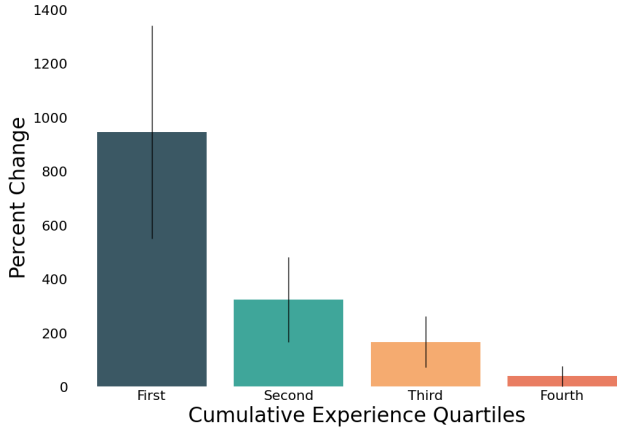
Figure 5: Market Composition Event-Study Class III to II



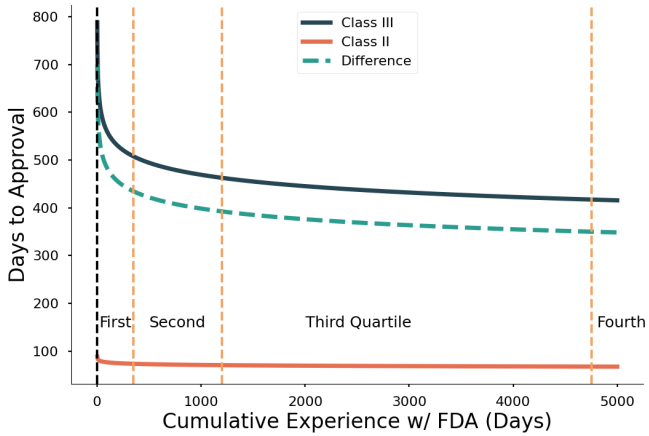
Note: This figure presents the estimates of the β_t coefficients from event-study equation 5 for my market composition measures. Only Class III to II down-classification events are considered. Data are analyzed at an annual frequency. Controls are device types matched on baseline averages innovation rates. The coefficient β_{-1} is omitted and serves as the reference period. The top-left subfigure illustrates the evolution of the rate of new firm entry, calculated using device approval data, relative to matched control groups. New firm entry represents firms that have never before submitted FDA documentation. The top-right subfigure illustrates the evolution of the rate of incumbent firm entry (a firm that has previously submitted FDA documents) in treated device type relative to controls. The bottom-left subfigure describes the evolution of new firm entry or firms that have never before received a granted patent, measured by patent data. The bottom-right subfigure presents the evolution of incumbent entry into treated device types relative to controls, measured by patent data. Conley–Taber 95% confidence intervals are provided.

Figure 6: Empirical and Simulated Experience-Specific Innovation Effects and Estimated Learning Curve

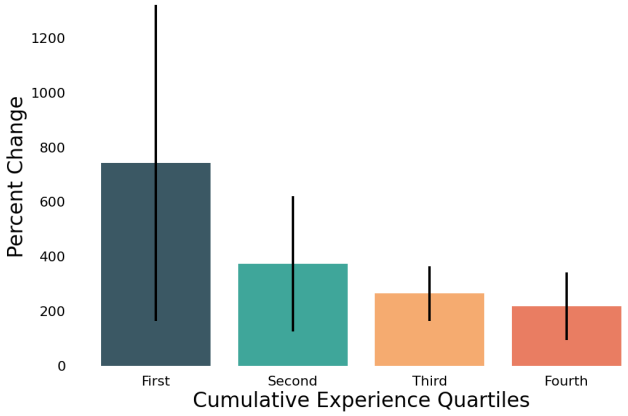
Panel A: Empirical Change in New Devices by Proficiency



Panel B: Estimated Learning Curves

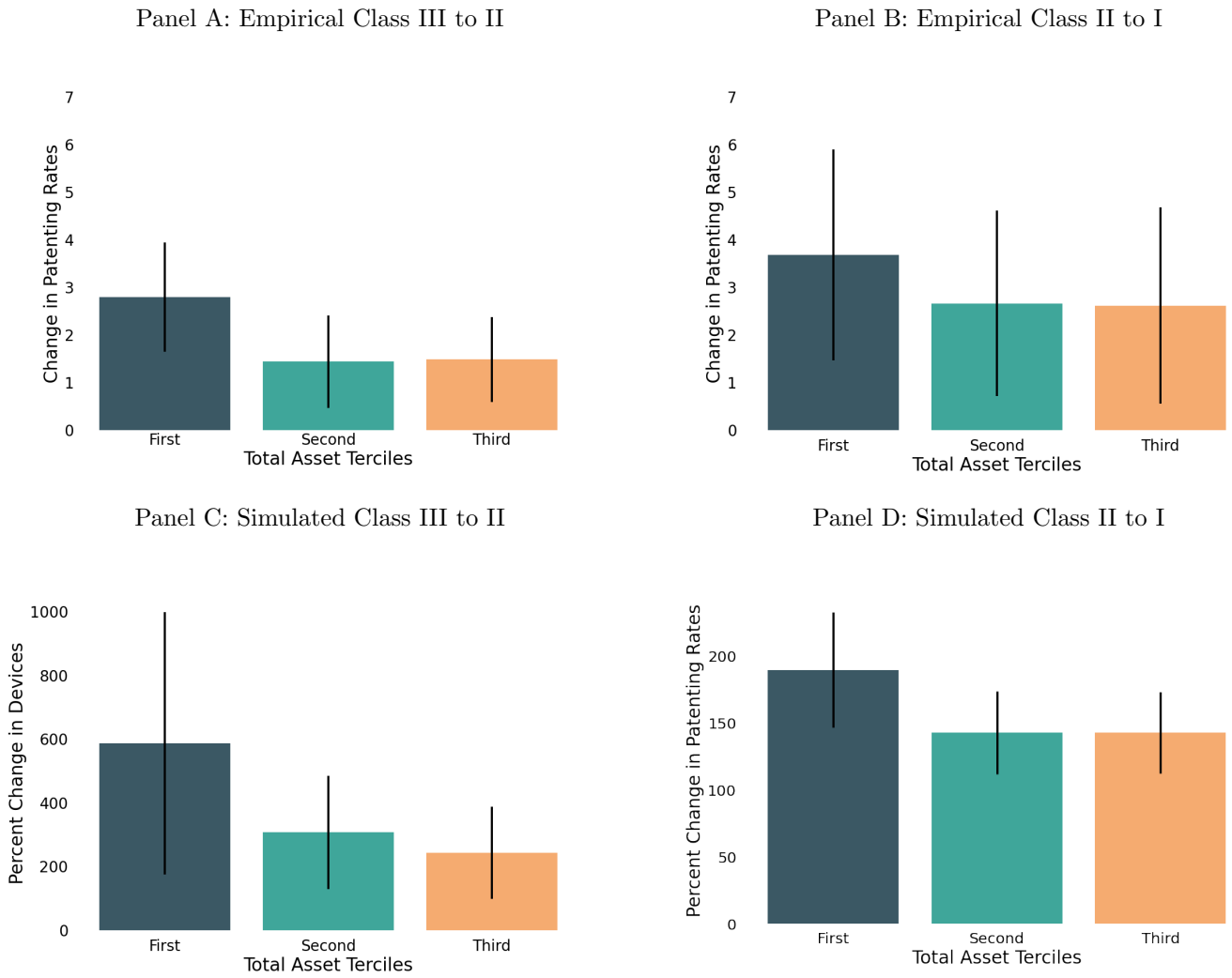


Panel C: Simulated Change in New Devices by Proficiency



Note: This figure presents the empirical and simulated experience-specific changes in the rates of newly marketed devices stemming from class III to II down-classification events and the learning curves estimated in equation B.1. Panel A provides the DID estimates of the rate of newly marketed devices in treated device types, relative to controls, by experience quartiles (T_{Sum}). DID estimates and standard errors are converted to percent changes. Firm experience is calculated by aggregating each firms' total time spent satisfying FDA regulations up to the time of submitting an approval for the current device. Panel B presents the estimated learning curves for satisfying Class III and Class II regulations. The difference between Class III and Class II approval delays at a given level of FDA experience is also provided. The x-axis indicates the number of days spent on previous approvals. The y-axis describes the number of days taken for a current Class III or Class II device to be approved. I provide divisions of cumulative experience quartiles seen in the data. I exclude observations with no prior experience to avoid undefined outcomes and biases from the extensive margin in the estimation. Panel C provides the simulated changes in the rate of newly marketed devices when approval delays are reduced to reflect a Class III to II down-classification event. The simulation exercise is described in appendix B and imposes distributional assumptions on the parameters in equation 1. The 95% confidence intervals overlay the estimates. The simulated confidence intervals are calculated using a Monte Carlo procedure. This procedure produces estimates across repeated random draws from the empirical distribution of firm characteristics.

Figure 7: Empirical and Simulated Effect of Down-Classification on Patenting Rates by Asset Terciles



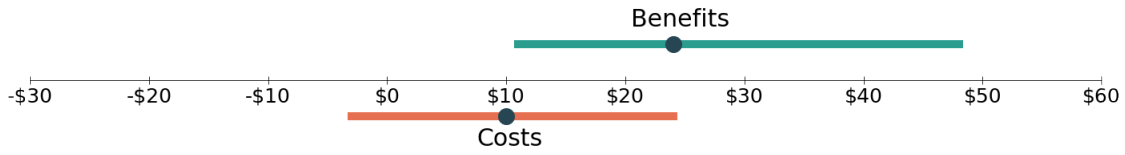
Note: This figure presents the DID estimates from equation 4 for the patenting rate across down-classification type and firm asset terciles and the simulation of these effects following appendix B. For the empirical estimates, I exclude patent data for private firms since I only observe firm asset data for publicly traded firms. Panel A presents the change in patenting rates in my Class III to II treated medical device types, relative to matched control groups, across asset terciles. The first tercile represents the bottom 33rd percentile of assets, the second represents the 33-66th percentile, and the third represents the 66-100th percentile. Panel B presents the change in patenting rates in my Class II to I treated medical device types, relative to matched control groups, across asset terciles. Panel C presents the simulated change in patenting rates from Class III to II down-classifications across asset terciles. Panel D presents the simulated change in patenting rates from Class II to I down-classifications across asset terciles. 95% confidence intervals overlay the estimates. Simulated confidence intervals are calculated using a Monte Carlo procedure. This procedure produces estimates across repeated random draws from the empirical distribution of firm characteristics.

Figure 8: Change in Emphasis on Safety by Firm Asset Terciles (II to I)

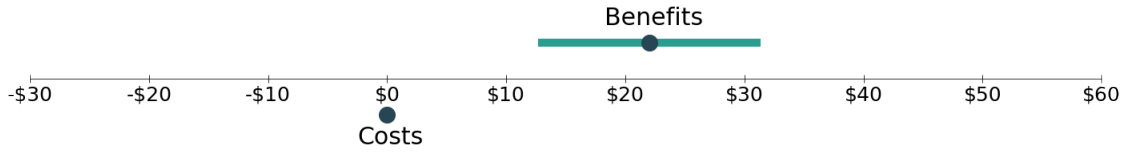
Note: This figure presents separate DID estimates of equation 4 for the change in the likelihood of device types exhibiting at least one annual occurrence of the given outcome variable by firm asset terciles. I set all outcomes greater than zero to one (LPM) as safety mentions and serious events are rare. The baseline outcome values across asset terciles are roughly equal and do not drive the disparate effects. The top figure presents the change in the likelihood for safety-related innovations, and the bottom figure illustrates this change for serious adverse events (death, hospitalization, or life-threatening event). Terciles are formed using the asset totals from firms that are publicly traded. The x-axis describes the tercile: first, second, or third, and the y-axis conveys the percent change in the likelihood. 95% confidence interval bars are provided.

Figure 9: Annual Costs and Benefits of Down-Classifications (Dollars in Millions)

Panel A: Class III to II Down-Classifications



Panel B: Class II to I Down-Classifications



Note: This figure presents the back-of-the-envelope calculations for the average yearly costs and benefits of down-classifications, in millions of dollars, across down-classified device types. Table 5 details these calculations and the underlying assumptions. Dollar amounts are provided in millions. Panel A presents the average yearly costs and benefits from down-classifying Class III devices. Panel B presents the average yearly costs and benefits from down-classifying Class II devices. Since I did not identify any costs associated with Class II down-classifications, as treated medical device types exhibited fewer adverse events, I treat the decline in adverse event rates as a benefit. Both panels A and B do not consider the informational value of FDA assurances regarding device quality and efficacy—although these benefits are likely low as the FDA chooses device types for which efficacy is easily verified. The cost of mortality is EPA's VSL of $10 million. I assume an average inpatient hospital stay costs $22,000 (Moses et al., 2019) while abstracting away from other costs. I assume creative destruction of 4/5 from the value of patents (Kogan et al., 2017). I do not consider private firm patent values. I also do not consider the scientific value of innovation. I assume no value from firm entry (e.g., not considering the value of new jobs). Using calculations from Medicare and UCSDH data, I assume UCSDH performs .08% of total U.S. procedures to identify the change in national procedure costs from deregulation.

Table 1: Summary Statistics

	N	Mean	SD	Range
FDA Admin. Data—Device Submissions (PMA and 510(k) Databases)				
Total	168,880	-	-	-
per Device Type	4,710 (Types)	35.5	110.8	[1, 2,457]
Total Submitting Firms	20,343	-	-	-
Firms per Device Type	4,710 (Types)	15.7	39.5	[1, 1,048]
Firm Regulatory Proficiency	4,660 (Types)	19.5yrs	65.4yrs	[0, 686.2yrs]*
FDA Admin. Data—Adverse Event Reports (MAUDE)				
Total	9,238,733	-	-	-
per Device Type	4,111 (Types)	2,353.3	18,939.9	[1, 0.6M]
Serious Events per Dev. type	2,400 (Types)	571.7	5186.8	[1, 0.15M]
Assets of Offending Firm	7,139,727	\$3.76B	\$5.77B	[\$0, \$0.79T]
USPTO Device Patents				
Total	1,248,292	-	-	-
per Device Type	2,113 (Types)	590.8	2077.4	[1, 23,056]
Citations	1,248,292	14.6	88.8	[1, 5,817]
Market Valuation	377,465	\$13.1M	\$30.7M	[\$45, \$1.9B]
Applicant Assets	377,465	\$26.7B	\$54.8B	[\$0.07M, \$1.1T]
UCSD Healthcare Claims Extract				
Total	495,519	-	-	-
per Procedure Code	528 (Codes)	880.4	2397.5	[1, 18,915]
Unique Patients	55,621	-	-	-
Price	453,079	\$135.7	\$389.0	[\$0, \$0.01M]
Price per Proc. Code	528 (Codes)	\$354.8	\$576.1	[\$0, \$5,401]

Note: For information on the collection of all FDA policymaking across the last 40 years, see table C.2. See Kogan et al. (2017) for more information on the patent market valuation data, which was merged into my patent dataset. The CRSP/Compustat database was used to derive the total assets of the firms applying for patent protection and is a proxy for firm size. Market values and applicant assets are only available for patents filed by publicly traded firms, representing roughly 25% of the total sample of patents. Missing observations account for the discrepancies between (i) the number of total FDA device types (5,542) and the number of device types represented in device submissions, adverse event reports, and patents (many device types have no associated patents), (ii) the total number of patents and the number of patents with market valuations and applicant assets, and (iii) the total number of claims and claims containing amounts paid. *"Regulatory proficiency" indicates the total number of days a firm has experienced approval delays across all its submitted devices.

Table 2: Effect of Down-Classifications on Innovation

		DID Estimates			
Down-Classification	Pre-mean (1)	Matched (2)	Intuitive (3)	Later (4)	Full (5)
A. Class III to II:					
Patenting Rate	7.95	14.99**	25.61**	26.65*	18.14
	(9.27)	(5.57)	(8.98)	(10.36)	(20.58)
Device Approval Rate	0.47	2.69***	2.36**	2.26**	2.22***
	(1.03)	(0.59)	(0.77)	(0.73)	(0.33)
Citations-Per-Patent Rate	9.06	16.59*	21.86*	19.43**	26.24***
	(20.65)	(7.48)	(9.81)	(6.41)	(5.62)
Average Patent Value	4.36	8.24***	11.29***	11.58***	10.50***
	(6.12)	(1.81)	(2.91)	(2.96)	(1.59)
Sample Size		1540	1056	920	60456
B. Class II to I:					
Patenting Rate	16.32	7.34	7.06	13.32**	29.17***
	(37.11)	(4.86)	(6.77)	(5.01)	(7.18)
Citations-Per-Patent Rate	0.64	6.85**	2.12*	3.98***	6.00***
	(0.48)	(2.30)	(1.08)	(0.84)	(1.43)
Average Patent Value	6.49	3.37***	0.90+	2.04***	6.13***
	(14.19)	(0.67)	(0.47)	(0.46)	(0.56)
Sample Size		15180	20592	27764	32472

Note: The table presents estimates of equation 4, which is a difference-in-differences (DID) style OLS regression model. Outcomes are derived from USPTO patent databases, FDA administrative data, and Kogan et al. (2017). Column (1) presents the 5-year baseline average of treated device types for the outcomes listed on the left-hand side. Columns (2)–(5) present DID estimates for the listed outcomes using different control groups. Namely, a matched control group, intuitively similar device types (treat similar diseases), "later treated" device types (treated after sample window), and the full sample, respectively. Device approvals are derived from FDA data and are not available for Class I devices. For column (4), Class III to II, control device types are treated after 2015; thus, all observations after 2015 are dropped. Confidence intervals are calculated using Conley–Taber test statistics. +, *, **, and *** correspond with statistical significance at the 0.10, 0.05, 0.01, and 0.001 levels respectively.

Table 3: Effect of Down-Classifications on Market Composition

		DID Estimates				
Down-Classification	Pre-mean (1)	Price (2)	Matched (3)	Intuitive (4)	Later (5)	Full (6)
A. Class III to II:						
Procedure Price	95.31	-58.25**	-43.54**	-	-	-27.50
	(123.95)	(21.16)	(15.66)	-	-	(144.11)
Sample Size		160	176	-	-	36240
Incumb. Entry (dev.)	0.40	-	1.58***	1.48**	1.46**	1.44***
	(0.91)	-	(0.36)	(0.54)	(0.52)	(0.22)
New Entry (dev.)	0.07	-	0.67***	0.70**	0.59**	0.63***
	(0.31)	-	(0.19)	(0.22)	(0.19)	(0.13)
Incumb. Entry (pat.)	1.47	-	1.91**	2.78**	3.56**	2.98*
	(1.78)	-	(0.59)	(1.01)	(1.34)	(1.48)
New Entry (pat.)	3.78	-	5.63***	11.19**	11.94**	8.88
	(4.76)	-	(1.61)	(3.75)	(4.31)	(6.32)
Sample Size		-	1364	1056	920	60456
B. Class II to I:						
Incumb. Entry (pat.)	2.26	-	0.04	0.32	0.61*	1.36**
	(4.33)	-	(0.45)	(0.36)	(0.29)	(0.42)
New Entry (pat.)	7.27	-	3.85+	2.60	4.87**	10.55***
	(16.87)	-	(1.99)	(2.10)	(1.57)	(2.07)
Sample Size		-	13552	20592	27764	32472

Note: The table presents estimates of equation 4, which is a difference-in-differences (DID) style OLS regression model. Column (1) presents the 5-year baseline average of treated device types for the outcomes listed on the left-hand side. Columns (2)–(6) present DID estimates for a given outcome using different control groups; These groups are (2) matched on baseline prices, (3) matched on baseline innovation and adverse event levels, (4) an intuitively comparable group, (5) a later treated group, and (6) the full sample of controls, respectively. Column (5) of Panel A uses control device types treated after 2015, so all observations after 2015 are dropped. Procedure prices were only available after 2004, restricting sample size. There are no price estimates in columns (4) and (5) due to data limitations. Confidence intervals are calculated using Conley–Taber test statistics. +, *, **, and *** correspond with statistical significance at the 0.10, 0.05, 0.01, and 0.001 levels respectively.

Table 4: Effect of Down-Classifications on Adverse Events

		DID Estimates			
Down-Classification	Pre-mean (1)	Matched (2)	Intuitive (3)	Later (4)	Full Sample (5)
A. Class III to II:					
Emphasis on Safety	0.16	0.073+	-	-	-
	(0.21)	(0.039)	-	-	-
Life-Threatening Event Rate	0.07	0.65	0.89	-0.92	-2.40
	(0.31)	(0.55)	(0.83)	(0.64)	(1.83)
Hospitalization Rate	0.25	2.38+	3.07	1.39	-3.48
	(0.84)	(1.27)	(1.94)	(1.16)	(3.72)
Mortality Rate	0.08	-1.21	1.08	-0.07	0.26
	(0.46)	(2.21)	(0.68)	(0.59)	(2.53)
Sample Size		616	672	552	38472
B. Class II to I:					
Emphasis on Safety	0.065	0.05***	-	-	-
	(0.218)	(0.012)	-	-	-
Life-Threatening Event Rate	0.07	-2.18	-0.36+	-3.24*	-3.18*
	(0.43)	(2.02)	(0.19)	(1.63)	(1.56)
Hospitalization Rate	0.17	-2.05***	-3.04+	-4.87*	-5.44*
	(0.94)	(0.60)	(1.56)	(2.35)	(2.54)
Mortality Rate	0.26	-0.43**	-0.27	-0.46+	-0.57*
	(2.13)	(0.14)	(0.20)	(0.26)	(0.27)
Sample Size		10332	13104	17668	20664

Note: The table presents estimates of equation 4, which is a difference-in-differences (DID) style OLS regression model. Column (1) presents the 5-year baseline average of treated device types for the outcomes listed on the left-hand side. Adverse event outcomes are derived from the FDA MAUDE database. Columns (2)–(5) present DID estimates for the listed outcomes using different control groups. Namely, a matched control group, intuitively similar device types (treat similar diseases), "later treated" device types (treated after sample window), and the full sample, respectively. For column (4), Class III to II, control device types are treated after 2015; thus, all observations after 2015 are dropped. Confidence intervals are calculated using Conley–Taber test statistics. +, *, **, and *** correspond with statistical significance at the 0.10, 0.05, 0.01, and 0.001 levels respectively.

Table 5: Costs and Benefits of Down-Classification

Assumptions

-Cost of mortality is EPA's VSL of $10 million.
-Average inpatient hospital stay costs $22,000 (Moses et al., 2019). No other costs.
-Creative destruction of 4/5 from value of patents (Kogan et al., 2017).
-Do not consider private firm patent values.
-Do not consider scientific value of innovation.
-No value of efficacy information from regulations.
-No value from firm entry (e.g., not considering value of new jobs).
-UCSDH performs .08% of total U.S. procedures (calculated from data).

		Outcome	Estimate	95% C.I.	Value	Total	95% C.I.
Class III to II	**Costs**	Mortality	1.08	[-0.3,2.4]	$10m	$10.8m	[-$3m, $24m]
		Hospital.	2.38	[-0.1,4.9]	$.02m	$.05m	[$0m, $0.1m]
						$10.9m	[-$3m, $24m]
	Benefits	Patented Inn.	5	[3.2,8.1]	$13m/5	$13m	[$8.2m, $21.1m]
		Prices	-$14.7m	[-$2.6,-$26.8]	-1	$14.7m	[$2.6m, $26.8m]
						$24.7m	[$11m, $48m]
Class II to I	**Costs**	Mortality	-0.43	[-0.7, -0.16]	$10m	-$4.3m	[-$7m, -$1.6m]
		Hospital.	-2.1	[-3.3, -0.9]	$0.02m	-$0.04m	[-$0.06m, $0]
						-$4.3m	[-$7m, -$1.6m]
	Benefits	Patented Inn.	9	[3.1, 14.9]	$10m/5	$18m	[$6m, $30m]
						$18m	[$6m, $30m]

Note: This table provides the back-of-the-envelope calculations of the costs and benefits of Class III to II and Class II to I down-classification events. Assumptions are detailed at the header of the table. Patent estimates are calculated using only publicly traded companies for which I can obtain patent values as calculated in Kogan et al. (2017). I provide 95% confidence intervals for the costs and benefits. Costs and benefits are annualized and averaged at the device type level (as defined by the FDA). The column "Value" is the value per unit of the estimate. In my data, procedures using treated medical device types generate, on average, $26,849 a year of health expenditures. Scaling this total to a national level ($26,849/ 0.0008, where .0008 is the share that UCSDH executes) gives roughly $33 million a year spent per treated procedure, on average. This total is similar to the average yearly cost of medical procedures seen when Medicare data is scaled to national expenditures, at $34.7 million a year per procedure. Since I find that costs, as measured by paid amounts, decrease by 44–62% a year, I use these percentage decreases in prices to calculate annual national expenditure changes per treated medical device type. These calculations are presented in the "Prices" row for Class III to II down-classifications. "Patented Inn." represents innovation that is patented by public firms, and "Hospital." represents hospitalizations.

Appendix Material

A The Social Planner's Regulation Problem

A.1 Model

In this appendix section, I conceptualize the regulating agency's decision to down-classify a medical device type. I characterize this decision as an optimal stopping problem, where there is value to waiting and learning a device type's inherent level of risk before down-classification.[29] This characterization aligns well with the FDA's current approach to regulating medical devices: FDA currently regulates radical new devices heavily in Class III to learn about the device type's inherent risk. Then, the FDA chooses when (if ever) to deregulate when the history of information on device risk suggests that stringent regulation is not necessary.

This model borrows from the seminal job search model of Jovanovic (1979) and the drug-approval model presented in Carpenter et al. (2010).[30] The agency considers medical device type (product code) j with health benefit γ_j and underlying danger μ_j. The health benefit γ_j represents improvements in life expectancy and quality of life, and danger represents the expected number of adverse events (e.g., deaths) over a given interval of time.[31] Medical device type j faces regulation R_c in Class c, where $c \in \{I, II, III\}$. Flows of innovation $I_j(R_c)$ in device type j are dependent on regulation and affect the health benefits and danger. The device type j is used at the rate N_j. Together, society reaps a benefit flow $B(I_j(R_c), N_j, \gamma_j)$

[29]This characterization is consistent with the FDA's description of the down-classification process, as desirable down-classification candidates are those for which sufficient valid scientific evidence has come to light to suggest that down-classification will not result in increased adverse events (see section 1.)

[30]Different from Carpenter et al. (2010), my empirical context analyzes the FDA's decision to reclassify broad types of medical innovation rather than its decision to approve a given drug or device. Importantly, the classification of a generic device type, and its accompanying requirements, has a greater bearing on approval likelihood and approval timelines than variation within device type at the individual device level. Also, the policy variation I observe is at the device-type level.

[31]For simplicity I assume that harm is the only uncertain variable, although other variables, such as the health benefit of a medical device type, could also be learned over time. I assume that a medical device type's danger is independent of its health benefit, or $\text{cov}(\mu_j, \gamma_j) = 0$. If these variables were not independent, the learning process would be quicker.

when medical device type j is regulated in Class c. The agency establishes regulation R_c for Class c devices to mitigate harm. The share of unmitigated harm in device type j is denoted by $M_j(R_c, I(R_c)) \in [0,1]$, with unmitigated harm decreasing in R_c. The agency values life lost from adverse events relative to lives saved from innovation flows at the rate ν.

The agency observes a series of adverse event reports for device type j. The cumulative evidence of harm, as observed in adverse event reports, evolves according to a Weiner process $X_j(t) = \mu_j t + \sigma z(t)$, which is a linear combination of the underlying danger μ_j and a random component. Assume that $\mu_j > 0,\ \sigma > 0$, and $X_j(0) = 0$, with $z(t) \sim N(0,t)$. Thus, $X_j(t)$ is normally distributed with mean $\mu_j t$ and variance $\sigma^2 t$. The agency applies Baye's Rule to the stochastic history of adverse events $X_{j,t}$ to learn about μ_j. I assume that σ is the same across device types, while μ_j is normally distributed across device types, with mean m and variance s.

With the device type subscript supressed, I charactize the agency's learning process. With time t in the current regulatory framework and cumulative adverse events $X(t) = x$, the above assumptions imply that the information on harm μ can be characterized by a normal posterior distribution (Chernoff, 1968), with

$$\begin{aligned} &\text{posterior mean } \equiv E_{xt}(\mu) = \hat{\mu}_t = \tfrac{\left(ms^{-1} + x\sigma^{-2}\right)}{(s^{-1} + t\sigma^{-2})} \text{ and} \\ &\text{posterior variance } \equiv S(t) = \tfrac{1}{(s^{-1} + t\sigma^{-2})}. \end{aligned} \tag{A.1}$$

The posterior variance $S(t)$ represents the agency's uncertainty about the true value of μ at any given time. Thus, as $S(t)$ increases, the option value of waiting increases, and as t increases, the option value of waiting decreases. By Chernoff (1968), $\hat{\mu}_t$ is normally distributed with mean m and variance $s - S(t)$.

I assume irrereversibility, or that once an agency down-classifies a medical device type from a class with high regulatory scrutiny ("H") to one with low regulatory scrutiny ("L," with $R_H > R_L$), they cannot subsequently up-classify. This assumption is consistent with what I see in the data. The FDA has down-classified hundreds of medical device types,

but rarely up-classifies device types. This is also consistent with a desire for "reputation protection," as noted in Carpenter (2004b), in which the FDA cannot recover its repuational losses by up-classifying a device type—the public already internalized the bad decision the agency made. Together, the agency thus faces an optimal stopping problem of the learning process $\hat{\mu}_t$, characterized by a law of motion $d\hat{\mu}(t) = \frac{S(t)}{\sigma} dz(t)$, with $\hat{\mu}(0) = m$, and the objective

$$\max_{T(\omega)} E\left\{\int_{T(\omega)}^{\infty} e^{-\delta t}[B(I(R_L),\cdot) - \nu M(R_L, I(R_L))\mu^*(t,\omega)]dt + \int_0^{T(\omega)} e^{-\delta t}[B(I(R_H),\cdot) - \nu M(R_H, I(R_H))\mu^*(t,\omega)]dt\right\}, \tag{A.2}$$

where δ is a discount factor and $\mu*$ is the agency's estimate of danger at the time of down-classification. The parameter ω denotes an elementary event in the probability space Ω, and t is the variable of integration. This objective illustrates that the agency should choose an optimal stopping time $T(\omega)$ only when the difference between the benefits of lifesaving innovation and the costs of device harm is expected to be at least as large as the same difference before down-classification. The optimal policy occurs at the boundary (see appendix A.2 for derivation)

$$\theta(t) = \frac{B(I(R_L),\cdot) - B(I(R_H),\cdot) - \frac{S(t)^2}{2\sigma^2} V_{\hat{\mu}\hat{\mu}}(\theta(t),t)}{\nu[M(R_L, I(R_L)) - M(R_H, I(R_H))]}, \tag{A.3}$$

when estimated harm is less than the time-dependent boundary, or when

$$\hat{\mu} < \frac{B(I(R_L),\cdot) - B(I(R_H),\cdot) - \frac{S(t)^2}{2\sigma^2} V_{\hat{\mu}\hat{\mu}}(\theta(t),t)}{\nu[M(R_L, I(R_L)) - M(R_H, I(R_H))]}. \tag{A.4}$$

The quantity $\frac{S(t)^2}{2\sigma^2} V_{\hat{\mu}\hat{\mu}}(\theta(t),t)$ represents the value of waiting and learning more about the harm of the device type.[32] Thus, down-classifications should occur if the estimate of

[32]Note that as t approaches infinity, I can extract the deterministic boundary, with no underlying uncertainty about harm, given by $\theta = \frac{B(I(R_L),\cdot) - B(I(R_H),\cdot)}{\nu[M(R_L, I(R_L)) - M(R_H, I(R_H))]}$, where the agency should down-classify if $\mu < \frac{B(I(R_L),\cdot) - B(I(R_H),\cdot)}{\nu[M(R_L, I(R_L)) - M(R_H, I(R_H))]}$. Naturally, if μ is certain, there is no value in waiting for additional information. In this setting, the agency would down-classify if danger is less than the net benefits of innovation divided by the relative value of net unmitigated harm after down-classification. However, in a finite-time

harm is less than the difference between the benefits from increased lifesaving innovation, less the option value of waiting, divided by the relative value of net unmitigated harm after down-classification.

This model generates several insights. First, the optimal time to down-classification is decreasing in the net flow of innovation. For example, if a high regulation environment dampens the flow of innovation relative to a low (or no) regulation environment, the agency should down-classify sooner. Second, the optimal time to down-classification is increasing in net unmitigated harm. Intuitively, if loose regulation mitigates harm as well as strict regulation, then down-classification should occur sooner. Third, if innovation itself mitigates harm (e.g., through more durable materials) and flows of innovation increase in a low-regulation environment, the agency should down-classify sooner. Lastly, if the agency prioritizes preventing device-related deaths above saving lives (from increased innovation), the optimal time to down-classification increases.

This model helps characterize a regulatory response that maximizes social welfare when there is an uncertain risk of product harm within the FDA's current regulatory framework. In practice, the FDA regulates medical devices with the intent to mitigate harm and, to a lesser extent, ensure efficacy, and does not consider the potential for innovation.[33] Since device harm is the central focus in down-classification decisions, average adverse event rates of down-classified device types closely resemble those of device types within their prospective class (see figure C.6).

My empirical analyses illuminate the net innovation flow $(B(I(R_L), \cdot) - B(I(R_H), \cdot))$ and

context, there will be an option value of waiting expressed by $\frac{S(t)^2}{2\sigma^2} V_{\hat{\mu}\hat{\mu}}(\theta(t), t)$.

[33]Note that the FDA does not explicitly state that a device type's scientific potential was an important driver for their decision to down-classify. This fact is somewhat crucial for my identifying assumptions, as selection into treatment due to innovative potential would violate the exclusion restriction (to the extent that my control groups do not also exhibit scientific potential). However, the FDA recently started promoting policies that incentivize innovation. In 2011, for example, the FDA launched the Medical device Innovation Initiative in response to Makower et al. (2010) to "facilitate innovation...and to understand the barriers developers face" (Center for Devices and Radiological Health, 2011). FDA officials often describe the difficulty of measuring innovation in the medical device space, underscoring the need for reliable measurement of scientific potential, the societal benefits of new medical device technologies, and the effects of FDA policies on innovation (the goals of this study).

net unmitigated harm ($M(R_L, I(R_L)) - M(R_H, I(R_H))$) that occur from down-classification events. Thus, my analyses determine the optimal time to deregulate a given medical device type. The option value of waiting, $\frac{S(t)^2}{2\sigma^2} V_{\hat{\mu}\hat{\mu}}(\theta(t), t)$, is an untractable parameter in my empirical setting, thus I cannot measure all deregulation costs that drive the optimal stopping time.

A.2 Proof of Optimal Stopping Problem Boundary Condition

The law of motion for maximization is given by $d\hat{\mu}(t) = \frac{S(t)}{\sigma} dz(t),\ \hat{\mu}(0) = m$. The optimization problem is defined as

$$\begin{aligned} \max_{T(\omega)} E \Bigg\{ & \int_{T(\omega)}^{\infty} e^{-\delta t} [B(I(R_L), \cdot) - \nu M(R_L, I(R_L)) \mu^*(t, \omega)] dt + \\ & \int_{0}^{T(\omega)} e^{-\delta t} [B(I(R_H), \cdot) - \nu M(R_H, I(R_H)) \mu^*(t, \omega)] dt \Bigg\}, \end{aligned} \tag{A.5}$$

where μ^* is the bayesian estimate of harm at the optimal stopping time, $M(R_c, I(R_c))$ is the mitigating factor, representing the amount a given regulation mitigates harm. By Jovanovic (1979), equation A.2 is equivalent to maximizing

$$\begin{aligned} \max_{T(\omega)} E e^{-\delta T(\omega)} \Bigg\{ & \frac{B(I(R_L), \cdot) - \nu M(R_L, I(R_L)) \mu^*(T(\omega), \omega)}{\delta} \\ & - \frac{B(I(R_H), \cdot) - \nu M(R_H, I(R_H)) \mu^*(T(\omega), \omega)}{\delta} \Bigg\} \end{aligned} \tag{A.6}$$

Using the Bellman equation and applying Ito's lemma to equation A.6, I have

$$\delta V(\hat{\mu}, t) = V_t(\hat{\mu}, t) + \frac{S(t)^2}{2\sigma^2} V_{\hat{\mu}\hat{\mu}}(\hat{\mu}, t). \tag{A.7}$$

Let $[\theta(t), t]$ be the boundary of the continuation region. The following conditions hold at this boundary,

Value matching:

$$V(\hat{\theta(t)}, t) = \frac{B(I(R_L), \cdot) - \nu M(R_L, I(R_L))\theta(t)}{\delta} - \frac{B(I(R_H), \cdot) - \nu M(R_H, I(R_H))\theta(t)}{\delta}$$

Smooth pasting:

$$\begin{aligned} V_t(\theta(t), t) =& \frac{d}{dt}\left[\frac{B(I(R_L), \cdot) - \nu M(R_L, I(R_L))\theta(t)}{\delta} - \frac{B(I(R_H), \cdot) - \nu M(R_H, I(R_H))\theta(t)}{\delta}\right] \\ &= 0 \text{ (by Shiryav (1973))} \end{aligned}$$

Plugging in the value matching and smooth pasting conditions above into equation A.7 gives

$$B(I(R_L), \cdot) - \nu M(R_L, I(R_L))\theta(t) - B(I(R_H), \cdot) + \nu M(R_H, I(R_H))\theta(t) - \frac{S(t)^2}{2\sigma^2} V_{\hat{\mu}\hat{\mu}}(\theta(t), t) = 0. \tag{A.8}$$

Solving for $\theta(t)$ in equation A.8 gives,

$$\theta(t) = \frac{B(I(R_L), \cdot) - B(I(R_H), \cdot) - \frac{S(t)^2}{2\sigma^2} V_{\hat{\mu}\hat{\mu}}(\theta(t), t)}{\nu[M(R_L, I(R_L)) - M(R_H, I(R_H))]}. \tag{A.9}$$

B Simulation Exercise

B.1 Estimation Framework for the Learning Curve Parameters

Inexperienced medical device manufacturers may face additional costs when bring a new medical device to market (Y Combinator, 2016; Makower et al., 2010). As presented in section 2, I model the additional costs from approval delays using a learning curve parameter. I model the relationship between the total approval delay, $T_{N,f}$ (measured in days), and cumulative experience, $\sum_{s=1}^{N} t_{s,f}$, given by

$$T_{N,f} = \beta(R_c) \left(\sum_{s=1}^{N} t_{s,f} \right)^{-\gamma}, \text{ where } \gamma > 0.$$

Recall that $\beta(R_c)$ represents the baseline approval delay in medical device type c, while $\sum_{s=1}^{N} t_{s,f}$ represents the sum of approval delays (in days) faced after having submitting N past projects.

More novel devices within a given medical device type may face longer approval delays if the FDA is more careful with these devices to ensure that new scientific characteristics do not lead to unexpected harm. However, the structure of Class III regulations helps distinguish between more or less novel innovation. As mentioned in section 1, firms that have already submitted an original PMA in a Class III medical device type may use PMA supplements for follow-on innovation within that device type. PMA supplements experience shorter approval delays and face fewer data requirements. On the other hand, the FDA requires original PMAs when firms have not yet submitted a PMA in a given Class III medical device type or when an incumbent firm invents a new device that is sufficiently novel. Thus, I include only approval delays that firms encountered when submitting original PMA documents in my analysis.[34]

I log-linearize equation B.1, to allow for OLS estimation of the parameter γ, and include medical device type and firm-level fixed effects, resulting in the following specification,

$$ln(T_{N,f}) = ln(\beta(R_c)) - \gamma ln \left(\sum_{s=1}^{N} t_{s,f} \right) + \alpha_c + \alpha_f + \epsilon_{c,f}. \tag{B.1}$$

Standard errors are clustered at the device-type-firm level. I exclude observations with no experience to avoid undefined outcomes in the estimation.

[34] I focus only on firms that have spent at least one day navigating FDA regulation to avoid potential confounders related to first-time innovators, including their tendency to "swing-for-the-fence" when confronted with barriers to entry (see Aghion et al. (2019)). This exclusion does not substantially change my results, with results remaining significant. I also perform the same empirical exercise for Class II device manufacturers as the sample size is much larger. For this exercise, I consider only 510(k) documents submitted for unique devices, finding significant, though smaller, results even after including product-code-by-year and firm fixed effects.

B.2 Simulations

As described in section 2, the firm's decision to innovate is determined by its expected profit

$$\underbrace{\alpha_{f,j}(R_c,\cdot)}_{\text{Payout}} - \underbrace{\chi_j T_{N,f}(R_c)}_{\text{Delay Cost}} - \underbrace{(\psi x^* + \mu(R_c, x^*))}_{\text{Damages \& Effort Costs}} - \underbrace{F(R_c, K_f)}_{\text{Fundraising Cost}} . \tag{B.2}$$

where $T_{N,f,c} = \beta(R_c)\left(\sum_{s=1}^{N} t_{s,f}\right)^{-\gamma}$, and $\alpha_{f,j} = q_{f,j}[p(v_{f,j}, R_c) - AC_{f,j}]$. For tractability, I assume that fundraising costs take the form $F(R_c, K_f) = \max(0, \chi_j T_{N,f} - K_f)$. In addition, since I do not observe firm expenditures on safety R&D, the pdf of damages as a function of capital, regulation, and safety efforts, or worst-case damages, I assume that damages and safety efforts are zero. This assumption is not innocuous as these costs are substantial. Since this simulation analysis, however, focuses on firm heterogeneity, the qualitative effect of the change in these costs after deregulation for small versus large firms would push in the direction of the changes in fundraising costs. Namely, small firms benefit from both lower fundraising costs and relatively smaller increased damages. Thus, if damages and effort costs were included, they would push the simulation results further toward my empirical results.

The learning curve parameters γ and $\beta(R_c)$ are estimated in section 5, with these values for Class III and Class II devices given in table C.13. I perform two simulation exercises to further illustrate the heterogeneous effects of down-classification and to emphasize potential areas for improvement. First, I separately simulate the effects of down-classifications across firm size and firm experience. The results of these simulations are provided in section 5, and I show that they are similar to the results generated in my empirical estimation. I then simulate the effects of a flattening of the learning curve on the rate of unique device inventions to highlight what might happen if FDA policies were easier to navigate.

To execute these simulations, I first generate distributions of device payouts, firm sizes, and firm FDA cumulative experience. I proxy for device payouts using the stock market valuations of medical devices assessed upon their patent grant announcements. Using patent valuation as a proxy requires the assumption that the market can adequately identify the

expected payoff that a given patented innovation will yield to a firm. The device payout distribution is generated by fitting a gamma distribution to the medical device patent values for Class III and Class II devices separately. I then fit a lognormal distribution to my firm size data to generate a distribution of asset values across firms. Lastly, I draw a distribution of firms' experience after fitting a gamma distribution to my firm FDA experience data.

Results from section 5 suggest that down-classifications change the price for a given medical device type as more firms enter to produce additional units of a given device. I model these dynamics using the price elasticity estimates calculated in section 5, and the corresponding changes in regulatory stringency across both down-classification types. The price elasticity, and the arc price elasticity across my discrete policy changes are given by,

$$\varepsilon_{p,R_c} = \frac{dln(p)}{dln(R_c)} \approx \frac{ln(p(R_c)) - ln(p(R_c'))}{ln(R_c) - ln(R_c')}. \tag{B.3}$$

Since the policy variation I analyze discretely changes regulatory stringency (instead of differential changes), I use the arc elasticity formula. Using patent valuations to measure the payoff of a device invention, $\alpha_{f,j} = q_{f,j}[p(v_{f,j}, R_c) - AC_{f,j}]$, I derive the following relationship between the elasticity of payoffs (ε_{α,R_c}) and prices with some subscripts supressed,

$$\frac{ln(\alpha(R_c)) - ln(\alpha(R_{c'}))}{ln(R_c) - ln(R_c')} = \frac{ln(q[p(R_c, \cdot) - AC]) - ln(q[p(R_{c'}, \cdot) - AC])}{ln(R_c) - ln(R_c')} = \frac{ln(\frac{p(R_c,\cdot) - AC}{p(R_{c'},\cdot) - AC})}{ln(\frac{R_c}{R_{c'}})}. \tag{B.4}$$

Since I do not measure the average cost of producing an additional unit of medical device type j, I assume that the average costs are small relative to price, such that

$$\frac{ln(\frac{p(R_c,\cdot) - AC}{p(R_{c'},\cdot) - AC})}{ln(\frac{R_c}{R_{c'}})} \approx \frac{ln(\frac{p(R_c,\cdot)}{p(R_{c'},\cdot)})}{ln(\frac{R_c}{R_{c'}})} = \frac{ln(p(R_c)) - ln(p(R_c'))}{ln(R_c) - ln(R_c')}, \tag{B.5}$$

which is the same expression in equation B.3. Indeed, medical device markets are known to exhibit long-run profits that are greater than zero, suggesting that price is larger than average costs (Burns, 2012). Thus, using elasticity estimates from section 5, I calculate the resulting

change in payouts after down-classification. This exercise requires the assumption of a one-to-one mapping between procedure price elasticities and the elasticities of negotiated prices between hospitals and device manufacturers, since my elasticity estimates relate to changes in procedure prices. More carefully, given a payout value $\alpha(R_c)$ and levels of regulatory stringency R_c and $R_{c'}$ in Classes c and c', I measure the change in the payout value from down-classification by plugging in the elasticity, ε_{α,R_c}, prior payout $\alpha(R_c)$, prior regulatory scrutiny R_c, and prospective regulatory scrutiny $R_{c'}$, and solving for the unknown value $\alpha(R_{c'})$ in the equation

$$\varepsilon_{\alpha,R_c} = \frac{ln(\alpha(R_c)) - ln(\alpha(R_{c'}))}{ln(R_c) - ln(R'_c)}. \tag{B.6}$$

Given an empirical estimate of the price elasticity, this equality allows me to measure the change in payouts upon down-classification. Since I do not measure a specific price elasticity for Class II down-classified device types, I assume the same price elasticity calculated for Class III down-classified device types.

I calibrate χ to match the cost of approval delays found in Makower et al. (2010) at the daily level for both Class III and II devices.

After calibration, I first simulate the decisions to invent a new medical device for each firm in the distribution before and after a Class III to II and Class II to I down-classification event occurs. I then take the difference between the total number of firms innovating before and after the event and divide this difference by the baseline number of firms innovating to generate a percentage change in unique devices. Figure 7 shows the simulated percent change in the number of devices invented across firm asset terciles for both down-classification event types. Figure 6 shows the percent change in the number of unique devices simulated across firm experience quartiles for Class III to II down-classifications. I do not include simulations for Class II to I down-classifications as the FDA data does not provide reliable information on new device innovation for Class I devices). Thus I cannot measure which firms, with their cumulative FDA experience, are deciding to innovate.

I also model how flattening the learning curve affects the rate of new device inventions

across the experience distribution. To this end, I anchor the days-to-approval value for the firm with the highest experience and iteratively reduce the learning parameter (γ) while solving for a $\beta(R_c)$ value that allows the new curve to pass through the anchored value. I then calculate the firms' decisions to innovate given the approval times corresponding to the new learning curve and take the difference between the decision after the learning curve is flattened and the decision at the baseline values of γ and β. I then sum these differences across each firm and calculate the percentage change in new device inventions relative to the baseline values. Figure C.10 shows the iterative flattening of the learning curve, and table C.14 provides the calculations of the percentage change in new device inventions.

C Additional Details

C.1 FDA Decision Rule for Reclassification

All Class II to I down-classifications were determined using a "device priority score." These scores were calculated using the following linear combination of evaluation factors,

$$\text{DPM} = 0.38\text{D} + 0.3\text{S} + 0.12\text{LS} + .08\text{U} + .08\text{B} + 0.04\text{E}. \tag{C.1}$$

In the model, D is the frequency of death, S is the frequency of serious injury, LS is the frequency of less serious injury, U is the frequency of use, B is the health benefit, and E is effectiveness. The FDA calculated the adverse event evaluation factor scores D, S, and LS with the following rule,

$$\text{Y} = \begin{cases} 100 \text{ if in "high" range,} \\ 50 \text{ if in "medium" range,} \\ 0 \text{ if in "low" range.} \end{cases} \tag{C.2}$$

The FDA pre-determined the three different ranges and their respective cutoffs, given

annual counts of the outcome Y. The evaluation factor scores for U, B, and E are given by

$$\mathrm{Y} = \begin{cases} 0 \text{ if in “high” range,} \\ 50 \text{ if in “medium” range,} \\ 100 \text{ if in “low” range.} \end{cases} \tag{C.3}$$

Intuitively, this means that given two devices with the same annual incidence of deaths and injuries, the device with the highest DPM score is the device that has the highest intrinsic risk per use, the lowest health benefit, and the least effectiveness. The FDA uses the resulting DPM score to flag marginal devices on the edge of their decision rule (see FDA (1995)). Other conditions for down-classification are uniformly satisfied across all down-classified types and would not affect the marginal decision.

I do not observe the pre-determined thresholds for D, S, and LS, and I do not observe B, U, and E. I proxy for the decision rule by taking a linear combination of the average yearly counts of deaths (D), serious events (S), and less-serious events (LS). This calculation is given by

$$\mathrm{DPM} = 0.38\mathrm{D} + 0.3\mathrm{S} + 0.12\mathrm{LS}. \tag{C.4}$$

I then compare the DID estimates from the treated device types in the top decile of calculated DPM scores against treated device types from the 0–90th percentile. In practice, U, B, and E would not influence the ordering of calculated DPM scores as the average DPM score of the top decile of medical device types is four times higher than the average DPM value of the device type at the 89th percentile. Additionally, device types with a high D evaluation factor also tend to have high S and LS evaluation factors; Thus, the stepwise construction of D, S, and LS in the FDA's decision rule would not substantially affect ordering.

C.2 Class I, II, and III Medical Device Regulations

Manufacturers of Class I devices (those perceived as low-risk) must simply abide by a standard set of safe marketing practices called "general controls."[35] A newly marketed medical device can be categorized as Class I if it is reasonably similar (e.g., same intended use and broad characteristics) to another device categorized as Class I. However, if a new medical device has distinct characteristics or intended use, the new device is given a new class III product code.[36]

Manufacturers of Class II devices are required to follow specific guidelines, called special controls, designed to mitigate device-specific risk and submit a 510(k) document, or "premarket notification."[37] Through the 510(k) process, a manufacturer must demonstrate that their device is "substantially equivalent" to a previously marketed device for which a "premarket approval" (PMA) is not required. A device is substantially equivalent if it has the same intended use and technological characteristics as the predicate device. As seen in table C.16, the 510(k) path is shorter and less costly than the more intensive PMA process described below. However, the 510(k) process can be expensive, with an average cost of $24 million (Makower et al., 2010). If the FDA finds that a device is not sufficiently similar to a predicate device, the manufacturer must file a PMA, which carries the most stringent requirements.

Manufacturers of Class III devices must perform clinical trials through the PMA process to ensure their new device is safe and effective before commercialization.[38] Class III device

[35]These devices are "low-risk" as they do not support or sustain human life and do not pose a potential unreasonable risk of illness or injury (e.g., a tongue depressor). 41% of all medical device types, or "product codes," fall under Class I. Of these, 90% are exempt from filing any documentation (aside from facility registration with the FDA).

[36]The FDA can then evaluate the safety and efficacy of new product codes and reclassify them, or a device manufacturer can submit a "De Novo" petition for the formal classification of a new device type. A new device can be classified as Class I or II if "the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or...[The device requires a 510(k) (even if its generic type is Class I) if] the device is intended for a use different from the intended use of a legally marketed device in that generic type of device...[or if] the modified device operates using a different fundamental scientific technology" (FDA, 2020a).

[37]56% of medical device product codes fall under this category.

[38]Pre-amendment class III devices (those existing before 1976) only have to submit a 510(k) if the FDA

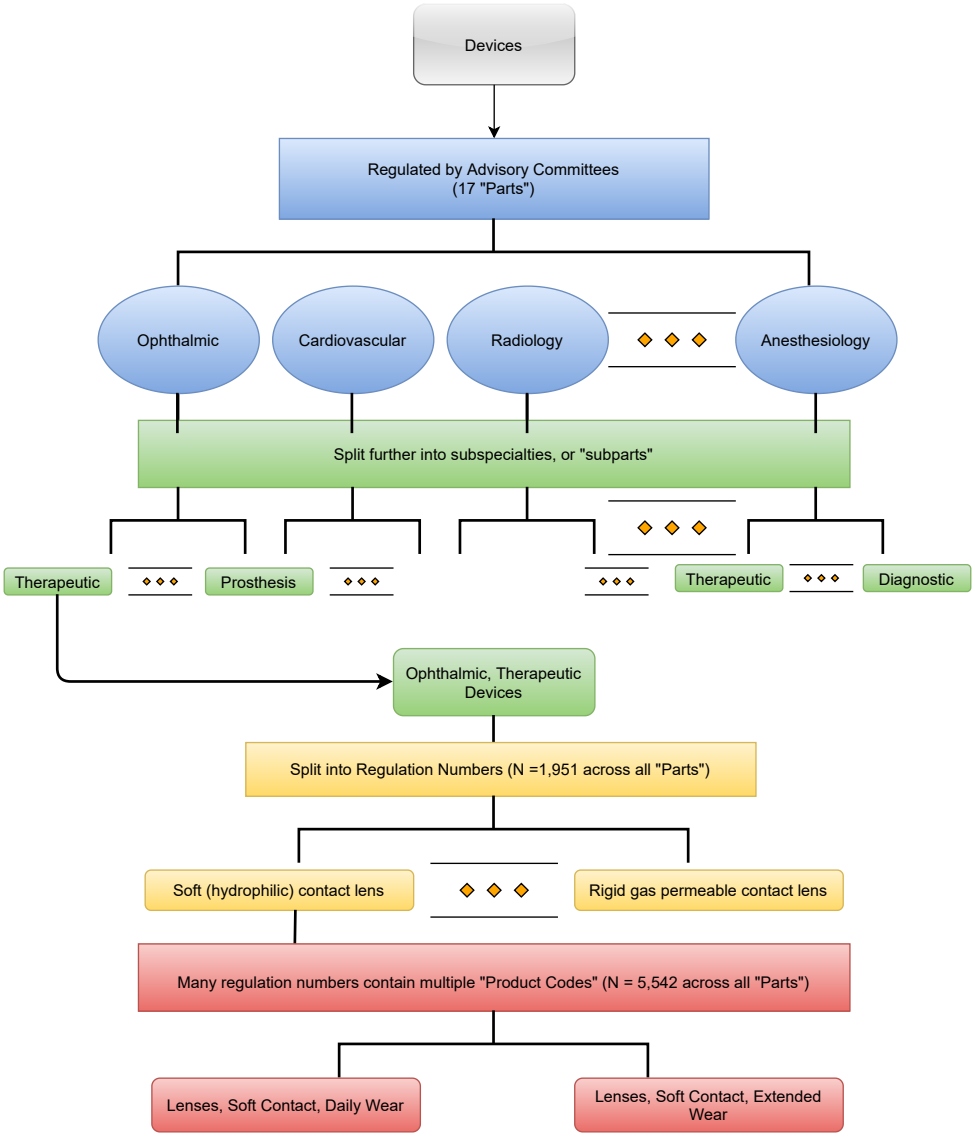
types are perceived as high-risk since not enough information exists to establish special controls that ensure safety and effectiveness (i.e., new device types) or if special controls do not adequately mitigate device risk.[39] The PMA process takes much longer than the 510(k) process (see table C.16), and costs, on average, $75 million (Makower et al., 2010). After a manufacturer has submitted a PMA document for their device, any small changes to their device that affect the device's safety or effectiveness require a PMA supplement submission. PMA supplements often do not require premarket clinical data and experience shorter review timelines (Johnson, 2012).[40]

has not issued a final order requiring PMA submission (Center for Devices and Radiological Health, 2018). A small percentage of 510(k)s also require a small amount of clinical data to support marketing clearance by the FDA.

[39]Roughly 2% of product codes currently fall under this classification, although these product codes represent an outsized portion of U.S. medical device spending (Meier, 2009).

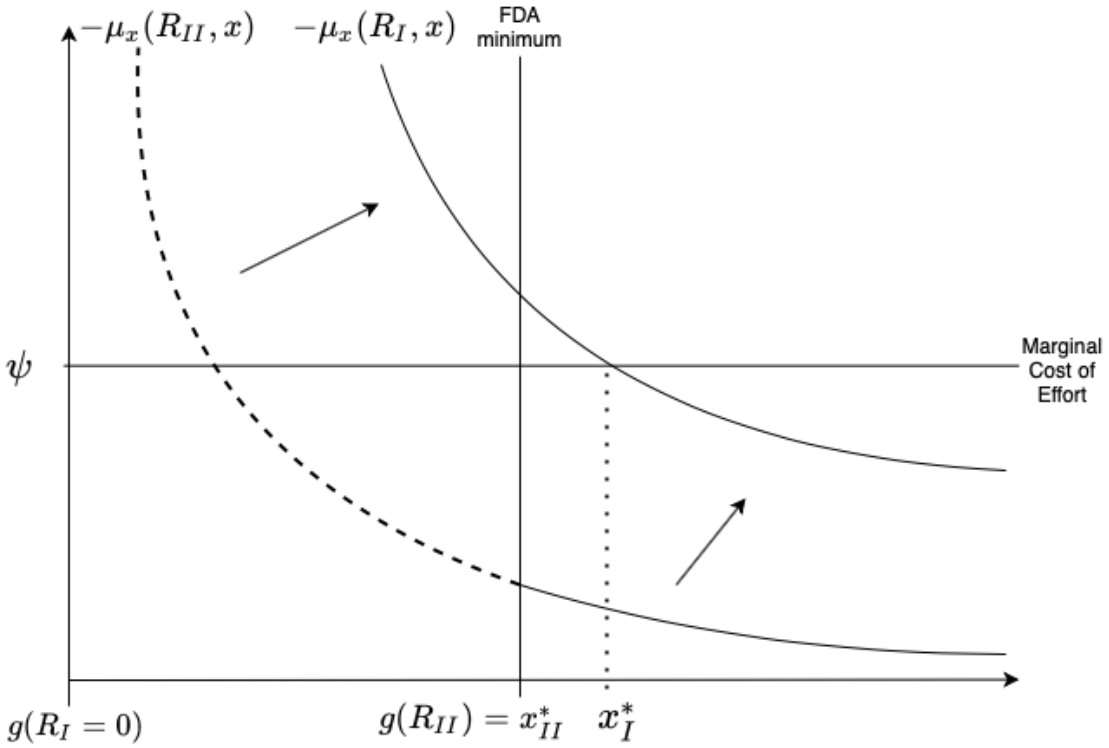
[40]However, the requirements associated with PMA supplements are dependent on the degree to which the new device has changed (see table C.16), with small changes (like labeling changes) requiring no fee and design changes requiring preclinical testing. As seen in table C.17, most submitted class III documentation is PMA supplements.

Appendix Figure C.1: FDA Regulatory Hierarchy for Medical Devices



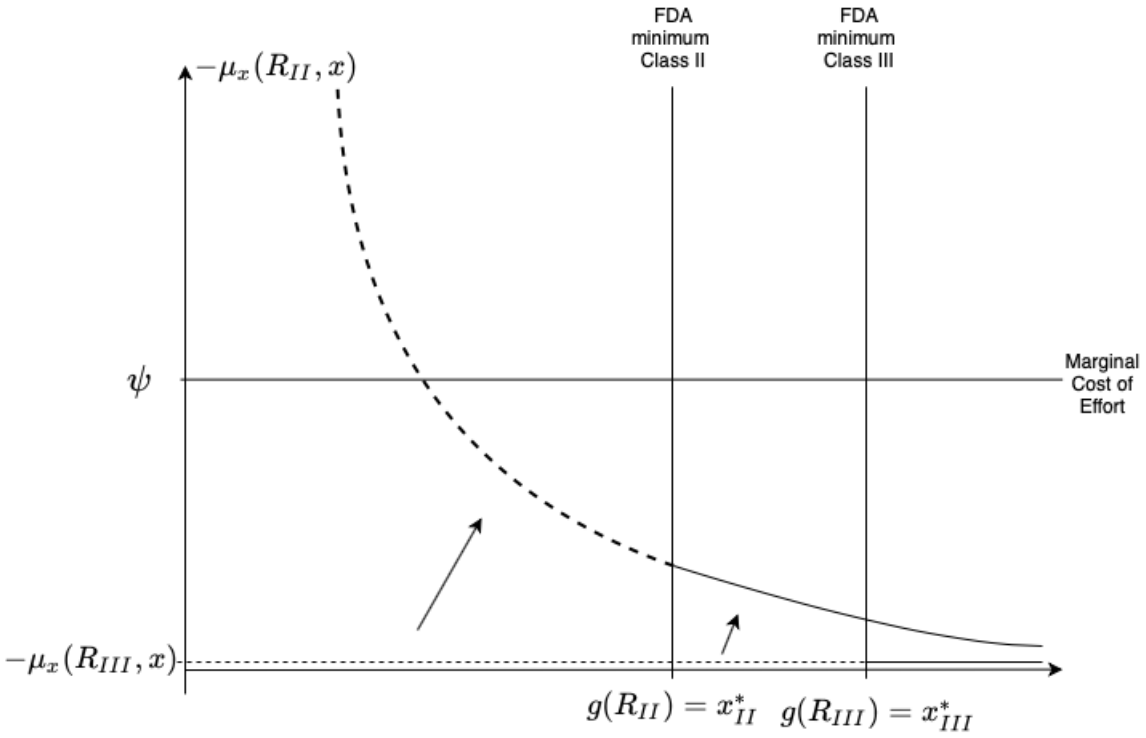
Note: This figure presents the hierarchy with which the FDA regulates medical devices. Devices are regulated at the highest level by "Parts," consisting of 17 advisory committees in distinct areas of medical expertise (i.e., Ophthalmic devices). Within a "Part," devices are categorized into "Subparts," like therapeutic or prosthetic Ophthalmic devices. Medical devices are then further distinguished by "Regulation Numbers." Regulation numbers are typically the level at which regulation occurs and consist of granular device types like soft contact lenses (a therapeutic Ophthalmic device). Lastly, devices are categorized into "product codes," representing the FDA's most granular device categorization (i.e., a daily-wear soft contact lens). Some Class III to II down-classifications target certain product codes within a regulation number.

Appendix Figure C.2: Class II to I Theoretical Change in Safety Effort



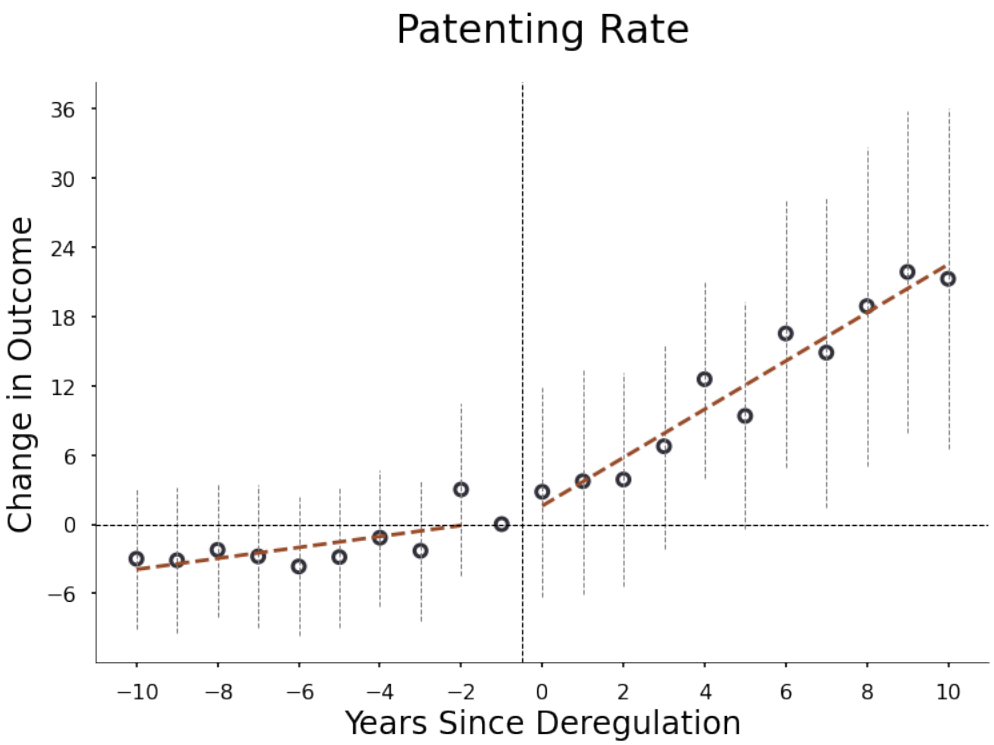
Note: This figure presents the comparative statics discussed in section 1 of the change in safety effort after deregulation. Deregulation events considered in this figure are those that move device types from Class II to I. The value R_{II} represents the regulatory stringency of Class II. The value R_I represents the stringency of Class I regulations. The x-axis indicates the level of safety effort exerted. The y-axis denotes the dollar values of the marginal benefit of safety effort and the marginal cost of safety effort. The counterfactual dotted section of the Class II marginal benefit curve represents the benefits of exerting effort below mandated levels while still achieving FDA approval. Shifts in the marginal benefit curve occur as fewer damages are precluded through federal preemption when regulatory stringency declines.

Appendix Figure C.3: Class III to II Theoretical Change in Safety Effort



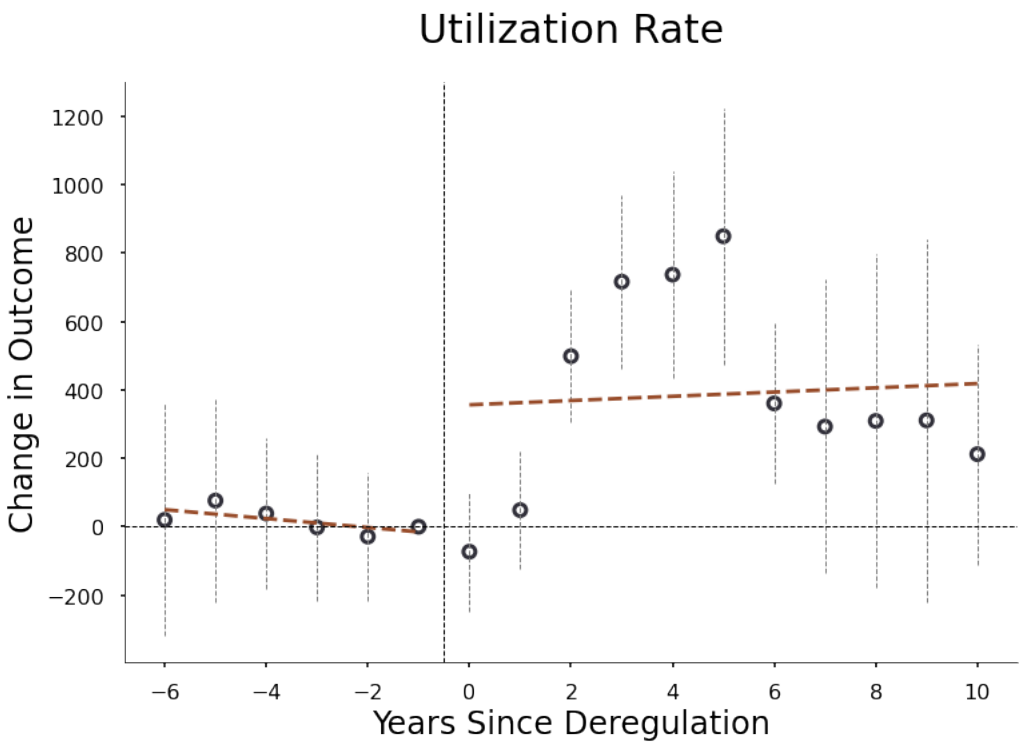
Note: This figure presents the comparative statics discussed in section 1 of the change in safety effort with regulation changes. Deregulation events considered in this figure are those that move device types from Class III to II. The x-axis indicates the level of safety effort exerted. The y-axis denotes the dollar values of the marginal benefit of safety effort and the marginal cost of safety effort. The counterfactual dotted section of the marginal benefit curves represents the benefits of exerting effort below mandated levels while still achieving FDA approval. The value R_{III} represents the regulatory stringency of Class III. The value R_{II} represents the stringency of Class II regulations. Shifts in the marginal benefit curve occur as fewer damages are precluded through federal preemption when regulatory stringency declines. Class III devices experience complete abatement of expected damages as approval guarantees preemption and thus exhibit no returns to safety efforts above mandated levels.

Appendix Figure C.4: Petitioned Down-Classification Events (Not FDA-Initated)



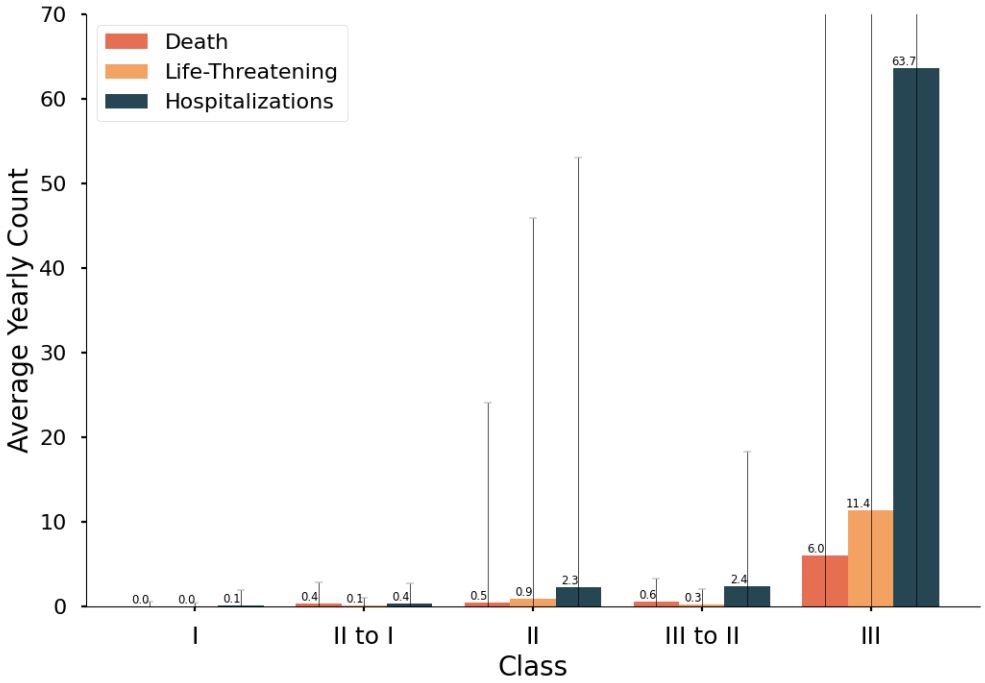
Note: This figure presents the estimates of the β_t coefficients from event-study equation 5 for the patent filing rate measure and illustrates the potential biases that stem from industry petition of down-classification. Outcome data are derived from USPTO patent data. Only Class III to II down-classification events petitioned by industry (not by the FDA's own initiative) are considered. Controls are device types matched on baseline averages of the outcome. The coefficient β_{-1} is omitted and serves as the reference period. Data are analyzed at an annual frequency. 95% confidence intervals are calculated following Conley and Taber (2011).

Appendix Figure C.5: Utilization Rates Event-Study



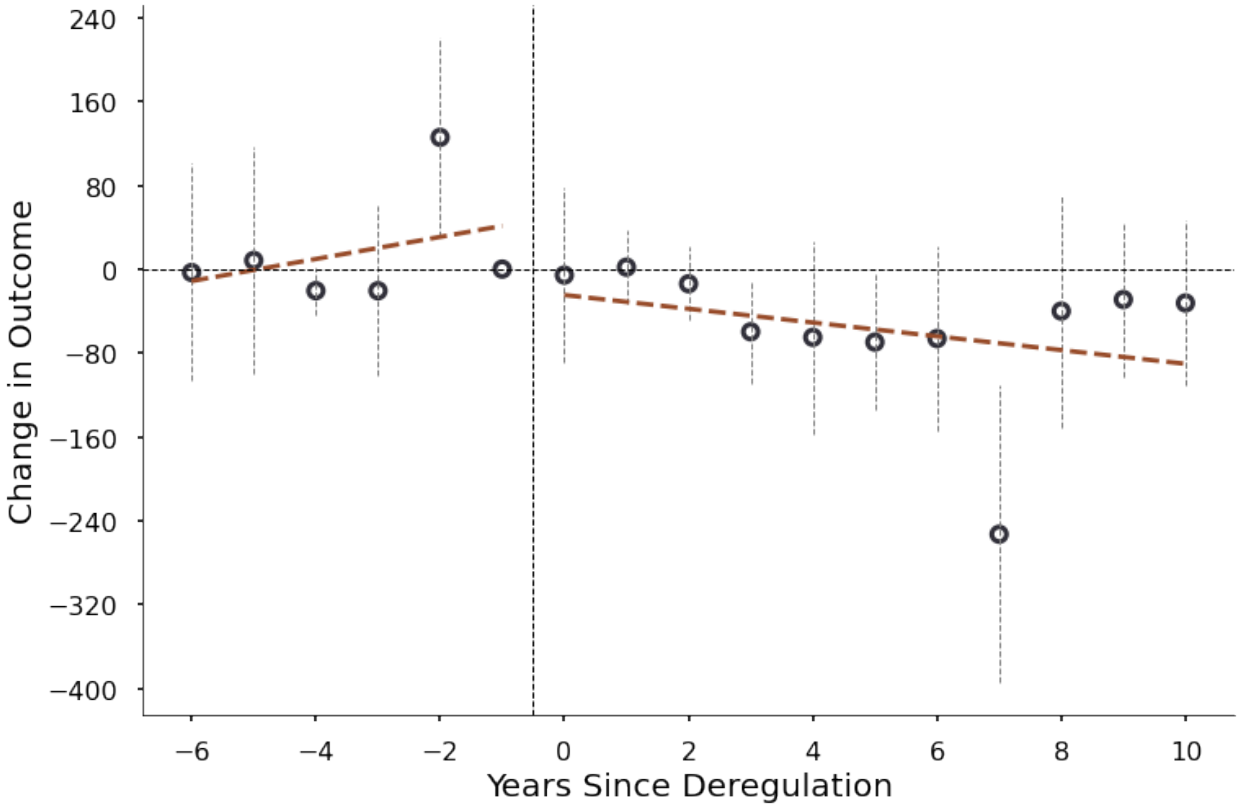
Note: This figure presents the estimates of the β_t coefficients from event-study equation 5 for the utilization rates of procedures that use treated or control medical device types. I do not have claims data before 2005; Thus, I only consider post-2005 Class III to II down-classification events. Controls are device types matched on baseline averages innovation rates. The coefficient β_{-1} is omitted and serves as the reference period. Data are analyzed at an annual frequency. Utilization is measured by the yearly number of paid claims for a given procedure. Claims data come from the UCSD healthcare system. Conley–Taber 95% confidence intervals are provided.

Appendix Figure C.6: Mean Yearly Adverse Event Counts by Device Type Class



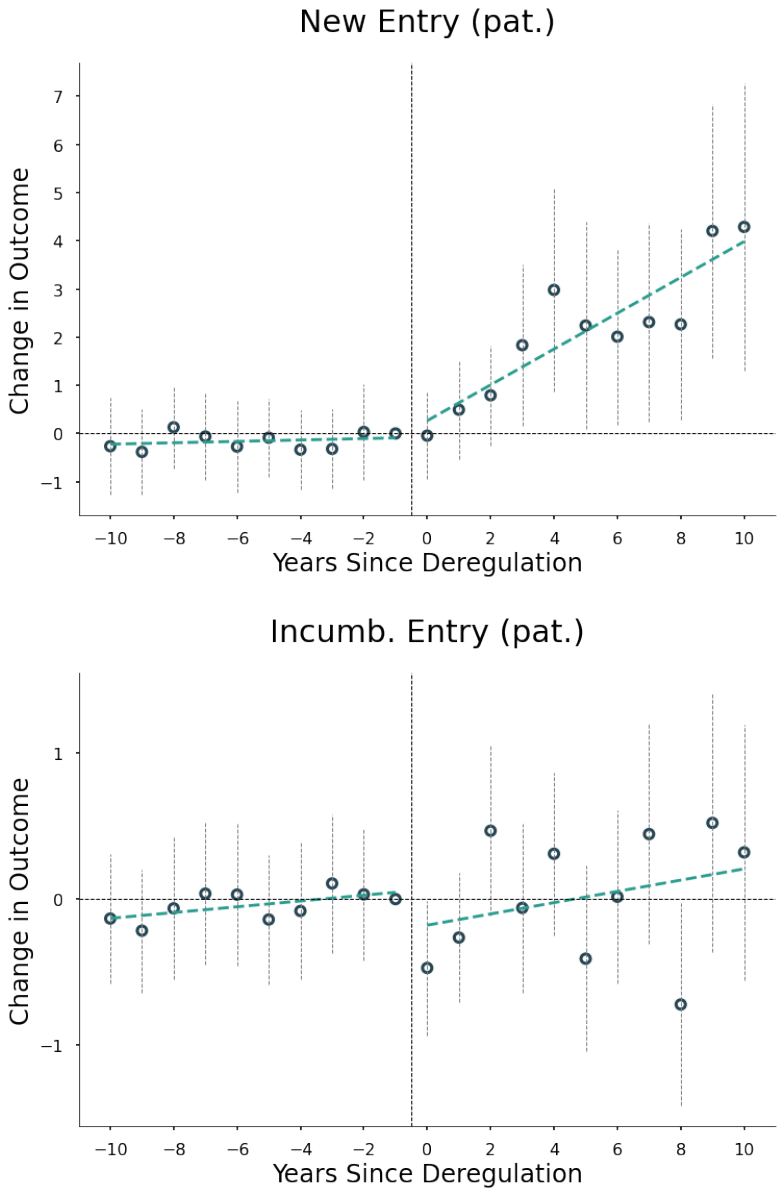
Note: This figure presents the annualized average counts of the specified adverse events for medical device types within the respective classification. The x-axis indicates the device type Class. The x-axis includes down-classified devices from Class III to II and Class II to I events separately. The y-axis details the average annualized count for a given class and adverse event type. The red bar represents the average number of yearly deaths across device types and years. The orange bar calculates a similar average for life-threatening events, and the blue bar calculates the average number of hospitalizations. These three variables are derived from the FDA MAUDE adverse event data. Standard error bands also overlay the average estimates.

Appendix Figure C.7: Procedure Price Event-Study Class III to II



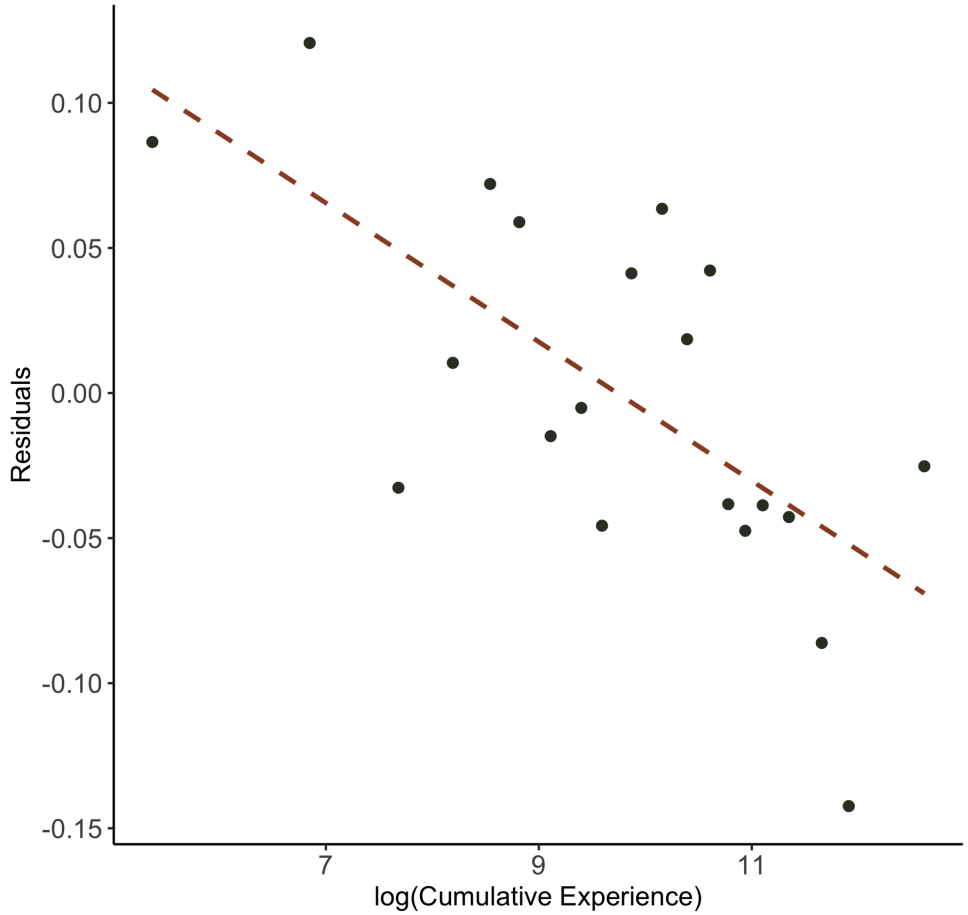
Note: This figure presents the estimates of the β_t coefficients from event-study equation 5 for the price component of my market composition measures. Controls are device types matched on baseline outcome averages. The coefficient β_{-1} is omitted and serves as the reference period. I do not have UCSDH claims data before 2005; Thus, I only consider post-2005 Class III to II down-classification events. Data are analyzed at an annual frequency. The price is determined by the amount insurers paid for a given procedure. The figure describes the evolution of the prices of procedures that use treated device types relative to control groups matched using pre-event price averages. Conley–Taber 95% confidence intervals are provided.

Appendix Figure C.8: Market Composition Event-Study Class II to I



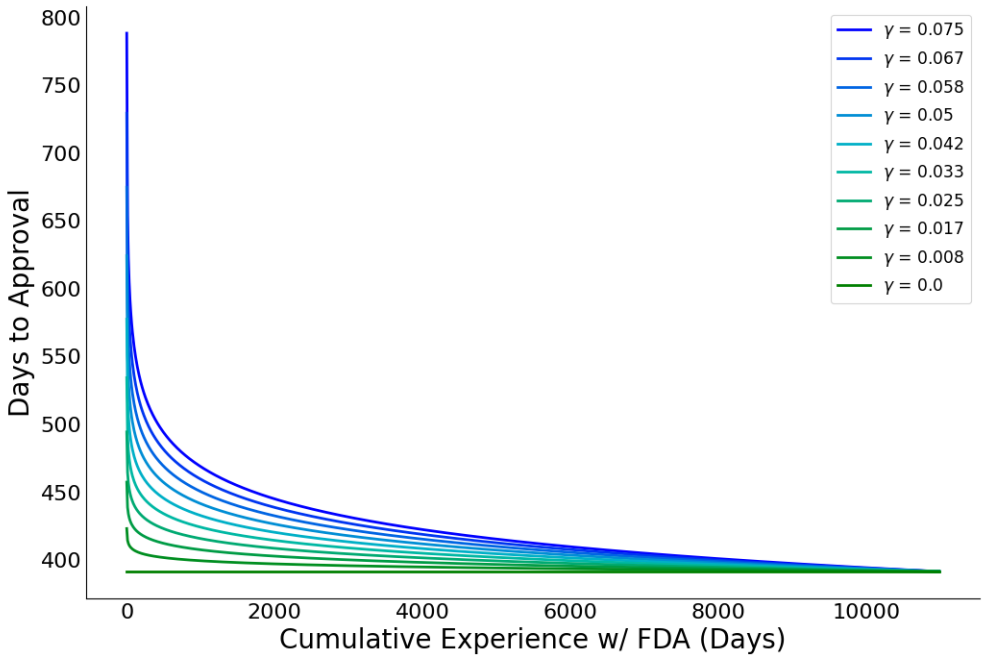
Note: This figure presents the estimates of the β_t coefficients from event-study equation 5 for my market composition measures. Only Class II to I down-classification events are considered. Data are analyzed at an annual frequency. Controls are device types matched on baseline outcome averages. The coefficient β_{-1} is omitted and serves as the reference period. The top subfigure illustrates the evolution of the rate of new firm entry (measured with patent data) relative to matched control groups. New firm entry represents firms that have never been granted a patent. The bottom subfigure illustrates the evolution of the rate of incumbent firm entry (firms that have received a granted patent), entering treated device types relative to matched controls. I do not include FDA-approved device measures of new and incumbent entry as I do not have reliable data on new Class I devices from FDA sources. 95% confidence intervals are provided.

Appendix Figure C.9: Binscatter Regression of Log Cumulative Experience vs. Residualized Days to Approval



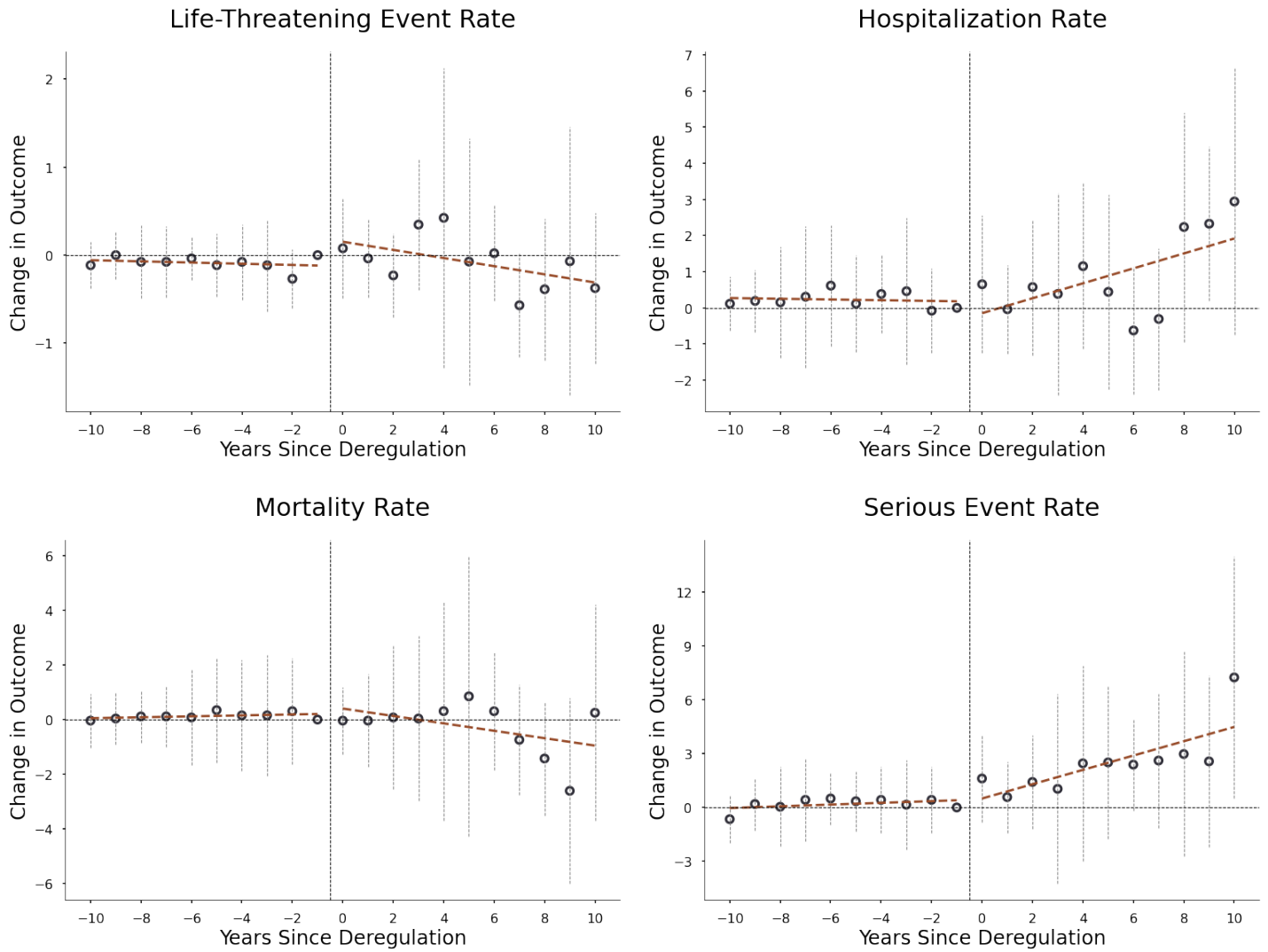
Note: This figure presents the estimated regression line, which estimates equation B.1 using OLS, together with a binscatter of residualized approval times against the log of the submitting firm's cumulative experience. Residualized approval times account for firm and device-type fixed effects. Each dot represents the average approval time of a cluster of document submissions for which submitting firms, on average, have a given level of FDA experience (after accounting for device-type and firm fixed effects). Only firms with positive cumulative experience are included in the regression.

Appendix Figure C.10: Flattening the Learning Curve Simulation



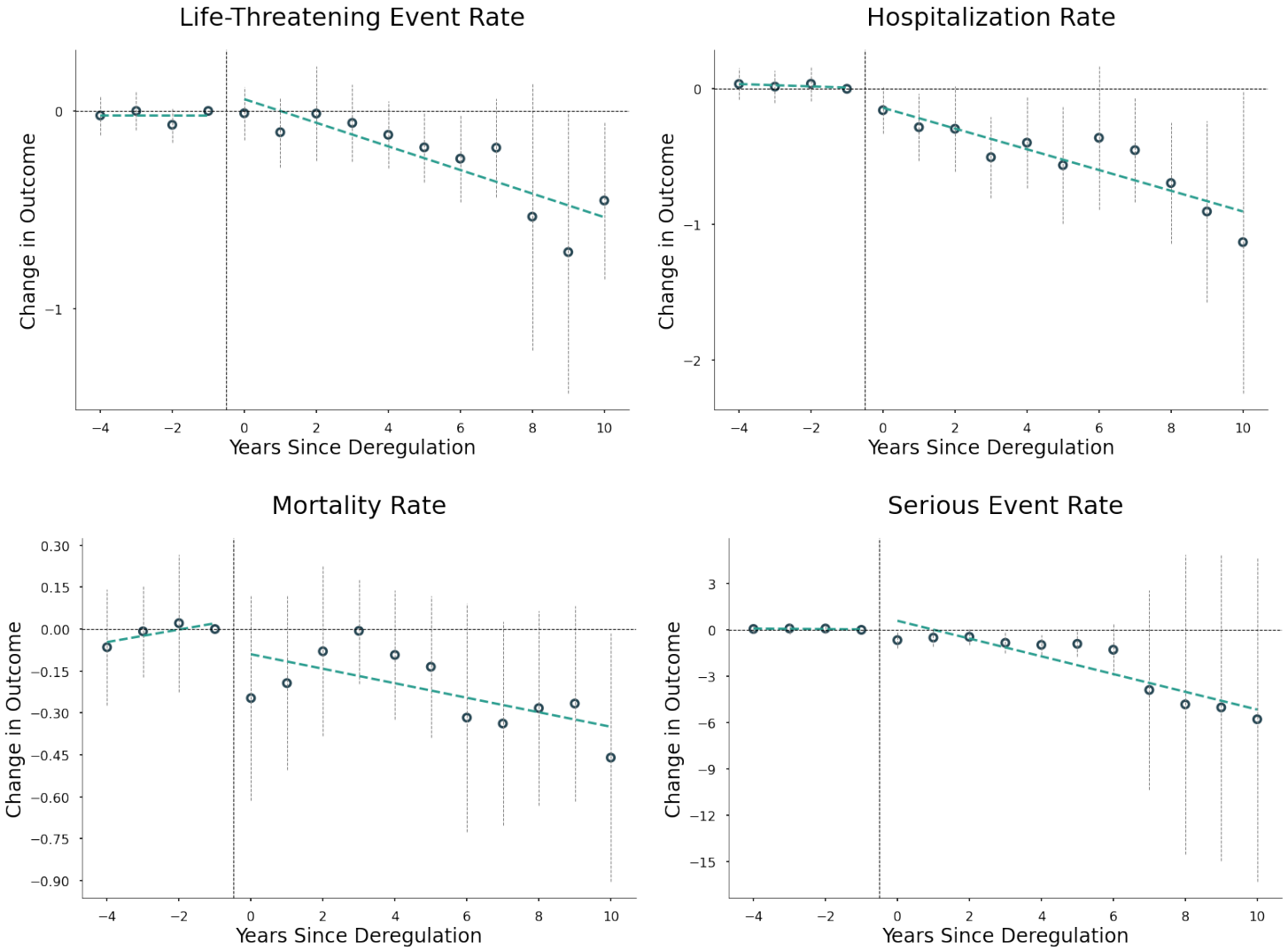
Note: This figure presents the simulation exercise of flattening the Class III learning curve estimated in equation B.1. I flatten the learning curve relative to the most experienced firm. The results of this simulation are provided in table C.14. Above, γ begins at its initial starting point estimated in equation B.1. Subsequent lines show the change in the learning curve as γ is reduced while maintaining the approval time of the top quartile of experienced firms. $T_{Sum,25}$ represents the bottom 25th percentile of cumulative FDA experience (in days), $T_{Sum,50}$ represents the 25-50th percentile, and $T_{Sum,75}$ represents the 50-75th percentile.

Appendix Figure C.11: Adverse Event Event-Study Class III to II



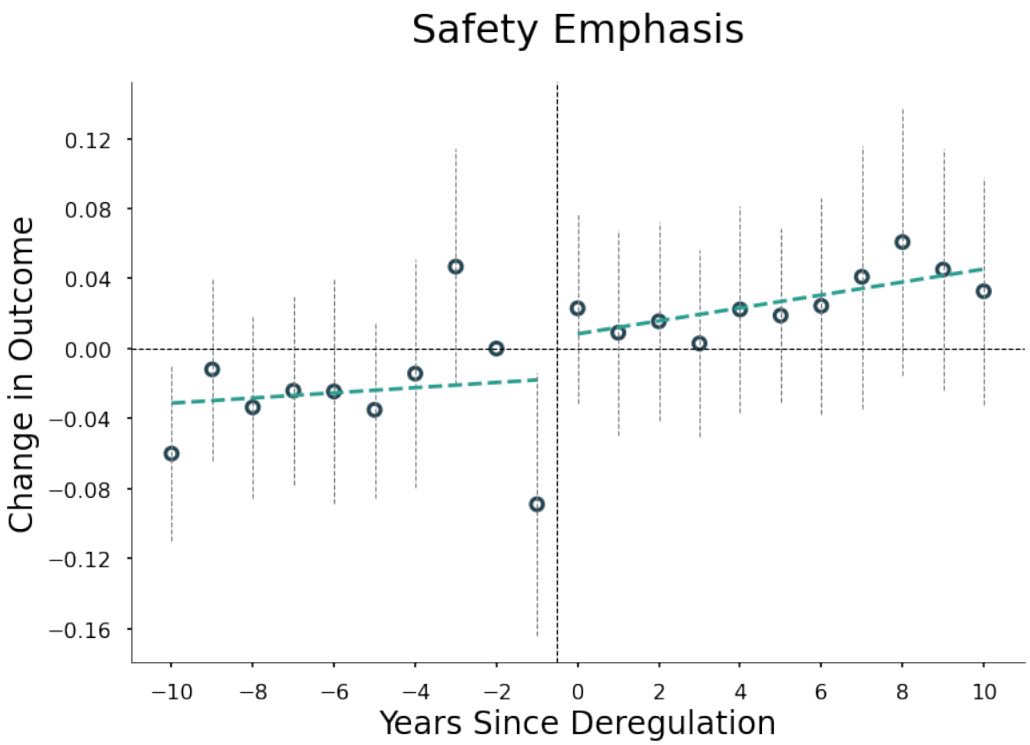
Note: This figure presents the estimates of the β_t coefficients from event-study equation 5 for my adverse event measures. Only Class III to II down-classification events are considered. Data are analyzed at an annual frequency. Controls are device types matched on baseline outcome averages. The coefficient β_{-1} is omitted and serves as the reference period. The top-left subfigure describes the evolution of the rate of life-threatening events stemming from the use of treated device types relative to control groups matched using baseline averages. The top-right subfigure describes the evolution of the rate of hospitalizations of treated device types relative to control groups. The bottom-left subfigure describes the evolution of the death rate. The bottom-right subfigure presents the evolution of the sum of all serious adverse events (life-threatening, death, hospitalizations, and disability) in treated device types relative to controls. Adverse events are derived from the FDA MAUDE database. Conley–Taber 95% confidence intervals are provided.

Appendix Figure C.12: Adverse Event Event-Study Class II to I



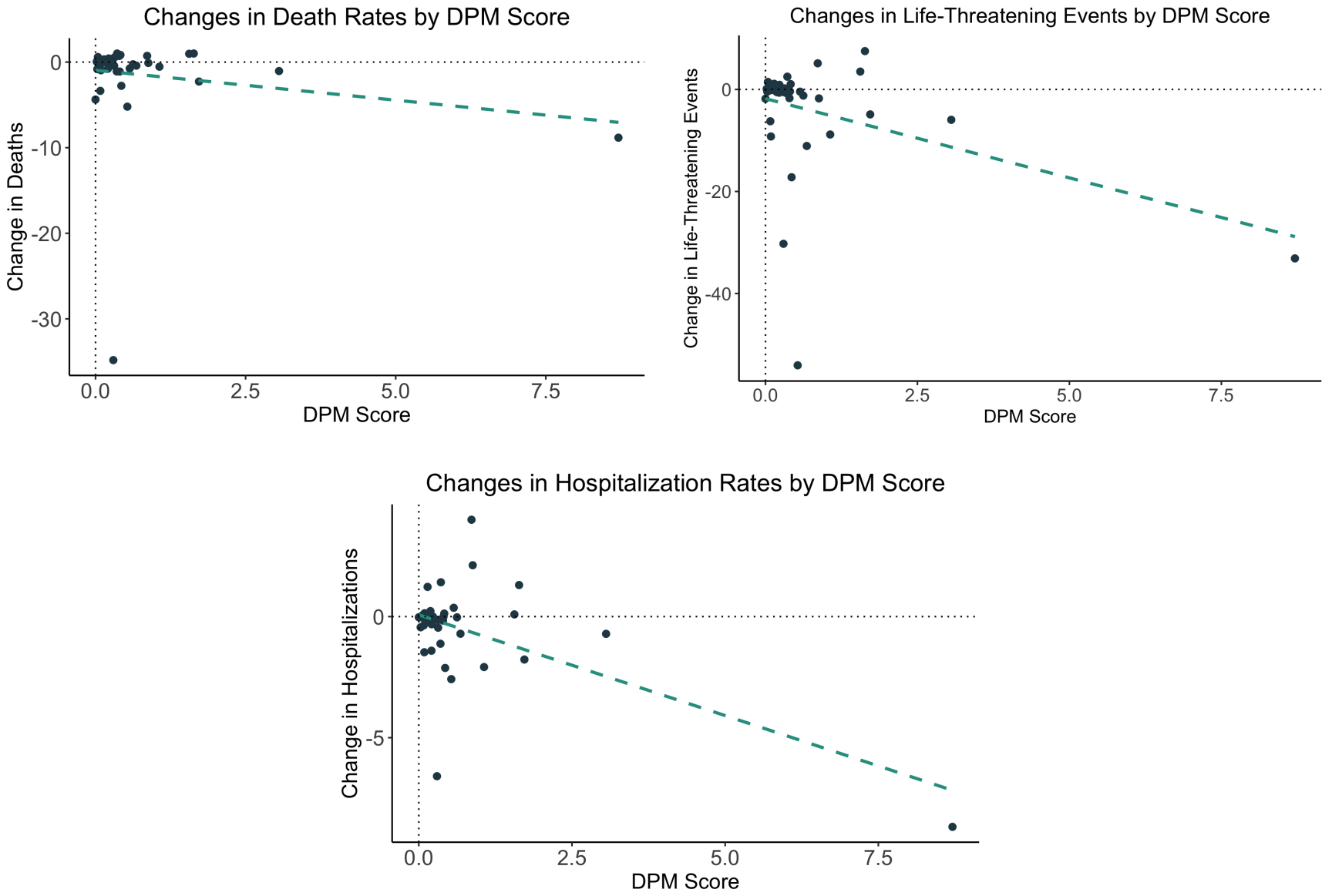
Note: This figure presents the estimates of the β_t coefficients from event-study equation 5 for my adverse event measures. Only Class II to I down-classification events are considered. Only four pre-periods are included because there are no prior adverse event data. Data are analyzed at an annual frequency. Controls are device types matched on baseline outcome averages. The coefficient β_{-1} is omitted and serves as the reference period. The top-left subfigure describes the evolution of the rate of life-threatening events stemming from the use of treated device types relative to control groups matched using baseline averages. The top-right subfigure illustrates the evolution of the rate of hospitalizations of treated device types relative to matched control groups. The bottom-left subfigure describes the relative evolution of the death rate. The bottom-right subfigure presents the relative evolution of the sum of all serious adverse events (life-threatening, death, hospitalizations, and disability) in treated device types. Adverse events are derived from the FDA MAUDE database. 95% confidence intervals are provided.

Appendix Figure C.13: Safety Emphasis Event-Study Class II to I



Note: This figure presents the estimates of the β_t coefficients from event-study quation 5 for inventors' emphases on safety. Only Class II to I down-classification events are estimated. Data are analyzed at an annual frequency. Controls are device types matched on baseline outcome averages. The coefficient β_{-2} is omitted and serves as the reference period (due to noise before the event). The figure describes the evolution of the proportion of patents that emphasize safety within patent texts. The volatility in the four years prior to the down-classification represents the congressional whiplash that occurred regarding whether to abolish the FDA. 95% confidence intervals are provided.

Appendix Figure C.14: Class II to I Changes in Adverse Event Rates at Margin of Decision Rule



Note: This figure presents separate DID estimates of equation 4 for each adverse event measure and each treated device type with a given proxy DPM score relative to matched controls. The DPM score is primarily an increasing function of the baseline average annual incidence of adverse events before deregulation (see appendix C.1). When the rightmost outlier is removed, the slopes of the fitted lines are still negative or zero. Controls for each treated device type are selected by matching based on DPM scores across both Class I and II devices that were not down-classified in the given period. The x-axes describe the same proxy DPM score across the three adverse event outcomes. The y-axes describe the change in the rate of the given adverse event type in the treated device type relative to matched control device type. The top-left figure shows the differences-in-differences estimates for the change in death rates across device types, the top-right figure shows the same for life-threatening events, and the bottom figure shows the same for hospitalizations. Adverse event data are from the FDA's MAUDE database. 95% confidence intervals are provided.

Appendix Table C.1: Down-Classified Class III Device Types Considered

Device Type Description	Part	Year Down-Classified
Tacrolimus test system.	Clinical Chemistry	2002
Nucleic acid-based in vitro diagnostic devices	Immunology	2014
Cutaneous carbon dioxide (PcCO2) monitor.	Anesthesiology	1988
Vascular embolization device.	Cardiovascular	1990
Vascular graft prosthesis.	Cardiovascular	2001
Electrical salivary stimulatory system.	Dental	2015
Extracorporeal shock wave lithotripter.	Gastro.-Urology	2000
Rigid gas permeable contact lens.	Ophthalmic	1994
Soft (hydrophilic) contact lens.	Ophthalmic	1994
Intervertebral body fusion device.	Orthopedic	2007
Bone sonometer.	Radiology	2008
Full-field digital mammography system.	Radiology	2010

Note: The table presents the device types which experienced a Class III to II down-classification by the FDA's own initiative and experienced at least one submitted PMA document prior to down-classification. These device types form my treated group in Class III to II down-classification analyses. I provide device type descriptions, in which part they pertain, and the year they were down-classified.

Appendix Table C.2: Reclassification Events Gathered

Reclassification Event	Number of Device Types
Unclassified $\Longrightarrow$ class I	14
Unclassified $\Longrightarrow$ class II (no previous PMAs)	106
Unclassified $\Longrightarrow$ class II (w/ previous PMAs)	3
Unclassified $\Longrightarrow$ class II (but 510(k) exempt)	5
Class I Official Exemptions	2104
Reclassification class I $\Longrightarrow$ II (Special Controls Only)	3
Reclassification class II $\Longrightarrow$ I	293
Reclassification class II $\Longrightarrow$ III	2
510(k) Exemption for class II	123
Reclassification class III $\Longrightarrow$ II	30
Reclassification class III $\Longrightarrow$ II (no previous PMAs)	50
Required PMA from Class III	64

Note: The table presents the reclassification events I identified over the past 40 years of the MDAs history. I study down-classifications from Class III to Class II and from Class II to Class I. Substantive down-classifications from Class III to II are a mix of pre- and post-amendment medical devices. Pre-amendment devices were those that had existed before the MDA enactment.

Appendix Table C.3: Effect of Down-Classifications on Innovation (Using Borusyak et al. (2021) estimator)

		DID Estimates			
Down-Classification	Pre-mean (1)	Matched (2)	Intuitive (3)	Later (4)	Full (5)
A. Class III to II:					
Patenting Rate	7.95	19.73*	27.70**	28.48**	22.11*
	(9.27)	(9.96)	(8.80)	(10.29)	(8.85)
Device Approval Rate	0.47	2.11***	1.85***	1.71***	1.76***
	(1.03)	(0.32)	(0.29)	(0.33)	(0.27)
Citations-Per-Patent Rate	9.06	17.60*	21.86*	17.07***	27.46***
	(20.65)	(7.61)	(8.76)	(4.90)	(7.15)
Average Patent Value	4.36	9.37***	11.72***	11.61***	11.82***
	(6.12)	(1.65)	(1.59)	(1.75)	(1.44)
Sample Size		1540	1056	920	60456
B. Class II to I:					
Patenting Rate	16.32	8.15	7.77	14.16**	31.04**
	(37.11)	(13.00)	(6.64)	(5.16)	(10.46)
Citations-Per-Patent Rate	0.64	6.84**	2.07+	4.01***	6.03***
	(0.48)	(2.09)	(1.18)	(0.94)	(1.42)
Average Patent Value	6.49	3.46***	0.86+	2.00***	5.00***
	(14.19)	(0.95)	(0.50)	(0.44)	(0.71)
Sample Size		15180	20592	27764	32472

Note: The table presents estimates of equation 4, which is a difference-in-differences (DID) style OLS regression model. In this analysis, I drop all device types that do not exhibit any positive quantity of the given outcome. Column (1) presents the 5-year baseline average of treated device types for the outcomes listed on the left-hand side. Columns (2)–(5) present DID estimates for the listed outcomes using different control groups. Namely, a matched control group, intuitively similar device types (treat similar diseases), "later treated" device types (treated after sample window), and the full sample, respectively. Confidence intervals are calculated using Conley–Taber test statistics. +, *, **, and *** correspond with statistical significance at the 0.10, 0.05, 0.01, and 0.001 levels respectively.

Appendix Table C.4: Effect of Down-Classifications on Market Composition (Using Borusyak et al. (2021) estimator)

		DID Estimates				
Down-Classification	Pre-mean (1)	Price (2)	Matched (3)	Intuitive (4)	Later (5)	Full (6)
A. Class III to II:						
Amount Paid	95.68	-89.73***	-75.84*	-	-	-51.99***
	(123.78)	(25.35)	(34.42)	-	-	(10.85)
Sample Size		480	176	-	-	36240
Incumb. Entry (dev.)	0.40	-	1.17***	1.09***	1.02***	1.08***
	(0.91)	-	(0.11)	(0.11)	(0.12)	(0.09)
New Entry (dev.)	0.07	-	0.60***	0.61***	0.52**	0.55**
	(0.31)	-	(0.17)	(0.17)	(0.19)	(0.17)
Incumb. Entry (pat.)	1.47	-	2.36***	3.01***	3.69***	2.82***
	(1.78)	-	(0.59)	(0.56)	(0.69)	(0.53)
New Entry (pat.)	3.78	-	7.29+	11.54**	12.02**	10.04**
	(4.76)	-	(4.33)	(3.85)	(4.60)	(3.86)
Sample Size		-	1364	1056	920	60456
B. Class II to I:						
Incumb. Entry (pat.)	2.26	-	0.08	0.35	0.65*	1.43**
	(4.33)	-	(0.68)	(0.36)	(0.29)	(0.49)
New Entry (pat.)	7.27	-	4.24	2.82	5.11**	11.10***
	(16.87)	-	(3.87)	(2.05)	(1.61)	(3.07)
Sample Size		-	13552	20592	27764	32472

Note: The table presents estimates of equation 4, which is a difference-in-differences (DID) style OLS regression model. In this analysis, I drop all device types that do not exhibit any positive quantity of the given outcome. Column (1) presents the 5-year baseline average of treated device types for the outcomes listed on the left-hand side. Columns (2)–(6) present DID estimates for a given outcome using different control groups. Namely, a group matched on baseline prices, a group matched on baseline innovation and adverse event levels, an intuitively comparable group, a later treated group, and the full sample of controls, respectively. Confidence intervals are calculated using Conley–Taber test statistics. +, *, **, and *** correspond with statistical significance at the 0.10, 0.05, 0.01, and 0.001 levels respectively.

Appendix Table C.5: Effect of Down-Classifications on Adverse Events (Using Borusyak et al. (2021) estimator)

		DID Estimates			
Down-Classification	Pre-mean (1)	Matched (2)	Intuitive (3)	Later (4)	Full Sample (5)
A. Class III to II:					
Emphasis on Safety	0.16	0.074+	-	-	-
	(0.21)	(0.038)	-	-	-
Life-Threatening Event Rate	0.07	0.59	0.81+	-0.58	-1.93
	(0.31)	(0.44)	(0.43)	(0.78)	(1.35)
Hospitalization Rate	0.25	3.36**	3.44**	2.27*	-2.21
	(0.84)	(1.14)	(1.14)	(0.93)	(1.97)
Mortality Rate	0.08	-0.50	1.08*	0.29	0.33
	(0.46)	(1.34)	(0.47)	(0.53)	(0.49)
Sample Size		588	644	528	38444
B. Class II to I:					
Emphasis on Safety	0.065	0.056***	-	-	-
	(0.218)	(0.012)	-	-	-
Life-Threatening Event Rate	0.07	-2.57	-0.36	-3.21	-3.16+
	(0.41)	(1.96)	(0.26)	(2.73)	(1.71)
Hospitalization Rate	0.15	-1.93**	-3.04	-4.84+	-5.44*
	(0.88)	(0.63)	(2.71)	(2.64)	(2.51)
Mortality Rate	0.23	-0.44*	-0.29	-0.47	-0.60***
	(1.98)	(0.17)	(0.29)	(0.29)	(0.17)
Sample Size		10332	13104	17668	20664

Note: The table presents estimates of equation 4, which is a difference-in-differences (DID) style OLS regression model. In this analysis, I drop all device types that do not exhibit any positive quantity of the given outcome. Column (1) presents the 5-year baseline average of treated device types for the outcomes listed on the left-hand side. Columns (2)–(5) present DID estimates for the listed outcomes using different control groups. Namely, a matched control group, intuitively similar device types (treat similar diseases), "later treated" device types (treated after sample window), and the full sample, respectively. For column (4), Class III to II, control device types are treated after 2015; thus, all observations after 2015 are dropped. Confidence intervals are calculated using Conley–Taber test statistics. +, *, **, and *** correspond with statistical significance at the 0.10, 0.05, 0.01, and 0.001 levels respectively.

Appendix Table C.6: Down-Classification Spillovers (Innovation)

		DID Estimates	
Down-Classification	Pre-mean (1)	Matched (2)	Full Sample (3)
A. Class III to II:			
Patenting Rate	7.95	1.67	-3.91
	(9.27)	(2.56)	(3.89)
Device Approval Rate	0.47	0.06	-0.01
	(1.03)	(0.14)	(0.29)
Sample Size		792	179520
B. Class II to I:			
Patenting Rate	19.12	-1.49	1.72
	(39.50)	(3.41)	(4.63)
Sample Size		7656	179872

Note: The table presents estimates of equation 4, which is a difference-in-differences (DID) style OLS regression model for device types that are closely related to treated medical device types. Column (1) presents the 5-year baseline average of closely related device types for the outcomes listed on the left-hand side. Columns and (2) and (3) present my OLS estimates of down-classifications on device types closely related to treated device types using different control criteria. Confidence intervals for my estimates in columns (2) and (3) are calculated using Conley–Taber test statistics. Column (2) presents the estimates when closely related groups are compared to matched control groups, whereas column (3) presents results from comparing against full sample controls. Standard errors allow for clusters at the PC level. +, *, **, and *** correspond with statistical significance at the 0.10, 0.05, 0.01, and 0.001 levels respectively.

Appendix Table C.7: Class III to II Device Types by Broad Device Category: Treated Group versus Intuitive Control Group

Treatment	Category Description	Count	Implant
0	Anesthesiology devices—monitoring devices	1	0
	Cardiovascular devices—cardiovascular prosthetic devices	2	2
	Clinical chemistry—test systems	1	0
	Dental devices—therapeutic devices	1	0
	Gastroenterology-urology devices—therapeutic devices	1	0
	Immunology and microbiology devices—serological reagents	1	0
	Ophthalmic devices—therapeutic devices	2	0
	Orthopedic devices—prosthetic devices	1	1
	Radiology devices—diagnostic devices	2	0
1	Anesthesiology devices—monitoring devices	1	0
	Cardiovascular devices—cardiovascular prosthetic devices	2	2
	Clinical chemistry—test systems	1	0
	Dental devices—therapeutic devices	1	0
	Gastroenterology-urology devices—therapeutic devices	1	0
	Immunology and microbiology devices—serological reagents	1	0
	Ophthalmic devices—therapeutic devices	2	0
	Orthopedic devices—prosthetic devices	1	1
	Radiology devices—diagnostic devices	2	0

Note: The table presents the broad device types used in the treatment and intuitive control groups. No life-sustaining devices are considered in the treatment and control groups. When "Treatment" is 0, the description counts refer to the control group and refer to the treated group otherwise. The column "Implant" indicates the counts of device types that are implantable in the given broad device category.

Appendix Table C.8: Class II to I Treated Device Types by Broad Category

Treatment	Category Description	Count	Implant
1	Anesthesiology devices—diagnostic devices	3	0
	Anesthesiology devices—miscellaneous	3	0
	Anesthesiology devices—monitoring devices	11	0
	Anesthesiology devices—therapeutic devices	23	0
	Cardiovascular devices—monitoring devices	5	0
	Cardiovascular devices—prosthetic devices	4	1
	Clinical chemistry—clinical chemistry test systems	6	0
	Clinical chemistry—clinical laboratory instruments	3	0
	Dental devices—diagnostic devices	2	0
	Dental devices—miscellaneous devices	1	0
	Dental devices—surgical devices	2	0
	Ear, nose, and throat devices—diagnostic devices	2	0
	Ear, nose, and throat devices—surgical devices	6	0
	Gastroenterology-urology devices—diagnostic devices	20	0
	Gastroenterology-urology devices—monitoring devices	1	0
	Gastroenterology-urology devices—surgical devices	10	0
	Gastroenterology-urology devices—therapeutic devices	19	1
	General and plastic surgery devices—surgical devices	1	0
	General hospital and personal use devices—gmiscellaneous devices	14	0
	General hospital and personal use devices—monitoring devices	5	0
	General hospital and personal use devices—therapeutic devices	7	0
	Hematology and pathology devices—manual hematology devices	4	0
	Hematology and pathology devices—used by blood manufacturer	4	0
	Immunology and microbiology devices—immunological test systems	14	0
	Immunology and microbiology devices—microbiology devices	1	0
	Immunology and microbiology devices—serological reagents	47	0
	Neurological devices—diagnostic devices	1	0
	Neurological devices—therapeutic devices	1	0
	Obstetrical and gynecological devices—odiagnostic devices	1	0
	Obstetrical and gynecological devices—surgical devices	6	0
	Obstetrical and gynecological devices—therapeutic devices	2	0
	Ophthalmic devices—diagnostic devices	4	0
	Ophthalmic devices—prosthetic devices	7	4
	Orthopedic devices—diagnostic devices	1	0
	Orthopedic devices—surgical devices	1	0
	Physical medicine devices—diagnostic devices	5	0
	Physical medicine devices—prosthetic devices	6	0
	Physical medicine devices—	19	0
	Radiology devices—diagnostic devices	9	0
	Radiology devices—miscellaneous devices	11	0
	Radiology devices—therapeutic devices	1	0

Note: The table presents the counts of broad device types used in the treatment group. No life-sustaining devices are considered. Implant counts are also provided.

Appendix Table C.9: Class II to I Intuitive Control Device Types by Category

Treatment	Category Description	Count	Implant
0	Anesthesiology devices—diagnostic devices	3	0
	Anesthesiology devices—miscellaneous	3	0
	Anesthesiology devices—monitoring devices	11	0
	Anesthesiology devices—therapeutic devices	23	0
	Cardiovascular devices—cardiovascular monitoring devices	5	0
	Cardiovascular devices—cardiovascular prosthetic devices	2	1
	Cardiovascular devices—cardiovascular surgical devices	2	0
	Clinical chemistry—clinical chemistry test systems	6	0
	Clinical chemistry—clinical laboratory instruments	3	0
	Dental devices—diagnostic devices	2	0
	Dental devices—miscellaneous devices	1	0
	Dental devices—surgical devices	2	0
	Ear, nose, and throat devices—diagnostic devices	2	0
	Ear, nose, and throat devices—surgical devices	6	0
	Gastroenterology-urology devices—diagnostic devices	20	0
	Gastroenterology-urology devices—monitoring devices	1	0
	Gastroenterology-urology devices—surgical devices	10	0
	Gastroenterology-urology devices—therapeutic devices	19	1
	General and plastic surgery devices—surgical devices	1	0
	General hospital and personal use devices—miscellaneous devices	14	0
	General hospital and personal use devices—monitoring devices	5	0
	General hospital and personal use devices—therapeutic devices	7	0
	Hematology and pathology devices—manual devices	4	0
	Hematology and pathology devices—used by blood manufacturer	4	0
	Immunology and microbiology devices—immunological test systems	14	0
	Immunology and microbiology devices—microbiology devices	1	0
	Immunology and microbiology devices—serological reagents	47	0
	Neurological devices—diagnostic devices	1	0
	Neurological devices—therapeutic devices	1	0
	Obstetrical and gynecological devices—diagnostic devices	1	0
	Obstetrical and gynecological devices—surgical devices	6	0
	Obstetrical and gynecological devices—therapeutic devices	2	0
	Ophthalmic devices—diagnostic devices	4	0
	Ophthalmic devices—prosthetic devices	4	4
	Ophthalmic devices—surgical devices	3	0
	Orthopedic devices—diagnostic devices	1	0
	Orthopedic devices—surgical devices	1	0
	Physical medicine devices—diagnostic devices	5	0
	Physical medicine devices—prosthetic devices	6	0
	Physical medicine devices—therapeutic devices	19	0
	Radiology devices—diagnostic devices	9	0
	Radiology devices—therapeutic devices	12	0

Note: The table presents the counts of broad device types used in the control group. No life-sustaining devices are considered. Implant counts are also provided.

Appendix Table C.10: Effect of Down-Classifications on Innovation (Drop No Counts)

		DID Estimates			
Down-Classification	Pre-mean (1)	Matched (2)	Intuitive (3)	Later (4)	Full (5)
A. Class III to II:					
Patenting Rate	7.95	15.31**	23.68*	24.64*	7.77
	(9.27)	(5.58)	(10.20)	(10.94)	(25.79)
Device Approval Rate	0.47	2.69***	2.36**	2.27**	2.22***
	(1.03)	(0.59)	(0.76)	(0.72)	(0.34)
Citations-Per-Patent Rate	9.06	16.87*	-5.61	15.91*	20.13**
	(20.65)	(7.57)	(13.90)	(6.22)	(7.58)
Average Patent Value	4.36	8.56***	9.88**	10.45**	8.14***
	(6.12)	(1.67)	(3.49)	(3.41)	(2.32)
Sample Size		1452	660	680	21340
B. Class II to I:					
Patenting Rate	16.32	7.34	13.72	25.22**	29.17***
	(37.11)	(4.87)	(12.54)	(9.61)	(7.19)
Citations-Per-Patent Rate	0.64	6.85**	4.13*	7.52***	6.00***
	(0.48)	(2.28)	(1.84)	(1.49)	(1.38)
Average Patent Value	6.49	3.58***	2.06*	4.35***	4.47***
	(14.19)	(0.72)	(0.93)	(1.03)	(0.77)
Sample Size		14740	9328	9768	25784

Note: The table presents estimates of equation 4, which is a difference-in-differences (DID) style OLS regression model. In this analysis, I drop all device types that do not exhibit any positive quantity of the given outcome. Column (1) presents the 5-year baseline average of treated device types for the outcomes listed on the left-hand side. Columns (2)–(5) present DID estimates for the listed outcomes using different control groups. Namely, a matched control group, intuitively similar device types (treat similar diseases), "later treated" device types (treated after sample window), and the full sample, respectively. Confidence intervals are calculated using Conley–Taber test statistics. +, *, **, and *** correspond with statistical significance at the 0.10, 0.05, 0.01, and 0.001 levels respectively.

Appendix Table C.11: Effect of Down-Classifications on Market Composition (Drop No Counts)

		DID Estimates				
Down-Classification	Pre-mean (1)	Price (2)	Matched (3)	Intuitive (4)	Later (5)	Full (6)
A. Class III to II:						
Procedure Price	95.31	-58.25**	-43.54**	-	-	-27.50
	(123.95)	(21.16)	(15.66)	-	-	(144.11)
Sample Size		160	176	-	-	36240
Incumb. Entry (dev.)	0.40	-	1.58***	1.50**	1.49**	1.44***
	(0.91)	-	(0.35)	(0.54)	(0.54)	(0.21)
New Entry (dev.)	0.07	-	0.94***	0.98**	0.79**	0.88***
	(0.31)	-	(0.23)	(0.31)	(0.26)	(0.20)
Incumb. Entry (pat.)	1.47	-	1.96***	2.19+	3.33*	1.28
	(1.78)	-	(0.59)	(1.12)	(1.52)	(1.40)
New Entry (pat.)	3.78	-	6.14***	11.75*	12.65**	6.10
	(4.76)	-	(1.65)	(4.57)	(4.79)	(9.19)
Sample Size		-	1276	616	680	23848
B. Class II to I:						
Incumb. Entry (pat.)	2.26	-	0.02	0.59	1.09+	1.33**
	(4.33)	-	(0.47)	(0.69)	(0.59)	(0.44)
New Entry (pat.)	7.27	-	4.00+	5.18	9.26**	10.11***
	(16.87)	-	(2.07)	(4.17)	(3.29)	(2.26)
Sample Size		-	13288	9988	12672	28952

Note: The table presents estimates of equation 4, which is a difference-in-differences (DID) style OLS regression model. In this analysis, I drop all device types that do not exhibit any positive quantity of the given outcome. Column (1) presents the 5-year baseline average of treated device types for the outcomes listed on the left-hand side. Columns (2)–(6) present DID estimates for a given outcome using different control groups. Namely, a group matched on baseline prices, a group matched on baseline innovation and adverse event levels, an intuitively comparable group, a later treated group, and the full sample of controls, respectively. Confidence intervals are calculated using Conley–Taber test statistics. +, *, **, and *** correspond with statistical significance at the 0.10, 0.05, 0.01, and 0.001 levels respectively.

Appendix Table C.12: Effect of Down-Classifications on Adverse Events (Drop No Counts)

		DID Estimates			
Down-Classification	Pre-mean (1)	Matched (2)	Intuitive (3)	Later (4)	Full Sample (5)
A. Class III to II:					
Emphasis on Safety	0.16	0.073+	-	-	-
	(0.21)	(0.039)	-	-	-
Life-Threatening Event Rate	0.07	1.31	1.64	-1.96	-8.57
	(0.31)	(0.82)	(1.11)	(1.26)	(5.72)
Hospitalization Rate	0.25	4.30**	5.32*	2.38	-9.43
	(0.84)	(1.62)	(2.38)	(1.96)	(8.09)
Mortality Rate	0.08	-3.28	2.78*	-0.09	0.16
	(0.46)	(4.72)	(1.40)	(1.23)	(7.50)
Sample Size		336	196	216	11452
B. Class II to I:					
Emphasis on Safety	0.065	0.05***	-	-	-
	(0.218)	(0.012)	-	-	-
Life-Threatening Event Rate	0.07	-8.07	-1.51+	-15.92*	-9.17*
	(0.43)	(5.07)	(0.78)	(7.85)	(4.38)
Hospitalization Rate	0.17	-6.25***	-7.80+	-16.76*	-11.63*
	(0.94)	(1.24)	(3.98)	(7.62)	(5.32)
Mortality Rate	0.26	-1.72***	-1.03	-2.60+	-1.70*
	(2.13)	(0.39)	(0.77)	(1.37)	(0.75)
Sample Size		3612	3276	3752	7168

Note: The table presents estimates of equation 4, which is a difference-in-differences (DID) style OLS regression model. In this analysis, I drop all device types that do not exhibit any positive quantity of the given outcome. Column (1) presents the 5-year baseline average of treated device types for the outcomes listed on the left-hand side. Columns (2)–(5) present DID estimates for the listed outcomes using different control groups. Namely, a matched control group, intuitively similar device types (treat similar diseases), "later treated" device types (treated after sample window), and the full sample, respectively. For column (4), Class III to II, control device types are treated after 2015; thus, all observations after 2015 are dropped. Confidence intervals are calculated using Conley–Taber test statistics. +, *, **, and *** correspond with statistical significance at the 0.10, 0.05, 0.01, and 0.001 levels respectively.

Appendix Table C.13: Estimation of Learning Curve Parameters

	Class III Coeff./SE	Class II Coeff./SE
γ	0.075*	0.032***
	(0.033)	(0.004)
$\beta(R_c)$	6.678***	4.481***
	(0.326)	(0.031)
N	631	84,909
Clusters	94	9,067
Device Type Effects	Yes	No
Firm Effects	Yes	Yes
Device Type by Year Effects	No	Yes
SEs in Parentheses	Clustered	Clustered

Note: The table presents the estimates of equation B.1, which estimates the learning coefficient γ and the baseline time requirement $\beta(R_c)$ for both Class III original PMA approvals (column 1) and Class II 510(k) approvals (column 2) of unique devices via OLS. The estimates for Class III devices are calculated by only considering the approval times of filed original PMAs by firms with at least one day of prior experience navigating FDA regulations. The estimates for Class II devices are calculated by only considering the approval times of 510(k) documents for unique devices that were submitted by firms with at least one day of prior experience navigating FDA regulations. Prior experience is calculated using approval times when filing any prior documentation type (510(k) or PMAs). Standard errors are clustered at the firm level. +, *, **, and *** correspond with statistical significance at the 0.10, 0.05, 0.01, and 0.001 levels respectively.

Appendix Table C.14: Flattening the Learning Curve Simulation—Unique Devices Approved

	Percent Changes				
γ	$T_{Sum,25}$	$T_{Sum,50}$	$T_{Sum,75}$	$T_{Sum,100}$	Total %Δ
0.075	0.0	0.0	0.0	0.0	0.0
	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)
0.067	13.3	10.2	4.8	2.49	6.19
	(10.17)	(8.12)	(3.84)	(2.95)	(5.29)
0.058	29.67	16.49	8.94	3.75	11.57
	(16.78)	(9.57)	(5.78)	(2.98)	(7.92)
0.05	59.0	25.64	14.07	6.47	19.32
	(26.66)	(12.88)	(6.0)	(4.82)	(11.38)
0.042	68.55	35.46	21.07	8.86	25.98
	(24.77)	(16.03)	(9.65)	(4.17)	(13.94)
0.033	85.34	46.38	23.74	9.35	31.75
	(31.51)	(20.97)	(10.22)	(4.66)	(17.95)
0.025	110.02	54.42	25.24	12.35	38.46
	(41.96)	(25.91)	(8.47)	(6.22)	(21.76)
0.017	150.65	64.74	36.93	14.69	48.77
	(61.78)	(22.15)	(12.04)	(7.11)	(25.41)
0.008	151.55	75.92	34.03	15.58	51.9
	(48.99)	(25.45)	(11.69)	(7.45)	(27.68)
0.0	186.41	88.62	43.45	19.13	63.32
	(74.03)	(29.59)	(11.61)	(7.67)	(33.3)

Note: This table presents the results of the simulation exercise described in appendix B, which simulates the effect of flattening the learning curve on the rate of unique devices approved at an annual frequency by asset quartiles. Figure C.10 illustrates this flattening exercise. Standard errors generated from a Monte Carlo procedure are presented in parenthesis below the estimates. This procedure produces estimates across repeated random draws from the empirical distribution of firm characteristics to calculate confidence intervals. I express changes as percent changes relative to the $\gamma = 0.075$ baseline. I flatten the learning curve relative to the firm with the highest experience in the data. In the table, γ begins at its initial starting point estimated in equation B.1. Subsequent rows in the table show the percent change in the rate of unique device approvals as γ, the learning rate, is reduced. These changes are presented for each experience quartile for Class III device manufacturers. $T_{Sum,25}$ represents the bottom 25th percentile of cumulative FDA experience (in days), $T_{Sum,50}$ represents the 25–50th percentile, $T_{Sum,75}$ represents the 50–75th percentile, and $T_{Sum,100}$ represents the 75th–100th percentile. The far-right column presents the total percent change in unique devices approved from a flattening of the learning curve relative to the baseline frequency of unique device approvals.

Appendix Table C.15: Cross-Correlation Between Firm Size and FDA Experience

Variables	Cumulative FDA Experience	Firm Assets
Cumulative FDA Experience	1.00	
Firm Assets	-0.00	1.00
	(1.00)	

Note: The table presents the correlation coefficients between firm assets (size) and firm cumulative FDA experience. Data includes firms in the FDA database that were fuzzy matched to publicly traded firms in the CRSP database.

Appendix Table C.16: Regulation by Approval Type and Class

Approval Type	Typical Class	Example Devices	User Fee (2021) (Small Business)	Processing Time	Data Required
510(k) Exempt	Class I (low risk)	Surgical caps, splints, surgeon's gloves	$5,546 ($5,546)	30 days	Registration
510(k)	Class II (moderate risk)	Ventilators, N95 respirators, diagnostic tests	$12,432 ($3,108)	6–12 months	Evaluate SE
PMA Supplement (Based on novelty)	Class III (high risk)	Pacemakers, replacement heart valves	$0–274,243 ($0–68,561)	0–12+ months	None–Clincial trial
PMA	Class III (high risk)	Pacemakers, replacement heart valves	$365,657 ($91,414)	12+ months	Clinical trail

The figure describes the different types of approvals required across regulatory classes. Most Class I device types are not required to submit 510(k)s and only require the manufacturer to register itself. Most Class II device types are required to submit 510(k)s, which is time-intensive and costly. Most Class III device types are required to submit PMAs, which is the most time-intensive and expensive. If a manufacturer has already filed a PMA within a given device type, a PMA supplement can be filed. PMA supplements can vary in their level of complexity and cost, contingent on the device's level of novelty. Small business fees are listed under the fee schedule in parenthesis. Examples of device types that fall under each regulatory class are provided.

Appendix Table C.17: Share of Document Types from Class III Device Types (PMA Required)

Documentation Type	Share	Count
Original PMA	0.08	3131
Supplemental PMAs by Type		
135 Review Track For 30-Day Notice	0.05	2076
30-Day Notice	0.43	18007
Normal 180 Day Track	0.21	8834
Normal 180 Day Track No User Fee	0.05	2200
Panel Track	0.01	292
Real-Time Process	0.13	5327
Special	0.00	2
Special (Immediate Track)	0.04	1549
THIRTY DAY TRACK	0.01	227

Note: This table presents the share of documents filed for class III devices that require PMA documentation for approval by PMA supplements and original PMA submission types. Original PMAs are required from new firms innovating in a device type or incumbent firms with sufficiently novel innovation. PMA supplements can be filed for follow-on innovation.