Regulating the Innovators:

Approval Costs and Innovation in Medical Technologies

Parker Rogers*

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Abstract

How does FDA regulation impact innovation, market structure, and product safety? I examine this question by exploiting FDA deregulation events that affected certain established medical device types but not others. A comprehensive analysis of data on innovation, safety, firm entry, prices, and regulatory changes reveals three key findings. First, deregulation significantly increased the quantity and quality of new technologies in affected device types, with the most pronounced increases observed among smaller and less regulation-experienced firms. Second, such events increased firm entry and reduced prices for medical procedures that utilize deregulated medical devices. Finally, there is no significant uptick in serious injuries and deaths due to defective devices post-deregulation. Interestingly, the deregulation of certain device types was associated with reduced adverse event rates, potentially due to firms increasing their emphasis on product safety in response to heightened litigation risk.

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While new technologies can improve well-being, they also pose risks. Regulatory agencies, like the U.S. Food and Drug Administration (FDA), aim to mitigate these risks through pre-market testing—a particularly compelling approach for potentially high-risk, groundbreaking innovations (Grennan and Town, 2020).[1] Yet, the benefits of this approach are less certain for lower-risk or well-established technologies, where innovation is typically incremental. Critics argue that such stringent regulation stifles innovation and competition by raising entry costs (Peltzman, 1973), while proponents contend that it actually fosters market entry and innovation by boosting public confidence in emerging products (Carpenter et al., 2010). Given that FDA-regulated products account for a $2.8 trillion market (FDA, 2020b), empirical evidence on these opposing views is important.

I advance this debate by measuring the impact of FDA regulation on innovation, market structure, and safety in established medical device categories. My approach is two-fold: I first consider instances of "down-regulation," where moderate-risk devices, such as soft contact lenses, were moved from stringent Class III to more moderate Class II requirements. Next, I analyze instances of "deregulation," where lower-risk items like ventilator tubing transitioned from Class II to minimal Class I requirements. This dual focus serves two purposes: It lets me compare the effects of rigorous FDA protocols, including clinical trials, against existing alternative, more relaxed policies. Furthermore, it allows me to estimate the local average treatment effects of easing regulations across a spectrum of safety risks and technological complexities——from generic, low-risk products to differentiated, moderate-risk innovations.

To infer the causal effect of these events, I compare affected device types to multiple control groups. These groups include device types matched on pre-event characteristics, intuitively similar devices, those deregulated later, and a broad set of unaffected devices. I find that my results are stable across these control groups. Further, comparing deregulated device types to control groups reveals no divergent pre-existing trends in the outcomes of

[1]Groundbreaking technologies often create new product markets, initially characterized by limited competition. In these oligopolistic markets, regulation helps align divergent public and private incentives for product quality (Spence, 1975).

interest, consistent with the "unpredictable" nature of these events as described by device manufacturers (Makower et al., 2010; Powell, 2018). This unpredictability is primarily due to the difficult-to-predict timing of when these regulatory shifts occur.[2]

In the medical device sector, regulations can profoundly affect even established, low-risk products. For example, down-regulation paved the way for a breakthrough in soft contact lenses, culminating in a patent worth $930 million (US-6478423-B1; Kogan et al. (2017)) and giving rise to the market-leading ACUVUE® brand.[3] Additionally, the industry's regulatory landscape highlights the tension between pre-emptive safety measures (ex-ante) and the deterring influence of potential legal consequences (ex-post). FDA approval shields manufacturers from certain legal liabilities, yet liability risk alone could be a compelling reason for firms to focus on safety, claiming up to 3.8% of annual revenues and directing innovation strategies (Fuhr et al., 2018; Galasso and Luo, 2017, 2018).[4]

An important contribution of this paper is the assembly of novel data on the implications of FDA regulation. Regulation affects many factors, and data on these factors are siloed, unorganized, and unconnected to medical device types, limiting research on this topic. I use a combination of programmatic online text extraction, text analysis algorithms, and hand linkages to create, merge, and harmonize the required data. When unified, these data comprehensively detail the effects of medical device regulation by device type. These data include all FDA device type regulation changes over the last 40 years and multiple corroborative measures of device innovation, innovator characteristics, innovation quality, market structure, prices, and device safety.

[2]The 1994 "down-regulation" of contact lenses offers a case in point. Announced during an FDA ophthalmic panel meeting, the agency had been "dealing with [the down-regulation event] for about ten years," constrained by essential "data that were needed to support [down-regulation] contained in PMAs and not publicly available." This delay exemplifies the often unpredictable timeline of regulatory actions. Furthermore, the FDA Modernization Act spurred numerous "deregulation" events, requiring the FDA to promptly identify medical devices suitable for deregulation. This list, in part, was crafted using a previously unknown, elementary measure of product safety, which I observe.

[3]Incremental innovations like these act as crucial links between groundbreaking advances and wider consumer adoption, elevating technological impact.

[4]The financial toll of liability can be monumental, illustrated by the $1 billion Stryker hip implant settlement in 2014 or Dow Corning's $3.2 billion breast implant settlement in 1998 (2023 USD).

My analysis of these data shows that down-regulation events increase the quantity and quality of new technologies in established categories. After down-regulating from Class III (high regulation) to II (moderate), device types exhibited a 200% increase in patent filings and FDA submissions compared to control groups, with no spillover effects on similar device types.[5] Patents filed after these events were also of significantly higher quality, as measured by a 200% increase in received citations and market valuations. After Class II to I deregulation, patent filing increased by a relatively modest 40%, but the quality of patent filings improved tenfold. Notably, smaller and less regulatory-experienced firms, which are most likely to produce groundbreaking innovation (Wu et al., 2019), showed the greatest increase in innovative activity.

Second, these regulatory shifts significantly altered market structure. Down-regulation spurred a tenfold increase in new entry (i.e., firms without previously approved devices) and quadrupled incumbent entry (i.e., firms with approved devices of another type) in treated device types. Meanwhile, deregulation significantly increased new entrants by 200% in treated types without influencing incumbent entry. The heightened competition associated with deregulation, predominantly impacting more generic, low-risk devices, translated to a significant 25% decrease in the prices of medical procedures utilizing these deregulated devices. By contrast, down-regulation—which also led to sharp increases in innovation and impacted more differentiated moderate-risk products—did not measurably affect prices.

These regulatory shifts yield considerable benefits, as the proponents of deregulation would predict, but what of product safety? Surprisingly, I find that deregulation can improve product safety. Despite some adverse event rates increasing after down-regulation (albeit insignificantly), deregulation is associated with significantly *lower* adverse event rates.[6] An analysis of patent texts also reveals that inventors focus more on product safety after

[5] These localized effects can be attributed to a high degree of specialization, where a significant number of device inventions stem from practicing physicians who operate within their highly specialized medical fields and actively employ these devices themselves ((NIM, 2010), Chatterji and Fabrizio (2016)).

[6] "Rates" are counts per device type-year. I do not normalize by utilization in my main analysis. However, I show, using a subset of devices for which I have claims data, that this finding is robust to normalization.

deregulation.

These product safety improvements following deregulation may be attributable to an increased risk of litigation. Specifically, instead of meeting Class II requirements, which the National Institute of Medicine deems as insufficient for product safety (IOM, 2011), inventors are incentivized to mitigate consumer injury risks to ward off legal repercussions after deregulation, as they no longer are protected from those risks. I substantiate this legal mechanism by using variation in firms' exposure to litigation after deregulation: Smaller firms expect less liability as they can resort to bankruptcy to avoid liability exceeding their assets (Shavell, 1986). I find that safety improvements are strongest among larger firms for which a larger share of liability is unavoidable. Moreover, a study of a subsequent deregulation event——where Class II devices already lacked pre-deregulation liability protections——shows no notable shifts in safety measures. This finding illustrates that legal liability could serve as a potential alternative safeguard for product safety, particularly for generic or low-risk product categories.

A simple calculation suggests that the benefits of these regulatory changes outweigh their costs. By considering both the cost of adverse events and the economic value of increased innovation, the unmeasured costs of down-regulation would need to be double the measured costs to offset the benefits of these events. Even more favorably, deregulation only yields benefits as adverse events *decline*. The annual benefits amount to $53 million per affected device type. Although these benefits may be specific to the deregulated device types, I find evidence suggesting a broader applicability: devices identified as the highest risk by the FDA but nevertheless deregulated showed the most marked reductions in adverse events. If this relationship holds, the potential annual benefits of deregulating all Class II device types could reach $132 billion, representing 77% of the current total yearly spending on medical devices.

I build a model that illustrates the range of possible consequences of regulatory shifts. The model incorporates the central concerns of medical device innovators. First, regulation

imposes approval delays, but firms shorten delays as they gain more experience navigating approval requirements through "learning by doing" (Arrow, 1971). Firms also face financing costs if approval costs exceed their assets (Buera and Shin, 2013; Moll, 2014). Lastly, when regulations are lifted (Class I), firms are exposed to more litigation from product design flaws, but small firms are exposed to less liability due to bankruptcy. This characterization of the firm's decision shapes the effects of deregulation: Deregulation can improve product safety and disproportionately benefit small firms and those with less regulatory experience.

A variety of products with established safety records are regulated in ways similar to medical devices. For instance, the regulation of generic drugs and genetically modified foods mirrors that of Class II devices. Furthermore, a wide range of products, ranging from aircraft and automobiles to over 15,000 consumer goods overseen by the Consumer Product Safety Commission, adhere to similar, albeit distinct, regulations (Schwartz and Appel, 2020; Schauzu, 2000; Pisani, 2011). While differing from medical devices in many ways, these products experience a degree of protection from litigation after regulatory compliance, highlighting the potential relevance of this study's findings to various product markets.

My findings contribute to several literatures. First, I add to the growing literature on the effects of public policy on medical innovation.[7] Despite the significant size of the global medical device market—valued at $500 billion, with projections nearing $1 trillion by 2030 (Stewart, 2022)—there is a lack of evidence on the impact of regulation on innovation in this sector. Previous studies by Stern (2017) and Grennan and Town (2020) use cross-group comparisons to suggest that regulations affect investments in Class III cardiovascular technologies; however, these studies do not address the broader impact of FDA regulation on innovation and focus only on high-risk technologies. This study fills this gap by examining the relationship between regulation and innovation using quasi-exogenous regulatory shocks across low to moderate-risk device types with varying regulatory stringency. Additionally, my study addresses the underexplored topic of the safety benefits of FDA regulation.

[7]See Mulligan (2021); Grennan and Town (2020); Clemens and Rogers (2020); Stern (2017); Budish et al. (2015); Acemoglu and Linn (2004); Finkelstein (2004).

I further contribute to a longstanding literature examining the tradeoffs between regulation and litigation.[8] A study by Philipson et al. (2010) finds that the combined approach of regulation and litigation is less efficient than employing regulation alone; however, it does not examine the comparative efficiency of each approach independently. I find that litigation can more effectively reduce adverse events while promoting innovation.

Lastly, my findings relate to the literature on endogenous growth (Romer, 1990). Recent work shows that labor regulations can influence innovation, the key determinant of economic growth (Acharya et al., 2014, 2013; Aghion et al., 2019). Other work shows that regulation can reduce market competition, creating long-run inefficiencies (Buettner, 2006; Aghion et al., 2009, 2005; Djankov et al., 2006; Hahn and Hird, 1991). I add to this literature by showing that product regulation reduces innovation and market competition. My findings, however, depart from the common presupposition that regulatory knowledge flows smoothly across firms: Deregulation disproportionately benefits firms with less regulatory experience, suggesting that regulatory proficiency stays with the firms that acquire it (akin to Azoulay et al. (2011)). These frictions amplify the costs of regulation and may advantage experienced multiproduct firms across a wide range of regulated products.

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

This section describes the structure and legal consequences of FDA medical device regulations. Medical devices include products like COVID-19 tests, pacemakers, X-ray machines, and spinal implants.

[8] See Coase (1960); Ehrlich and Posner (1974); Kolstad et al. (1990); Glaeser et al. (2001); Shavell (1986); Kessler (2010); Shavell (2018). For impacts of liability and tort reforms on innovation see Galasso and Luo (2017, 2018).

1.1 Enactment of Medical Device Regulations

In 1976, the Medical Device Amendments (MDA) expanded the FDA's oversight to include medical devices. According to these new laws, medical devices were grouped into generic types to allow targeted regulation. "Daily-wear soft contact lenses," for example, is a device type regulated differently than "extended-wear soft contact lenses." The policy variation I study occurs at the level of these generic device types, and I refer to them as "device types."

Device types are organized into a three-tier risk classification system. Manufacturers of Class I low-risk devices must 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 to an already marketed device.[9] This process of proving "substantial equivalence" has been criticized by many, including the National Institute of Medicine, as being insufficient for establishing safety (IOM, 2011) while imposing substantial costs. The 510(k) process, on average, costs firms $24 million (Makower et al., 2010) and delays commercialization by ten months. Class III, high-risk device manufacturers must conduct clinical trials via the "premarket approval" (PMA) process to ensure their new device is safe and effective before commercialization. The PMA process is 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 A.3 provides more details.

1.2 Down-Classification of Medical Device Types

The FDA can "down-classify" medical device types to a lower class based on their observed safety outcomes in the market. The FDA regulates new, markedly novel devices in Class III to ensure safety under unknown risks.[10] Surveillance data from marketed devices clarify

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

[10] In 1997, the FDA began allowing manufacturers of markedly novel devices to petition for a direct Class II or I classification under the "De Novo" process by showing that best practices assure the safety and efficacy of their device. However, all the device types I consider existed before 1997 and thus were either automatically or intentionally classified into Class III.

these risks and inform the FDA's choice to down-classify into Class II (see Figure 1).[11] These events are described by manufacturers as "unpredictable," suggesting the difficulty of anticipating such policy changes (Makower et al., 2010; Powell, 2018). While it is probable that the FDA will deregulate some lower-risk device types within a class, the specific types affected and the timing of such events are "as-good-as-random."[12] 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.

By contrast, the FDA follows a more systematic approach when deciding which devices to reclassify from Class II to I. However, the timing of these events is also "as-good-as-random," often resulting from sporadic congressional actions. After a 1995 congressional mandate, the FDA scored all Class II devices based on average yearly adverse event counts and down-classified those that fell below a previously unknown threshold (FDA, 1995). Although this policy seems to justify using a regression discontinuity design, the limited number of device types at the threshold precludes this approach. Instead, I utilize a set of unaffected Class I device types, including previously deregulated and consistently Class I devices that would have received similar scores as control groups. Importantly, scores were not contingent on potential changes in adverse events or trends.[13] My event study results reaffirm these assessments.

It is worth noting that down-classification only occurs in 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.

[11] Additionally, 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).

[12] For example, the deregulation of contact lenses took the FDA a decade to announce after an internal decision was made.

[13] See Appendix A.1 for more details and an example of Class II to I events.

1.3 Regulation versus Litigation: Federal Preemption

In the US, medical device firms incur damages from tort claims amounting to as much as 3.8% of annual revenues (Fuhr et al., 2018). Galasso and Luo (2018) show that this liability risk chills innovation and can bankrupt smaller firms. Compared to Europe, the US is particularly litigious, with class-action lawsuits, high punitive damage payouts, and few damage caps (Guendling, 2016). These conditions make liability risk a "powerful incentive for improving product safety" (Bravman v. Baxter Healthcare Corp., 1994).[14]

However, FDA approval shields medical device manufacturers from product liability, creating a stark tradeoff between regulation and litigation. This safeguard, called "federal preemption," is upheld by Riegel v. Medtronic Inc. (2008), a Supreme Court case ruling that Class III device approvals bar legal tort claims against device manufacturers. Moreover, during the 1990s, when the deregulation events I analyze occurred, Class II devices were also generally protected from liability after clearance (Flaherty Jr, 2008).[15] Class I devices are not FDA-approved, exposing manufacturers to litigation.

2 Conceptual Framework

In this section, I model R&D as a two-stage process: development and commercialization. First, firms invent and patent a new product, improve its safety profile, and raise capital to cover commercialization. Second, firms bring their products to market by attaining regulatory approval, forming distribution networks, etc. The model builds on that of Budish et al. (2015), who formalize the impacts of commercialization lags on innovation. For comparability, I follow their notation closely wherever possible. I introduce into their framework two alternative policy regimes (i.e., regulation and litigation), which include differences in commercialization lags, liability risk, and financing costs.

[14]Bravman v. Baxter Healthcare Corp., 842 F. Supp. 747, 761 (S.D.N.Y. 1994).

[15]Some Class II devices are still protected today. See Appendix B.2 for more information on the evolving litigation environment over time.

The model's purpose is to illustrate the range of possible consequences of deregulation, to connect these to underlying fundamentals, and, in particular, to relate these effects to firm traits. In turn, the insights from this model will be helpful for interpreting my empirical results. My model considers the medical device industry, though its implications may apply to other regulated products.

2.1 Model Preliminaries

Undirected R&D yields stochastic inventions to a representative, profit-maximizing firm. Upon realizing the new technology, the firm decides if it will allocate capital for directed R&D to (i) improve the product's safety profile during the development phase and (ii) commercialize the invention. The firm makes this decision in one of two environments: regulation "R" or litigation "L." The model is characterized by the following parameters:

Timing Parameters.—The year a firm realizes and develops an invention is given by t_{invent}, which I normalize to zero. The years it takes to commercialize the product is $t_{comm,f}$. In the medical device industry, FDA approval plays a key role in delaying commercialization (Makower et al., 2010; Pietzsch et al., 2012).[16] Thus, for concreteness, think of $t_{comm,f}$ as the approval delay. Under litigation L, there are no approval delays (i.e., $t_{comm,f,L} = 0$). In the regulated environment, approval delays are positive but decrease with regulatory experience (Olson, 1997; Carpenter, 2004b; Makower et al., 2010; Chatterji, 2009).[17] Following Arrow (1971), I model this relationship by equating the present delay $t_{comm,f}$ to the learning curve $\beta\, T_f^{-\gamma}$, where T_f is prior experience, β is the delay with no prior experience (i.e., $T = 1$) and $\gamma > 0$. Delay costs are given by $\chi t_{comm,f}$, where χ is the yearly cost of approval delays.[18]

[16] Approval delays in other areas of health care, like delays in securing medical procedure reimbursement codes, have also been shown to play a key role in innovation (Dranove et al., 2022).

[17] Two factors may explain this pattern, both of which are driven by the complexity of the regulatory process. First, inexperienced firms report difficulty benefiting from hired regulatory experts and must instead learn the process independently (Y Combinator, 2016). From the regulator's perspective, having prior experience with a firm reduces the uncertainty about the quality of its products, which may merit shorter review times (Olson, 1997; Carpenter, 2004b).

[18] Makower et al. (2010) find an average monthly cost of $1.3 million for Class III approval delays (e.g.,

Financing Costs.—Smaller firms must raise external capital to cover the costs of development and commercialization at time t_{invent}.[19] Fundraising can be difficult: 56% of small medical device firms claim funding as a central challenge (Emergo, 2019). Following Stein (2003), I capture these financing frictions by assuming deadweight costs given by $C(e_f)$, where $C(\ )$ is an increasing convex function of external funds e_f (similar to the R&D model of Stern (2017)). External funds e_f are equal to the difference between the non-financing costs and internal capital K_f. I omit other costs of commercialization for simplicity.

Regulated and Deregulated Effective Lives.—A successfully commercialized product becomes less relevant over time. For expositional ease, I describe the neoclassical risk-adjusted discount factor of the R&D project as δ, which includes obsolescence and commercialization risk.[20,21] Firms enjoy longer or shorter effective product lives depending on the regulatory environment. Under regulation, I define an invention's *Regulated Effective Life (REL)* as the expected years it will be commercialized and non-obsolete in present value terms as discounted by the regulated firm. The effective life of the regulated product begins at time $t_{comm,f}$, yielding an effective life of $REL_f = \sum_{t_{comm,f}}^{\infty} \delta^t = \delta^{t_{comm,f}}/(1-\delta)$. By contrast, in a deregulated environment N, I define an invention's *Effective Life (EL)* similar to *REL*, except the lifespan of the product starts at t_{invent}, given by $EL = \sum_{t=0}^{\infty} \delta^t = 1/(1-\delta)$. Notice that $REL_f < EL$ by definition, as regulated profit flows are delayed.

Expected Damages and Safety Effort Costs.—Borrowing from Shavell (1986) and Boomhower (2019), if a firm chooses to commercialize its product, it exerts x_f effort to improve product

clinical trial costs, etc.). I assume $t_{comm,f}$ and several other parameters below are deterministic for simplicity.

[19] For simplicity, I assume firms finance their project instantaneously. Although fundraising could prolong commercialization delays, removing this assumption does not change my theoretical results.

[20] A product may also face a probability of successful commercialization p, which may be appropriately modeled as a function of safety effort; however, the FDA approves 80%–90% of all medical device submissions (GAO, 2009). Thus, for simplicity, I assume that approval is certain given a firm achieves the mandated safety effort, and I abstract away from other non-approval-related commercialization uncertainty. Including product denial and commercialization risks does not meaningfully change my theoretical insights.

[21] Although obsolescence risk is more appropriately modeled as endogenous to R&D investments, I follow the patent literature and take it as exogenous (Budish et al., 2015).

safety, costing ψ per unit, at t_{invent}.[22] Under litigation L, a commercialized product generates stochastic adverse events that yield $\phi(x_f; \vec{Z})$ legal damages per year, a random variable with expected value $D(x_f; \vec{Z})$ and vector $\vec{Z}$ containing other factors that influence damages in expectation (e.g., firm seizable assets K_f, the litigation environment, damage caps). The expected damages function $D(\ )$ is a positive decreasing convex function of safety effort x_f. The firm exerts effort to maximize the returns to commercialization by equating the marginal cost of effort $\psi + C_x(\psi x_f^* - K_f)$ to the present value of its marginal benefits $-EL \cdot D'(x_f^*; \vec{Z})$ (i.e., marginal abatement of expected damages). By contrast, under regulation R, the firm is exposed to no legal damages due to federal preemption. Thus, firms exert the mandated level of safety effort $\underline{x}$, as any further effort yields no return.

Profits.—If the product is successfully commercialized and non-obsolete, it generates profits π per year for the innovating firm. Although regulation can affect profits by altering market structure, I do not model this relationship, focusing instead on motivating my firm composition and product safety results. Thus, for simplicity, I assume that deregulation increases the aggregate level of R&D, consistent with my empirical findings, which implies that deregulation does not cut profits enough to outweigh declines in commercialization costs.[23] I assume only expert regulators can perceive safety effort (i.e., asymmetric information); hence, safety effort does not affect profits once a product is approved.

2.2 Characterization of the Investment Decision

In the regulated environment R, firm f expects to receive profits from commercializing a device for REL_f years. The firm will develop and commercialize its invention if and only if

[22] For simplicity, I assume firms exert safety effort instantaneously. Alternatively, safety efforts could prolong commercialization delays. Modeling such delays, however, would not change the model implications.

[23] Note that this assumption also places an upper bound on the value of legal damages and safety effort costs after deregulation.

these expected profits exceed the combined delay, safety effort, and financing costs:[24]

$$\text{Regulated Firm Invests} \iff \underbrace{REL_f}_{\substack{\text{Regulated}\\ \text{effective life}}} \cdot \underbrace{\pi_R}_{\text{Profits}} \geq \underbrace{\chi t_{comm,f}}_{\text{Delay costs}} + \underbrace{\psi \underline{x}}_{\substack{\text{Mandated safety}\\ \text{effort costs}}} + \underbrace{C(e_{f,R})}_{\substack{\text{Financing}\\ \text{costs}}}. \quad (1)$$

The amount of external capital $e_{f,R}$ needed to finance the project is given by the difference between the non-financing commercialization costs and the firm's internal capital K_f (i.e., $e_{f,R} = \chi t_{comm,f} + \psi \underline{x} - K_f$ if $e_{f,R} \geq 0$, and 0 otherwise).

In the litigation environment L, firm f will choose to commercialize if and only if the net expected profits (less expected damages) are greater than the combined safety effort and financing costs:[25]

$$\text{Deregulated Firm Invests} \iff \underbrace{EL}_{\substack{\text{Effective}\\ \text{life}}} \cdot [\underbrace{\pi_L}_{\text{Profits}} - \underbrace{D(x_f^*; \vec{Z})}_{\substack{\text{Expected}\\ \text{damages}}}] \geq \underbrace{\psi x_f^*}_{\substack{\text{Optimal safety}\\ \text{effort costs}}} + \underbrace{C(e_{f,L})}_{\substack{\text{Financing}\\ \text{costs}}}. \quad (2)$$

The amount of external capital $e_{f,L}$ needed to finance the project is given by the difference between safety effort costs $\psi x_f^*$and the firm's internal capital K_f.

Notice the key differences between the investment incentives in environments R and L: firms that commercialize in L (i) expect legal damages, (ii) choose and pay for an optimal level of safety effort, (iii) enjoy a longer effective life of their products, and (iv) do not incur delay costs.[26]

2.3 Distortions from Regulation

I focus on model implications related to distortions in firm participation and safety efforts resulting from regulation. Throughout, I assume that deregulation increases the level of

[24]Notice the implicit assumption that firms do not consider the future benefits of regulatory experience (i.e., learning by doing) in their investment decisions. This assumption is consistent with a large literature documenting that managers maximize short-term rather than long-term firm value (Budish et al., 2015).

[25]Note that financing frictions do not affect the payment of damages since they can be financed with profits (i.e., in expectation, damages will always be less than profits if a firm chooses to commercialize).

[26]Profits and financing costs also differ across these environments; however, the direction of the difference is ambiguous (e.g., if expected damages are large, safety effort costs could increase financing costs).

R&D activity. This assumption is supported by my empirical results and allows me to more clearly motivate the less intuitive results I find in my analysis.

First, I explore how deregulation can improve product safety. If mandated levels of safety effort are low enough, deregulation can improve safety by increasing the net incentives for safety improvements. I state this formally as follows:

PROPOSITION 1. *(Deregulation can increase firm safety efforts) If the marginal cost of regulated effort is less than the ex-post marginal benefit of that effort (i.e.,* $\psi + C_x(\underline{x}) < -EL \cdot D'(\underline{x})$*), then deregulation will increase firm safety effort.*

Figure G.1 helps clarify the necessary conditions for proposition 1. The figure shows that the ex-ante-mandated safety effort is sufficiently low, leading the deregulated firm to exert more effort. This proposition implies that ineffective regulations could make products less safe. I show in Section 5 that Class II regulations may lead to such an outcome. These insights, however, may be specific to the litigious US environment. For example, if a country aggressively caps damages (represented in $\vec{Z}$), firms would face lower expected damages, and safety effort could drop relative to regulated levels.

Another factor influencing a firm's expected damages is the value of its seizable assets. Following insights on the "judgment proof problem" (Shavell, 1986), when damages exceed the value of a firm's seizable assets, the difference can be discharged through bankruptcy. This option protects small firms from worst-case damages, lowering expected damages and the marginal benefit of exerting safety effort. Thus, if deregulation increases safety efforts, it will do so most for large firms. I state this as follows (and more formally in Appendix C):

PROPOSITION 2. *(Deregulation introduces bankruptcy distortion) Assume firm A has fewer assets than firm B (i.e.,* $K_A < K_B$*) and has too few assets to cover its worst-case damages. Firms A and B are otherwise identical. If deregulation increases firms' safety effort (see Proposition 1), then firm B will increase its safety efforts the most.*

The next distortion I detail arises from regulatory complexity (i.e., the delays from com-

plex regulatory requirements). Complexity distorts the composition of firms that commercialize as inexperienced firms reap lower returns from commercialization. Deregulation removes these distortions and disproportionately increases the returns to commercialization for inexperienced firms. To formalize this claim, I present the following proposition:[27]

PROPOSITION 3. *(Deregulation disproportionately benefits inexperienced firms) If firm A has less regulatory experience than firm B (i.e., $T_A < T_B$; all else equal), then deregulation increases the returns to commercialization most for firm A.*

An example helps illustrate the potentially dramatic implications of proposition 3. Consider firm A has no prior experience, and firm B has one previously commercialized project that was delayed for two years. Consistent with the values of the learning curve parameters γ and β estimated in Section F.1, firm A must wait out a two-year delay. By contrast, firm B waits out a one-year delay, incurring 50% lower delay costs than firm A and enjoying a longer effective life of its product. Although deregulation removes delay-related costs for both firms, the increase in returns to commercialization is at least twice as large for firm A.

Lastly, I discuss distortions that arise from financing frictions and regulation. Small firms incur deadweight costs when raising capital to commercialize their products (Gaglani, 2014; Emergo, 2019). Deregulation can decrease commercialization costs and financing costs, especially for small firms. I state this claim formally as follows:

PROPOSITION 4. *(Deregulation can disproportionately benefit smaller firms) Assume firm A is smaller than firm B and has non-zero financing costs when regulated (i.e., $K_A < K_B$ and $K_A < \chi t_{comm,A} + \psi \underline{x}$). Firms A and B are otherwise identical. If deregulation does not increase financing costs for firm A (i.e., $\psi x_A^* < \chi t_{comm,A} + \psi \underline{x}$), then deregulation increases commercialization returns most for firm A.*

However, deregulation could lead to lower returns to commercialization for small firms if financing costs increase after deregulation. For example, if deregulation induces enough

[27] Proofs are presented in Appendix D.

additional safety effort costs to outweigh the decrease in approval delay costs, financing costs could increase for smaller firms. By contrast, if the assumptions hold, Proposition 2 will amplify Proposition 4 as small firms face lower expected damages and lower safety effort costs after deregulation and, thus, even lower financing costs.

3 Data

To conduct my empirical analysis, I compile data from eight 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 and a data catalog is presented in Figure G.2.

FDA Device Submissions (PMA and 510(k) Databases). A 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 submitted" 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 a given point in time.

FDA Down-Classification Events. To conduct a comprehensive analysis of FDA down-classification events, I compiled a complete record of 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 in response to an industry petition, as this distinction is empirically im-

portant. Figure G.3 shows that device types subject to a petitioned down-classification demonstrate a notable anticipatory increase in patent filings in the year leading up to the announcement, with long-run impacts more than double those observed in non-petitioned events. The Class III to II events I consider are those enacted by the FDA's own initiative where the affected device types had at least one PMA submission prior to down-classification.[28] For Class II to I events, I consider affected device types with at least one 510(k) 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 using reported deaths, hospitalizations, and life-threatening events for each device type from 1992–2019. I follow 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 G.4). For the top 300 manufacturers by adverse event volume, I hand-linked firm names listed on adverse event reports to data on firm assets. Asset totals are derived for public firms using data from CRSP/Compustat. This linkage allows heterogeneity analyses of device safety by firm size.

USPTO Patent Grants Extract. Patents offer an additional measure of innovation to support my "unique devices approved" measure. However, there is no standard dataset linking medical devices to their associated patents (as does the Orange Book data for drugs). To address this, I follow a three-step procedure to create a patent-based measure of innovation for each device type. First, I compile a list of keywords from each FDA device type description. Second, I use a computer program to collect all patents granted by the USPTO that contain those keywords in their text. Third, I calculate the annual number of patents filed within each device type based on the date the patent was first filed. The resulting dataset

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

is a panel of yearly patent counts across 5,000 FDA-defined medical device types from 1976 to 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 provides corroborative evidence. In Section 5, I show that the estimates of changes in patent filing rates and device submission rates are quite similar for Class III to II events. Appendix E provides more details on the patent collection process.

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 it received from other patents and its market value.[29] Patent market values are derived from Kogan et al. (2017) and are deflated to 2019 (million) dollars using the CPI. These values are based on the increase in the patent assignee's stock price resulting from a USPTO announcement of patent 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.[30] This variable allows me to directly analyze how down-classification affects inventors' emphases on improving device safety, corroborating adverse event analyses. Lastly, to analyze how down-classification affects innovation from firms of different sizes, I link total firm asset holdings from the CRSP/Compustat database to patent applicants.

Truven Health MarketScan Database ("Marketscan"). Marketscan offers a relatively com-

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

[30]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 searched 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 (i.e., no scientific advancements in product safety). See Table G.1 for a list of keywords used.

prehensive monthly panel of employer-sponsored commercial health insurance claims from 1996 to 2013. To my knowledge, no dataset, even ECRI *PriceGuide*, consistently captures the direct prices paid by medical providers for devices before 2011. Marketscan data can, however, indirectly reflect these prices, particularly when the devices represent a significant portion of the total costs of medical procedures. Consequently, I focus on associating specific medical procedures with distinct medical device types, aiming to illuminate the impacts of down-classification on health care prices.[31] To construct control groups, I assembled two sets of procedures: the first set includes procedures matched to the treated procedures based on pre-event prices across all procedure codes. The second set comprises procedure codes specifically related to medical devices. Subsequently, I calculated the average payment for procedures linked to each device type for each year, leading to a panel that delineates the pricing dynamics for each device type by year.

4 Empirical Strategy

My strategy for estimating the effects of down-classification includes "stacked" 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 avoids potential biases 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).[32] This approach assembles event-specific panel data using each treated group $r \in \{1, \ldots, N^1\}$ and

[31] In all, using google search terms, I linked 17 Class III to II down-classified medical device types with corresponding Healthcare Common Procedure Coding System (HCPCS) procedure codes, encompassing level 1 and 2 codes. This includes device types for which there were industry petitions for down-classification. I incorporated these industry-petitioned device types to increase the number of treated categories with associated HCPCS codes. In the same way, I also associated 45 Class II to I down-classified device types with their relevant HCPCS codes.

[32] 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 G.2, G.3, and G.4).

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

$$Y_{t,c,r} = \gamma_{c,r} + \gamma_{t,r} + \beta_1 1\{\text{reclass}\}_{t,c,r} + \varepsilon_{t,c,r}. \tag{3}$$

In equation 3, 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 occurred in device type c. The outcomes of interest are denoted by $Y_{t,c,r}$. Event-by-time fixed effects ($\gamma_{t,r}$) and 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 3 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, my specification relies on the assumption that differential trends in the outcomes of interest do not pre-date the down-classification events. To test this assumption, I estimate a stacked event-study design using OLS, given by

$$Y_{t,c,r} = \gamma_{c,r} + \gamma_{t,r} + \sum_{k(t,c)\neq -1} \beta_k 1\{\text{Treated}\}_{c,r} \times I_{k(t,c)} + \varepsilon_{t,c,r}, \tag{4}$$

In equation 4, $1\{\text{Treated}\}_{c,r}$ is an indicator for whether device type c in event panel r has been subject to down-classification. $I_{k(t,c)}$ are indicators for years relative to the down-classification. I define $k(t,c) = 0$ as the year of down-classification. Thus, coefficients β_k represent the difference-in-differences estimate of the change in the outcome in a given period relative to the year before down-classification (i.e., the omitted year $k(t,c) = -1$). Standard

errors for each β_k 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 introduce devices under new regulations before enactment. Thus, for FDA-derived outcome 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 $k(t, c) = 0$ 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 less dangerous than 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 broadly comprises 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. The second group includes "later-treated" control device types that were down-classified after treated device types and after the latest sample year.[33] This "later-treated" group allows me to compare only device types that the FDA deemed appropriate for the same kind of down-classification. If later-treated device types are different from those treated earlier, the later-treated group may produce biased estimates. To ensure comparability, I formed the third control group, a

[33]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.

data-driven matched control group computed 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.[34]

Finally, I provide a set of "intuitive" controls. This fourth set of controls includes medical device types that 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 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 G.6 for Class III to II down-classifications, and in Tables G.7 and G.8 for Class II to I down-classifications. Although the estimates are similar relative to 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 Tables G.9, G.10, and G.11. My findings are robust to these restrictions.

As with every non-experimental research design, selection into treatment is a primary concern. Since the FDA's down-classification of medical device types is based on baseline adverse event rates, I cannot ascertain how down-classification would impact adverse event rates for a randomly chosen device type.[35] Consequently, my estimates represent local average treatment effects (LATEs) among lower-risk device types within a given class. However, for Class II to I events, I can observe the FDA's decision rule, allowing me to select comparison groups that closely resemble treated groups based on this rule. This decision rule also enables me to assess how adverse event effects change for the marginal device (i.e., the

[34]See Table G.5 for spillover estimates.

[35]Importantly, the FDA does not choose device types based on innovative potential or the potential for market structure effects. See Appendix A.1 for more details.

most dangerous down-classified devices). Notably, I find stronger effects for marginal devices, suggesting that my findings could generalize to other Class II devices not chosen for deregulation.

5 Results

This section presents estimates of equations 3 and 4, which capture the effect of down-classification on various outcomes of interest. Subsection 5.1 presents the effects on the flow and quality of innovation. Subsection 5.2 provides the effects on market structure. Subsection 5.3 details how the effects of down-classification on innovation and market structure differ by firm characteristics. Subsection 5.4 presents the effects on device safety.

5.1 Changes in Innovation

Table 2 reports estimates of equation 3 for my innovation outcomes.[36] Panel A provides estimates for Class III to II events, and Panel B provides estimates for Class II to I events. Column (1) reports a 5-year pre-treatment mean of the outcomes for treated groups. Columns (2)–(5) report the estimates of equation 3 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.

Table 2, Panel A indicates that Class III to II events ("down-regulation") led to statistically significant increases in patenting rates, unique device submissions, mean citations-per-patent, and mean patent values relative to control group comparisons (Columns 2–5). Depending on the control group, the results reveal that these events generated 189%–470% more patents and new device submissions per year per affected device type (pre-means: 8 patents/yr; 0.5 devices/yr). Patents filed after these events received 180% more citations and exhibited similar increases in market values. Panel B of Table 2 shows that patents filed

[36]Table G.9 presents the results from only including device types with some positive outcome counts.

after Class II to I deregulations received 330%–1,070% more citations and yielded 10%–50% higher market values, suggesting differential impacts on scientific and private values. These results are robust across comparison groups (Columns 2–5). Although economically significant, the increase in patenting rates from deregulation was not statistically significant under my preferred specification.

I examine the dynamics of the innovation responses by estimating the event-study equation 4. Figure 2 plots the innovation responses (i.e., the β_k coefficients) for down-regulation and deregulation events when using the "matched" control groups.[37] The results of this analysis provide several insights for interpreting my findings. First, trends in all outcomes were similar in treatment and matched control groups for ten years before the events; trends were also similar against other control groups (not shown). This insight strengthens the identifying assumptions that (i) treatment and control groups would have exhibited similar trends in outcomes absent the policy change, (ii) policies were not anticipated, and (iii) policies were not endogenous to increases in innovative activity. Second, Figure 2 indicates a persistent increase in the flow of innovation, suggesting that these events led to investments in new technologies that would not otherwise have occurred, rather than a forward shift in the timing of those investments.

Lastly, Figure 2 demonstrates a nuanced technological response to down-regulation. Post-down-regulation, the growth in new technologies, as evidenced by patent filings (Panel a), was gradual. In contrast, the market witnessed a swift increase in device submissions, encompassing both new *and* existing technologies (Panel b). This initial rapid increase in device submissions can be attributed to several factors. First, firms may quickly market "on-the-shelf" ideas and products that previously were stalled due to the expensive approval process. Second, firms may promptly repurpose existing technologies for new medical uses. Third, down-regulation streamlines the approval process, allowing products at different stages of testing to enter the market swiftly. Lastly, since, until recently, E.U. regulations

[37] Figures G.5 and G.6 show event-study estimates for the innovation quality variables.

were more lenient, firms may have introduced their E.U.-approved devices to U.S. markets after down-classification (Grennan and Town, 2020). By contrast, patenting rates increase gradually after down-regulation, consistent with the time-intensive R&D process. Patenting rates, unlike device submissions, are not affected by sudden influxes of existing technologies as these technologies are either already patented or are non-patentable. In particular, if a firm files a patent in one country, it must file patents in other countries where 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 Structure

To investigate the effect of down-regulation and deregulation on market structure, I re-estimate equation 3 focusing on five key outcomes: new and incumbent firm entry, each assessed separately by data source, and the pricing of procedures involving affected device types. The findings, detailed in Table 3, Panel A, reveal that down-regulation significantly increased both incumbent and new firm entry across various control groups (Columns 3–6) and data sources (patents and FDA devices).[38] Strikingly, new firm entry increased by 840%–1,000% (baseline: 0.1 firms/yr) according to FDA data and by 150%–420% as per patent data. The difference in magnitudes between these data sources suggests that down-regulation facilitates greater access to existing technologies. Furthermore, incumbent firms also expanded their entry into new device types by 400% in FDA data and by 130%–240% in patent data.

The first row of Table 3 addresses procedure pricing after down-regulation, suggesting a 10–25% rise in logged prices for procedures using down-regulated devices, although only one estimate is statistically significant. This price increase may be attributed to improved product quality due to increased innovation. Additionally, providers may be relatively insen-

[38]Table G.10 includes only device types with recorded positive outcome counts.

sitive to the prices of down-regulated devices as these devices are integral to more complex procedures. Lastly, these devices may contribute a relatively small share of procedure costs.

Panel B of the same table explores the impact of deregulation on firm entry, with patent data revealing a 50%-145% increase in new firm patenting post-deregulation, though with marginal significance under the preferred specification. In contrast, incumbent firm entry shows no significant change. This disparity suggests that deregulation potentially lowers entry barriers more for new firms than for incumbents.

The first row of Panel B in Table 3 shows deregulation leading to a 13–20% decrease in logged prices for procedures using affected devices. This decline is statistically significant in two of three estimates. The discrepancy in price effects between down-regulation and deregulation may stem from a relatively modest boost in innovation after deregulation contrasted with significant firm entry increases. Additionally, the deregulated devices are often more generic and form a larger share of overall procedure costs, exemplified by the substantial cost share of items like salmonella test kits in salmonella test procedure costs.

Finally, event-study estimates (Fig. 3) reinforce these findings.[39] These estimates confirm that the effects are persistent (when present) and suggest that the identifying assumptions (i)–(iii) (listed above) hold. For similar reasons given above, Panel (a) illustrates a gradual increase in patenting by new firms (reflecting the slow pace of R&D), juxtaposed with a sharp rise in new firm device submissions after down-regulation, presented in Figure G.7, Panel (a). Figure 3, Panel (d) also shows a trend of declining procedure prices over time, starting a year after deregulation. This gradual price adjustment is consistent with the contractual nature of healthcare markets, where hospitals periodically renegotiate contracts with suppliers and insurers (Reinhardt, 2006; Grennan and Swanson, 2020). In contrast, Panel (c) suggests that prices did not measurably change after down-regulation.

[39]Figure G.7 plots these coefficients for incumbent entry and new entry measured by FDA device submission data.

5.3 Heterogeneity in Firm Size and Regulatory Proficiency

The average treatment effects previously estimated overlook heterogeneity in firm size and regulatory proficiency. In this subsection, I separately estimate equation 3 across firm size and proficiency quantiles for the outcomes of interest. I link this heterogeneity analysis to the propositions in Section 2 to gain further insight into the mechanisms that drive the overall results. The identified mechanisms highlight design elements that may make regulation more amenable to small and inexperienced firms.

Firm Proficiency. To examine how regulation affects firms with different regulatory proficiencies, I estimate equation 3 for the device submission outcome across proficiency quartiles. I center this analysis on FDA data, allowing a cleaner linkage between firms, proficiency, and innovation. Panel A of Figure 4 presents the findings expressed as percent changes relative to pre-event averages. The results show that down-regulation generated statistically significant increases in new device submissions across proficiency quartiles. However, this increase was substantially more pronounced among firms with less experience navigating regulatory processes. Firms in the lowest proficiency quartile exhibited a 1,000% increase in new device submissions, contrasted with a 50% increase from firms in the highest quartile.[40] These results indicate a quickly diminishing response as proficiency levels rise. This pattern is consistent with the estimated learning curves presented in Figure 4, Panel B, where firms with the lowest proficiency benefit most from reduced approval delays. Such reductions lead to much lower commercialization costs for inexperienced firms, thereby spurring greater increases in their commercialization activities, in line with predictions made in proposition 3.

Streamlining and simplifying regulatory processes could help less regulation-proficient firms.[41] For example, Stern (2017) shows that when the FDA sets approval expectations by

[40]These findings are not driven by larger firms forming small subsidiaries to evade liability risks (i.e., judgment proofing). For example, only 1 out of 20 new spinal implant manufacturers entering the market after down-regulation were subsidiaries.

[41]In multiple interviews, inventors described to me the FDA approval process as "byzantine" and "too much for us to navigate alone."

publishing guidance documents, approval times for newer firms drop by roughly 40 percent. To simulate the potential impact of such regulatory efforts on innovation, I progressively reduce the gap in delays between inexperienced and proficient firms by lowering the learning rate γ and then measuring R&D responses among a hypothetical distribution of firms (see Figure G.8 and Appendix F.2 for more details). The outcomes of this simulation, as shown in Table G.12, imply that flattening the learning curve could boost the submission of unique devices by up to 63%, with the largest gains seen among the least proficient firms.

Firm Size. To assess how regulation impacts firms differentially based on their internal financial resources, I analyzed the patenting rate outcome across different terciles of asset holdings. This evaluation, conducted for both types of down-classification events, is detailed in Figure G.9, Panels (a) and (b).[42] Interestingly, both event types are associated with a more pronounced increase in patenting rates among firms in the lowest asset tercile.

From the perspective of my theoretical framework, these varied effects suggest that post-down-classification, profits tend to rise, and smaller firms benefit from relatively lower financing costs, even though they might face higher safety effort costs. These findings align with the hypotheses in Section 2 and suggest that small and inexperienced firms face relatively high regulatory costs to innovate.

Caution is warranted in interpreting these results, as other factors correlated with a firm's size and proficiency might also play a role in their R&D responses. However, the striking similarity between the empirical results and the predictions in Section 2, coupled with manufacturers expressing that regulatory proficiency and financing costs are key factors influencing R&D decisions, supports these conclusions.[43]

[42] I focus on patents for two reasons. First, they can be linked easily to patent applicants and capital holdings. Second, patents allow comparisons across down-classification types.

[43] Firm size, the most obvious potential confounder, is uncorrelated with firm FDA experience (see Table G.13). This lack of correlation may result from publicly traded companies having high baseline assets relative to the average MedTech firm.

5.4 Changes in Device Safety

I examine the impact of down-classification on device safety by re-estimating equation 3 for two different outcomes: the rate of adverse events and the degree of emphasis on safety by inventors. Table 4, Panel A shows that down-regulation is not associated with statistically significant changes in adverse event rates or in safety emphasis compared to control groups.[44] Nevertheless, the estimates indicate an economically meaningful increase in hospitalizations under my preferred specification.

By contrast, Table 4, Panel B shows that deregulation is associated with substantial improvements in device safety. This panel highlights significant reductions in hospitalization rates, life-threatening incidents, and fatalities across most control groups, along with a significant increase in safety-focused innovation. The results indicate a 93–97% reduction in annual hospitalizations and a 49–69% decrease in deaths per year per treated device type (pre-mean: 0.3 deaths/yr). Additionally, I observed a 100% rise in the share of patents emphasizing safety advancements, reinforcing the trends seen in FDA adverse event reports.[45]

Figure 5 illustrates how down-classification impacts device safety over time, plotting the β_k coefficients estimated from event-study equation 4.[46] Panel (a) indicates a gradual, albeit insignificant, uptick in serious event rates—encompassing hospitalizations, deaths, life-threatening incidents, and disability—after down-regulation, while Panel (b) indicates a gradual and significant decline in serious adverse events alongside an increase in safety emphasis by inventors, as seen in Figure G.12. Notably, adverse event rates are not normalized by device utilization. To account for potential impacts from changes in utilization, I normalized annual adverse event reports by the number of medical procedures involving these devices.[47] Panel (c) shows that this normalization removes the uptick in adverse events

[44] Table G.11 includes results limited to device types with recorded positive outcomes.

[45] Inventors also show a heightened focus on quality in patent texts post-deregulation, implying that removing regulatory efficacy/quality controls does not diminish quality.

[46] Figures G.10, G.11 present event studies for the different types of serious adverse events separately.

[47] I normalized adverse events of 46 deregulated device types and six down-regulated device types that could be associated with specific medical procedures, encompassing approximately half of the affected types. Only down-classified device types affected between 1996 and 2013 (excluding endpoint years) were included

post down-regulation, while Panel (d) shows that the improved safety post-deregulation remains.[48]

The question arises: how does deregulation *enhance* device safety? One compelling explanation is that deregulation exposes firms to heightened litigation risk, thereby incentivizing a stronger focus on safety. To elucidate this mechanism, I conduct two complementary analyses. First, I leverage variation in ex-post exposure to legal liability by firm size to isolate liability as a key factor. Smaller firms, able to mitigate severe damages via bankruptcy ("judgment proof"), contrast with larger firms that cannot. If liability risk plays a central role, deregulation should lead to relatively large increases in device safety among larger firms, as hypothesized in Section 2. Indeed, Figure 6, Panel (a) displays a marked 100% increase in the likelihood of larger firms demonstrating at least one safety innovation. Smaller firms, in comparison, exhibit a less pronounced response. Corroborating this finding, Figure 6, Panel (b) demonstrates a more substantial reduction in the likelihood of serious adverse events among these firms.

The second analysis compares my main findings to a 2015 deregulation event where devices were not protected from liability before deregulation. This comparison, detailed in Appendix B, shows no safety improvements after the 2015 event, underscoring the role of liability in driving safety enhancements rather than other potential factors like increased competition, innovation, or relief from regulatory constraints that might mechanically limit firms' innovative capabilities.

Some caveats accompany my device safety analysis. First, the FDA down-classifies Class III device types for which prospective regulation adequately mitigates harm. Thus, the absence of impact on product safety represents a local average treatment effect. For Class II to

in the analysis, as claims data outside of this timeframe was unavailable. Notably, normalizable devices demonstrate, on average, higher annual counts of serious adverse events compared to non-normalizable ones. Consequently, this leads to a relatively high normalized baseline rate of serious events per procedure, as depicted in Panels (c) and (d), when juxtaposed with the average base rate of serious adverse events across all affected device types, as shown in Panels (a) and (b).

[48]Figure G.13 presents non-normalized serious adverse event counts for the subset of device types with associated procedures, yielding similar results to the non-normalized full sample.

I events, however, I assess the FDA's decisions using the described decision rule in Appendix A.1 and estimate equation 3 for each treated device type matched with a control based on the rule's assigned score. Figure G.14 demonstrates more pronounced safety improvements among marginal device types relative to less dangerous treated device types. Thus, my results could extend to most current Class II device types, with 95% exhibiting fewer adverse events than the most marginal deregulated type. Second, while regulatory decisions may influence adverse event reporting, several factors, including stringent enforcement mechanisms and the absence of changes after the 2015 event, suggest that this is not a major concern. For a comprehensive discussion on these issues and additional details that support my conclusions, please see Appendix B.3.

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

This section assesses the costs and benefits associated with down-classification, building on the key findings presented in Section 5. The first key finding is that down-classification increases patenting rates. Estimating the social value of this innovation is inherently challenging, yet for this analysis, the value is approximated based on the combined market value of each additional patent, taking into account the effects of creative destruction and business stealing by conservatively assuming these represent 80% of the patent's value. Additionally, I found that deregulation reduced adverse event rates. The valuation of this decrease incorporates the statistical value of lives saved and a monetary assessment of prevented hospitalizations, as per the estimations in Moses et al. (2019). The assumptions and detailed calculations underpinning these valuations are thoroughly outlined in Table 5.

Table 5 summarizes the costs and benefits of down-classification events. For Class III to II down-regulation, the unmeasured costs would need to be twice as large as the measured costs to outweigh the benefits. In contrast, Class II to I deregulations exhibit no measurable costs, demonstrating instead a combination of decreased adverse events and increased innovation.

The benefits of deregulation equate to approximately $53 million annually per treated device type. Extrapolating these findings, if all 2,500 current Class II devices were deregulated, the potential annual net benefits could reach $132 billion, equivalent to 77% of the value of the US medical device market.

I do not include all the costs and benefits of deregulation in these calculations. For costs, I do not account for the potential loss or attenuation of the informational value of FDA approvals resulting from down-classification (see Grennan and Town (2020)). However, given that one criterion for down-classification is the ease of verifying and maintaining device efficacy post-deregulation, these costs are likely minimal. Additionally, the value of waiting to down-classify to learn more about a device type's inherent risk is not considered (i.e., the option value of waiting). Nonetheless, given that deregulation leads to lower adverse event rates, delaying deregulation may not offer significant value. Lastly, the potential political costs of misguided deregulation are not quantified.

On the benefits side, several unmeasured factors are noteworthy. These include reductions in FDA administrative costs, health care cost reductions from deregulation, the economic value of new jobs created following firm entry, the benefits of innovation from private firms, and the broader scientific value of such innovation.

7 Discussion and Conclusion

This paper analyzes the effect of regulation on medical device innovation, market structure, and adverse events. My theoretical model clarifies how "learning by doing" and financing costs make regulation especially burdensome for small and inexperienced firms investing in the development of new technologies. In turn, the model shows that deregulation increases the profitability of innovation most for these types of firms and may raise the net incentives to improve product safety by exposing firms to greater liability risk. I then investigate these insights, and my broader questions, empirically in the context of the medical device industry,

where complex regulations prevent litigation. For my empirical analysis, I developed a data set that combines various sources on innovation, market dynamics, firm characteristics, and product safety. I find that down-regulation disproportionately benefits small and inexperienced firms and broadly accelerates technological progress and firm entry. This change in market structure can reduce related healthcare prices. Lastly, deregulation is associated with a significant decrease in adverse events, providing evidence that legal liability risk creates strong incentives to improve product safety relative to the requirements of medical device regulation. Increases in product safety are highest among devices originating from large firms that have the most assets at risk in liability proceedings, providing additional evidence supporting liability as the driver of this result.

A back-of-the-envelope calculation suggests that deregulation exhibited higher measured benefits than costs. Class II to I events are associated with net benefits amounting to $53 million per year per treated device type. These benefits are higher for marginal, higher-risk device types, suggesting my results may generalize to other Class II devices.[49] These results align with sentiments from the National Institute of Medicine and physician commentators, which have criticized the effectiveness of Class II regulations and have advocated for alternatives that ensure quality and encourage innovation. My results suggest that deregulating Class II devices, relying instead on the deterrent effects of litigation, is one such alternative: litigation can improve product safety and hasten innovation.

Class III to II down-regulation, however, is difficult to evaluate. On the one hand, I find that the benefits of deregulation, namely a 470% increase in the availability of new technologies, are quite large. In the short run, the magnitude of this increase is consistent with deregulation removing the wedge between the available technologies in the E.U. and the U.S. For example, over 80% of cardiac stents marketed in the E.U. are unavailable in the U.S., a potential byproduct of regulation (Grennan and Town, 2020). In the long run, the increase in the development of new technologies is persistent. In practice, however,

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

these events present the FDA with asymmetric costs and benefits; an increase in salient device-related deaths could degrade the regulator's reputation and undermine its more cost-effective efforts elsewhere (Carpenter, 2004a,b). In contrast, the technological benefits that come from deregulation are more abstract. Thus, the FDA's optimal strategy may be "too conservative" (Isakov et al., 2019) relative to the social optimum to uphold its reputation at the expense of innovation. This asymmetry is evident in FDA documents outlining the criteria for down-classification as the value of forgone innovation is not considered. This study seeks to clarify these forgone benefits. However, more empirical research is needed to assess the costs of regulatory mistakes and the value of regulator reputation.

My study focuses on the large and growing medical device market, but the results may also be relevant to other settings with similar regulations. For instance, FDA regulations for Class III devices are similar to those in the EU, and requirements for these devices resemble those for brand-name drugs in the US and other countries (Van Norman, 2016).[50] Additionally, Class II device regulations are similar to those used abroad and resemble those for generic drugs—which are also protected from product design tort claims after FDA approval—and genetically modified (GM) foods (Schwartz and Appel, 2020; Schauzu, 2000). These similarities suggest that medical technology and food regulations may slow innovation and increase market concentration worldwide. Lastly, my analysis highlights the potential issues that arise when regulators use imperfect proxies or heuristics to evaluate product quality, such as the "substantial equivalence" heuristic used for Class II devices, generic drugs, tobacco products, and GM foods. These heuristics may be particularly pervasive when product quality is hard to verify or when regulators are under-resourced. In such situations, a robust legal system with impartial judges and high damage caps may better incentivize product safety through litigation.

[50]Tabarrok (2000) offers some evidence that FDA pharmaceutical regulations are too stringent.

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Figures and Tables

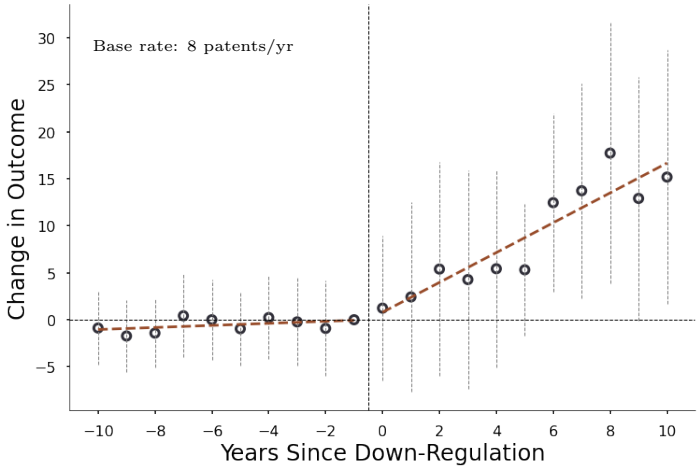
Figure 1: Background on Medical Device Regulations

Class	Risk	Time	Cost	Liability
3	High	54 months	$75 million	None
2	Moderate	10 months	$24 million	None*
1	Low	30 days (registration)	$5,000	All

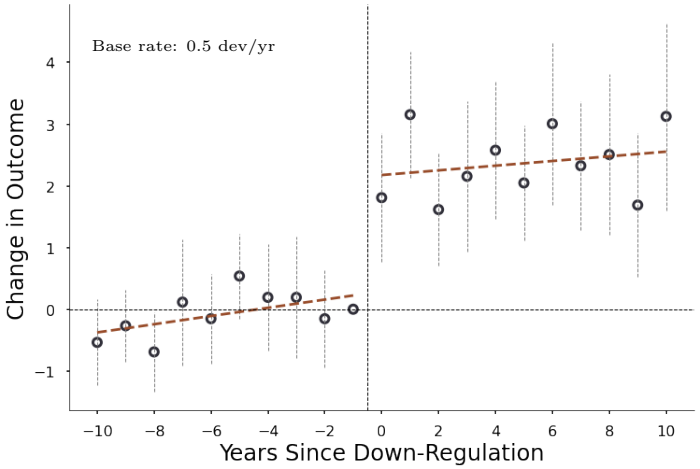
Note: This figure presents background on FDA Medical device regulations and the down-classification policy changes I leverage in my analysis. The FDA assigned device types to one of three classes, each corresponding to a level of perceived risk, which requires a certain amount of time spent approving the device and associated costs. The time and cost values are averages within the given class derived from Makower et al. (2010). The first column includes examples of Class III to II and Class II to I down-classifications. For Class III to II, examples include spinal fusion devices and full-field digital mammography machines. For Class II to I, examples include hospital beds and ventilator tubing. *While Class II devices were protected from legal liability during the historical era analyzed, only contemporary Class II medical devices with "special controls" requirements are typically protected from product liability (Costello and Pham, 2016).

Figure 2: Effect of Down-Classification on Innovation

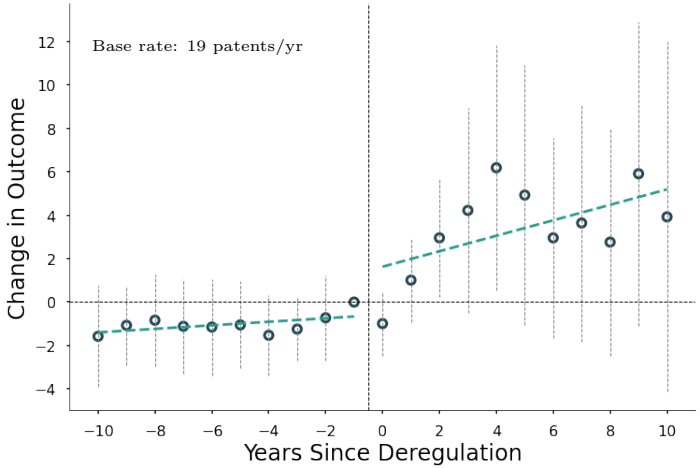
(a) Patenting Rate, Down-Regulation (Class III to II)



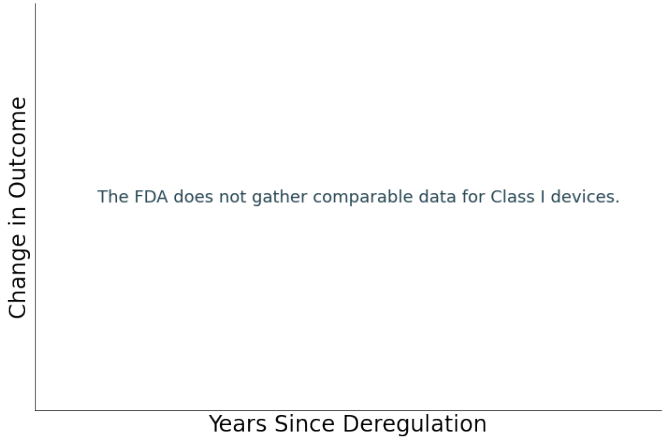
(b) Device Submission Rate, Down-Regulation



(c) Patenting Rate, Deregulation (Class II to I)



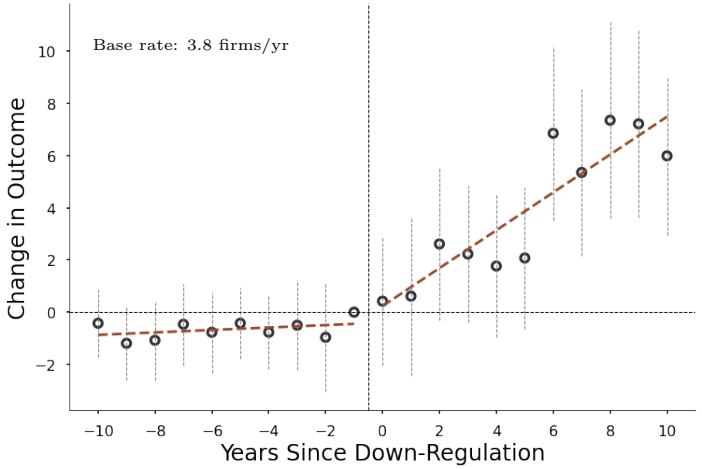
(d) Device Submission Rate, Deregulation



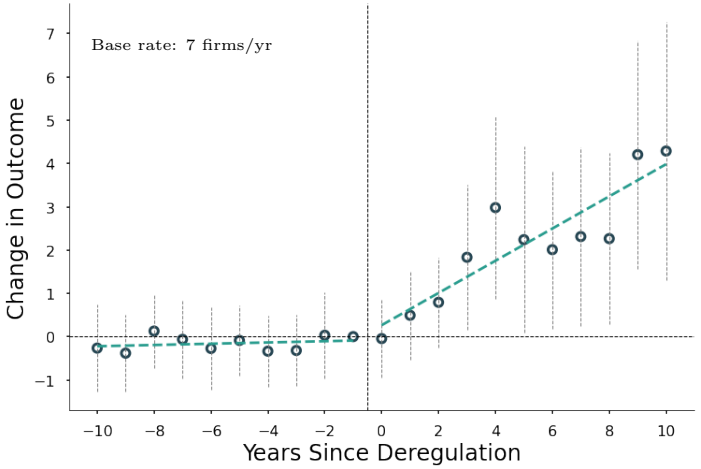
Note: This figure presents the β_k coefficient estimates from the event-study equation (refer to Eq. 4) for innovation outcomes. Device types in control groups are matched based on pre-event outcome averages (levels). The coefficient β_{-1} serves as the reference and is therefore omitted. Data is analyzed annually. Every panel traces the trajectory of outcomes in treated groups compared to controls surrounding the down-classification event. Panel (a) depicts the annual patent filing trends before and after down-regulation events (Class III to II). Panel (b) shows the annual evolution of device submissions to the FDA. Panel (c) portrays patenting trends for deregulated device types (Class II to I). For clarity, Panel (d) lacks data on Class I device submissions due to their non-mandatory nature for market entry. Standard errors for down-regulation events follow the methodology of Conley and Taber (2011). 95% confidence intervals are provided.

Figure 3: Effects of Down-Classification on Market Structure

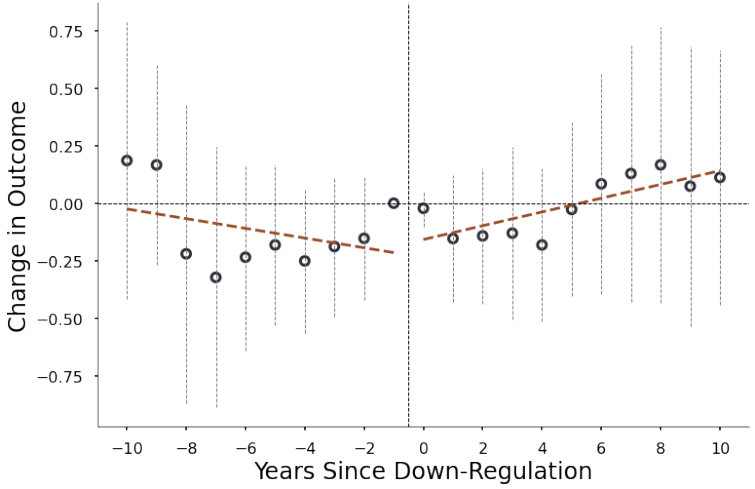
(a) New Firms Patenting, Down-Regulation (Class III to II)



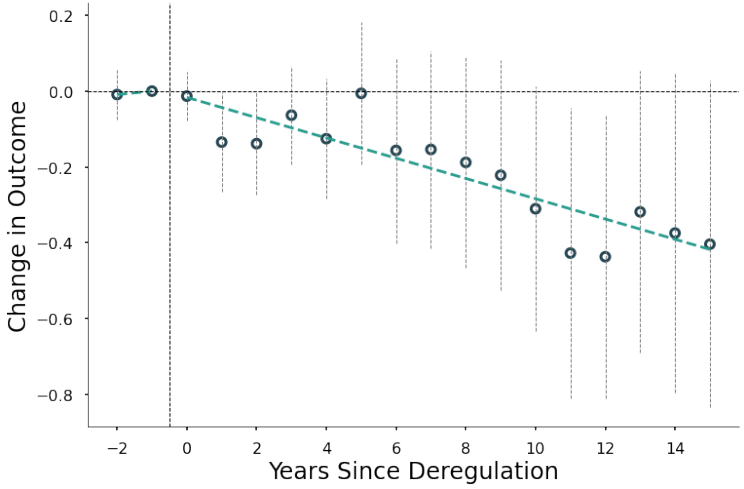
(b) New Firms Patenting, Deregulation (Class II to I)



(c) Logged Price, Down-Regulation



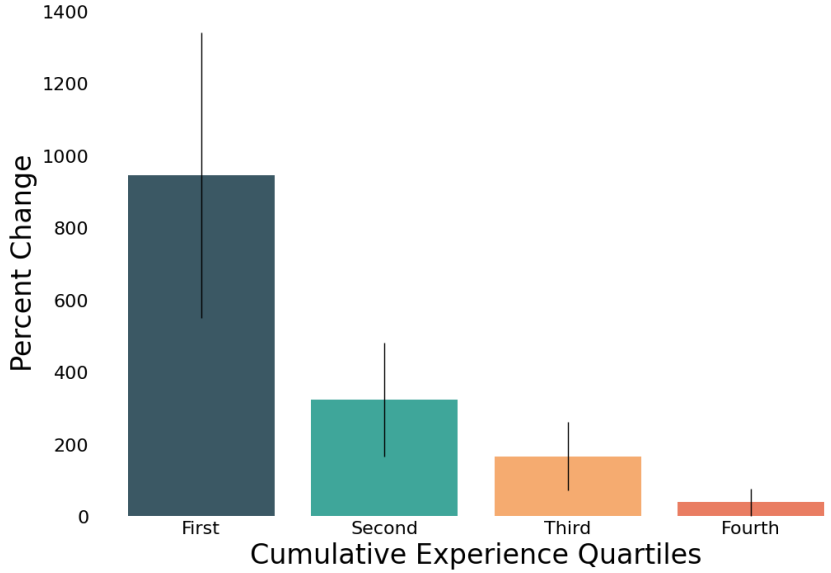
(d) Logged Price, Deregulation



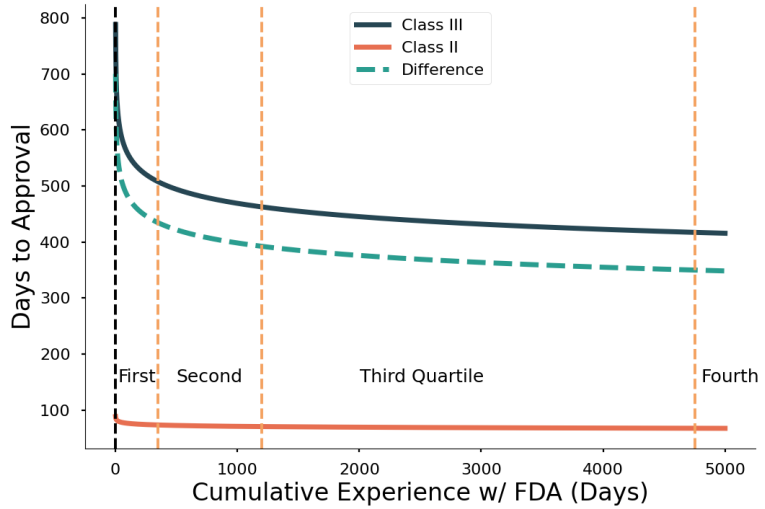
Note: This figure presents the β_k coefficient estimates from the event-study equation (refer to Eq. 4) for outcomes related to market structure. Device types in control groups are matched based on pre-event outcome averages. The coefficient β_{-1} serves as the reference and is therefore omitted. Data is analyzed annually. Each panel contrasts the treated groups' outcomes with control groups around the time of the down-classification event. Specifically, Panel (a) depicts the annual count of new firms patenting around the time of down-regulation events (Class III to II). Panel (b) shows the count of new firms patenting around deregulation events (Class II to I). Panel (c) charts the progression of logged prices for medical procedures using down-regulated device types. Panel (d) provides a similar analysis for deregulated device types for which I only have two years of pre-event claims data. Standard errors for down-regulation events follow the methodology of Conley and Taber (2011). 95% confidence intervals are provided.

Figure 4: Effects on Innovation by Experience and Estimated Learning Curves

Panel A: Change in New Devices by Proficiency



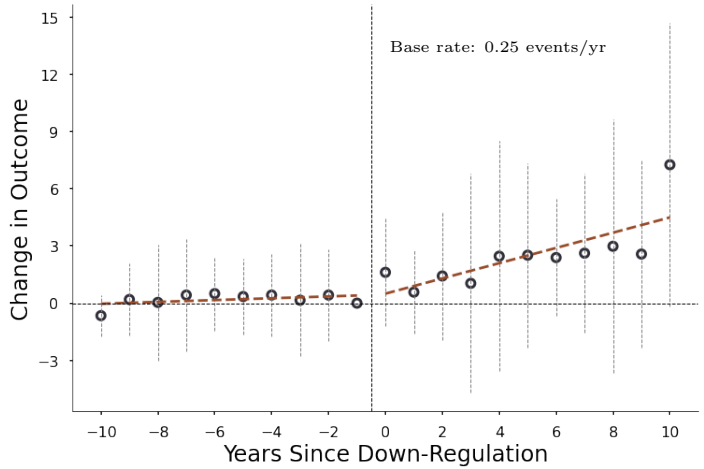
Panel B: Estimated Learning Curves



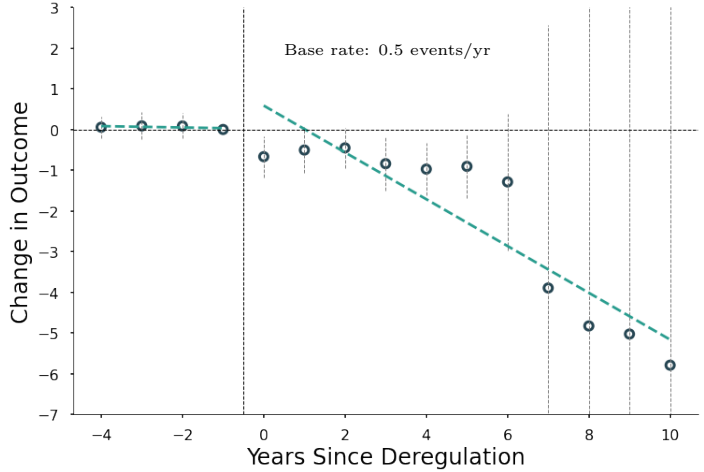
Note: This figure presents the experience-specific changes in the rates of newly marketed devices stemming from class III to II down-classification events and the learning curves estimated in equation F.1. Panel A provides the DID estimates of the rate of newly marketed devices in treated device types, 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 firm's 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. 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 5: Effects of Down-Classification on Product Safety

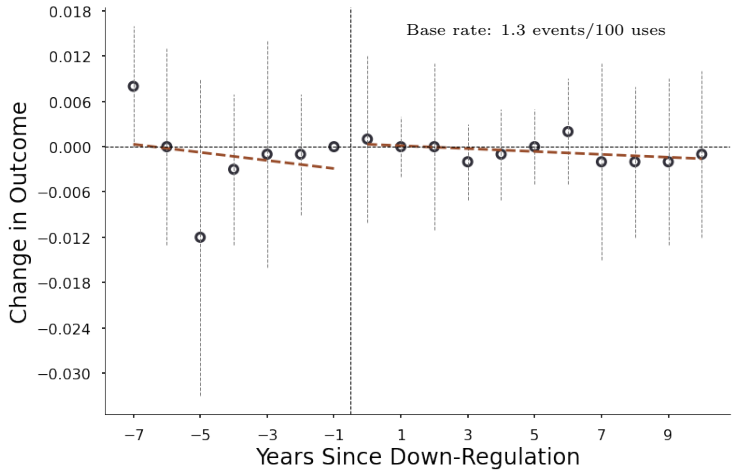
(a) Serious Adverse Events, Down-Regulation



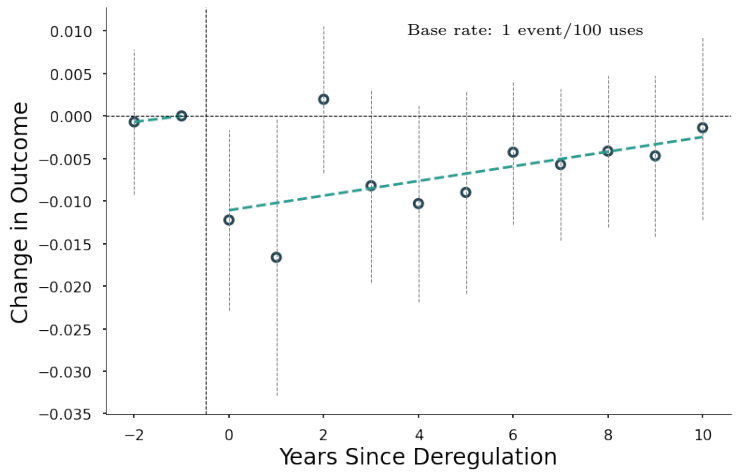
(b) Serious Adverse Events, Deregulation



(c) Serious Adverse Events, Down-Regulation, Normalized



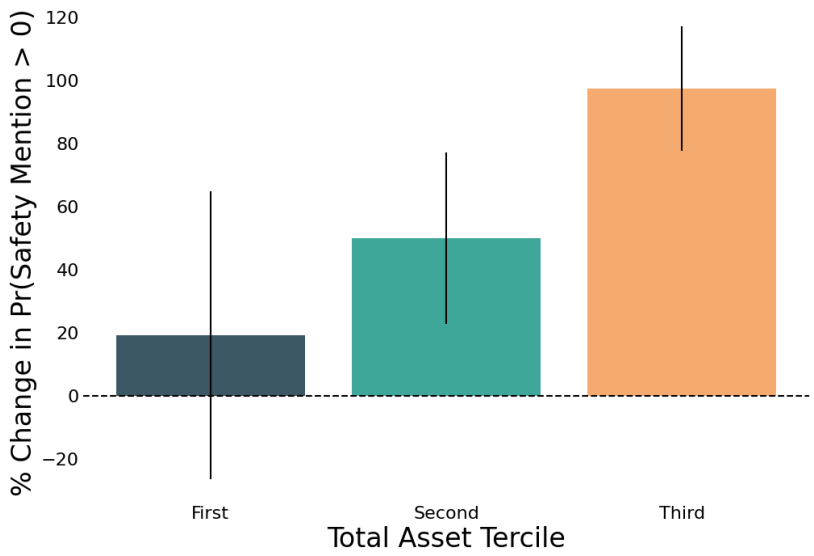
(d) Serious Adverse Events, Deregulation, Normalized



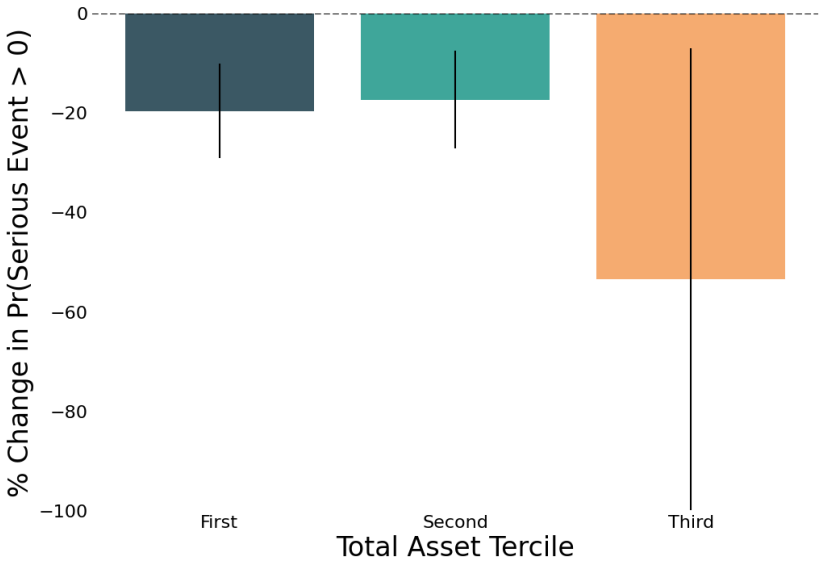
Note: The figure displays the estimates of the β_k coefficients from the event-study equation (see Eq. 4) for serious adverse events, encompassing life-threatening incidents, mortality, hospitalizations, and disability. Control groups comprise device types matched on pre-event outcome averages. The β_{-1} coefficient is the reference and thus excluded. Analyses utilize annual data. Panel (a) traces serious adverse events for down-regulated devices against matched controls. Panel (b) does the same for deregulated devices. In Panel (c), the adverse events for down-regulated devices are scaled by device usage, while Panel (d) reflects this normalization for deregulated devices. Confidence intervals are set at 95%.

Figure 6: Change in Product Safety by Firm Asset Terciles (II to I)

(a) Change in Safety Effort by Firm Assets



(b) Change in Serious Events by Firm Assets



Note: This figure offers separate DID (Difference-in-Differences) estimates from equation 3 for changes in the probability of different device types having at least one instance of the specified outcome annually, categorized by firm asset terciles. To account for the rarity of safety mentions and serious events, all non-zero outcomes are coded as "one" in a Linear Probability Model (LPM). The baseline frequencies of these outcomes are approximately equal across asset terciles, suggesting that the observed differences are not driven by baseline disparities. Panel (a) details changes in the likelihood of safety-related innovations, while Panel (b) focuses on serious adverse events (including death, hospitalization, or life-threatening incidents). The terciles are based on asset totals from publicly traded firms. The x-axis represents the asset terciles (first, second, or third), and the y-axis indicates the percentage change in likelihood. Bars representing 95% confidence intervals are included.

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]
Marketscan Claims Data				
Total	7.2B procs.	-	-	-
Procedures per proc. Code	17,379 (Codes)	26550.4	0.37M	[11, 33.9M]
Price per proc.–yr	181,659	\$731.9	\$1604.8	[\$0, \$0.12M]

Note: Tables G.14, G.15, and G.16 provide summary statistics for each class independently. 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)	(5.43)	(8.80)	(10.23)	(20.64)
Device Approval Rate	0.47	2.69***	2.36**	2.26**	2.22***
	(1.03)	(0.59)	(0.76)	(0.72)	(0.34)
Citations-Per-Patent Rate	9.06	16.59*	21.86*	19.43**	26.24***
	(20.65)	(7.60)	(9.71)	(6.56)	(5.46)
Average Patent Value	11.19	21.16***	29.01***	29.76***	26.99***
	(15.73)	(4.74)	(7.78)	(7.77)	(4.36)
Sample Size		1540	1056	920	60456
B. Class II to I:					
Patenting Rate	19.12	7.34	7.06	13.32**	29.17***
	(39.50)	(4.78)	(6.53)	(5.17)	(7.44)
Citations-Per-Patent Rate	0.75	6.85**	2.12*	3.98***	6.00***
	(0.43)	(2.34)	(1.06)	(0.86)	(1.39)
Average Patent Value	19.04	8.65***	2.31+	5.23***	13.03***
	(38.75)	(1.75)	(1.22)	(1.17)	(1.71)
Sample Size		15180	20592	27764	32472

Note: The table presents estimates of equation 3, 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 submissions 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. Symbols +, *, **, 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 Structure

		DID Estimates				
Down-Classification	Pre-mean (1)	All CPTs (2)	Matched (3)	Intuitive (4)	Later (5)	Full (6)
A. Class III to II:						
Procedure Price	518.26†	0.09	0.22*	-	-	0.2
	(839.25)	(0.11)	(0.09)	-	-	(0.17)
Sample Size		612	612	-	-	52200
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:						
Procedure Price	339.75†	-0.22**	-0.142*	-	-	-0.08
	(806.84)	(0.08)	(0.06)	-	-	(0.08)
Sample Size		1620	1620	-	-	52704
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 uses a DiD style OLS regression model (equation 3). Column (1) shows the 5-year pre-event mean for the treated device types, while Columns (2)–(6) provide DID estimates using various control groups: (2) matches baseline prices to controls among all procedure codes, (3) matches outcomes to medical device controls, (4) uses an intuitively similar group, (5) includes a later-treated group, and (6) employs the full control sample. Price data is available only from 1996–2013, limiting the sample size. Due to data constraints, Columns (4)–(6) do not include price estimates. † Pre-mean prices are reported in non-logarithmic form, while estimates are logged. Confidence intervals are based on Conley–Taber test statistics. Symbols +, *, **, and *** denote 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 (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 3, 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. Symbols +, *, **, 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 ($2019).
-Average inpatient hospital stay costs $22,000 (Moses et al., 2019). No other costs.
-Attribute 80% of patent value to business stealing/creative destruction (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).

		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]	$32m/5	$32m	[$20.5m, $51.8m]
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]	$27m/5	$48.6m	[$16.7m, $80.5m]

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). Patent values are deflated to 2019 (million) dollars using the CPI. 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. 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 Additional Details on FDA Regulations

In this appendix, I provide more detail on FDA regulations. First, I describe how the FDA determined the Class II to I down-classifications. Second, I detail the decision-making criteria surrounding the down-classification of Class III devices to Class II. Lastly, I describe Class III, II, and I regulations in more detail.

A.1 FDA Decision Rule for Class II to I Events

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,

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

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,

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

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

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

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

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

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.

A.2 FDA Decision Rule for Class III to II Events

Class III to II events are much less mechanical. When considering down-classifying a Class III device, the FDA analyzes the health risks of the device and whether Class II regulations will reasonably mitigate those risks. It makes these assessments by consulting the medical literature, internal data (i.e., premarket approval applications, equipment problems in the past resulting in recalls and adverse events), and clinical experiences with the device.

An illustrative example of a Class III to II event is the down-classification of daily-wear soft contact lenses in 1994. In the minutes of the 1994 ophthalmic panel meeting in which the FDA announced this event, the FDA cites safety information contained in submitted PMAs as the reason for down-classification. However, the timing of this event is "as good as random." In this same document, the FDA cites that it had been "dealing with [the down-classification event] for about ten years" and that because "the data that were needed to support reclassification were contained in PMAs and were not publicly available," they could not act. Thus, bureaucratic hurdles make these policies difficult to predict, making the timing of the events unlikely to be correlated with changes in outcomes beyond the effects of down-classification. Upon reclassification, the number of unique daily-wear soft contact lenses submitted for approval rose sharply, as the number of new extended-wear contact lenses, which remained in Class III, remained steady (see Figure G.15).[51]

A.3 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."[52] A newly marketed medical

[51] Note that because I cannot observe the safety variables that drive Class III to II events, it is difficult for me to extrapolate the product safety results I find in these events to other Class III devices that were not down-classified. Because I do not observe these variables, I do not know what the "marginal" device type would be; thus, I cannot determine whether the average effects differ from the marginal effects.

[52] 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).

device can be categorized as Class I if it is reasonably similar (i.e., 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.[53]

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 "pre-market notification."[54] Through the 510(k) process, a manufacturer must demonstrate that their device is "substantially equivalent" to a previously marketed device for which a "pre-market approval" (PMA) is not required. A device is substantially equivalent if it has the same intended use and technological characteristics as the predicate device. 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.[55] Class III device 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.[56] The PMA process takes much longer than the 510(k) process, and costs, on average, $75 million (Makower et al., 2010). After a manufacturer

[53]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).

[54]56% of medical device product codes fall under this category.

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

[56]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).

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).[57]

B Validation of Class II to I Product Safety Results

This appendix aims to validate the findings on product safety for Class II to I events. To strengthen the evidence of increased product safety after such events, this section includes an additional measure of product safety: device recalls. Furthermore, it examines a 2015 Class II to I event, where legal liability remained largely unchanged after deregulation.

B.1 Validation Using Device Recall Data

Device recalls are a valuable indicator of product safety. Recalls reflect manufacturers' efforts to address significant device defects and associated health risks by voluntarily removing affected devices from the market. The FDA can enforce recalls when necessary.

There are several advantages of using device recalls to measure safety. First, changes in recall counts are less likely to be influenced by variations in device utilization compared to adverse events, as manufacturers consider utilization when deciding on recalls. Second, recalls are supervised or mandated by the FDA, ensuring compliance with specific criteria. Lastly, recall events address substantial product safety issues that require significant action and are challenging to conceal, making them easily measurable and reliable indicators of product safety. However, a limitation is that recall data is available only from 2000 onward, while the deregulation events analyzed occurred in 1996 and 1998. Thus, the main text of this paper primarily focuses on other product safety outcomes. Nevertheless, considering the

[57]However, the requirements associated with PMA supplements are dependent on the degree to which the new device has changed, with small changes (like labeling changes) requiring no fee and design changes requiring preclinical testing. Most submitted class III documentation is from PMA supplements.

time it takes for new technologies and reduced adverse event rates to materialize, there is potential to capture some of the safety effects of these events using recall data.

This section presents device recall results that align with the findings from the adverse event and patent text analysis. To accomplish this, I analyzed FDA administrative data on medical device recalls by device type from 2000 to 2022. Although recall data immediately surrounding the events is unavailable, I leverage the dynamic nature of safety improvements following the events to capture the long-run improvements using recall data. Figure 2, Panel (b) illustrates that down-regulation triggers an immediate surge in available technologies. Although Class I device submission data is not available, it is plausible that an initial influx of technologies contributes to the slight immediate reduction in life-threatening events, hospitalizations, deaths, and the aggregate measure of serious events depicted in Figure G.11 (with only the decrease in hospitalizations being statistically significant). Subsequently, Figure 2, Panel (c) demonstrates a gradual increase in patenting rates over time, consistent with the time-intensive R&D process, reaching its peak approximately four years after down-classification. The adoption and commercialization of these new technologies likely require additional time, resulting in a second decline in life-threatening events, hospitalizations, and mortality rates approximately five to seven years after the down-classification events (as shown in Figure G.11). Therefore, by comparing recalls between the treated and control groups from 2000 onward, I could capture the long-run improvement in product safety resulting from down-classification.

Figure G.16 presents the average number of recalls per year for affected device types compared to the same matched control group used in the adverse event analysis. It is important to note that the matching procedure is based on pre-event adverse event counts, utilizing available data. The figure shows similar recall counts for up to seven years after the events (i.e., 2003) and before the full realization of innovation and adverse event effects. After this point, the trends diverge, leading to a persistent decline in recalls among the down-classified products relative to the matched control group over the subsequent 20-year

period.

Figure G.16 also provides results of a formalized comparison using an event-study analysis. Due to missing recall data for the years surrounding the events, I impute a constant rate of zero device recalls for both the treated and control groups in the immediate pre- and post-event periods. Consequently, no divergent pre-trends or effects are expected in the treated groups relative to controls within the three years pre- and post-event. However, the figure also demonstrates no divergent trends during event times 4 to 6, where data is available, and trends only diverge after the second drop in adverse events, after the new products have had sufficient time to penetrate the market and influence outcomes. This divergence is characterized by a significant decline in device recalls starting seven years after deregulation, with further amplification in subsequent years. This long-run decrease, equivalent to 0.5 device recalls per year per device type, represents a 50% decline compared to the control mean, providing further support for the observed increases in product safety measured through adverse events and patent text analysis.

B.2 2015 Class II to I Event With No Change in Liability

I further validate my product safety results from the 1996/8 events by comparing them to those of a 2015 event. During this event, more than 200 Class II device types were deregulated, with no substantial changes in the legal liability environment, as discussed in the following paragraph. However, similar to the 1996/8 events, this down-classification reduced the costs of introducing new devices in affected markets by removing 510(k) requirements.[58] The analysis of the 2015 event revealed no significant changes in product safety, further supporting the assessment that legal liability is the primary driving force behind product safety improvements.

Prior to the Supreme Court case Medtronic Inc. v. Lohr (1996), virtually every court held that Class II approvals preempted state tort claims (Flaherty Jr, 2008). Figure G.17

[58]The 2015 event marked the first major down-classification of Class II devices since the 1996/8 events that I analyzed in my main specification.

shows. However, a series of court cases since 1996, including Medtronic Inc. v. Lohr (1996), introduced ambiguity regarding the preemptive effect of 510(k) approvals. Consequently, the prevailing understanding shifted to recognize that Class II devices generally lacked protection from legal liability. The Supreme Court case Riegel v. Medtronic Inc. (2008) reinstated some legal safeguards for Class II devices, but these protections only applied to device types that met specific "special controls" requirements aimed at ensuring safety and efficacy (Costello and Pham, 2016).[59] However, most Class II devices affected by the 2015 event did not receive a list of special controls, leaving them without liability protection.[60]

The crucial difference between these events is that the 1996/8 event transitioned device types from a regulation-only to a liability-only environment, while the 2015 event shifted them from a regulatory-and-liability to a liability-only environment. This distinction allows me to isolate the specific influence of legal liability on product safety, separate from other factors such as changes in market structure, competition, innovation, and adverse event reporting behavior after deregulation, as these factors would be similarly affected by both types of events.

In analyzing the effects of the 2015 Class II to I event on product safety, I applied the same matching procedure used for the 1996/8 events to identify suitable control groups. Using the same empirical strategy, I compare hospitalizations, life-threatening events, mortality, and an aggregated "serious events" outcome in treated groups with matched control groups (i.e., my preferred specification).

The analysis of the 2015 event reveals no significant changes in product safety. Figure

[59]The recent court case Kelsey v. Alcon Laboratories Inc. (2019) offers an example of a Class II approval barring legal claims through preemption. In this case, the plaintiff claimed that Alcon's contact lens disinfectant did not prevent a severe eye infection due to a product flaw. However, the disinfectant was approved as a Class II regulated device and was subject to special controls. The district court handling the case deemed that the FDA's approval adequately tested the product's safety, preventing legal liability. This is just one of many recent instances where Class II medical devices have been protected from design defect claims through preemption. Other examples include cases involving latex gloves, contact lenses, tampons, condoms, angioplasty catheters, wound dressing, tissue adhesive with wound closure device, a hemorrhoid prevention pressure wedge, and electrical stimulation devices (Munford, 2018).

[60]These special controls are mostly only issued to device types that are down-classified from Class III to II.

G.18 replicates Figure G.11 for the 2015 event, illustrating the event-study estimates of the changes in life-threatening events, hospitalizations, deaths, and serious events associated with affected device types. The figure demonstrates that there were no significant or economically meaningful changes in any of these outcomes for the 2015 event.

Furthermore, Figure G.19 replicates Figure G.16 for the 2015 event and shows no significant changes in recalls for up to eight years after the deregulation. The absence of effects on recalls, combined with the lack of impact on other adverse event outcomes, provides compelling evidence on two fronts. First, it indicates that moving devices to a lower class with less regulation does not inherently reduce adverse event reporting due to changes in monitoring, for example. Second, it suggests that legal liability, rather than other factors affected by deregulation, such as market structure and innovation, is the primary driver of product safety improvements.

When considering the potential welfare effects of the 2015 event compared to the 1996/8 events, I find that the absence of changes in product safety from the 2015 event is possibly offset by a more substantial increase in innovation. Figure G.20 demonstrates the relatively sharp increase in new firms patenting following the 2015 event. Within two years, new entry rates increased by 50%, compared to a statistically insignificant 13.7% increase two years after the 1996/8 events.[61] These results suggest an effect on innovation and entry that is 3.6 times stronger after the 2015 event, reflecting a decrease in regulatory costs without the corresponding increase in litigation costs seen in the 1996/8 events. Therefore, it is plausible that the contemporary benefits of deregulation could be even larger than those in the 1990s due to more pronounced increases in innovation and entry. The value of increased innovation and entry, which accounted for approximately 80% of the total value of deregulation in the 1996/8 events, is over three times larger for contemporary Class II to I deregulation events.

These findings align with the theoretical framework discussed in Section 2. The frame-

[61]The analysis is restricted to two years post-policy due to data limitations. The 2015 event led to an additional five new firms per year relative to pre-event means, and the 1996/8 events led to one new firm per year.

work implies that if legal damages incentivize safety efforts beyond the requirements of the FDA, as suggested in Section 5, product safety may not change after the 2015 event. Thus, the lack of substantial change in product safety after the 2015 event is expected, given that the liability environment remained unchanged while the regulatory environment, with its lower effective safety standard, was lifted.

Regarding innovation, before the 2015 event, firms operated within a dual-regulation environment, facing both legal damages and FDA regulation. Consequently, the deregulation in 2015 likely increased net returns to commercialization and innovation more substantially than the 1996/8 event, as it imposed no additional costs. By contrast, the 1996/8 event introduced firms to legal damages.

B.3 Limitations of Adverse Event Data

The FDA cautions against using adverse event reports as a safety measure due to the absence of utilization data, potential under-reporting, inaccuracies, and lack of verification (CDRH, 2023). I address each of these issues in turn.

First, the FDA does not provide device utilization numbers alongside the adverse event report data, making it difficult to compare adverse event counts across different devices to analyze product safety. For example, a higher number of adverse event reports for a particular device may simply reflect a larger user base rather than a higher level of danger associated with the device. In my analysis, I use a difference-in-differences strategy, which means that if utilization changes differ between the treatment and control groups, it could bias my estimates of the effect of deregulation on product safety. In my case, I perform a separate analysis that utilizes adverse event reports normalized by the number of medical procedures performed in the given year that use a given device type. I show that my down-classification results are attenuated, and my deregulation results are robust to normalization.

Second, under-reporting of adverse events is possible, as reporting is mandatory only for serious adverse events and for manufacturers. Furthermore, deregulation may lead to higher

under-reporting by firms in the treated groups due to reduced oversight. However, there are two reassuring insights. First, my analysis focuses solely on serious adverse events reported by manufacturers, which are mandatory (FDA, 2020c) and subject to enforcement through financial penalties and criminal resolution (Bragg et al., 2018; Emergo, 2022).[62] Second, when examining the 2015 Class II to I event, where the litigation environment remained unchanged, I did not find significant changes in adverse event reporting, suggesting that deregulation does not mechanically reduce reporting. Additionally, the FDA's announcement of the Class II to I events mentioned new authorities that enabled closer monitoring of the affected devices to "take appropriate remedial action if necessary" (FDA, 1995), indicating that adverse event reports would be harder to conceal.

Third, adverse event reports may be inaccurate as they are not verified by the FDA. If manufacturers selectively submit inaccurate reports due to deregulation, it could bias my estimates. However, there is no evidence to support the notion that deregulation impacts reporting rates, given the lack of significant changes in adverse event reports following the 2015 event. Moreover, my focus on serious adverse events, which are closely monitored and mandated, enhances the reliability of the data compared to other types of adverse events like product breaks. Lastly, while adverse event reports may sometimes inaccurately attribute adverse event outcomes to a specific device, the absence of effects from the 2015 event, along with my emphasis on more closely monitored adverse event outcomes and the consistent results between my analysis of inventors' emphases on safety and device recalls, provide reassurance.

Lastly, the coverage of FDA MAUDE data broadened during the timeline of my primary analysis. Initially, in 1993, the data included reports from user facilities (i.e., providers), distributors, and voluntary submissions. However, reports from manufacturers were incorporated starting in 1996, coinciding with many of my earliest deregulation events (Ensign

[62]Both user facilities (i.e., hospitals) and manufacturers are required to report serious adverse events to the FDA. Thus, if one entity fails to report an event, but the FDA is notified by the other entity, it implicates noncompliance.

and Cohen, 2017). This expansion likely explains the extremely large decline in adverse events, relative to pre-event averages, observed after deregulation events (as shown in Table 4, Panel B), as reports increased in both treatment and control groups. To validate the consistency of my findings amidst this surge in reports, I analyzed serious adverse event reports by categorizing the sources into manufacturers and non-manufacturers. The latter category, being unaffected by the spike in reporting frequency, provides a clearer picture. As depicted in Figure G.21, Panel (a), the rate of serious adverse events reported by non-manufacturers also decreased following deregulation. Panel (b) reflects my primary results presented in Figure 5, given that manufacturers comprised most of the reports after 1996. Intriguingly, the wider confidence intervals in later periods in the analysis of manufacturer reports appear to be a consequence of the increased reporting by manufacturers, amplifying the variance in outcomes over time.

C Bankruptcy Protection Model Extension

Following insights from the literature on the "judgment 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. To reflect the bankruptcy option, I augment the model above to include expected damages that differ by firm assets K_f. I define the unspent capital available to cover damages as u_f. Unspent capital includes the capital not spent on commercialization costs ($K_f - c_f$) and profits from the current period, given by $u_f = \pi + K_f - c_f$. This term incorporates the simplifying assumption that net profits from the last period are distributed as devidends.[63] The upper bound of legal damages is given by $\bar{\phi}$.

Let ν represent the total realized damages from product defects, with probability distribution function $f(\nu; x_f^*, \vec{Z})$. In the presence of bankruptcy, the expected damages are given

[63] I could relax this assumption by letting u be equal to the unspent capital and the sum of all prior net profits up to a given point in time. This would mean that firms would tend to grow larger and eventually be unable to file for bankruptcy. However, the theoretical insights remain the same as initially smaller firms will face fewer expected damages for some time.

by

$$\text{Expected Damages } = \begin{cases} D(x_f^*; \vec{Z}) & \text{if } u \geq \bar{\phi}, \\ \underbrace{\left[\int_0^u \nu f(\nu; x_f^*, \vec{Z}) d\nu + \int_u^{\bar{\phi}} K f(\nu; x_f^*, \vec{Z}) d\nu\right]}_{D^T(x_f^*; \vec{Z})} & \text{else.} \end{cases} \tag{C.1}$$

In words, if the firm's capital stock is at least as high as worst-case damages, the expected damages are the same as above, and the investment decision is unchanged. Smaller firms, however, confront a truncated damages distribution, where all possible damages outcomes higher than the firm's unspent capital stock u_f are fixed at u_f. Thus, instead of paying these outsized damages, the firm declares bankruptcy and contributes the value of its total assets to partially cover its damages. Hence, expected damages $D^T(x_f^*; \vec{Z})$ are determined by the probability-weighted sum of damages from 0 to u_f, plus the probability-weighted sum of u_f for all damages higher than u_f. Assume that the marginal benefit of safety effort for small firms is less than large firms at the same levels of safety effort, as there are fewer damages to abate (e.g., $-D_T'(x_f; \vec{Z}) < -D'(x_f; \vec{Z})$ for all x_f)

Bankruptcy protection changes the incentives to improve product safety for small firms. Deregulation introduces firms to legal damages; however, bankruptcy protects small firms from worst-case damages, lowering the marginal benefit of exerting safety effort. Thus, small firms exert less safety effort than large firms. I state this formally as follows:

Proposition 5. *(Deregulation introduces bankruptcy distortion) Assume firm A has less internal capital than (i) firm B (i.e., $K_A < K_B$) and (ii) its worst-case damages outcomes (i.e., $K_A < \bar{\phi}$). Firms A and B are otherwise identical. If deregulation leads to an increase in safety effort (see proposition 1 part ii), firm B will increase its safety efforts most (i.e., $x_B^* - \underline{x} > x_A^* - \underline{x}$). This occurs if and only if $x_B^* > x_A^*$ (which can stack with proposition 4 part ii, if capital is also below safety effort costs).*

D Proofs

D.1 Proof of Proposition 1

Assume that $\psi + C_x(\psi\underline{x} - K) \ < - \ EL \cdot \ D'(\underline{x})$. Assume, by way of contradiction, that $x_f^* < \underline{x}$. Since x_f^* is the optimal safety effort, this implies that

$$\psi + C_x(\psi x_f^* - K) \ = - \ EL \cdot \ D'(x_f^*). \tag{D.1}$$

However, since $x_f^* < \underline{x}$, we know that $C_x(\psi x_f^* - K) \leq C_x(\underline{x} - K)$ as costs are strictly increasing in x (given that $K \leq x$). We also know that $D'(x_f^*) < D'(\underline{x})$ as $D'(\ )$ is strictly increasing in x. Thus, $- \ EL \cdot \ D'(x_f^*) > - \ EL \cdot \ D'(\underline{x})$. Together, these inequalities imply that

$$\psi + C_x(\underline{x} - K) \ > - \ EL \cdot \ D'(\underline{x}). \tag{D.2}$$

A contradiction. Thus, $x_f^* > \underline{x}$. See figure G.1 for a graphical illustration of this proof.

D.2 Proof of Proposition 2

Assume that deregulation leads to an increase in safety effort $x_A^* > \underline{x}$ and $x_B^* > \underline{x}$. I want to show that $x_A^* - \underline{x} < x_B^* - \underline{x}$. It suffices to show that $x_A^* < x_B^*$. Note that safety effort for deregulated firm B is chosen such that

$$\psi + C_x(\psi x_B^* - K_B) \ = - \ EL \cdot \ D'(x_B^*). \tag{D.3}$$

And for firm A:

$$\psi + C_x(\psi x_A^* - K_A) \ = - \ EL \cdot \ D_T'(x_A^*). \tag{D.4}$$

Since $D_T'(x) < D'(x)$ for all x, this means that

$$\psi + C_x(\psi x_A^* - K_A) \ < - \ EL \cdot \ D'(x_B^*). \tag{D.5}$$

Assume, by way of contradiction, that $x_A^* > x_B^*$. This implies that $\psi + C_x(\psi x_A^* - K_A) \ > - \ EL \cdot \ D'(x_B^*)$, since $\psi + C_x(\psi x_A^* - K_A) > \psi + C_x(\psi x_B^* - K_B)$ as $C_x(\ )$ is strictly increasing in x and decreasing in K ($K_A < K_B$, which further strengthens the inequality if $K_A < \psi x_A^*$, or capital is less than safety effort costs). A contradiction. Thus $x_A^* < x_B^*$.

D.3 Proof of Proposition 3

Note that, under regulation R, $T_A < T_B$, thus $t_{comm,a} > t_{comm,b}$; thus, for firm A, commercialization costs are strictly larger, financing costs are larger (if non-zero), and the effective life of the invention is shorter. Thus, the returns to commercialization are strictly lower for firm A.

Under the litigation environment L, there are no complexity distortions, thus the returns to commercialization are equal between firms A and B. We can formalize these insights as

$$Returns_{A,R} - Returns_{B,R} < 0 \text{ and } Returns_{A,L} - Returns_{B,L} = 0.$$

The difference in the change in the returns to commercialization from deregulation between firm A and B is given by:

$$DiD = (Returns_{A,L} - Returns_{A,R}) - (Returns_{B,L} - Returns_{B,R}). \tag{D.6}$$

We WTS that this difference is positive or that the increase in returns is higher for firm A. Rewriting equation D.6, gives:

$$DiD = (Returns_{A,L} - Returns_{B,L}) - (Returns_{A,R} - Returns_{B,R}). \tag{D.7}$$

From part equation D.3 we get

$$DiD = -(Returns_{A,R} - Returns_{B,R}) > 0. \tag{D.8}$$

Thus, the increases in returns to commercialization are greatest at firm A.

D.4 Proof of Proposition 4

Note that under the given conditions, small firms face lower expected damages and safety effort costs under deregulation than large firms (see proposition 1). Thus, deregulation would lead to larger returns from commercialization for smaller firms than larger firms, all else equal. Therefore, showing that the returns from commercialization increase most for small firms through the financing channel is sufficient, given that bankruptcy distortions would broaden the conditions under which deregulation disproportionately benefits small firms. Hence, for simplicity, I consider only the financing channel and the conditions that guarantee outsized small-firm benefits.

Consider firm A's profit function with external funds $e_{R,A}$, given by:

$$REL \ \cdot \ \pi_R - \chi t_{comm} - \psi \underline{x} - C(e_{R,A}).$$

Note that firm A's external capital is positive (i.e., $e_{R,A} > 0$) since its internal capital is less than its non-financing commercialization costs (i.e., $K_A < c$); thus, due to nonzero capital frictions, its financing costs are positive (i.e., $C(e_{R,A}) > 0$).

Firm B's internal capital is greater than firm A's; thus, its external capital is less than firm A's, and its financing costs are less than firm A's. Firm A and firm B have identical profit functions aside from financing costs; thus, firm B's expected net profit is greater than that of firm A. Thus, either firm A's commercialization activity is the same as that of firm B ("non-marginal") or firm A's commercialization activity is less than firm B's.

Now for the litigation environment L, the returns to commercialization are given by:

$$Returns = EL \cdot [\pi_N - D(x_f^*; \vec{Z})] - \psi x_f^* - C(\psi = x^* - K_f). \tag{D.9}$$

For a moment, think of x as not fixed. Since $K_A < K_B$, profits π, and EL are the same between the two firm types, at every value of x, the returns for firm A are strictly less than the returns for firm B, due to increased financing costs. If we assume bankruptcy, firm A also has lower expected damages than firm B and $x_A^* < x_B^*$, which would further increase the Assume, by way of contradiction, that exists an optimal safety effort for firm A x_A^* such that returns to firm A are larger than the returns to firm B at its maximum safety effort x_B^*. Since the returns to firm B are strictly larger than the returns to firm A at each value of x, there exists some x' such that $Returns_B(x') > Returns_A(x^*)$. However, this implies that $Returns_B(x') > Returns_B(x_B^*)$, even though x_B^* is maximizes returns. A contradiction. Thus, firm A's returns are lower than firm B's. Further, commercialization activity is lower than firm B's. However, it could be the case that returns are negative in the litigation environment for both firms. If so, then commercialization is the same across both firms ("non-marginal").

Thus, we have

$$Returns_{A,L} - Returns_{B,L} < 0 \text{ and } Returns_{A,R} - Returns_{B,R} < 0. \tag{D.10}$$

I want to also show that the sign of the following difference-in-differences is ambiguous: $(Returns_{A,L} - Returns_{A,R}) - (Returns_{B,L} - Returns_{B,R})$. We have that $(Returns_{A,L} - Returns_{A,R}) - (Returns_{B,L} - Returns_{B,R}) = (Returns_{A,L} - Returns_{B,L}) - (Returns_{A,R} - Returns_{B,R})$. We know this difference could be positive or negative. The first and second differences are both negative, thus the sign of the difference-in-differences depends on the relative changes in profits, damages, and delay costs. However, note that if capital is greater than optimal deregulated safety effort costs (i.e., $K_A \geq \psi x_A^*$), despite being lower than non-financing costs before deregulation, then $(Returns_{A,L} - Returns_{B,L}) = 0$ as there would be

no financing costs to differentiate the returns of the two firms; thus, the change in returns would be larger for firm A. Note that if we also consider that damages for smaller firms are lower, due to bankruptcy, then $(Returns_{A,L} - Returns_{B,L}) > 0$. Thus, in both cases, the larger change in returns for firm A would translate into a larger increase in net profits if both firms A and B experience increases in net profits from deregulation.

E Patent Data Collection

In this appendix section, I describe the process for collecting patents by device type in more detail. I also evaluate the accuracy of the procedure and demonstrate that my results are robust to intuitive restrictions to the generated patent sample.

E.1 Procedure for Gathering Patents by Device Type

The patent collection process begins by gathering a set of FDA device type descriptions for over 5,000 medical device types. These descriptions consist of both a broad FDA regulation number description and a narrower FDA device name description. To prepare these descriptions for keyword searches, I remove stop words, punctuation marks, and duplicate words. For example, the regulation number description "Implantable pacemaker pulse generator" and device type description "Leadless Pacemaker" would be transformed into the search string "implantable pacemaker pulse generator leadless." Next, I search the full text of the universe of US patent documents and gather all patents that contain all of the keywords in the search string. This process is repeated for all device types.

In some instances, patents are included in more than one device type. In such cases, I drop the patent from all but one randomly chosen device type.

E.2 Examining the Accuracy of the Procedure

Naturally, keyword searches that link patents to device types can sometimes lead to false positive and false negative errors. For example, one of the most common inclusion errors I encountered was when keyword searches mistakenly linked drug-related patents to medical device types, according to the Cooperative Patent Classification (CPC) system. However, these discrepancies between the CPC classifications and my linkages may not always be erroneous, as some drug technologies may be complementary to certain device types. Therefore, using keyword searches instead of the CPC system can be useful for capturing complementary technologies, but using both can provide a way to validate my data. Below, I present a few examples of patents I identified through random sampling of drug-related patents, which may or may not be inclusion errors.

First, the patent "US-10428030-B2" describes a compound that can be used as a diagnostic tool in combination with Nuclear Magnetic Resonance Imaging (NMRI). According to the Cooperative Patent Classification (CPC) system, this compound is classified as a drug rather than a medical device. However, when I searched patent texts using the medical device type keywords "nuclear magnetic resonance imaging diagnostic systems," the patent was included in my results. Even though the compound itself is not a device, it may be possible that innovation in these types of compounds increases when NMRI diagnostic systems (complementary technologies) are deregulated. The patent "US-10314846-B2" is another example of this technological complementarity. My keyword search technique includes these complementary technologies while relying on patent classifications alone would not, as the compound is labeled as a drug (i.e., A61P25/14–Drugs for disorders of the nervous system for treating abnormal movements, e.g., chorea, dyskinesia).

Another example of the benefits of using keyword searches is demonstrated when searching for patent documents containing the keywords "cyclosporine test system." In this case, the patent "US-10011612-B2" is included in the results. According to the Cooperative Patent Classification (CPC) system, this patent is classified as a drug (i.e., A61P1/16–Drugs for dis-

orders of the alimentary tract or the digestive system for liver or gallbladder disorders, such as hepatoprotective agents, cholagogues, and lithophytic). As described in the patent, the drug is administered in combination with other agents, such as an anti-inflammatory drug, antimicrobial agent, anti-angiogenesis agent, immunosuppressant, antibody, steroid, an ocular antihypertensive drug, or a combination of these agents. Examples of these agents include cyclosporine. The administration of such drugs is typically monitored using cyclosporine tests to ensure that appropriate levels of the drug are in a patient's system. Therefore, it is plausible that increased innovation in and cheaper acquisition of cyclosporine test systems could lead to increases in innovation in cyclosporine immunosuppressants.

However, this type of sensitivity in keyword searches can also result in inclusion errors. For example, when I searched patent texts for the device type "soft contact lens daily wear," I included a patent for a drug that treats corneal ulcers (eye ulcers). This patent was included in my results because it mentions that the drug can be administered as a contact lens or reservoir, among other methods. While there may be some technological complementarities between contact lenses and this type of drug, the connection is weaker. Nonetheless, this example demonstrates how keyword searches can sometimes include patents that may seem only tangentially related.

Although there may be valid reasons to include drug-related technologies and other non-medical-device technologies in my patent data, I also demonstrate that my results are not sensitive to restricting my patent data only to medical devices in the following section.

E.3 Robustness of Procedure

To validate the results of my main specification that analyzes patent data collected using keyword searches, I use the CPC system to restrict my patent sample to only include medical devices and find that my results are robust. To restrict the sample, I only keep collected patents that fall under the "Medical or Veterinary Science Hygiene" CPC categories (i.e., include "A61"), but that exclude patents classified as drugs (i.e., not "A61P"). This restriction

reduces the number of included patents from 1,248,289 to 239,315 patents. In the CSV file linked here, I provide the top three CPC labels for patents collected in each device type for all affected Class III devices used in my analysis. In another CSV file linked here, I provide the top three CPC labels for patents collected in each device type for all affected Class II devices used in my analysis. Notice that the descriptions of most top CPC codes correspond with the descriptions of medical device types.

Table G.17 presents the estimates of equation 3 using the restricted patent sample for my patenting rate outcomes. The table reveals that the estimates remain large in magnitude and statistically significant. In fact, the percentage change in patenting rates relative to pre-event means is larger for both Class III to II and Class II to I events. However, the magnitude of the effects is reduced by approximately one-third, signifying that approximately one-third of the effect on patenting in my main specification may be due to positive spillovers into complementary technologies. Figure G.22 shows the estimates from an event-study analysis and suggests that the results from my main specification are robust when using this restricted sample of patents.

Lastly, my estimates for the outcome defined as the number of new FDA device submissions (i.e., the "Device Submission Rate") also support my patenting results by showing similar increases in innovation.

F Learning Curve Estimation and Simulations

F.1 Estimation Framework for the Learning Curve Parameters

Medical device manufacturers that are inexperienced with regulation may face additional costs when bringing 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. I model the relationship between the approval delay of project N for firm f, $t_{comm,N,f}$ (measured in days), and cumulative experience, $\sum_{s=1}^{N-1} t_{comm,s,f}$, by the following

equation:

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

Recall that $\beta(R_c)$ represents the baseline approval delay in medical device type c under regulation R (R can be Class III or II in practice), while $\sum_{s=1}^{N} t_{comm,s,f}$ represents the sum of approval delays (in days) faced after having submitted $N-1$ 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 A.3, 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 to condition on device novelty. This ensures that novelty is not driving approval delays.[64] For Class II devices, I ensure consistent novelty across devices by only considering documentation submissions for devices with unique brand names.

I log-linearize equation F.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,

[64] 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.

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

For Class III devices, I include device type and firm fixed effects. For Class II devices, I include firm- and device type-by-year fixed effects, as I have enough observations within those more granular fixed effects to estimate the coefficients. Standard errors are clustered at the device-type-firm level. I exclude observations with no experience to avoid undefined outcomes in the estimation

The estimates of the learning curve parameters are significant for both Class III and II documentation submissions (see Table G.18).

F.2 Simulation: Flattening the Learning Curve

As described in Section 2, firm f's decision to innovate under regulation is determined by its return to commercialization

$$REL_f \cdot \pi_{R,f} - \chi t_{comm,f} - \psi \underline{x} - C(e_{R,f}), \tag{F.2}$$

where $t_{comm,f} = \beta\left(\sum_{s=1}^{N-1} t_{comm,s,f}\right)^{-\gamma}$. For tractability, I assume that financing costs take the form $C(e) = \max(0, \chi_j t_{comm,f} + \psi \underline{x} - K_f)$. In addition, since I do not observe firm expenditures on safety R&D, the distribution of damages, safety efforts, or worst-case damages, I assume that damages and safety efforts are vanishingly small relative to profits and delay costs. This assumption is likely not innocuous as these costs are substantial, but it allows me to draw broader insights under my limitations by focusing on changes in delay costs that come from reducing regulatory complexity.

The learning curve parameters γ and $\beta(R_c)$ are presented in Table G.18 for Class III and Class II devices. I simulate the effect of flattening the learning curve on the rate of unique device inventions from Class III device manufacturers to assess the counterfactual of less complex FDA regulations. I calibrate χ to match the cost of approval delays found in

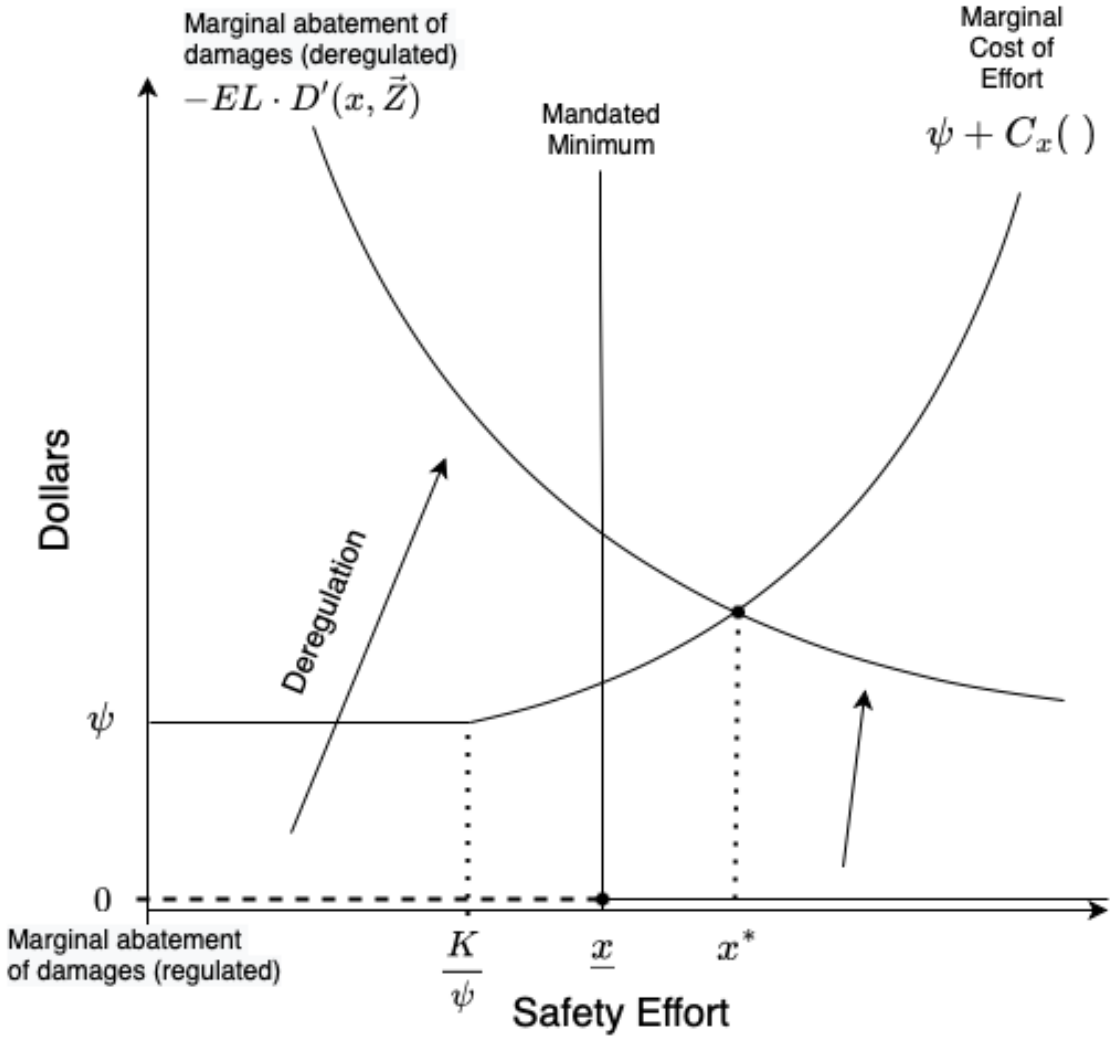
Makower et al. (2010) at the daily level for both Class III and II devices.

To execute these simulations, I first generate distributions of expected profits, firm sizes, and firm FDA regulatory experience. I proxy for expected discounted profits (i.e., $REL_f \cdot \pi_{R,f}$) using patent market valuations. This proxy requires the assumption that the market can adequately identify the expected discounted lifetime payout that a given patented innovation will yield to a firm and that this value is reflected in the change of the assignee's stock market price upon patent grant announcement. The device payout distribution is generated by fitting a gamma distribution to the medical device patent market valuations for Class III devices. I then fit a lognormal distribution to my firm size data to generate a distribution of asset values across firms. Lastly, I fit a gamma distribution to my firm FDA experience data.

After sampling from these fitted distributions to form a set of representative firms, I model how flattening the learning curve affects the rate of new device inventions across these firms. To this end, I anchor the right tail of the learning curve to the approval delay of the firm with the highest regulatory experience in my data 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 calculate the difference between the ex-post investment decisions (i.e., after the learning curve is flattened) and the ex-ante investment decisions (i.e., 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 G.8 shows the iterative flattening of the learning curve, and Table G.12 provides the calculations of the percentage change in new device inventions.

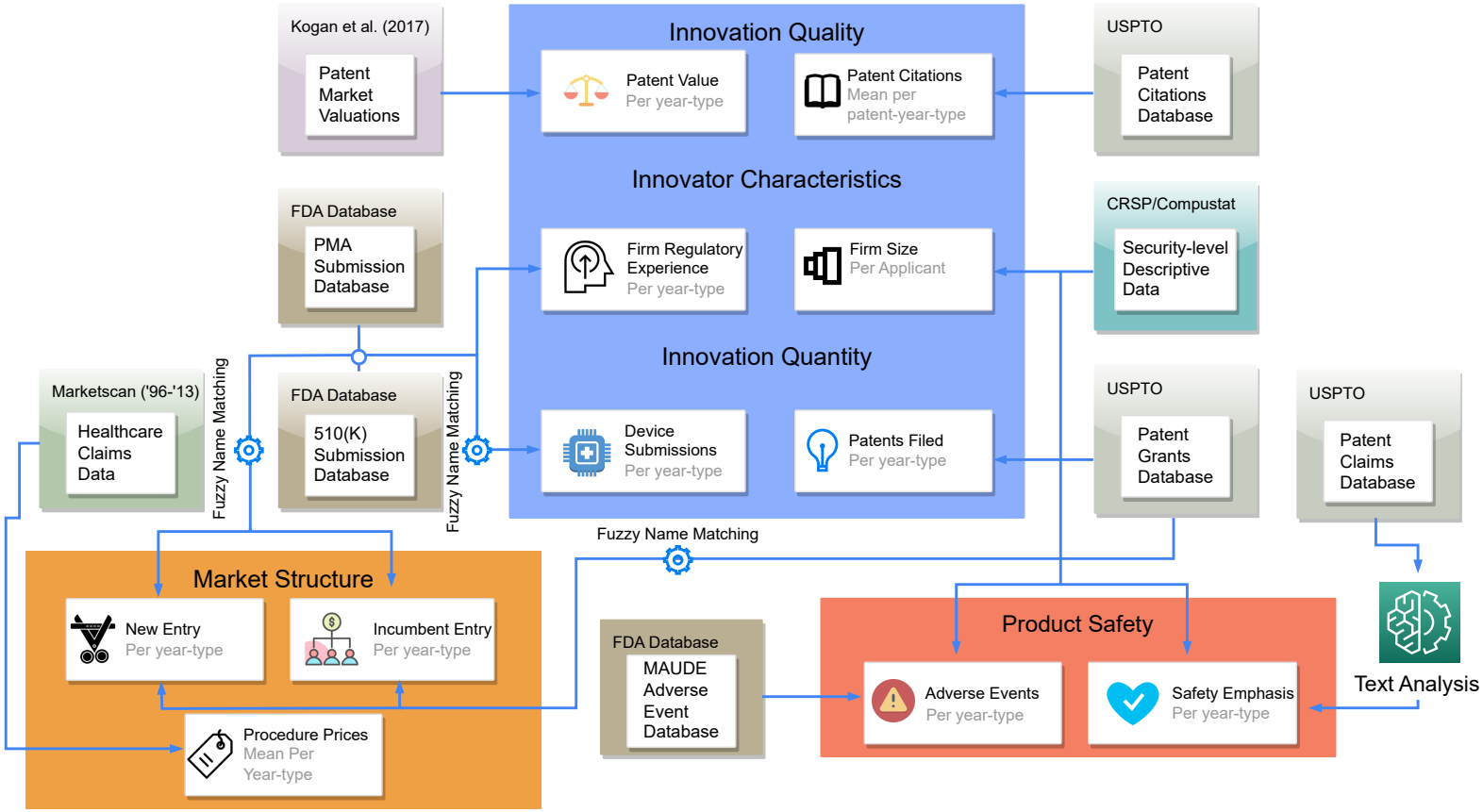
G Supplemental Figures and Tables

Appendix Figure G.1: Theoretical Change in Safety Effort after Deregulation



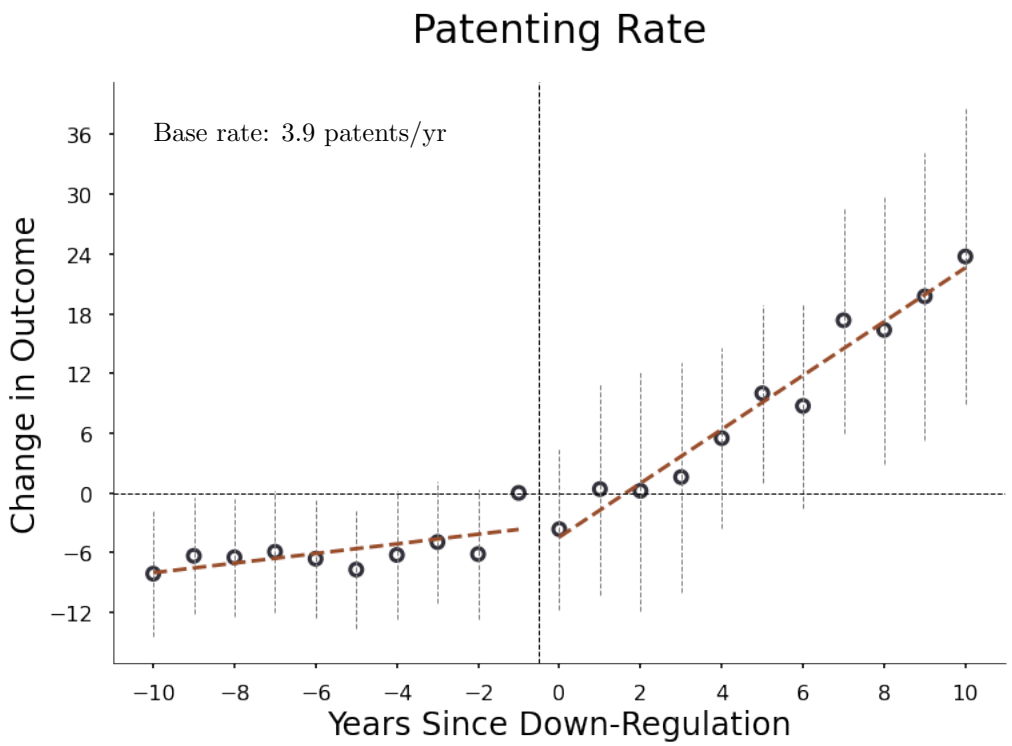
Note: This figure presents a possible change in the level of safety effort after deregulation. This scenario is one in which deregulation could lead to an increase in safety effort, given a sufficient increase in damages, as described in Section 1. The x-axis indicates the level of safety effort exerted. The y-axis denotes the monetary value. The marginal cost of effort curve indicates a marginal cost of ψ at initial values of safety effort before financing costs are incurred, at which point marginal costs increase with effort. The marginal abatement of damages curve under regulation is always equal to zero due to federal preemption. The counterfactual dotted section of the marginal abatement curve under regulation represents the marginal abatement of damages from exerting effort below mandated levels while still achieving FDA approval. Deregulation shifts the marginal abatement curve as legal damages are no longer prevented by federal preemption. The value x^* represents the optimal level of safety effort after deregulation (i.e., where the marginal cost of safety effort is equal to the marginal abatement of expected damages). The value $\underline{x}$ represents the mandated level of safety effort. The vector $\vec{Z}$ contains other factors that affect a firm's legal damages in expectation, which might be specific to the given legal system, like damage caps.

Appendix Figure G.2: Data Catalog



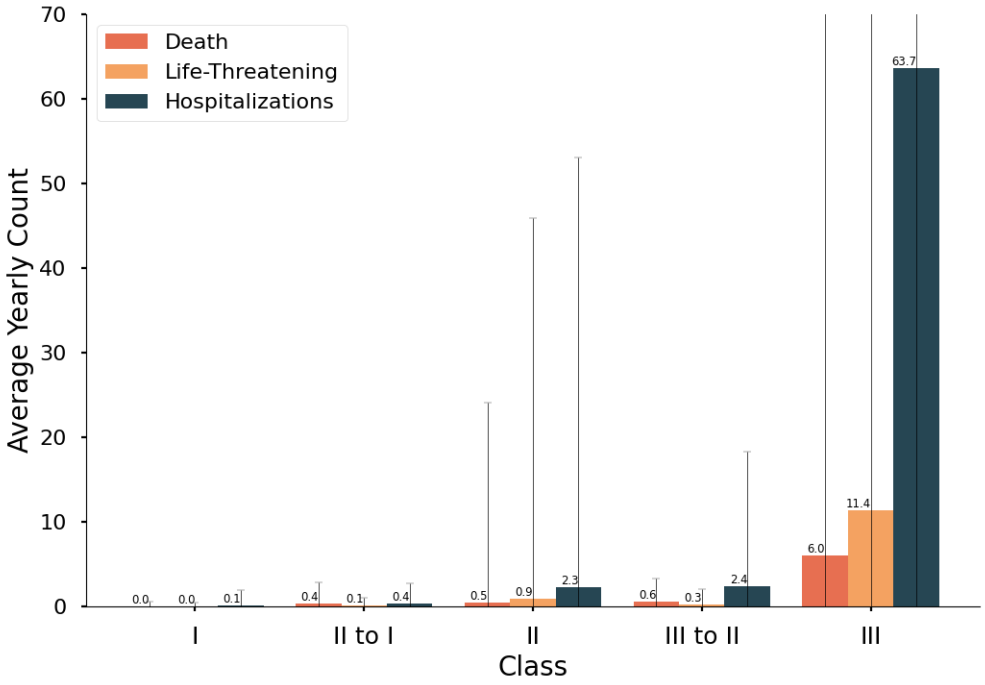
Note: This figure presents a catalog of the various data sources used in this study. The three broad outcomes are represented by the three colored boxes: blue innovation, orange market structure, and red product safety. Each broad outcome contains various specific outcomes measured, in most cases, by two different data sources. Buttons on the exterior represent data sources. The blue arrows connect the data sources to outcome measures. The cogs indicate when algorithms were used to process the data into an outcome measure. The green "Text Analysis" cog represents the word2vec algorithm used to extract safety-related keywords from patent claims data.

Appendix Figure G.3: Petitioned Down-Regulation Events (Not FDA-Initated)



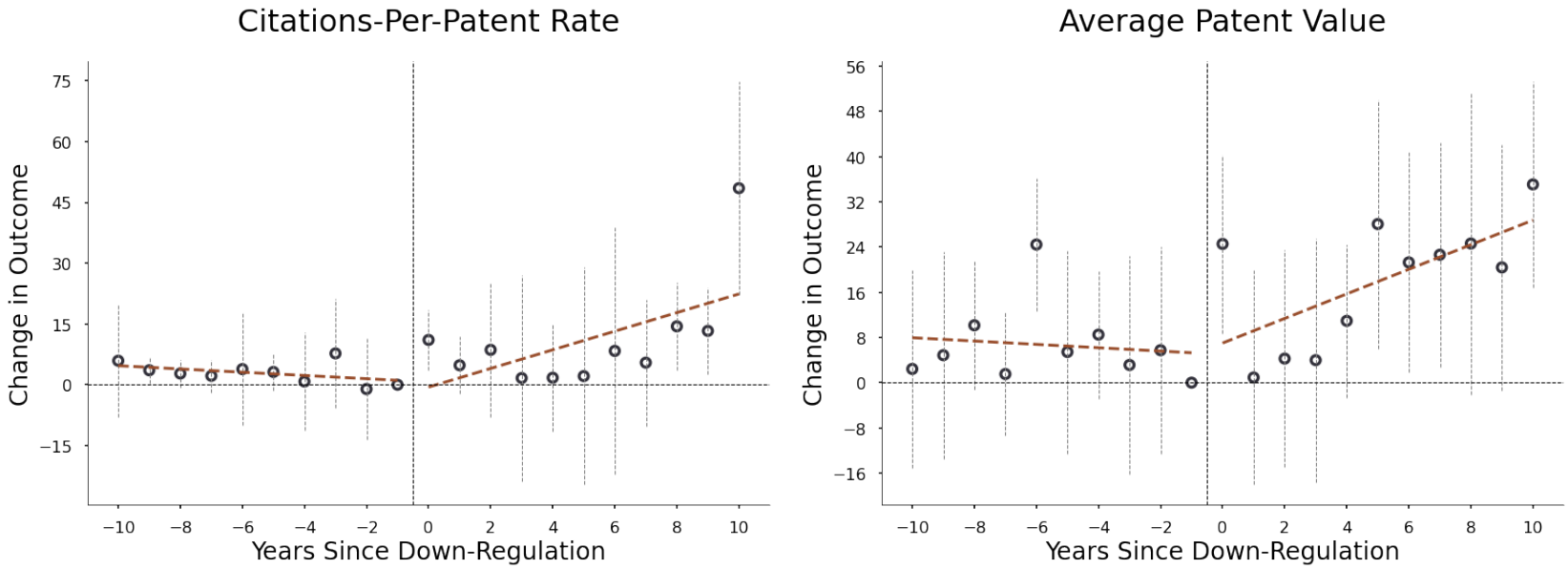
Note: This figure presents the estimates of the β_k coefficients from event-study equation 4 for the patent filing rate measure and illustrates the potential biases that stem from industry petition of down-classification. Outcome data are derived from USPTO patent data. Only Class III to II down-classification 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 G.4: Mean Yearly Adverse Event Counts by Device Type Class



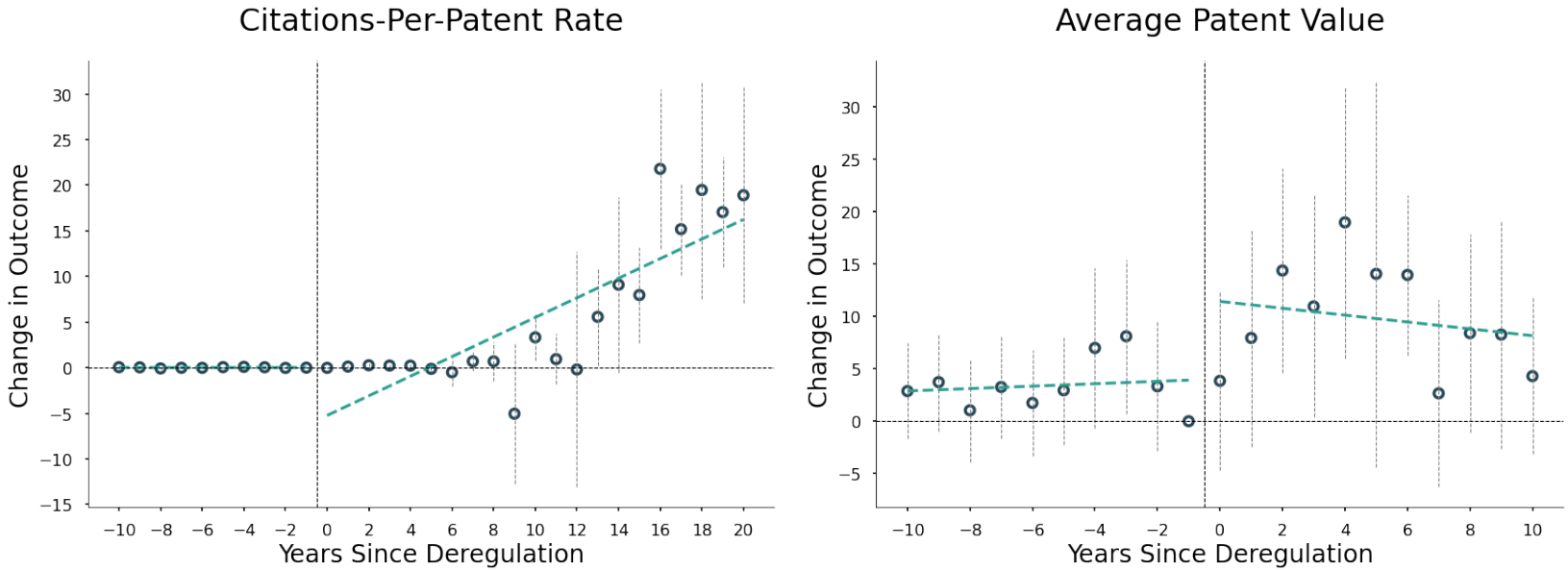
Note: This figure presents the annualized average counts of the specified adverse events for medical device types within the respective classification. The x-axis indicates the device type Class. The x-axis includes down-classified devices from Class III to II and Class II to I events separately. The 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 G.5: Innovation Quality Event Study Class III to II



Note: This figure presents the estimates of the β_k coefficients from the event-study equation 4 for the innovation quality 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 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 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. Patent values are deflated to 2019 (million) dollars using the CPI. Standard errors are calculated following Conley and Taber (2011).

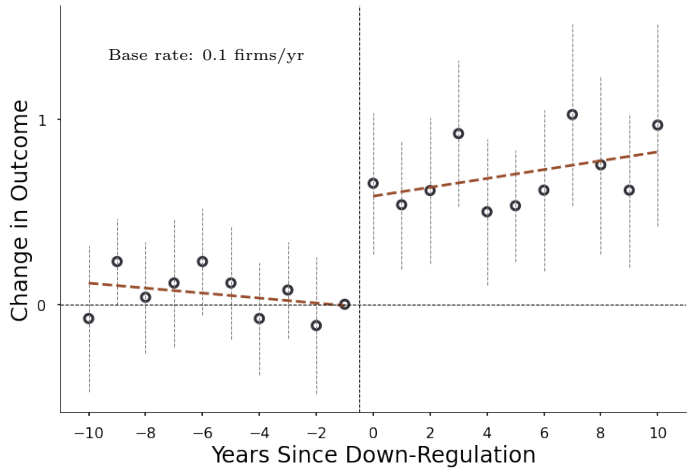
Appendix Figure G.6: Innovation Quality Event Study Class II to I



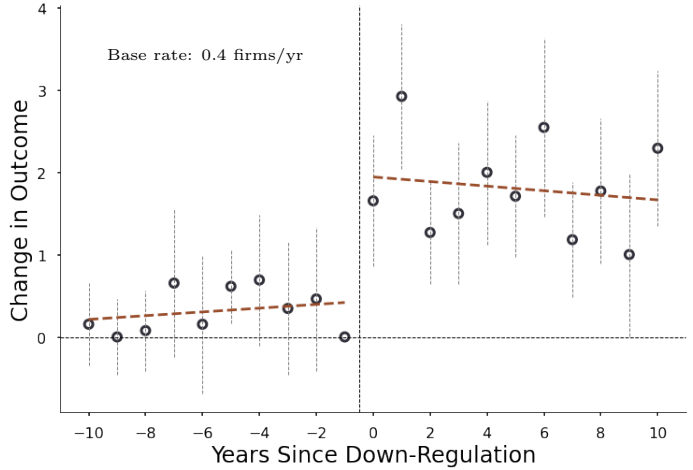
Note: This figure presents the estimates of the β_k coefficients from event-study equation 4 for my innovation quality measures. Only Class II to I down-classification events are considered. Controls are device types matched on baseline averages of the outcome. The coefficient β_{-1} is omitted and serves as the reference period. Data are analyzed at an annual frequency. The 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 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. Patent values are deflated to 2019 (million) dollars using the CPI.

Appendix Figure G.7: Down-Classification and Market Structure (Incumbent Entry and Other Measures)

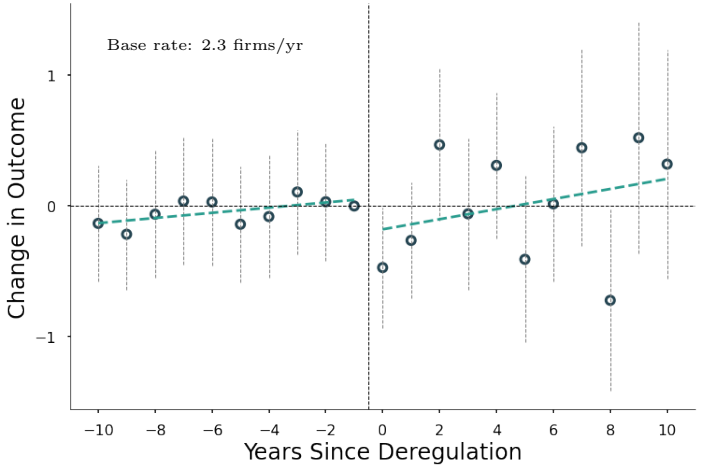
(a) New Entry (Device Data), Down-Regulation (III to II)



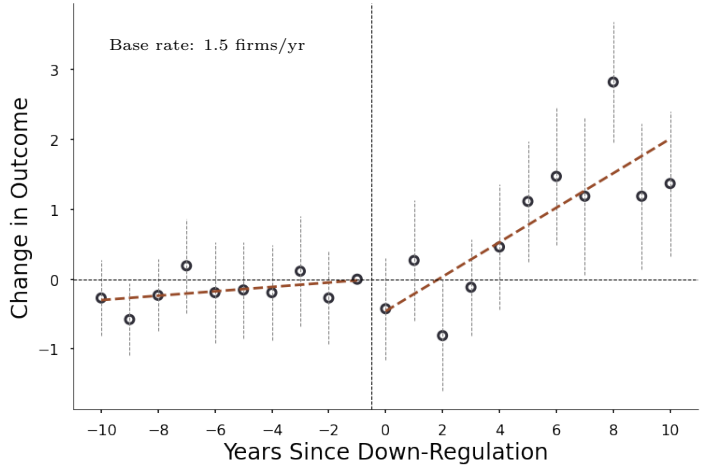
(b) Incumbent Entry (Device), Down-Regulation



(c) Incumbent Entry (Patents), Deregulation (II to I)

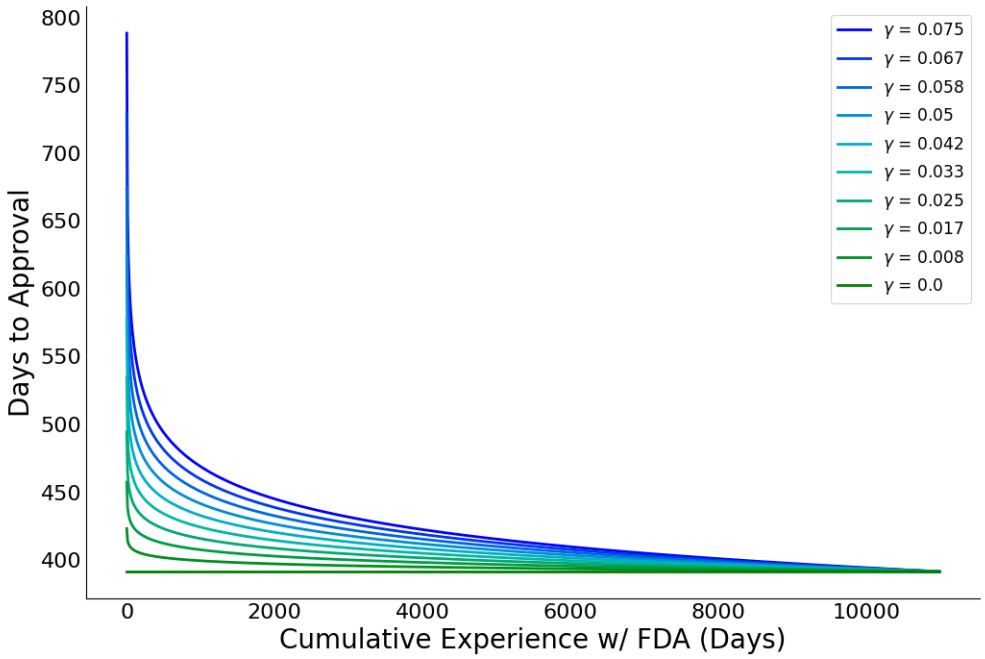


(d) Incumbent Entry (Patents), Down-Regulation



Note: The figure displays the estimates of the β_k coefficients from the event-study equation (see Eq. 4) for incumbent entry and new entry using patent or FDA device submission data. Control groups comprise device types matched on pre-event outcome averages. The β_{-1} coefficient is the reference and thus excluded. Analyses utilize annual data. Panel (a) traces new entry among down-regulated devices, measured using FDA device submission data, against matched controls. Panel (b) does the same for incumbent entry. Panel (d) does the same as Panel (b) but uses patent data. Panel (c) plots changes in incumbent entry among deregulated device types, measured using patent data. Confidence intervals are set at 95%.

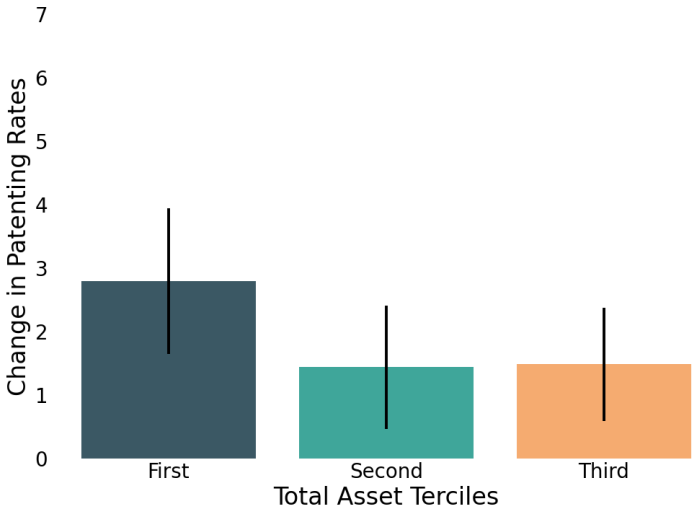
Appendix Figure G.8: Flattening the Learning Curve Simulation



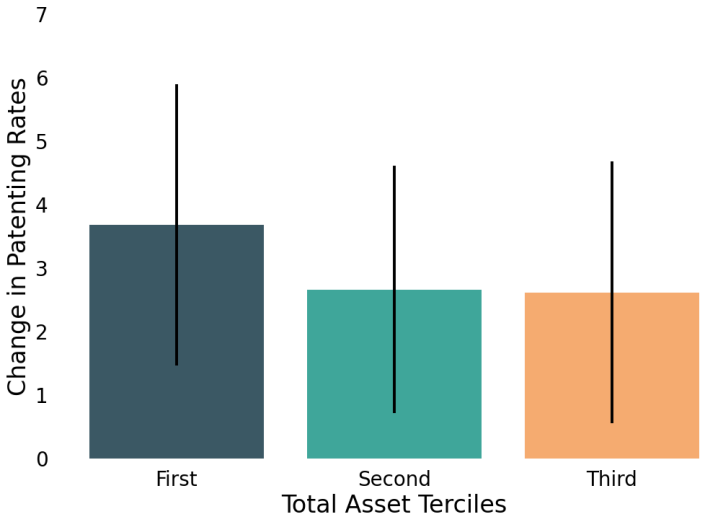
Note: This figure presents the simulation exercise of flattening the Class III learning curve estimated in equation F.1. I flatten the learning curve relative to the most experienced firm. The results of this simulation are provided in Table G.12. Above, γ begins at its initial starting point estimated in equation F.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 G.9: Effect of Down-Classification on Patenting Rates by Asset Terciles

Panel (a): Class III to II

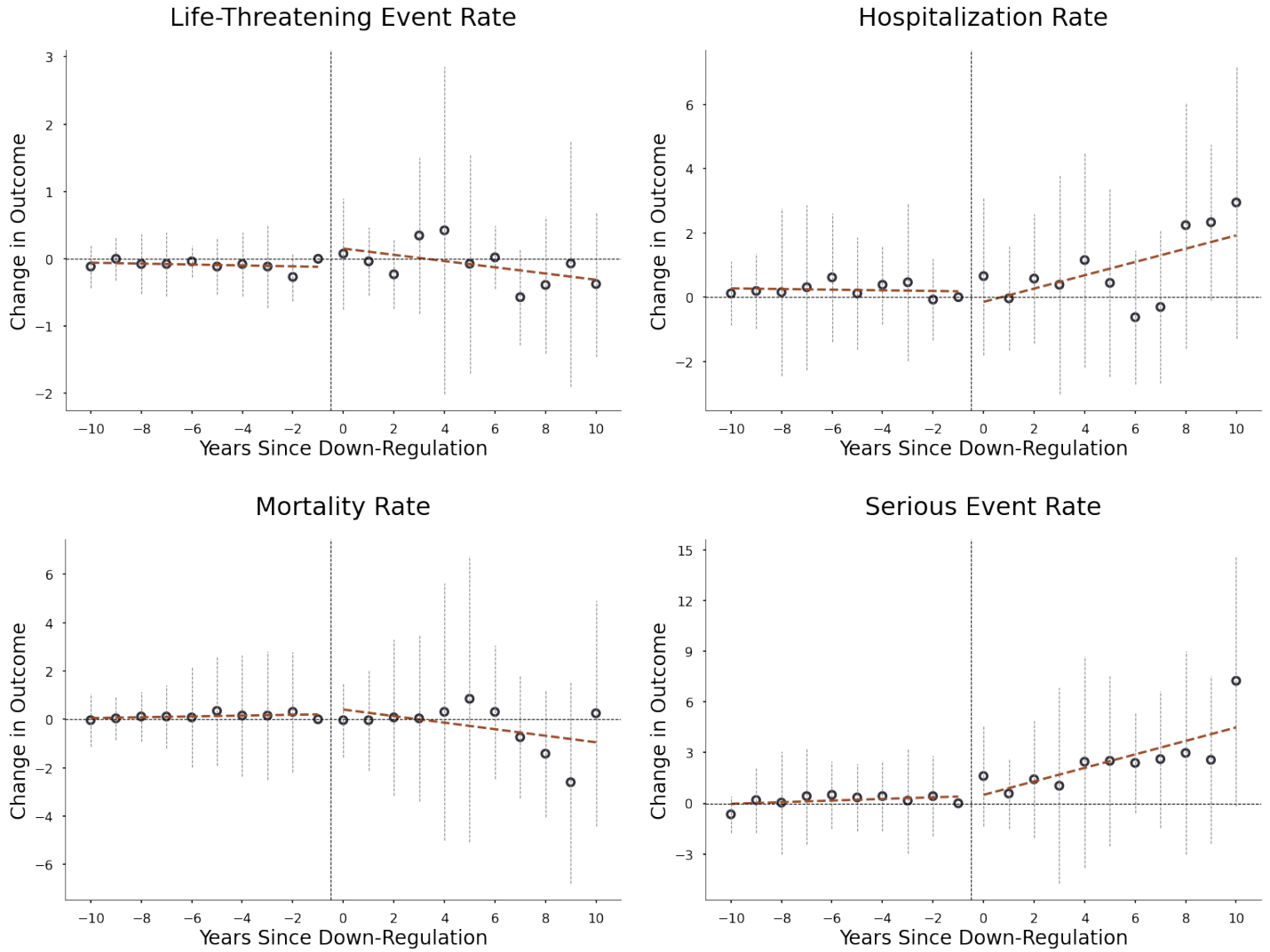


Panel (b): Class II to I



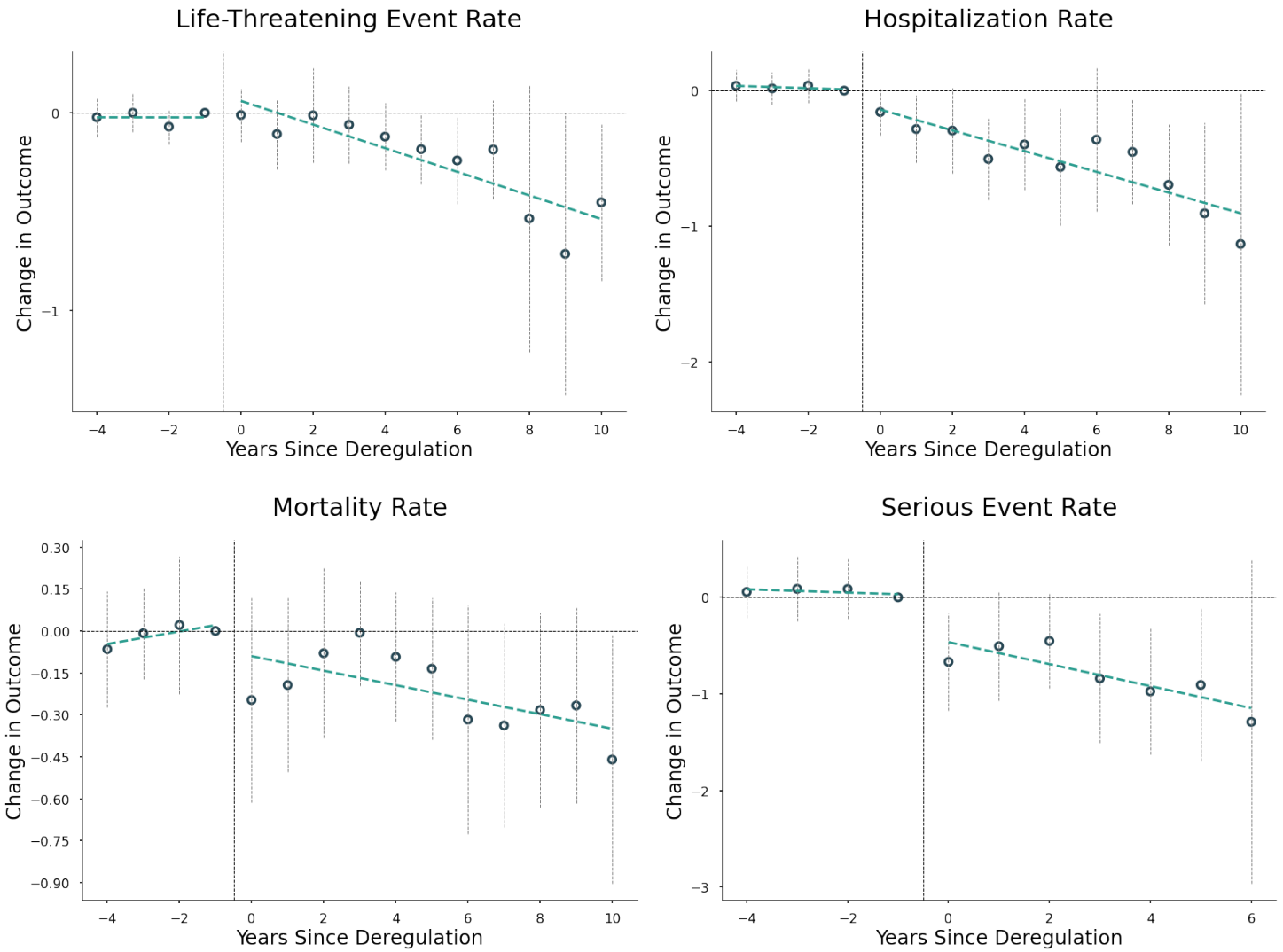
Note: This figure presents the DID estimates from equation 3 for the patenting rate across down-classification types and firm asset terciles. For the empirical estimates, I exclude patent data for private firms since I only observe firm asset data for publicly traded firms. Panel A presents the change 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 33rd–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. 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.

Appendix Figure G.10: Adverse Event Event Study Class III to II



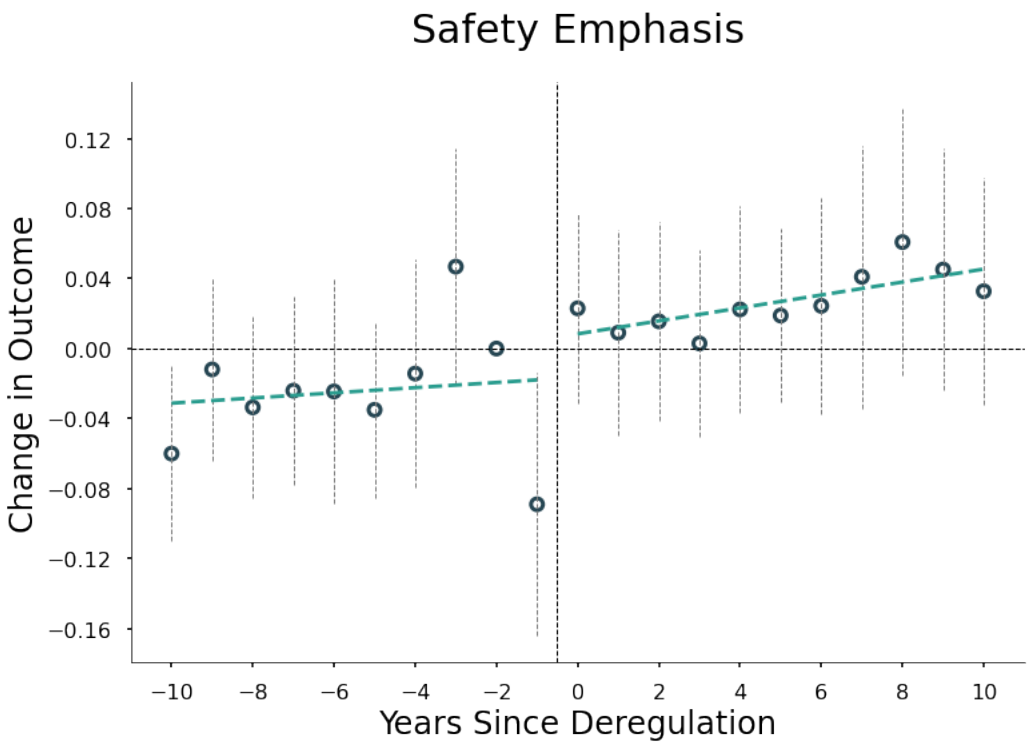
Note: This figure presents the estimates of the β_k coefficients from event-study equation 4 for my adverse event measures. Only Class III to II down-classification events are considered. Data are analyzed at an annual frequency. Controls are device types matched on baseline outcome averages. The coefficient 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 G.11: Adverse Event Event Study Class II to I



Note: This figure presents the estimates of the β_k coefficients from event-study equation 4 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.

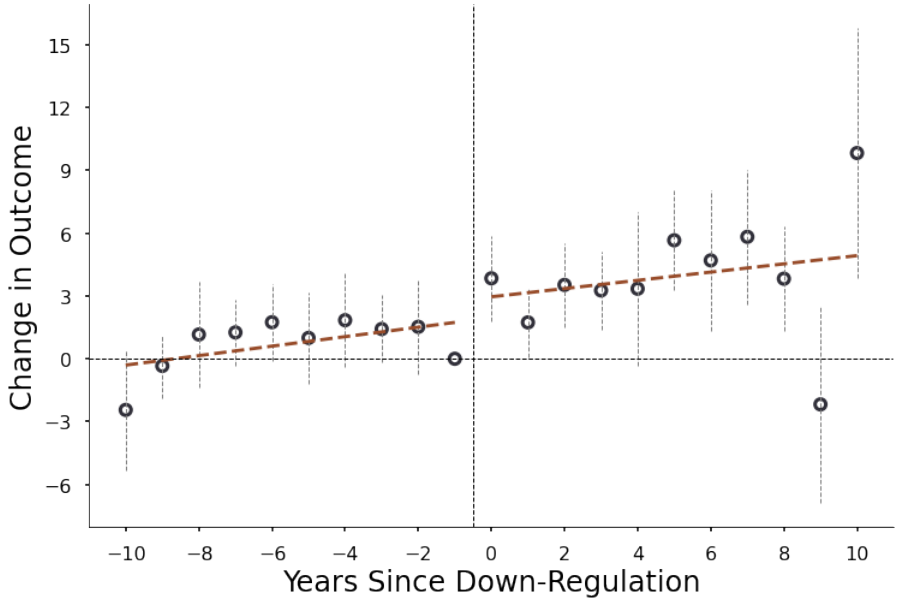
Appendix Figure G.12: Safety Emphasis Event Study Class II to I



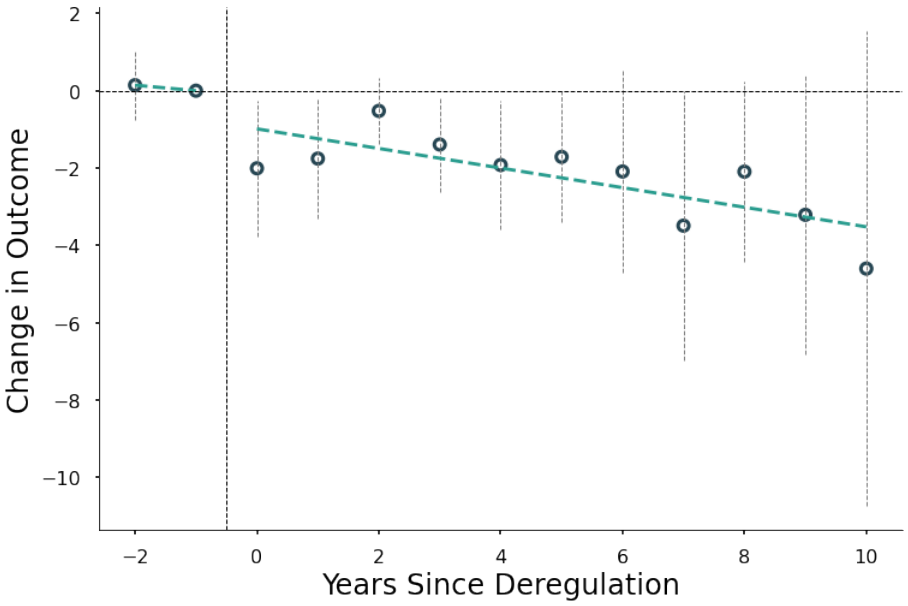
Note: This figure presents the estimates of the β_k coefficients from event-study equation 4 for inventors' emphases on safety. Only Class II to I down-classification events are estimated. Data are analyzed at an annual frequency. Controls are device types matched on baseline outcome averages. The coefficient 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 G.13: Down-Classification and Product Safety — Normalizable Device Types

(a) Down-Regulation, Serious Events

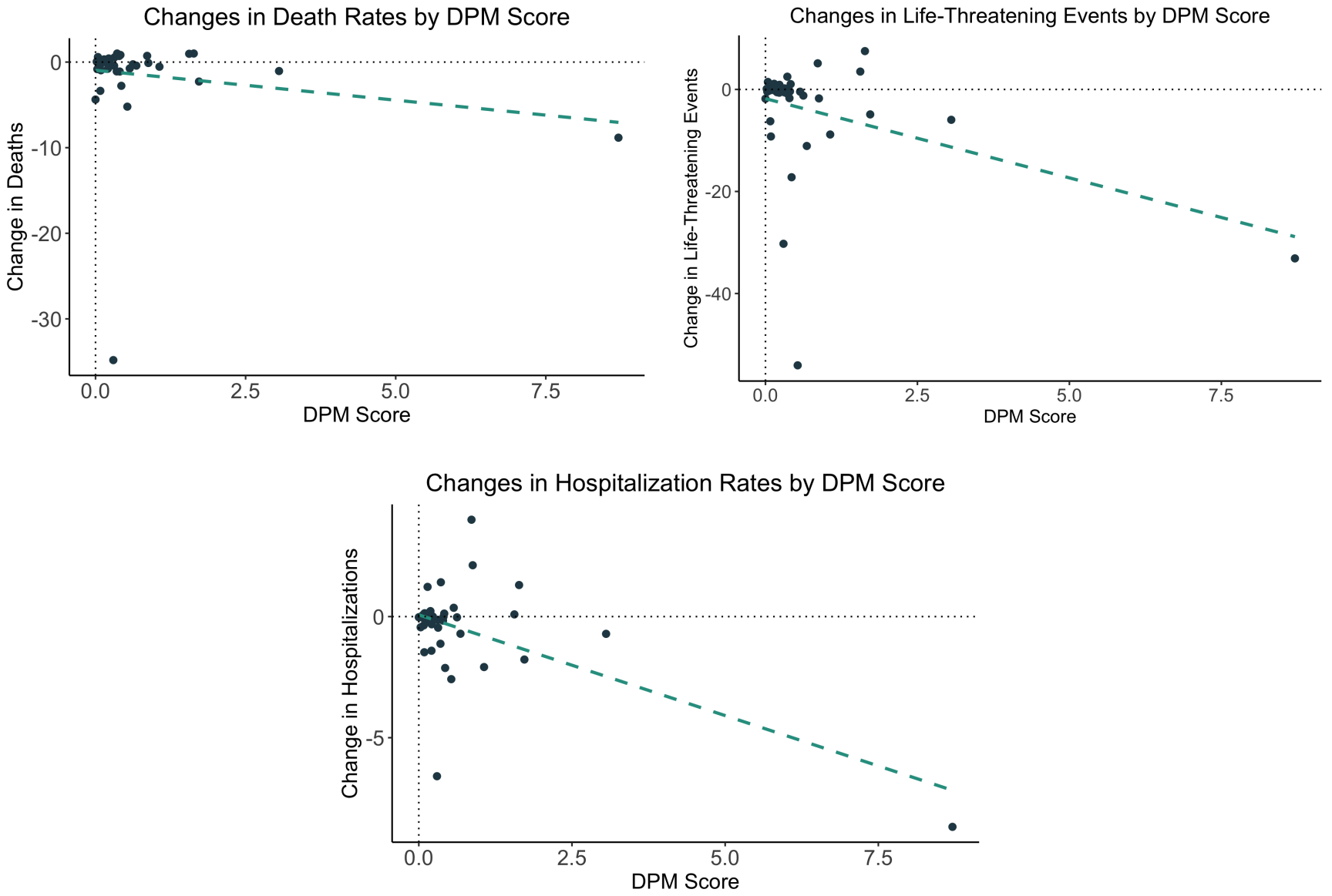


(b) Deregulation, Serious Events



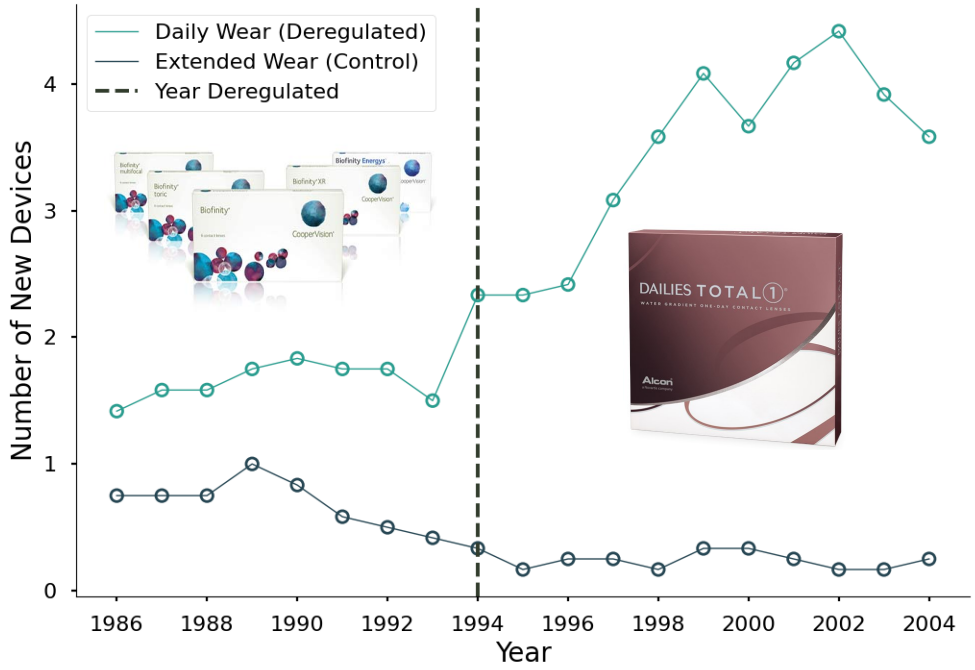
Note: This figure presents the estimates of the β_k coefficients from event-study equation 4 for my serious adverse event measures. Device types included in this analysis are only those associated with medical procedures in the Marketscan claims data. Data are analyzed at an annual frequency. Controls are device types matched on baseline outcome averages. The coefficient β_{-1} is omitted and serves as the reference period. Panel(a) describes the evolution of the serious event reports surrounding down-regulations relative to control groups. Panel (b) describes the same for deregulation events. Adverse events are derived from the FDA MAUDE database. Conley–Taber 95% confidence intervals are provided.

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



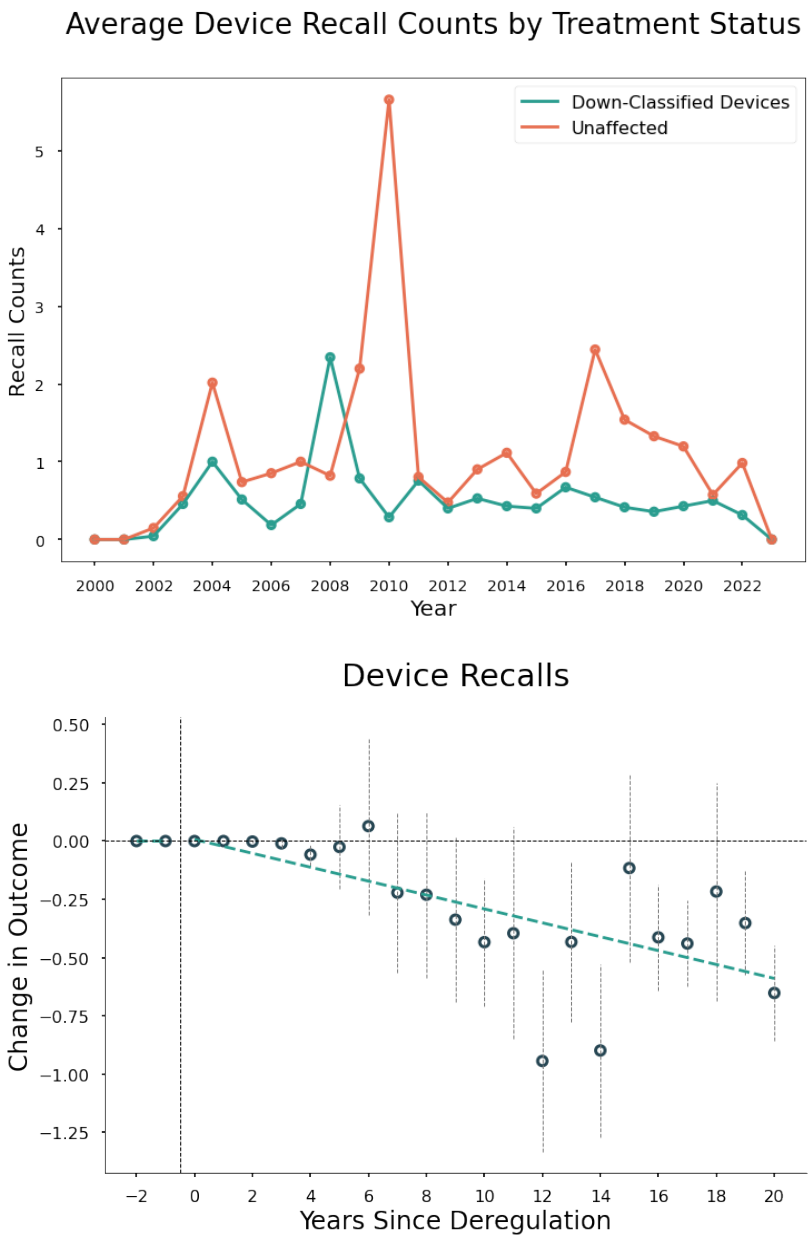
Note: This figure presents separate DID estimates of equation 3 for each adverse event measure and each treated device type with a given proxy DPM score relative to matched controls. The DPM score is primarily an increasing function of the baseline average annual incidence of adverse events before deregulation (see Appendix A.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 Figure G.15: Contact Lens Use Case—III to II Down-Classification



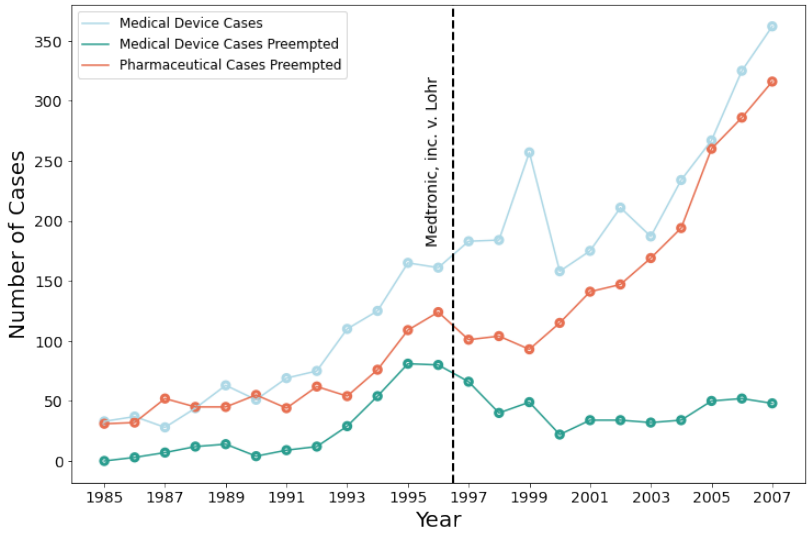
Note: This figure presents an example of a Class III to II down-classification event. In 1994, the FDA down-classified daily-wear soft contact lenses to Class II but kept extended-wear soft contact lenses in Class III. The x-axis measures the year, and the y-axis measures the number of unique contact lens devices submitted to the FDA for approval in a given year. The green line represents daily-wear contact lenses submitted for approval (deregulated), and the blue line represents extended-wear soft contact lenses submitted for approval (remained in Class III). The vertical black line represents the year of reclassification. The left-imposed picture shows an example of a soft contact lens invented before reclassification. The right-imposed picture shows an example of a soft contact lens invented after reclassification.

Appendix Figure G.16: Device Recall Analysis—Class II to I



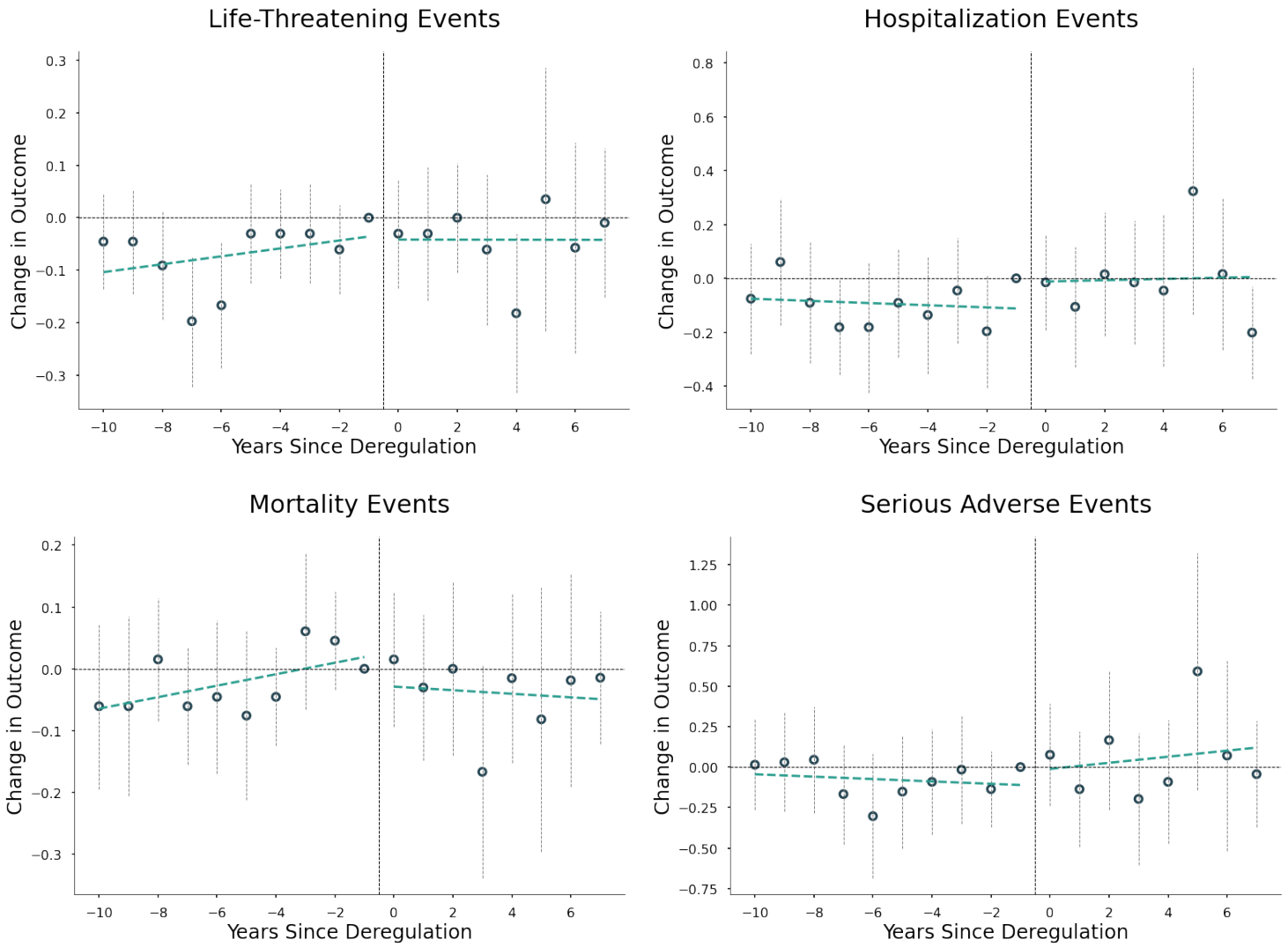
Note: This figure illustrates the device recall analysis for the Class II to I events. The top subfigure displays the average device recall counts by treatment status from 2000 to 2023. The bottom subfigure shows the event-study estimates of the change in device recalls over time. Recall counts for event times $-2 \leq t \leq 3$ are constant at zero due to the missing recall data for those specific years.

Appendix Figure G.17: Evolution of Medical Device Legal Environment



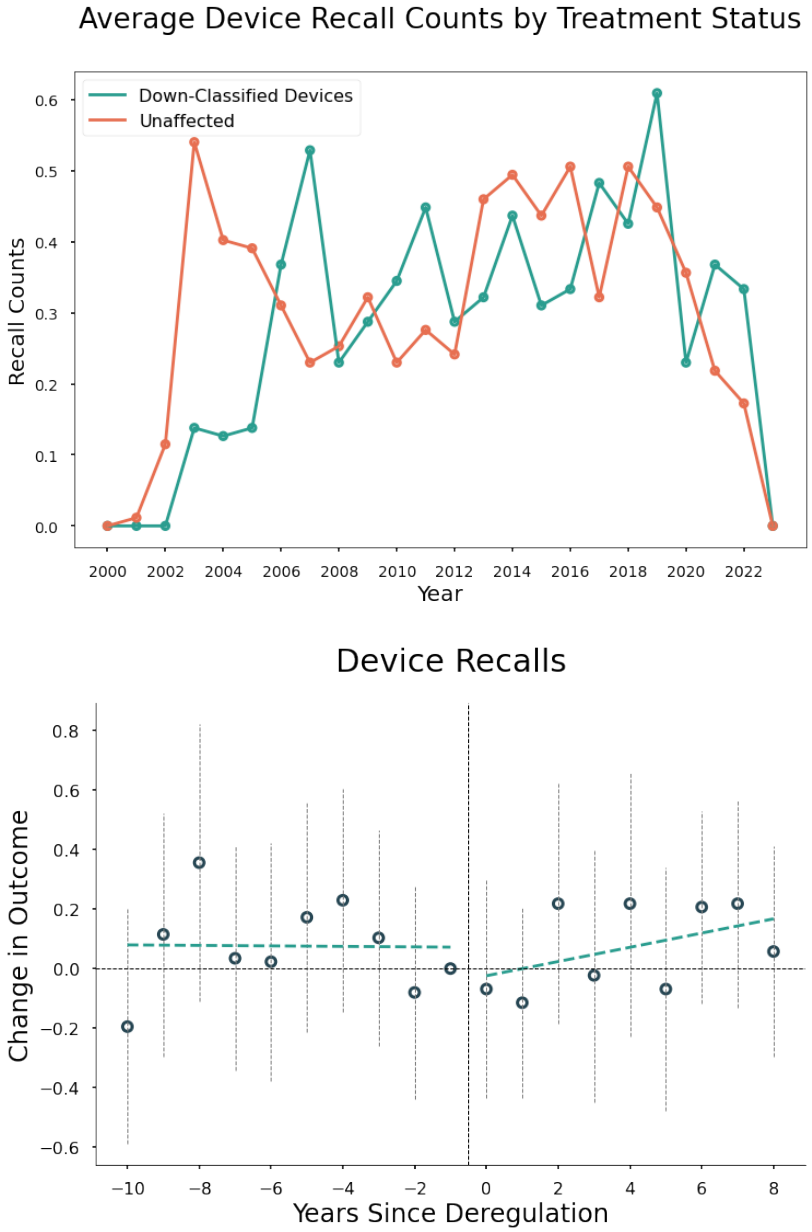
Note: The chart depicts yearly counts of medical device tort claims and highlights those referencing "preemption." It also includes counts for pharmaceutical tort cases mentioning "preemption." Data is sourced from Nexis Uni and is based on searches for "Medical device tort," "medical device tort preempt," and "pharmaceutical tort preempt." The vertical dotted line marks 1996, the year of the Supreme Court's Medtronic, Inc. v. Lohr decision, which significantly impacted the regulatory environment by withdrawing legal protections for Class II devices.

Appendix Figure G.18: Adverse Event Event Study—Class II to I, 2015



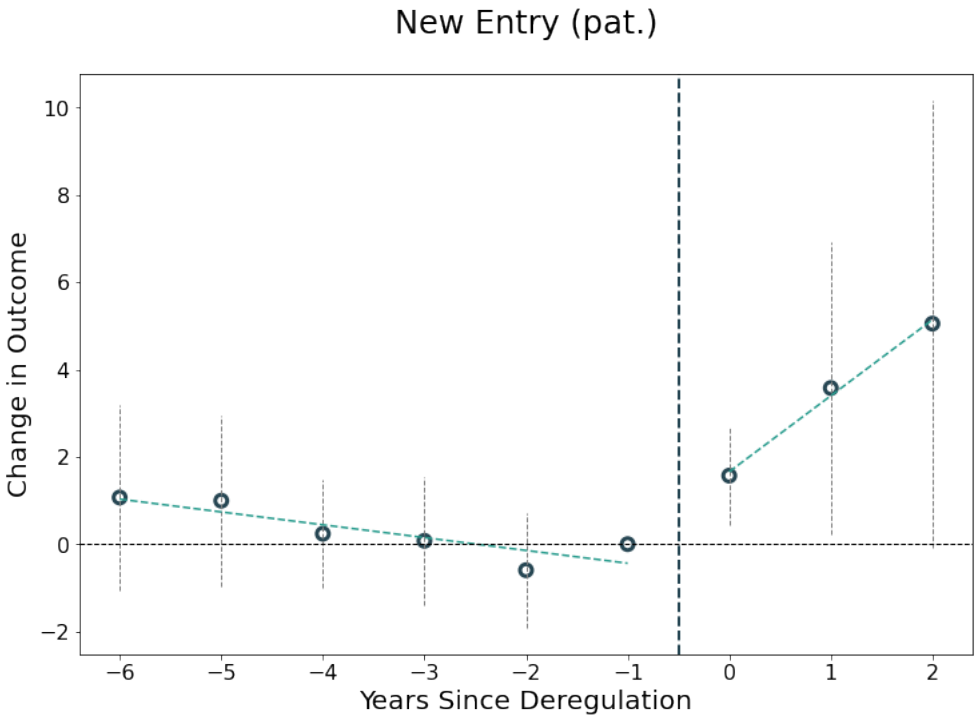
Note: This figure presents the estimates of the β_k coefficients from event-study equation 4 for my adverse event measures before and after the 2015 event. The 2015 event significantly reduced the costs of commercializing new technologies but had no impact on legal liability risk, which is the mechanism I propose for driving product safety improvements after deregulation. Data are analyzed annually, and controls consist of device types matched based on baseline outcome averages. The coefficient β_{-1} serves as a reference period and is omitted. The subfigures provide information on changes in the rate of life-threatening events, hospitalizations, mortality, and the sum of all serious adverse events (life-threatening, death, hospitalizations, and disability) for treated device types compared to matched control groups. Adverse events are derived from the FDA MAUDE database, and 95% confidence intervals are provided.

Appendix Figure G.19: Device Recall Analysis—Class II to I, 2015



Note: This figure illustrates the device recall analysis for the 2015 Class II to I event. The top subfigure displays the average device recall counts by treatment status from 2000 to 2023. The bottom subfigure shows the event-study estimates of the change in device recalls over time. 95% confidence intervals are provided.

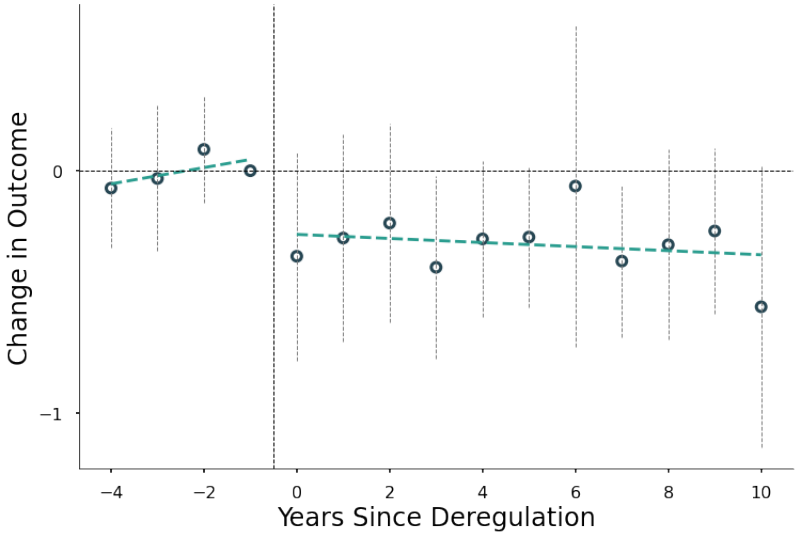
Appendix Figure G.20: Effects of 2015 Class II to I Event on New Entry



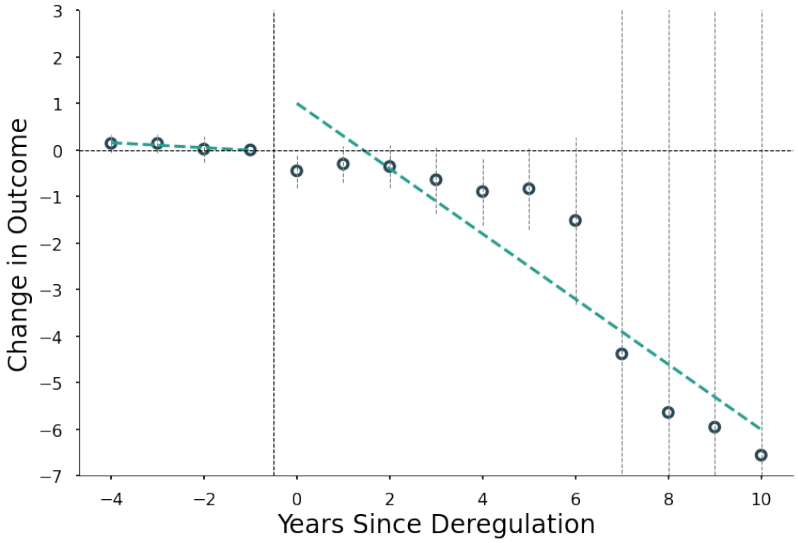
Note: This figure presents the estimates of the β_k coefficients from event-study. Controls are device types matched on baseline average innovation rates. The coefficient β_{-1} is omitted and serves as the reference period. Data are analyzed at an annual frequency. The entry rate is measured by the yearly number of new firms patenting in a given device type. Patent data comes from the USPTO patent database. 95% confidence intervals are provided.

Appendix Figure G.21: Serious Adverse Event Changes by Reporter Type—Class II to I

(a) Serious Adverse Events, Excluding Manufacturers

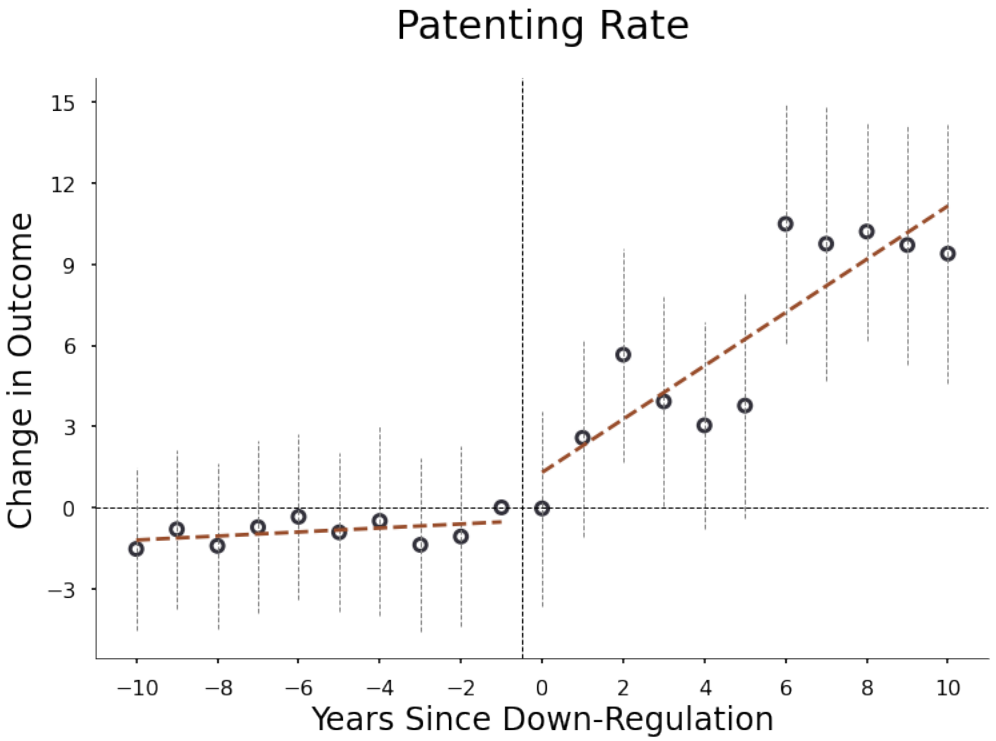


(b) Serious Adverse Events, Manufacturers



Note: The figure displays the estimates of the β_k coefficients from the event-study equation (see Eq. 4) for serious adverse events, encompassing life-threatening incidents, mortality, hospitalizations, and disability, differentiated by the source of the adverse event report. Results are presented separately for manufacturer reports and reports from all other sources. Control groups consist of device types matched on pre-event outcome averages. The β_{-1} coefficient is the reference and thus excluded. Analyses utilize annual data. Panel (a) traces serious adverse events for down-regulated devices against matched controls based on reports from non-manufacturer sources. Panel (b) offers a parallel analysis but exclusively considers serious adverse event reports originating from manufacturers. Confidence intervals are set at 95%.

Appendix Figure G.22: Effects of Class III to II Events on Patenting Rates: Restricted Patent Sample



Note: This figure presents the estimates of the β_k coefficients from event-study equation 4 for patenting rates using the restricted patent sample described in Appendix E. Compare to Figure 2, Panel (a). Controls are device types matched on baseline average innovation rates. The coefficient β_{-1} is omitted and serves as the reference period. Data are analyzed at an annual frequency. The patenting rate is measured by the yearly number of patents filed in a given device type. Patent data comes from the USPTO patent database. Conley–Taber 95% confidence intervals are provided.

Appendix Table G.1: Keywords Used in Text Analysis of Patent Claims

Safety Advancement Keywords	
safety	hazard
safe	danger
safer	dangerous
endangering	harming
precautions	injuring
unsafe	injury
hazardous	jeopardizing
failsafe	risk
safely	complication
dangerous	jeopardizing

Note: The table presents the keywords related to product safety that were extracted using the Word2Vec algorithm. I label a patent as advancing safety if any of the above words are included in its claims section. Importantly, patent examiners heavily scrutinize the patent claims text for accuracy as the text codifies the right to singular ownership of the claimed advancement. Interestingly, some keywords indicate safety advancements in what the product is not: some inventors claim advancements in product safety by moving away from constructions that are "hazardous," "unsafe," or "dangerous." It is important to note that inventors would not reasonably claim a product advancement that would lead to more injuries. Thus, one can assume that these negative mentions can still be attributable to safety improvements.

Appendix Table G.2: 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*	29.12***	29.95**	22.12*
	(9.27)	(9.96)	(8.79)	(10.34)	(8.85)
Device Approval Rate	0.47	2.11***	1.91***	1.75***	1.77***
	(1.03)	(0.33)	(0.29)	(0.33)	(0.28)
Citations-Per-Patent Rate	9.06	17.60*	23.13*	19.18***	27.48***
	(20.65)	(7.62)	(9.00)	(4.79)	(7.16)
Average Patent Value	11.19	24.07***	32.35***	32.25***	30.38***
	(15.73)	(4.24)	(3.78)	(4.27)	(3.69)
Sample Size		1540	1056	920	60456
B. Class II to I:					
Patenting Rate	19.12	8.15	7.71	14.15**	31.04**
	(39.50)	(13.01)	(6.67)	(5.17)	(10.47)
Citations-Per-Patent Rate	0.75	6.84**	2.07+	4.01***	6.03***
	(0.43)	(2.09)	(1.17)	(0.94)	(1.42)
Average Patent Value	19.04	8.90***	2.24+	5.16***	12.87***
	(38.75)	(2.43)	(1.31)	(1.14)	(1.82)
Sample Size		15180	20592	27764	32472

Note: The table presents estimates of equation 3, 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 G.3: Market Structure (Borusyak et al. (2021) estimator)

		DID Estimates				
Down-Classification	Pre-mean (1)	All CPTs (2)	Matched (3)	Intuitive (4)	Later (5)	Full (6)
A. Class III to II:						
Procedure Price	518.26†	-0.05	0.02	-	-	0.09
	(839.25)	(0.14)	(0.1)	-	-	(0.06)
Sample Size		612	612	-	-	52200
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:						
Procedure Price	339.75†	-0.21*	-0.14+	-	-	-0.08
	(806.84)	(0.1)	(0.08)	-	-	(0.06)
Sample Size		1620	1620	-	-	52704
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 uses a DiD style OLS regression model (equation 3). In this analysis, I drop all device types that do not exhibit any positive quantity of the given outcome. Column (1) shows the 5-year pre-event mean for the treated device types, while Columns (2)–(6) provide DID estimates using various control groups: (2) matches baseline prices to controls among all procedure codes, (3) matches outcomes to medical device controls, (4) uses an intuitively similar group, (5) includes a later-treated group, and (6) employs the full control sample. Price data is available only from 1996–2013, limiting the sample size. Due to data constraints, Columns (4)–(6) do not include price estimates. † Pre-mean prices are reported in non-logarithmic form, while estimates are logged. Confidence intervals are based on Conley–Taber test statistics. Symbols +, *, **, and *** denote statistical significance at the 0.10, 0.05, 0.01, and 0.001 levels, respectively.

Appendix Table G.4: 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 3, 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 G.5: 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 3, 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 (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 G.6: 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 G.7: 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—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 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—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	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 G.8: 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 G.9: 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)	(5.66)	(10.01)	(10.95)	(24.03)
Device Approval Rate	0.47	2.69***	2.36**	2.27**	2.22***
	(1.03)	(0.59)	(0.77)	(0.74)	(0.35)
Citations-Per-Patent Rate	9.06	16.87*	-5.61	15.91*	20.13**
	(20.65)	(7.77)	(14.05)	(6.32)	(7.13)
Average Patent Value	11.19	22.00***	25.38**	26.84**	20.91***
	(15.73)	(4.29)	(8.95)	(8.67)	(6.00)
Sample Size		1452	660	680	21340
B. Class II to I:					
Patenting Rate	19.12	7.34	13.72	25.22**	29.17***
	(39.50)	(4.66)	(12.61)	(9.60)	(7.29)
Citations-Per-Patent Rate	0.75	6.85**	12.94*	7.52***	6.00***
	(0.43)	(2.28)	(6.39)	(1.52)	(1.39)
Average Patent Value	19.04	9.20***	5.31*	11.18***	11.48***
	(38.75)	(1.85)	(2.45)	(2.77)	(1.93)
Sample Size		14740	9328	9768	25784

Note: The table presents estimates of equation 3, 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 G.10: Market Structure Estimates (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	518.26†	0.09	0.22*	-	-	0.2
	(839.25)	(0.11)	(0.09)	-	-	(0.17)
Sample Size		612	612	-	-	52200
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:						
Procedure Price	339.75†	-0.22**	-0.142*	-	-	-0.08
	(806.84)	(0.08)	(0.06)	-	-	(0.08)
Sample Size		1620	1620	-	-	52704
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 3, 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 G.11: 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 3, 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 G.12: 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 F.2, which simulates the effect of flattening the learning curve on the rate of unique devices approved at an annual frequency by asset quartiles. Figure G.8 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 F.1. Subsequent rows in the table show the percent change in the rate of unique device submissions 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 submissions.

Appendix Table G.13: 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 G.14: Summary Statistics – Class I

	N	Mean	SD	Range
FDA Admin. Data—Device Submissions (PMA and 510(k) Databases)				
Total	30,797	-	-	-
per Device Type	1,560 (Types)	19.7	78.1	[1, 1,927]
Total Submitting Firms	5,253	-	-	-
Firms per Device Type	1,560 (Types)	11.3	36.7	[1, 1,048]
Firm Regulatory Proficiency	1,554 (Types)	6.1yrs	18.2yrs	[0, 603.7yrs]*
FDA Admin. Data—Adverse Event Reports (MAUDE)				
Total	475,782	-	-	-
per Device Type	1,264 (Types)	376.4	2550.8	[1, 52,526]
Serious Events per Dev. type	612 (Types)	25.6	107.3	[1.0, 1,547]
Assets of Offending Firm	271,715	$3.2B	$12.7B	[0, $0.7T]
USPTO Device Patents				
Total	671,665	-	-	-
per Device Type	961 (Types)	698.9	2453.4	[1, 23,056]
Citations	671,665	10.6	56.4	[1, 5,067]
Market Valuation	201,638	$12.5M	$30M	[$40, $1.7B]
Applicant Assets	192,619	$26.1B	$53.5B	[$0.07M, $0.79T]

Note: This table presents summary statistics only for Class I devices. 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. *"Regulatory proficiency" indicates the total number of days a firm has experienced approval delays across all its submitted devices.

Appendix Table G.15: Summary Statistics – Class II

	N	Mean	SD	Range
FDA Admin. Data—Device Submissions (PMA and 510(k) Databases)				
Total	118,820	-	-	-
per Device Type	2,496 (Types)	47.6	131.2	[1, 2,457]
Total Submitting Firms	13,657	-	-	-
Firms per Device Type	2496 (Types)	20.7	44.2	[1, 747]
Firm Regulatory Proficiency	2,466 (Types)	11.9yrs	38.3yrs	[0, 669.3 yrs]*
FDA Admin. Data—Adverse Event Reports (MAUDE)				
Total	4,510,435	-	-	-
per Device Type	1,975 (Types)	2,283.8	162,560	[1, 0.41M]
Serious Events per Dev. type	1,238 (Types)	344.3	2,402	[1, 46,502]
Assets of Offending Firm	2,818,635	\$3.3B	\$6.3B	[\$0, \$0.7T]
USPTO Device Patents				
Total	567,204	-	-	-
per Device Type	1,100 (Types)	515.6	1,732.6	[1, 17,559]
Citations	567,213	19.2	115.8	[1, 5817]
Market Valuation	173,194	\$13.8M	\$31.5M	[0, \$1.9B]
Applicant Assets	164,686	\$27.5B	\$56.6B	[\$0.2M, \$0.7T]

This table presents summary statistics only for Class II devices. 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. *"Regulatory proficiency" indicates the total number of days a firm has experienced approval delays across all its submitted devices.

Appendix Table G.16: Summary Statistics – Class III

	N	Mean	SD	Range
FDA Admin. Data—Device Submissions (PMA and 510(k) Databases)				
Total	3,395	-	-	-
per Device Type	59 (Types)	57.5	148.1	[1, 795]
Total Submitting Firms	109	-	-	-
Firms per Device Type	59 (Types)	7.3	12.3	[1, 57]
Firm Regulatory Proficiency	3,184 (Types)	49.8yrs	74.7yrs	[0, 667.4yrs]*
FDA Admin. Data—Adverse Event Reports (MAUDE)				
Total	976,693	-	-	-
per Device Type	101 (Types)	9,670.2	32,432.6	[1, 0.2M]
Serious Events per Dev. type	78 (Types)	2,871	13,442.2	[1, 0.1M]
Assets of Offending Firm	786,010	$4.6B	$6.2B	[$0.6M, $0.7T]
USPTO Device Patents				
Total	9,423	-	-	-
per Device Type	52 (Types)	181.2	453.7	[1, 2536]
Citations	9,424	21.6	97.7	[1, 4265]
Market Valuation	2,633	$16.7M	$30.5M	[$0, $440M]
Applicant Assets	2,500	$15.5B	$33.6B	[$1.1M , $0.9T]

This table presents summary statistics only for Class III devices. 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. *"Regulatory proficiency" indicates the total number of days a firm has experienced approval delays across all its submitted devices.

Appendix Table G.17: Effect of Down-Classifications on Innovation: Restricted Patent Sample

		DID Estimates			
Down-Classification	Pre-mean (1)	Matched (2)	Intuitive (3)	Later (4)	Full (5)
A. Class III to II:					
Patenting Rate	4.6	10.8**	15.81**	15.79*	14.07*
	(6.18)	(3.3)	(5.9)	(6.88)	(6.68)
Sample Size		1628	1056	920	60456
B. Class II to I:					
Patenting Rate	3.99	4.8*	1.91	3.01*	6.97**
	(13.74)	(2.26)	(1.61)	(1.48)	(2.5)
Sample Size		12540	20592	27764	32472

Note: The table presents estimates of equation 3, which is a difference-in-differences (DID) style OLS regression model. This table differs from Table 2 in that it presents estimates from an estimation that uses a restricted patent sample described in Appendix E, and only presents the patenting rate outcome. Simply put, patents in this analysis include only those labeled as health-related and non-drug by patent examiners. Patents are derived from the USPTO patent database. 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 G.18: Estimation of Learning Curve Parameters (in Days)

	Class III Coeff./SE	Class II Coeff./SE
γ	0.075*	0.032***
	(0.033)	(0.004)
$log(\beta(R_c))$	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 F.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.