Regulating the Innovators:

Approval Costs and Innovation in Medical Technologies

Parker Rogers*

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Abstract

How does FDA regulation affect innovation and market concentration? I examine this question by exploiting FDA deregulation events that affected certain medical device types but not others. I collect comprehensive data on medical device innovation, device safety, firm entry, prices, and regulatory changes and enhance these data using text analysis methods. My analysis of these data reveals three key findings. First, deregulation events significantly increased the quantity and quality of new technologies in affected medical device types relative to controls. These increases are particularly strong among small and inexperienced firms. Second, these events increased firm entry and reduced prices for medical procedures that utilize affected medical device types. Finally, rates of serious injuries and deaths attributable to defective devices did not significantly increase following these events. Interestingly, deregulating certain device types was associated with reduced adverse event rates, possibly due to firms increasing their emphasis on product safety in response to increased litigation risk.

*University of California at San Diego, Economics Department, 9500 Gilman Drive #0508, La Jolla, CA 92093-0508. E-mail: *parogers@ucsd.edu.* Many thanks to Yue Chu, Yilan Jiang, and Yutong Wu for excellent research assistance. Thanks to Jeffrey Clemens, Josh Graff Zivin, Paul Niehaus, Craig McIntosh, Gordon Dahl, John Van Reenen, Heidi Williams, Matthew Grennan, Ariel Stern, Daniel Carpenter, Judson Boomhower, Itzik Fadlon, Karthik Muralidharan, Alexander Gelber, Mark Jacobsen, Aaron Kesselheim, Josh Makower, Jeffrey McCullough, Nicholson Price, Maggie Shi, Paul Kindsgrab, Ryan Hill, Alex Everhart, Nathaniel Bechhofer, Yunan Ji, Max Edwards, and Rachel Olvera for excellent feedback. I also thank participants at ASHEcon 2021, Young Economist Symposium 2021, SOCAE 2021, WEAI Graduate Student Workshop, and UCSD Applied Micro. Thanks also to Parag Agnihotri and Kimberly Ruprecht for their generous help.

While new technologies can improve consumer well-being, they can also cause harm. One way to mitigate harm is through regulation that requires innovators to demonstrate the safety of their products before commercialization, an ex-ante approach taken by the U.S. Food & Drug Administration (FDA). Another strategy relies on the threat of ex-post litigation to deter harm. A decades-long debate considers these alternatives. Critics of regulation claim that it chills innovation and market competition by raising entry costs (Peltzman, 1973) and that litigation is more efficient (Coase, 1960). Proponents counter that regulation increases public confidence in products marketed by lesser-known firms, encouraging entry and innovation (Carpenter et al., 2010). Clear evidence testing these claims is important given the $2.8 trillion market size of FDA-regulated products alone (FDA, 2020b).

I advance this debate by measuring the impact of FDA regulation on innovation and market structure. To study this relationship, I first consider a *less stringent* regime by examining deregulation events that moved, or "down-classified," certain higher-risk medical device types, like spinal implants, from stringent (Class III) to moderate (Class II) testing requirements. Second, I consider the *litigation* alternative by analyzing events that moved lower-risk device types, like ventilator tubing, from moderate (Class II) to no testing requirements (Class I), exposing innovators to more litigation. Examining both of these types of events is valuable for two reasons: First, it allows me to measure the impact of strict FDA regulation (i.e., clinical trials) relative to the existing alternative policies. Second, it enables me to estimate local average treatment effects among deregulated devices at different points in the distribution of safety risk (low-to-moderate risk versus moderate-to-high risk devices).

I infer the causal effect of these events by comparing affected device types to a variety of possible control groups. These groups include device types matched on pre-event means, intuitively similar devices, later-deregulated devices, and a broad set of unaffected devices. I find that my results are stable across these control groups. Further, comparing deregulated device types to control groups reveals no divergent pre-existing trends in the outcomes of interest, consistent with the "unpredictable" characterization of these events by device manufacturers (Makower et al., 2010; Powell, 2018).

An important contribution of this paper is the assembly of novel data on the tradeoffs 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.

My analysis of these data shows that down-classification events increase the quantity and quality of new technologies. After moving from Class III (high regulation) to II (moderate), device types exhibited a 200% increase in patenting and FDA submission rates relative to control groups. Patents filed after these events were also of significantly higher quality, as measured by a 200% increase in received citations and market valuations. These effects do not spill over into similar device types.[1] For Class II to I deregulations, the rate of patent filings increased by 50%, though insignificantly, and the quality of patent filings exhibited a significant 10-fold improvement, suggesting that litigation better promotes innovation. There is substantial heterogeneity in how firms respond to deregulation as increases in innovation are strongest among smaller firms and those with the least regulatory experience—the same subset of firms found most likely to produce groundbreaking innovation (Wu et al., 2019).

Second, these events led to significant changes in market structure. Class III to II events generated a ten-fold increase in new entry (i.e., firms with no approved devices) and a four-fold increase in incumbent entry (i.e., firms with approved devices of another type) into treated device types. Increased competition impacted health care prices: Using claims data from a university hospital system, I find that these events were associated with a significant

[1] These localized effects could be explained by extreme specialization: many device inventions originate from practicing physicians or researchers acting within their medical specialty (NIM, 2010).

40% drop in the prices of medical procedures that use deregulated device types relative to controls.[2] Class II to I events led to a significant 200% increase in new entry into treated device types, with no effect on incumbent entry, suggesting that litigation obstructs new firm entry less than regulation.

Down-classification yields considerable benefits, as the proponents of deregulation would predict, but what of product safety? Perhaps counterintuitively, I find that deregulation can improve product safety by exposing firms to more litigation. Despite some adverse event rates increasing after Class III to II events (albeit insignificantly), Class II to I events are associated with significantly *lower* adverse event rates.[3] My analysis of patent texts also reveals that inventors focus more on product safety after deregulation. These results suggest that litigation encourages product safety more than regulation: Instead of meeting Class II requirements, which the National Institute of Medicine deems as insufficient for product safety (IOM, 2011), inventors must decrease the likelihood that their products injure consumers to prevent litigation. I identify litigation as a mechanism using variation in firms' exposure to litigation after deregulation: Smaller firms expect less liability as they can use bankruptcy to avoid liability that exceeds their assets (Shavell, 1986). I find that safety improvements are strongest at larger firms for which a larger share of liability is unavoidable.

A back-of-the-envelope calculation suggests that the benefits of these events outweigh the costs. Accounting for the cost of adverse events and the value of increased innovation and decreased health care prices, the unmeasured costs of Class III to II events would need to be larger than the measured costs to justify Class III regulation. For Class II to I events, there are virtually no measurable costs of down-classifications as adverse events *decline*. By contrast, the benefit of these events amounts to more than $22 million a year per device type. Although these benefits are based on local average treatment effects among deregulated device types, I find evidence that these benefits may generalize to current Class II device

[2]This price drop could even be mechanically driven by the 68% reduction in testing costs from these events (Makower et al., 2010), which may reduce markups intended to recover regulatory costs.

[3]"Rates" are counts per device type-year. I do not normalize by utilization, but I show that this normalization would likely strengthen my adverse event estimates as deregulation increases utilization.

types: More dangerous, marginal deregulated device types (according to the FDA's decision rule) exhibit the largest decreases in adverse events. If this relationship holds, the yearly forgone benefits could amount to as much as $55 billion across 2,500 current Class II device types, or nearly 32% of the annual value of medical devices consumed.

I build a model that illustrates the range of possible consequences of deregulation. 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.

My findings contribute to several literatures. First, I add to the growing literature on the effects of public policy on medical innovation.[4] Despite the significant size of the medical device market, valued at around $500 billion and projected to reach nearly $1 trillion by 2030 (Stewart, 2022), there is a lack of evidence on the impact of regulation on innovation in this sector. Groundbreaking research on the topic by Stern (2017) and Grennan and Town (2020) uses cross-group comparisons to suggest that regulations affect investments in Class III cardiovascular technologies. These studies, however, do not address the broader impact of FDA regulation on innovation. My research fills this gap by examining the relationship between regulation and innovation using quasi-exogenous regulatory shocks across a range of device types and at several levels of regulatory stringency. I also evaluate the safety benefits of device regulation, an area that has received little attention.

I also add to a longstanding literature on the tradeoffs between regulation and litigation (Coase, 1960; Ehrlich and Posner, 1974; Kolstad et al., 1990; Glaeser et al., 2001; Shavell,

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

1986, 2018). Regulation, a preventive strategy, sets a lower bar on product safety, whereas litigation, a deterrence strategy, punishes those who violate standards through the courts (Kessler, 2010). A study by Philipson et al. (2010) finds that regulation and litigation together are less efficient than regulation alone, but did not examine which approach is more efficient on its own. I find that litigation can more effectively prevent 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, are inconsistent with 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.

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.[5] 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 E.3 provides more details.

1.2 Deregulation of Medical Device Types

The FDA can lower the class of a medical device type after observing the safety outcomes of marketed devices. Without any safety information, the FDA regulates new, markedly novel devices in Class III to ensure safety in the presence of unknown risks.[6] Surveillance data from

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

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

marketed devices clarify these risks and inform the FDA's choice to move a device type into Class II, or "down-classify" (see figure 1).[7] These events are described by manufacturers as "unpredictable," suggesting the difficulty of anticipating such policy changes (Powell, 2018). My empirical analysis supports this assessment as I do not find evidence of divergent pre-existing trends when comparing down-classified device types to control groups.

By contrast, the Class II to I down-classifications I study are systematic. In 1995, 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 change appears to justify using a regression discontinuity design, the sparseness of device types at the threshold does not permit this approach. Instead, a series of unaffected Class I device types that would have received similar scores as treated device types serve as appropriate controls. These types include previously deregulated and always Class I device types. Importantly, scores were not contingent on potential changes in adverse events or trends.[8] My event-study results reaffirm these assessments.

It is worth noting that deregulation 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.

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

[7] 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).

[8] See appendix E.1 for more details and for an example of Class III to II events.

damage caps (Guendling, 2016). These conditions make liability risk a powerful incentive for ensuring the safety of products marketed in the US.

However, FDA approval shields medical device manufacturers from product liability, creating a stark tradeoff between regulation and litigation. This protection, called "federal preemption," is upheld by Riegel v. Medtronic Inc. (2008), a supreme court case establishing that Class III device approvals bar legal claims against device manufacturers. The Class II devices I analyze are also often protected from litigation as they are FDA-approved and subject to "special controls" requirements that ensure safety and efficacy (Costello and Pham, 2016).[9] 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.

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

[9] 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).

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).[10] 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).[11] 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.[12]

Financing Costs.—Smaller firms must raise external capital to cover the costs of development and commercialization at time t_{invent}.[13] Fundraising can be difficult: 56% of small

[10]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).

[11]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).

[12]I assume $t_{comm,f}$ and several other parameters below are deterministic for simplicity.

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

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.[14,15] 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 safety, costing ψ per unit, at t_{invent}.[16] 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

[14]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.

[15]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).

[16]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.

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.[17] 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 these expected profits exceed the combined delay, safety effort, and financing costs:[18]

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

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

[18] 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).

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:[19]

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

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.[20]

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 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:

[19]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).

[20]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).

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 2 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 complex 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:[21]

[21] Proofs are presented in appendix B.

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 C.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 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 F.1.

FDA Device Submissions (PMA and 510(k) Databases). The primary dataset used in this study is derived from FDA administrative data on the universe of medical devices submitted for FDA approval. These data combine the FDA's PMA and 510(k) databases to cover both Class III and II devices. Submissions include the submitting company name, device brand name, medical device type, and submission and approval dates. I use fuzzy matching to form three measures of market dynamics and innovation. First, I measure "new entry" by identifying firms submitting approval documents for the first time. Second, I also form a measure of "incumbent entry," by locating firms that have filed prior approval documents but are starting to submit for approval in a given device type. Third, I isolate the first occurrence of unique device brand names within a device type to form the "unique devices 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 the given point in time.

FDA Deregulation Events. To provide a comprehensive analysis of FDA deregulation events, I collect all down-classifications from 1980 to 2015. For Class III to II events, I also indicate whether the event was motivated by the FDA's "own initiative" or by an industry petition. This distinction is empirically important. Figure F.2 shows that device types that experience a petitioned down-classification exhibit divergent pre-trends in patenting rates in the five years before the event. The Class III to II events I consider are those enacted by the FDA's own initiative and for which down-classified device types experienced at least one PMA document submission beforehand.[22] For Class II to I events, I consider affected device types that experienced at least one 510(k) document submission beforehand.

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

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 F.3). 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 with their associated patents (similar to 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 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 D 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.[23] Patent market values (in millions USD) are derived from Kogan et al. (2017). These values are based on the increase in the patent assignee's stock price resulting from a USPTO announcement of patent 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.[24] This variable allows me to directly analyze how deregulation affects inventors' emphases on improving device safety, corroborating adverse event analyses. Lastly, to analyze how deregulation affects innovation from firms of different sizes, I link total firm asset holdings from the CRSP/Compustat database to patent applicants.

UCSD Health Insurance Claims Extract. Insurance claims data from UCSD Health provide information on how healthcare prices respond to deregulation. To my knowledge, no available data, including ECRI *PriceGuide*, reliably measures the direct prices that providers pay for medical devices before 2011. As another option, device prices could also be reflected in insurance claims data, provided that device costs comprise a substantial share of procedure costs. However, insurance claims databases before 2011 do not measure exact paid amounts at the procedure level, the granularity necessary for attributing costs to device usage. Thus, I acquire claims data from UC San Diego Health that detail prices at the Current Procedural Terminology (CPT) level. I then identify claims with procedures that use medical device

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

[24] To construct a comprehensive list of keywords related to medical device safety, I use Word2Vec, an algorithm that maps text to a vector space, with proximity indicating semantic similarity. After gathering semantically similar keywords, I search patent claims to identify whether a patent contained any of the keywords of interest and calculate the fraction of patents that mention these keywords in a given device-type-year. If no patents were filed in a given year, I set the fraction of patents mentioning safety to zero (i.e., no scientific advancements in product safety). See table F.4 for a list of keywords used.

types that were down-classified since 2006.[25] To form control groups, I collect a set of procedures that use matched control device types and randomly select 100 procedures. Together, these data contain nearly 500,000 unique patient claims from 2005–2020. I then take the average amount paid for a given procedure in a given year, forming a panel of procedure-year prices.[26]

4 Empirical Strategy

My strategy for estimating the effects of deregulation 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).[27] This approach assembles event-specific panel data using each treated group $r \in \{1, \ldots, N^1\}$ and all admissible controls. Then, all event-specific panels are stacked while allowing unique time and group fixed effects for each panel. Thus, the estimating equation is given by

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

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

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

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

[27] 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 F.5, F.6, and F.7).

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

$$Y_{t,c,r} = \gamma_{c,r} + \gamma_{t,r} + \sum_{t \neq 0} \beta_t 1\{\text{Treated}\}_{c,r} \times 1\{\text{Years from Reclass}\}_{t,r} + \varepsilon_{t,c,r}. \tag{4}$$

In equation 4, the omitted interaction between the treated group indicators (i.e., $1\{\text{Treated}\}_{c,r}$) and the time dummy variables (i.e., $1\{\text{Years from Reclass}\}_{t,r}$) aligns with the year the event occurred. Thus, each parameter β_t represents the difference-in-differences estimate of the change in the outcome in a given period relative to that reference period. Standard errors for each β_t are calculated using Conley and Taber (2011).

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

Identifying control device types that track the counterfactual development of the outcome variables is a central challenge in my empirical context. Controls could be unsuitable for several reasons. Control device types, for example, could be affected by unique scientific developments, have lower scientific potential, or face different market forces. Alternatively, some device types could be affected by spillovers from treated device types. Lastly, the FDA selects device types for down-classification based on inherent risk. Thus, down-classified devices may be 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.[28] 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 form the third control group, a 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.[29]

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

[28]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.

[29]See table F.8 for spillover estimates.

control groups are given in table F.9 for Class III to II down-classifications, and in tables F.10 and F.11 for Class II to I down-classifications. Although the estimates are similar across control groups, the matched control groups constitute my preferred specification.

Additionally, some medical device types may never exhibit adverse events or innovative activity and thus would be incomparable to those that do. Thus, I also provide results from analyses that consider only treated and control device types with positive counts of a given outcome in the appendix tables F.12, F.13, and F.14. My findings are robust to these restrictions.

As with every non-experimental research design, selection into treatment is a primary concern. Since the FDA selects medical device types to down-classify based on baseline yearly adverse event rates, down-classification may be endogenous to changes in adverse event rates.[30] Thus, I cannot ascertain how deregulation would affect the adverse event rates for a randomly chosen device type. However, I can speak to the optimality of the FDA's decisions on the margin of their rule (i.e., the most dangerous down-classified devices).

5 Results

This section presents estimates of equations 3 and 4, which capture the effect of deregulation 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 deregulation 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.[31] Panel A provides estimates for Class III to II events, and panel B provides estimates for Class II to I events. Col-

[30]See appendix E.1 for more details.

[31]Table F.12 presents the results from only including device types with some positive outcome counts.

umn (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 led to statistically significant increases in patenting rates, unique device submissions, mean citations-per-patent, and mean patent values across 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 after Class II to I events (i.e., complete deregulation) received 330%–1,070% more citations and yielded 10%–50% higher market values, suggesting a divergence between scientific and private value. These results are robust across comparison groups (columns 2–5). Although economically significant, the increase in patenting rates from Class II to I events was not statistically significant under my preferred specification.

I examine the dynamics of the innovation responses by estimating the event-study equation 4. The top subpanels of figures 3 and 4 plot the innovation responses (i.e., β_t coefficients) for Class III to II and II to I events, respectively, when using the "matched" control groups.[32] The results of this analysis provide several insights for interpreting my findings. First, trends in all outcomes were similar in treatment and control groups for ten years before deregulation; trends were also similar for 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, figures 3 and 4 indicate a persistent increase in the flow of innovation, suggesting that these events led

[32] Figures F.4 and F.5 show event-study estimates for the innovation quality variables.

to investments in new technologies that would not otherwise have occurred, rather than a forward shift in the timing of those investments.

Lastly, the event-study estimates for Class III to II events suggest that the increase in new technologies (i.e., patents) was slow, whereas the upsurge in access to new *and* existing technologies (i.e., unique devices submitted) was fast. This distinction, thus, is driven by rapid changes in the availability of existing technologies. First, firms may have "on-the-shelf" ideas and products that they have not commercialized due to the expensive approval process. Second, firms may promptly repurpose existing technologies for new indications. Third, deregulation accelerates the approval pipeline, leading to a sudden influx of products at different ex-ante stages of approval. Lastly, since, until recently, E.U. regulations were more lenient, firms may have introduced their E.U.-approved devices to U.S. markets after deregulation (Grennan and Town, 2020). By contrast, patenting rates increase gradually after deregulation, consistent with the time-intensive R&D process. U.S. patenting rates, unlike device submissions, are not affected by sudden influxes of existing technologies as these technologies are either already patented or are not patentable. In particular, if a firm files a patent in one country, it must file patents in other countries 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 (Firm Entrants and Prices)

To investigate the effect of deregulation on market structure, I reestimate equation 3 for five different outcomes: new and incumbent firm entry measured separately by each data source and prices for procedures that use device types of interest. Table 3 presents the estimates.[33] The structure of table 3 is similar to that of table 2, with the exception of an additional comparison group matched on pre-event prices (column 2). Panel A reveals that

[33]Table F.13 presents results from including only device types with some positive outcome counts.

Class III to II events led to statistically significant increases in incumbent and new firm entry across control groups (columns 3–6) and data sources (patents and FDA devices). Strikingly, these events increased the rate of new firm entry by 840%–1,000% (pre-mean: 0.1 firms/yr) when measured by FDA data and by 150%–420% when measured by patent data.[34] The discrepancy between the magnitudes of these two estimates suggests a strong increase in the availability of existing technologies. Regarding the effects on incumbent firms, these events increased incumbent entry by 400% when measured by FDA data and by 130%–240% when measured by patent data.

The procedure price estimates are reported in the first row of table 3. The results show that Class III to II events are associated with a statistically significant decrease in the prices of procedures that use treated device types when using two out of three control groups (columns 2 and 3). The estimates translate to a 33–40% drop in prices, plausibly driven by the increase in firm entry and competition (Busso and Galiani, 2019).[35] There are several reasons why these price results should be interpreted with some caution. First, my price data is only available after 2004, restricting the number of treated device types I study to five. Second, the estimate generated using the entire sample of procedures as controls (column 6) is quite noisy, indicating that the results are less robust. Lastly, UCSD healthcare claims data only cover one regional hospital system.

Table 3, panel B shows the effect of Class II to I events on new and incumbent firm entry as measured by patent data (device data is unavailable for Class I). The results indicate that these events increased new firm patenting by 50%–145%, though the estimate under my

[34]Supply-side factors may not be the sole driver of these dramatic changes in market structure. As shown in figure F.6, there were considerable equilibrium forces at play: After the number of suppliers of treated device types increased, demand increased for procedures that use treated devices three years after deregulation, plausibly driven by lower prices. No significant pre-trends are measured.

[35]The example of spinal implant deregulation highlights the plausibility of these price estimates. There are several margins along which a drop in the price of spinal implants could affect the overall costs of spinal fusion procedures. First, spinal implants account for roughly 40% of the costs of spinal fusion procedures (Beckerman et al., 2020). Thus, the direct effect of a drop in the prices paid for spinal implants could measurably change the procedure price. Moreover, new technology could be labor-saving, reducing the costs of labor required to perform the procedure. Lastly, a lower price for spinal implants could attract more providers to offer the procedure, potentially driving down prices further.

preferred specification is only marginally significant. By contrast, incumbent firm entry is statistically and economically insignificant under my preferred specification. The distinction between the new and incumbent results suggests that litigation may obstruct new entry less than regulation, but both environments similarly impact incumbent firms.

To help interpret these findings, I present event-study estimates of equation 4 for my market structure outcomes. The β_t coefficients are shown in the bottom subfigures of figures 3 and 4 for Class III to II and Class II to I events, respectively.[36] The figures suggest that identifying assumptions (i)–(iii) (listed above) are satisfied and that, when present, the estimated effects are persistent. For similar reasons given above, figures F.8 and 4 illustrate a gradual increase in the rate of new firms patenting (slow R&D), while FDA device data reveals a sharp increase in device submissions from new firms (includes existing technologies). Figure F.7 reveals that procedure prices dropped two years after the events, despite sharp increases in firm entry. This lagged response is consistent with the contractual nature of healthcare markets; prices are "sticky" as hospitals periodically renegotiate contracts with suppliers and insurers (Reinhardt, 2006; Grennan and Swanson, 2020).

5.3 Heterogeneity in Firm Proficiency and Size

The average treatment effects estimated in the last two sections 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,

[36] Figure F.7 plots these coefficients for the Class III to II price outcome, and figure F.8 plots these coefficients for the Class III to II market structure outcomes measured using patent data.

proficiency, and innovation. Panel A of figure 5 presents the results expressed as percent changes relative to pre-event averages. Class III to II events generated statistically significant increases in new device submissions across proficiency quartiles. However, the events were associated with much higher increases among inexperienced firms. Firms in the first proficiency quartile exhibited a 1,000% increase in new device submissions compared to a 50% increase from firms in the top quartile.[37] These results indicate a quickly diminishing response while moving up the proficiency distribution. This pattern is consistent with the estimated learning curves presented in figure 5, panel B as firms in the lowest proficiency quartile benefit from the highest reduction in approval delays. This reduction translates into outsized decreases in commercialization costs for inexperienced firms and, thus, higher increases in commercialization activity (as claimed in proposition 3).

Designing regulation that is simpler and standardized could help less regulation-proficient firms.[38] For example, Stern (2017) shows that when the FDA sets approval expectations by publishing guidance documents, approvals times of new firms drop by roughly 40 percent. To simulate the impact of these types of efforts on innovation, I iteratively shrink the gap in delays between inexperienced and proficient firms by lowering the learning rate γ while measuring R&D response from a hypothetical distribution of firms (see figure F.9 and appendix **??** for more details). Table F.15 presents the results of this simulation. The results suggest that flattening the learning curve could increase the number of unique devices approved up to 63%, with the least proficient firms exhibiting the largest gains.

Firm Size. To assess how regulation impacts firms with different levels of internal capital, I estimate equation 3 across capital terciles for the patenting rate outcome. I perform this analysis for both down-classification types. Figure 6, panels A and B present the results.[39]

[37] Strategic judgment proofing is not driving these results. In other words, these effects are not driven by larger firms forming small subsidiaries to shield themselves from liability. For example, only 1 out of 20 new spinal implant manufacturers entering the market after deregulation were subsidiaries.

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

[39] 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.

Both event types are associated with larger increases in patenting rates among firms in the bottom tercile of asset holdings.

Interpreting the heterogeneous effects of regulation through the lens of my conceptual framework indicates that profits increase after deregulation and that small firms face lower financing costs after deregulation, despite incurring potentially higher safety effort costs. These results confirm aspects of the propositions in section 2 and suggest that small and inexperienced firms face relatively high regulatory costs to innovate.

The results of this subsection should be interpreted with some caution. Other factors may be correlated with firm size and proficiency that also contribute to these R&D responses. However, in addition to the striking similarity between the empirical results and the predictions made in section 2, device manufacturers express that regulatory proficiency and financing costs are key factors that influence R&D decisions.[40]

5.4 Changes in Device Safety

I examine whether deregulation is associated with decreased device safety by reestimating equation 3 for two different outcomes: the rate of adverse events and the rate at which inventors emphasize safety. Table 4 details the results and is structured like table 2.[41] Table 4, panel A reveals that Class III to II events are not associated with statistically significant changes in adverse event rates and inventor emphasis across control groups. However, these events are associated with economically significant increases in hospitalization rates under my preferred specification.

Table 4, panel B shows that Class II to I events are associated with statistically significant *reductions* in the rates of hospitalizations and deaths across three out of four control groups. In contrast to Panel A, all but two estimates are significant at the 10% level, and all suggest improvements in device safety. The results indicate an associated 93–97% reduction in hos-

[40] Firm size, the most obvious potential confounder, is uncorrelated with firm FDA experience (see table F.16). This lack of correlation may result from publicly traded companies having high baseline assets relative to the average MedTech firm.

[41] Table F.14 presents the results from including only device types with some positive outcome counts.

pitalizations and a 49–69% reduction in deaths per year per treated device type (pre-mean: 0.3 deaths/yr). Panel B reveals that these events are also associated with a statistically significant 100% *increase* in the share of patents that emphasize an advancement in product safety, corroborating the results generated by the FDA adverse event report outcomes.

How could deregulation *improve* device safety? A compelling answer is that deregulation exposes firms to more litigation, which may increase the net incentives to improve device safety.[42] To shed further light on liability as the mechanism for this change, I use variation in ex-post exposure to legal liability by firm size. Small firms can avoid worst-case damages through bankruptcy, while large firms cannot. If liability risk plays a central role, deregulation should lead to disproportionate increases in device safety among larger firms. Indeed, the top subfigure of figure 7 shows that larger firms in the top tercile of asset holdings exhibit a significant 100% increase in the likelihood of demonstrating at least one safety innovation per year per treated device type. By contrast, smaller firms respond much less dramatically. The bottom subfigure of figure 7 mirrors this finding and shows a more significant drop in the likelihood of serious adverse events among larger firms.

Figures F.10, F.11, and F.12 illustrate the dynamics of my device safety findings. These figures plot the β_t coefficients estimated from event-study equation 4. Figure F.10 shows that Class III to II events are associated with a gradual increase in hospitalization rates and serious event rates as new devices are invented and marketed within treated device types. Figure F.11 shows that Class II to I events are associated with a persistent and gradual decrease in adverse events as inventors increase their emphasis on safer technologies (see also figure F.12).

A few caveats accompany my device safety analysis. First, the FDA explicitly down-

[42]Several other potential mechanisms may contribute to improved product safety after Class II to I down-classifications. For example, deregulation may increase competition among firms, which may encourage them to focus more on product safety as a means of differentiation. Additionally, deregulation can lead to increased innovation, which may result in more product safety innovations. However, I do not observe similar safety improvements after Class III to II down-classifications, where innovation and market competition tend to increase more significantly. It is also possible that, after deregulation, firms are no longer constrained by regulatory parameters such as substantial equivalence, allowing them to more freely innovate in the realm of product safety.

classifies device types for which prospective regulation adequately mitigates harm. Thus, the insignificant adverse event results associated with Class III to II events should be interpreted as a local average treatment effect. For Class II to I events, however, I use the FDA decision rule described in appendix E.1 to assess whether the FDA's decisions are optimal on the margin (i.e., at higher "DPM scores"). Accordingly, I separately estimate equation 3 for each treated device type relative to a matched control (matched based on DPM score) and plot the relationship between the effect size and the score value. Figure F.13 shows that marginal device types are associated with *fewer* deaths when compared to control groups, relative to less dangerous treated device types. This pattern may generalize to most current Class II device types, of which 95% exhibit fewer adverse events than the most marginal deregulated device type.

Second, the FDA does not normalize adverse event rates by device utilization due to data limitations. Growth in utilization would increase the likelihood of adverse events. Thus, fluctuations in adverse event rates reflect changes in product safety *and* utilization. Hence, using adverse event rates as a signal of product safety provides a conservative estimate of the net benefit of deregulation as deregulation increases utilization. Figure F.6 shows that, although no pre-trends are present, utilization rates of treated medical device types significantly increase three years after Class III to II deregulations, plausibly due to increased supply. Although I do not have similar utilization data for Class II to I events, treated device types also exhibit increased supply after deregulation. All else equal, if the demand curve is not perfectly inelastic, an outward shift in the supply curve would increase utilization.

Lastly, media and regulatory decisions may influence adverse event reports. Manufacturers, for example, could be less likely to report adverse events if they are subject to less regulatory scrutiny or if reports are more likely to make news after deregulation. However, I focus on mandatory reports of deaths or severe injuries from hospitals and device manufacturers, which are less sensitive to these factors than voluntary reports of less severe injuries (FDA, 2020c). The FDA enforces the reporting of serious events using financial penalties and criminal resolution (Bragg et al., 2018; Emergo, 2022).[43]

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

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

Table 5 presents the measured costs and benefits of down-classification decisions. To justify the FDA's decision rule for Class III to II down-classifications, the unmeasured costs (e.g., political risks) associated with these events would have to be larger than the measured costs. Class II to I down-classifications do not exhibit any measurable costs as they are associated with *fewer* adverse events and more innovative activity. The benefits of these down-classifications, including fewer adverse events, amount to roughly $24 million per year per treated device type, even at the margin of the most dangerous treated devices ex-ante. Since there are 2,500 Class II devices, the yearly forgone net benefits from stalling deregulation could amount to as much as $60 billion, or nearly 34% of the value of medical devices consumed each year.

[43]Both user facilities (i.e., hospitals) and manufacturers are required to report serious adverse events to the FDA. Thus, if either entity fails to report an event, but the FDA is notified by the other (or other sources like end users), then it is implicated in incompliance. Additionally, the FDA *increased* its monitoring of deregulated device types to take appropriate remedial action if products had become less safe, which would make it it more difficult for firms marketing affected devices to hide adverse events relative to those marketing unaffected devices (FDA, 1995).

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

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

7 Discussion and Conclusion

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 develop a data set that combines eight underlying sources on innovation, market dynamics, firm characteristics, and product safety. I find that deregulation disproportionately benefits small and inexperienced firms and broadly accelerates technological progress and firm entry. This change in market structure reduces related healthcare prices. Lastly, Class II to I down-classifications are 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 $24 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.[44] 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, hasten innovation, and lower administrative costs.

Class III to II events, however, are 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 access to new technologies is persistent as patenting rates increase dramatically. In practice, however, 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

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

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 pharmaceuticals in the US and other countries (Van Norman, 2016).[45] Additionally, Class II device regulations are similar to those used abroad and resemble those for generic drugs—which are also protected from product design 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.

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

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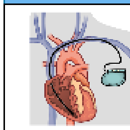
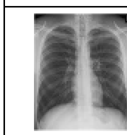
Figures and Tables

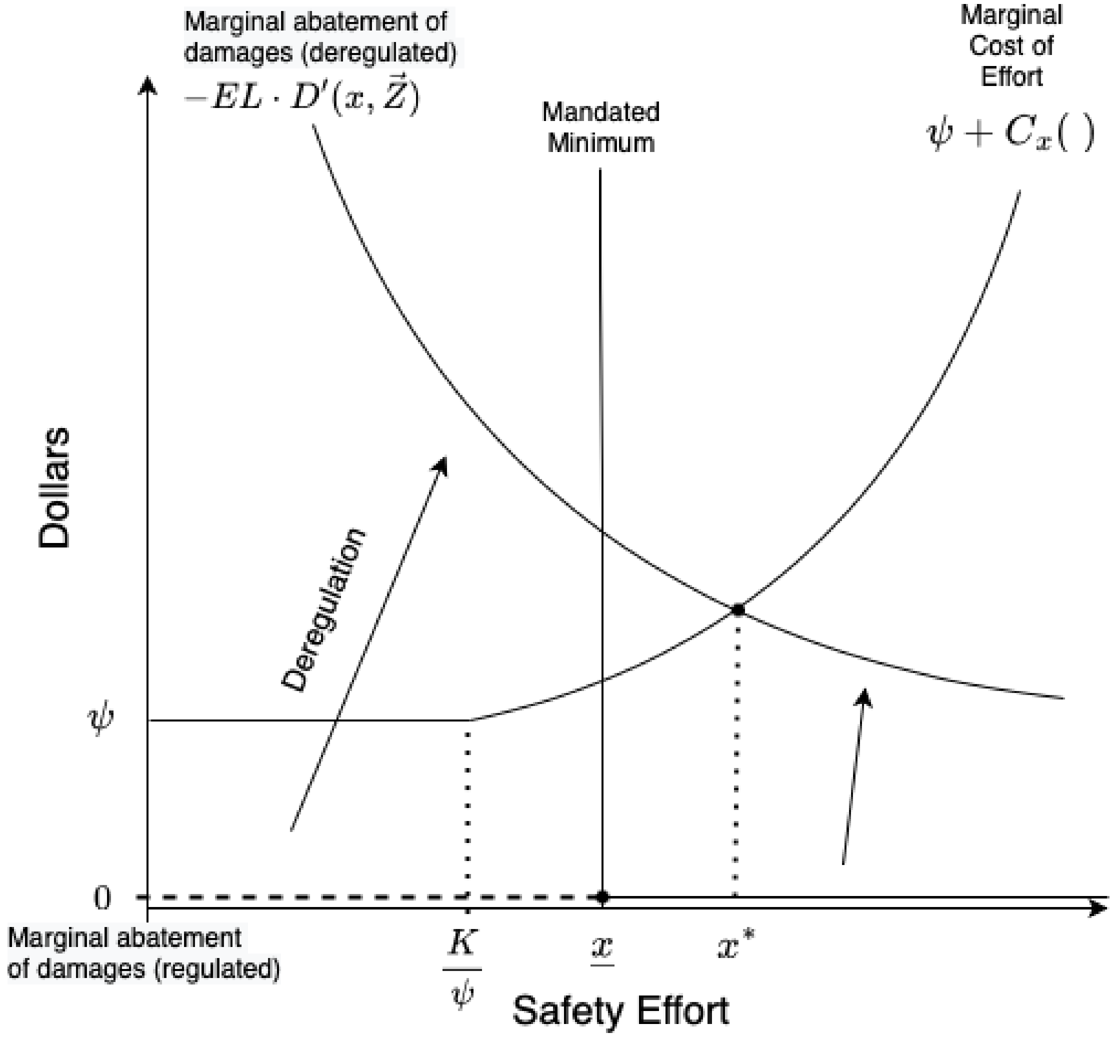
Figure 1: Background on Medical Device Regulations

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

Deregulation

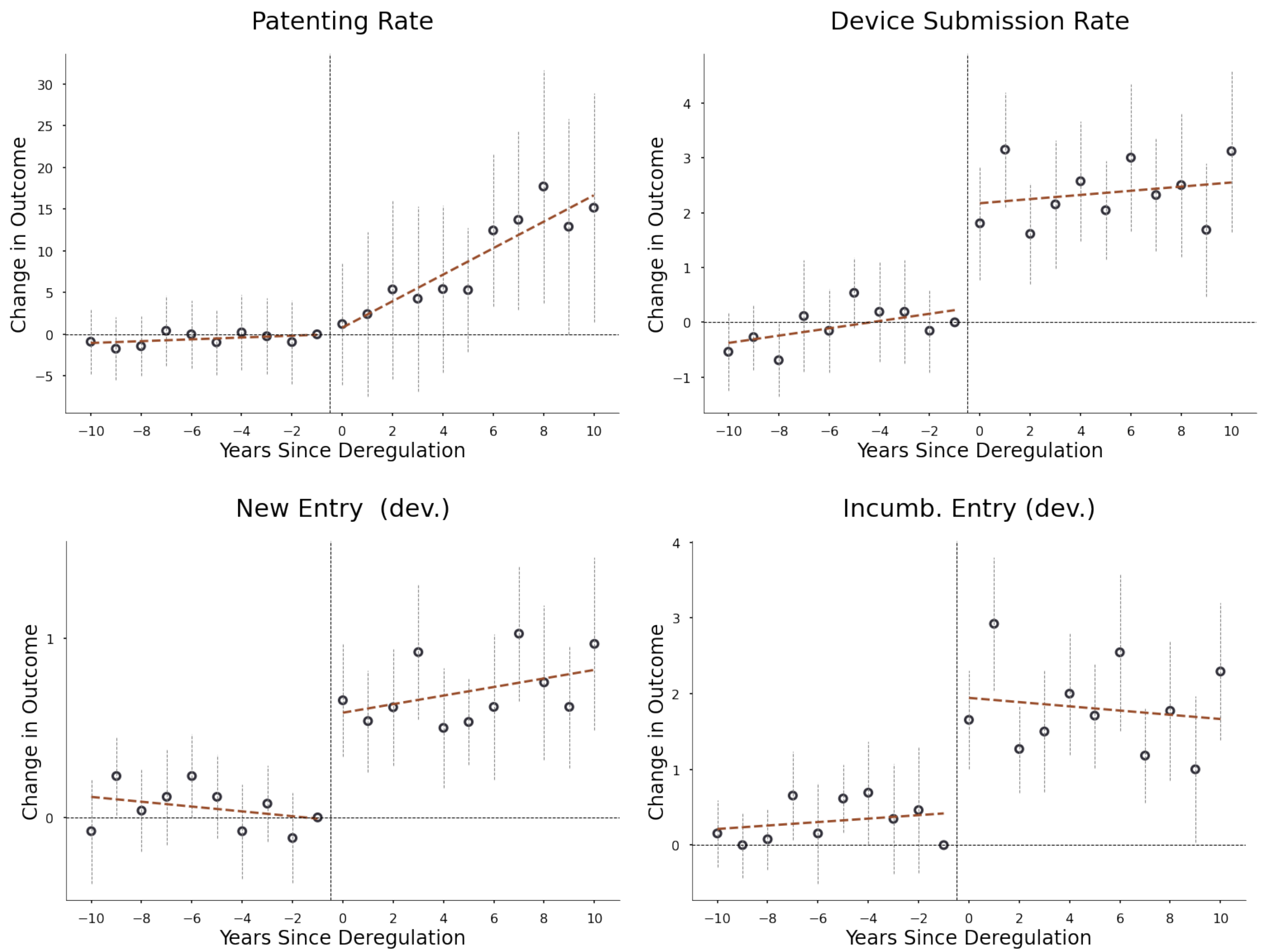
Note: This figure presents background on FDA Medical device regulations and the deregulation policy changes I leverage in my analysis. Device types are placed into one of three classes, each corresponding to a level of perceived risk. Higher perceived risk requires a longer approval process and additional costs to conduct testing and maintain business operations before a product is approved. The time and cost values are averages within the given class and are derived from Makower et al. (2010). While learning about a device type's underlying risk, the FDA can deregulate a device type by moving it from a higher-risk class to a lower-risk class (called "down-classification"). This decision dramatically reduces the approval delays and costs that device manufacturers confront. The FDA rarely reclassifies device types into a higher-risk class. The last column includes examples of Class III, II, and I devices, namely, pacemakers, x-ray machines, and tongue depressors, respectively. *Medical devices with attendant "special controls" requirements (Class II devices) are often protected from product liability (Costello and Pham, 2016). However, there is no supreme court precedent that guarantees preemption; thus, courts exercise some discretion in their interpretation of federal preemption with Class II devices.

Figure 2: Theoretical Change in Safety Effort after Deregulation



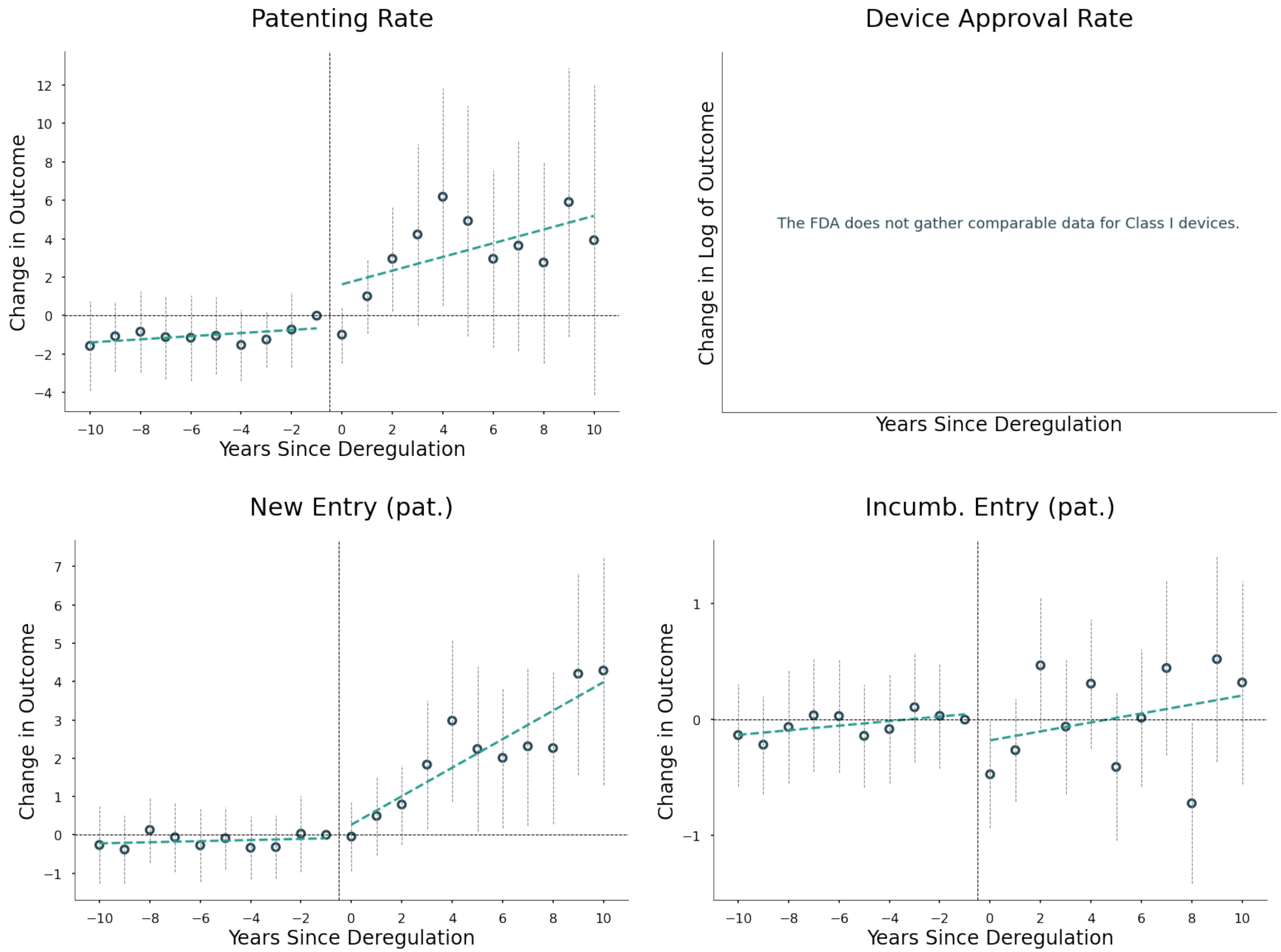
Note: This figure presents a possible change in the level of safety effort after deregulation. This scenario is one in which deregulation could lead to an increase in safety effort, given a sufficient increase in damages, as described in section 1. The x-axis indicates the level of safety effort exerted. 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.

Figure 3: Effects of Class III to II Events (High to Moderate Regulation)



Note: This figure presents the estimates of the β_t coefficients from the event-study equation 4 for some innovation and market structure outcomes. Only Class III to II down-classification events are considered. Controls are device types matched on baseline averages of the outcome. The coefficient β_{-1} is omitted and serves as the reference period. Data are analyzed at an annual frequency. The top-left subfigure illustrates the evolution of patents filed per year in treated device types relative to matched control groups. The top-right subfigure describes the evolution of unique devices approved per year by the FDA for treated device types relative to control groups. The bottom-left subfigure illustrates the evolution of the rate of new firm entry (counts per year), calculated using device submission data relative to matched control groups. New firm entry represents firms that have never before submitted FDA documentation. The bottom-right subfigure illustrates the evolution of the rate of incumbent firm entry (counts per year of firms that have previously submitted FDA documents) in treated device type relative to controls. Standard errors are calculated following Conley and Taber (2011).

Figure 4: Effects of Class II to I Events (Moderate to Low Regulation)

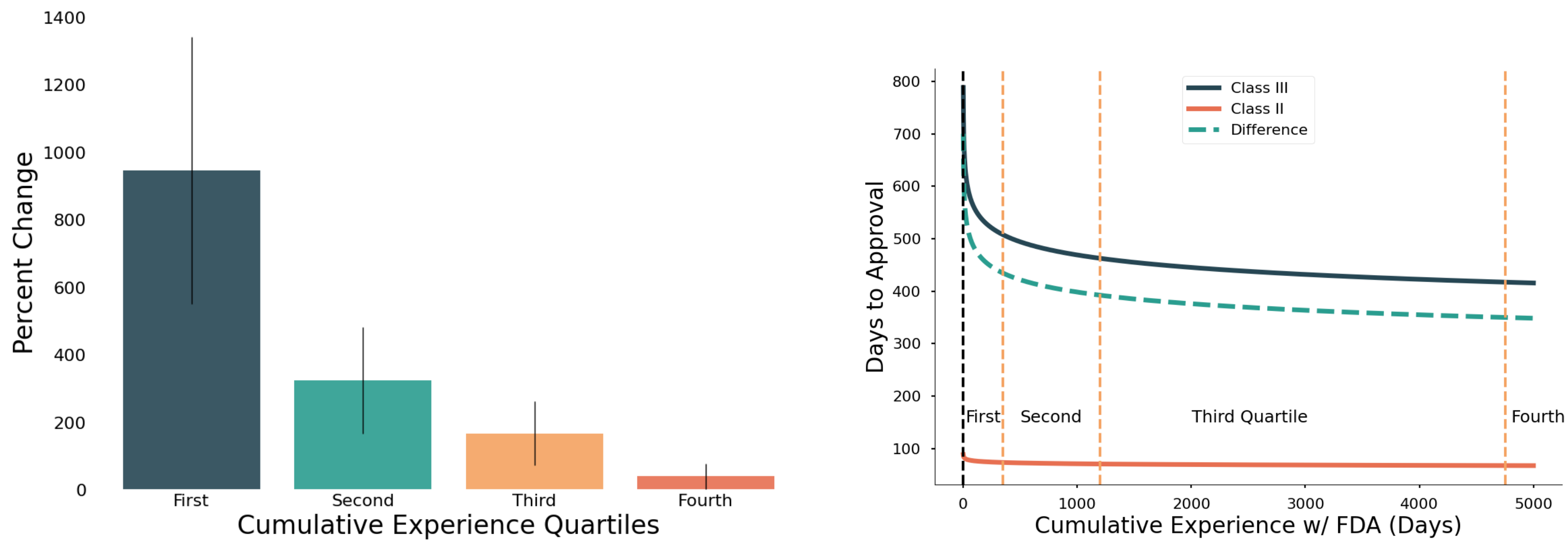


Note: This figure presents the estimates of the β_t coefficients from event-study equation 4 for some innovation and market structure outcomes. Only Class II to I down-classification events are considered. Controls are device types matched on baseline averages of the outcome. The coefficient β_{-1} is omitted and serves as the reference period. Data are analyzed at an annual frequency. The top-left subfigure illustrates the evolution of the patenting rate of treated device types relative to matched control groups. The top-right subfigure is blank, as there is no comparable data for Class I approved devices. The bottom-left subfigure illustrates the evolution of the rate of new firm entry (measured by new firms patenting) relative to matched control groups. The bottom-right subfigure illustrates the evolution of the rate of incumbent firm entry (firms that have received a granted patent), entering treated device types relative to matched controls. I do not include FDA-approved device measures of new and incumbent entry as I do not have reliable data on new Class I devices from FDA sources. 95% confidence intervals are provided.

Figure 5: Effects on Innovation by Experience and Estimated Learning Curves

Panel A: Change in New Devices by Proficiency

Panel B: Estimated Learning Curves

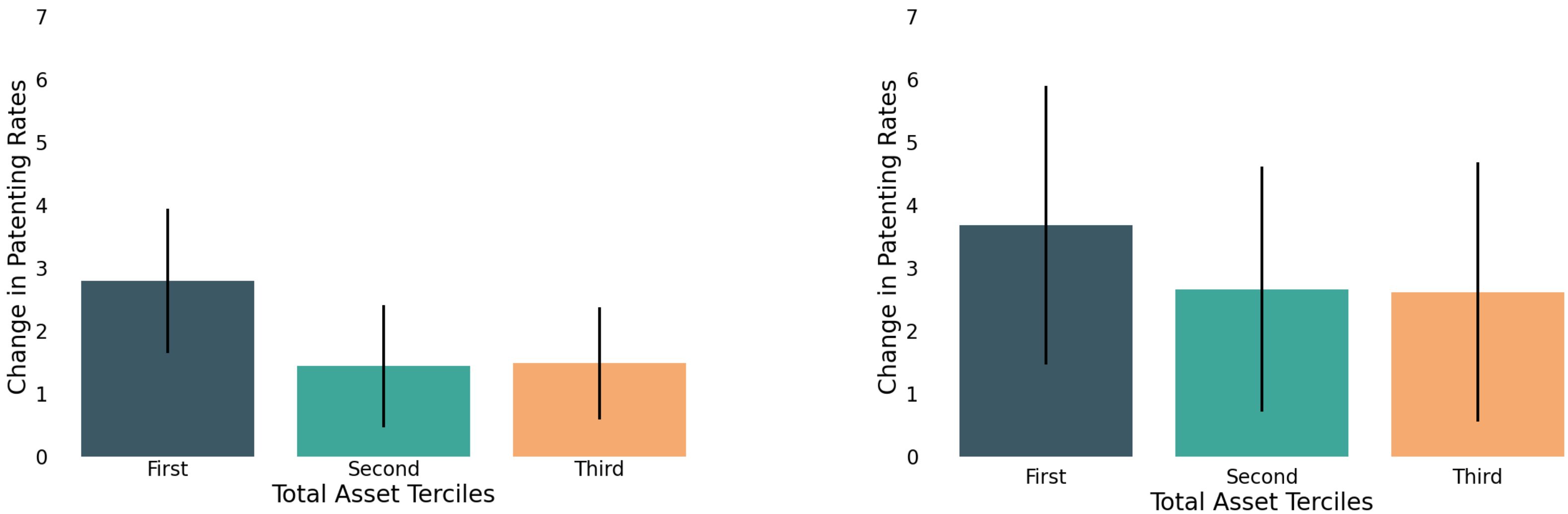


Note: This figure presents the experience-specific changes in the rates of newly marketed devices stemming from class III to II down-classification events and the learning curves estimated in equation C.1. Panel A provides the DID estimates of the rate of newly marketed devices in treated device types, 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 6: Effect of Down-Classification on Patenting Rates by Asset Terciles

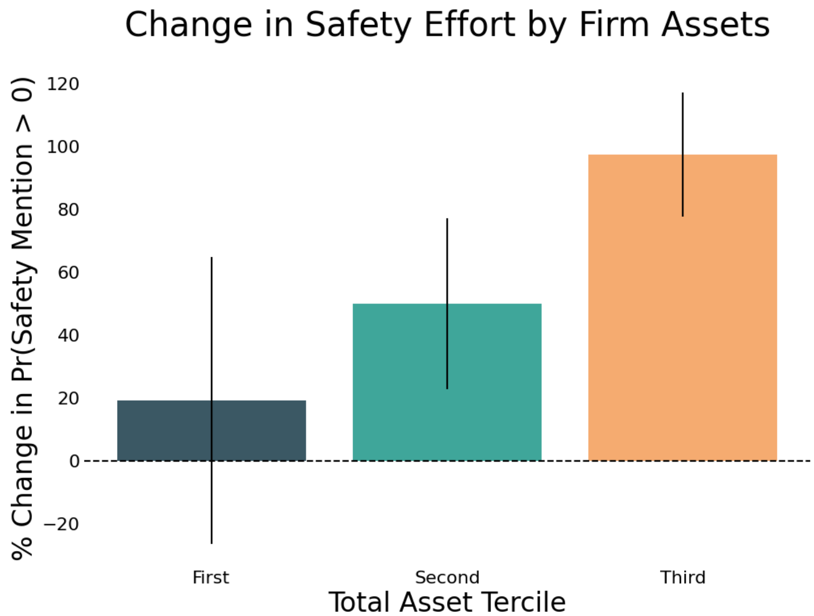
Panel A: Class III to II

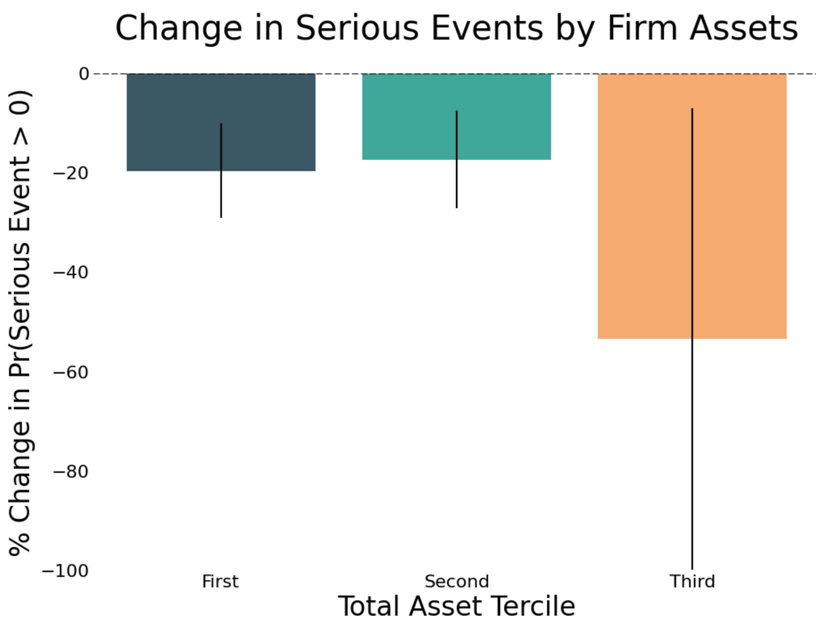
Panel B: Class II to I



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.

Figure 7: Change in Emphasis on Safety by Firm Asset Terciles (II to I)





Note: This figure presents separate DID estimates of equation 3 for the change in the likelihood of device types exhibiting at least one annual occurrence of the given outcome variable by firm asset terciles. I set all outcomes greater than zero to one (LPM) as safety mentions and serious events are rare. The baseline outcome values across asset terciles are roughly equal and do not drive these disparate effects. The top figure presents the change in the likelihood of safety-related innovations, and the bottom figure illustrates this change for serious adverse events (death, hospitalization, or life-threatening event). Terciles are formed using the asset totals from firms that are publicly traded. The x-axis describes the tercile: first, second, or third, and the y-axis conveys the percent change in the likelihood. 95% confidence interval bars are provided.

Table 1: Summary Statistics

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

Note: Tables F.1, F.2, and F.3 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

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

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

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

Table 4: Effect of Down-Classifications on Adverse Events

		DID Estimates			
	Pre-mean	Matched	Intuitive	Later	Full
Down-Classification	(1)	(2)	(3)	(4)	(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. +, *, **, and *** correspond with statistical significance at the 0.10, 0.05, 0.01, and 0.001 levels, respectively.

Table 5: Costs and Benefits of Down-Classification

Assumptions

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

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

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

Appendix Material

A 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.[46] 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 by

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

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

[46] 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.

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).*

B Proofs

B.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

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

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

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

A contradiction. Thus, $x_f^* > \underline{x}$. See figure 2 for a graphical illustration of this proof.

B.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

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

And for firm A:

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

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

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

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 $x_A^* < x_B^*$.

B.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:

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

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

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

From part equation B.3 we get

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

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

B.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:

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

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

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

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.

C Bankruptcy Protection Model Extension

C.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 E.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.[47] 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 C.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,

[47] 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.

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

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 F.17).

C.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

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

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 F.17 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 F.9 shows the iterative flattening of the learning curve, and table F.15 provides the calculations of the percentage change in new device inventions.

D 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.

D.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.

D.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 disorders 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.

D.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 F.18 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 F.15 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.

E Additional Details

E.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,

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

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,

$$\mathrm{Y} = \begin{cases} 100 \text{ if in ``high'' range,} \\ 50 \text{ if in ``medium'' range,} \\ 0 \text{ if in ``low'' range.} \end{cases} \tag{E.2}$$

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

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

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

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

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.

E.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 deregulation. 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 deregulation. 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 F.14).[48]

E.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."[49] A newly marketed medical

[48]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.

[49]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.[50]

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."[51] 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.[52] 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.[53] The PMA process takes much longer than the 510(k) process, and costs, on average, $75 million (Makower et al., 2010). After a manufacturer

[50]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).

[51]56% of medical device product codes fall under this category.

[52]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.

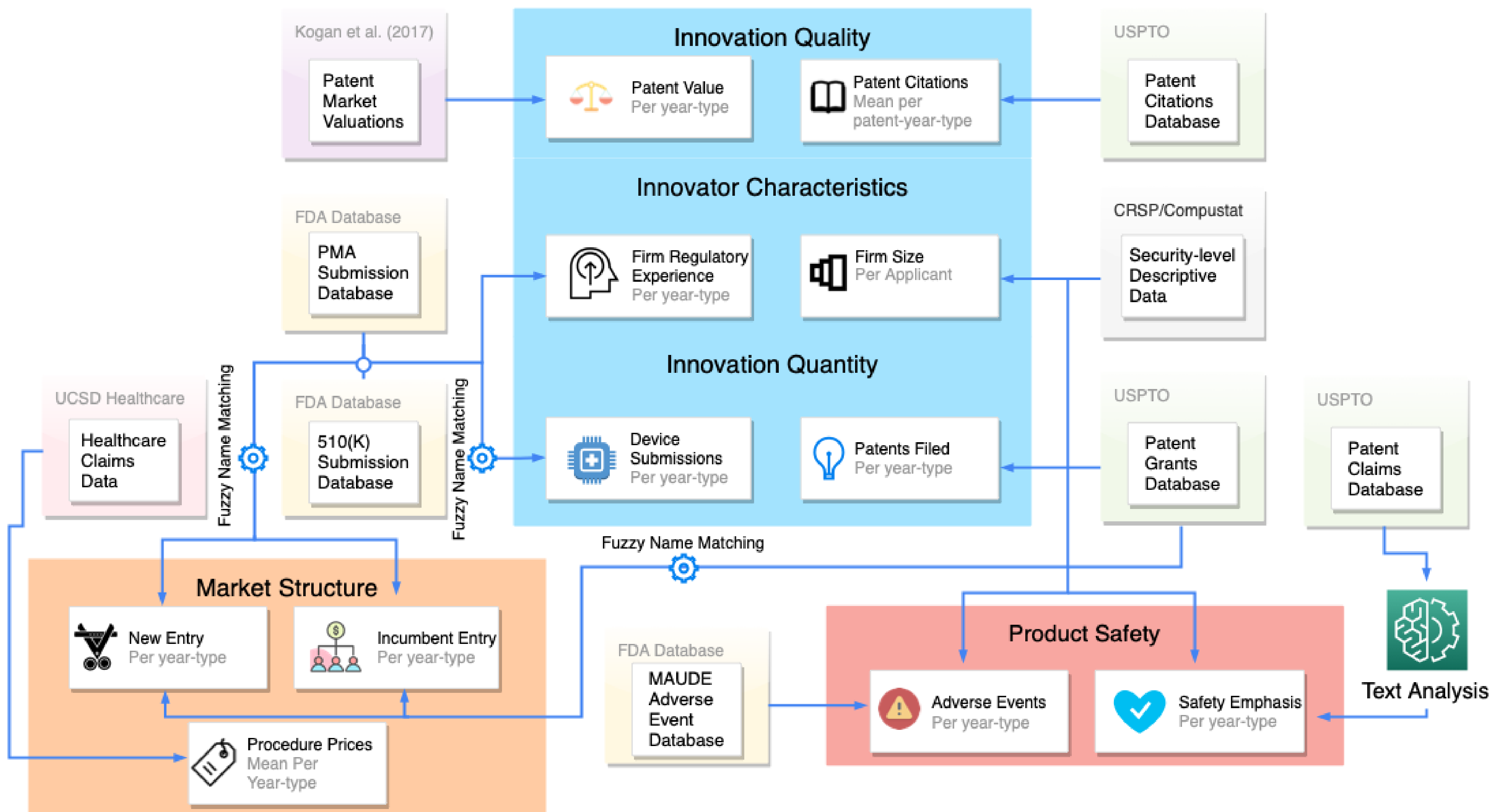
[53]Roughly 2% of product codes currently fall under this classification, although these product codes represent an outsized portion of U.S. medical device spending (Meier, 2009).

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).[54]

[54]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.

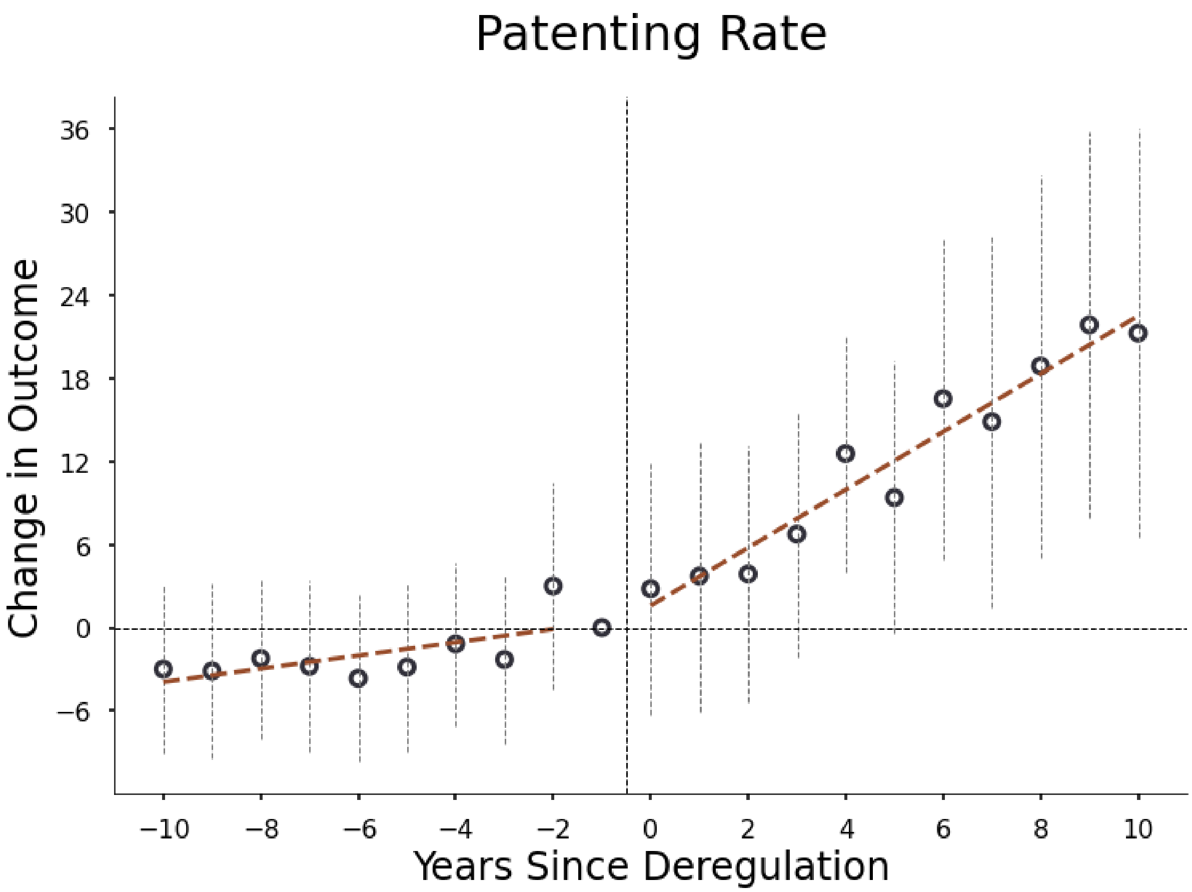
F Supplemental Figures and Tables

Appendix Figure F.1: Data Catalog



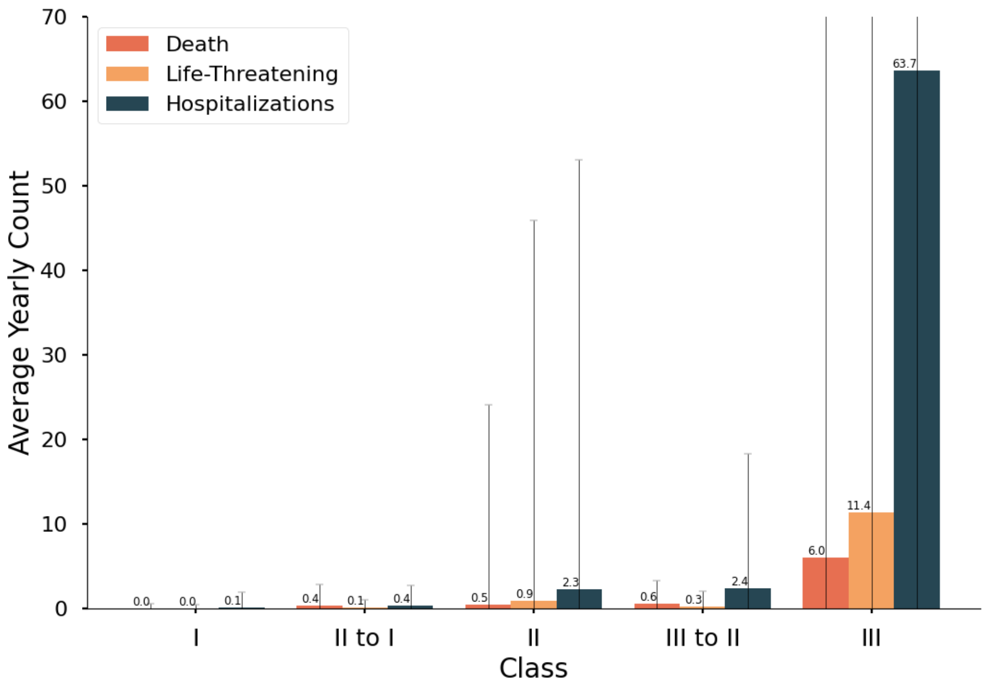
Note: This figure presents a catalog of the various data sources used in this study. The three broad outcomes are represented by the three colored boxes: blue innovation, orange market structure, and red product safety. Each broad outcome contains various specific outcomes measured, in most cases, by 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 F.2: Petitioned Down-Classification Events (Not FDA-Initated)



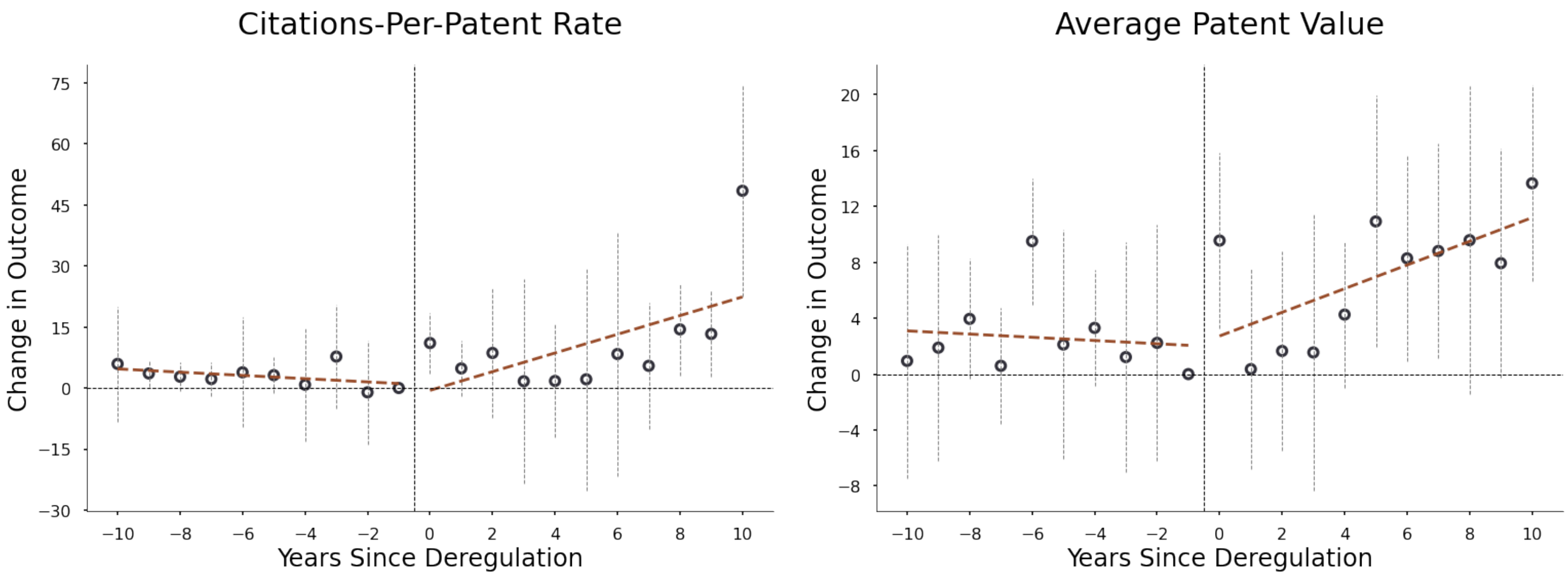
Note: This figure presents the estimates of the β_t coefficients from event-study equation 4 for the patent filing rate measure and illustrates the potential biases that stem from industry petition of down-classification. Outcome data are derived from USPTO patent data. Only Class III to II down-classification 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 F.3: Mean Yearly Adverse Event Counts by Device Type Class



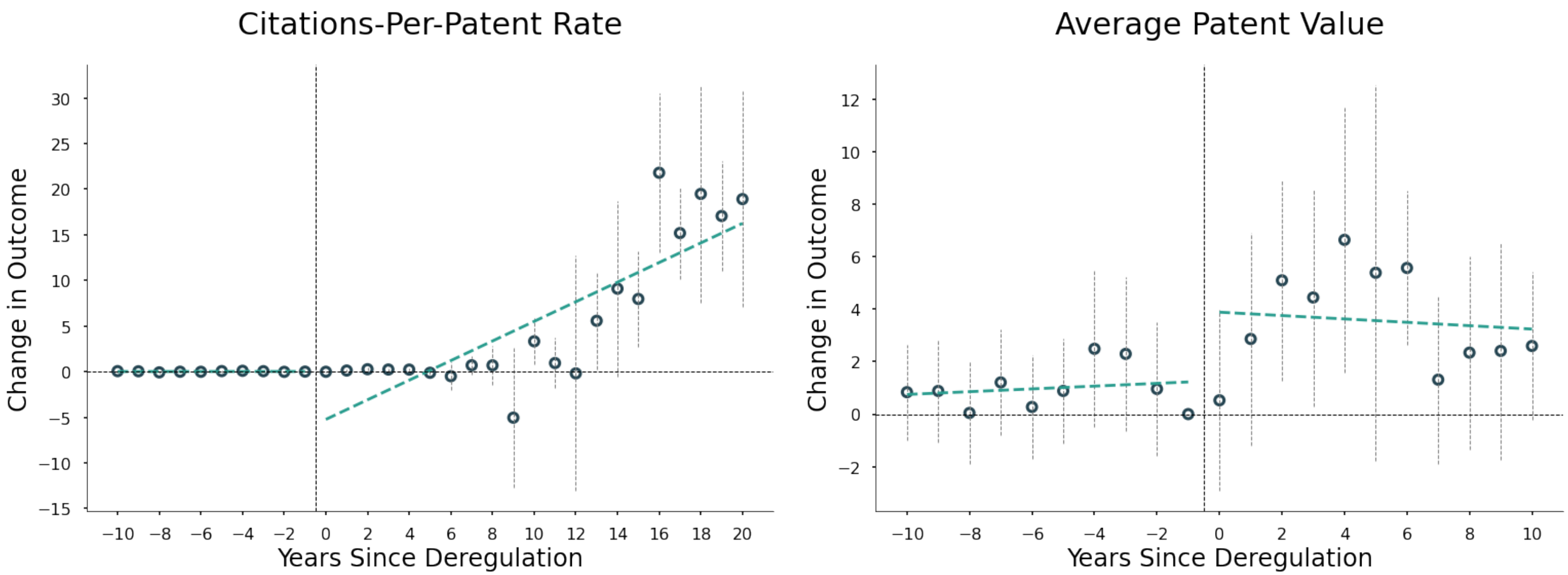
Note: This figure presents the annualized average counts of the specified adverse events for medical device types within the respective classification. The x-axis indicates the device type Class. The x-axis includes down-classified devices from Class III to II and Class II to I events separately. The 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 F.4: Innovation Quality Event Study Class III to II



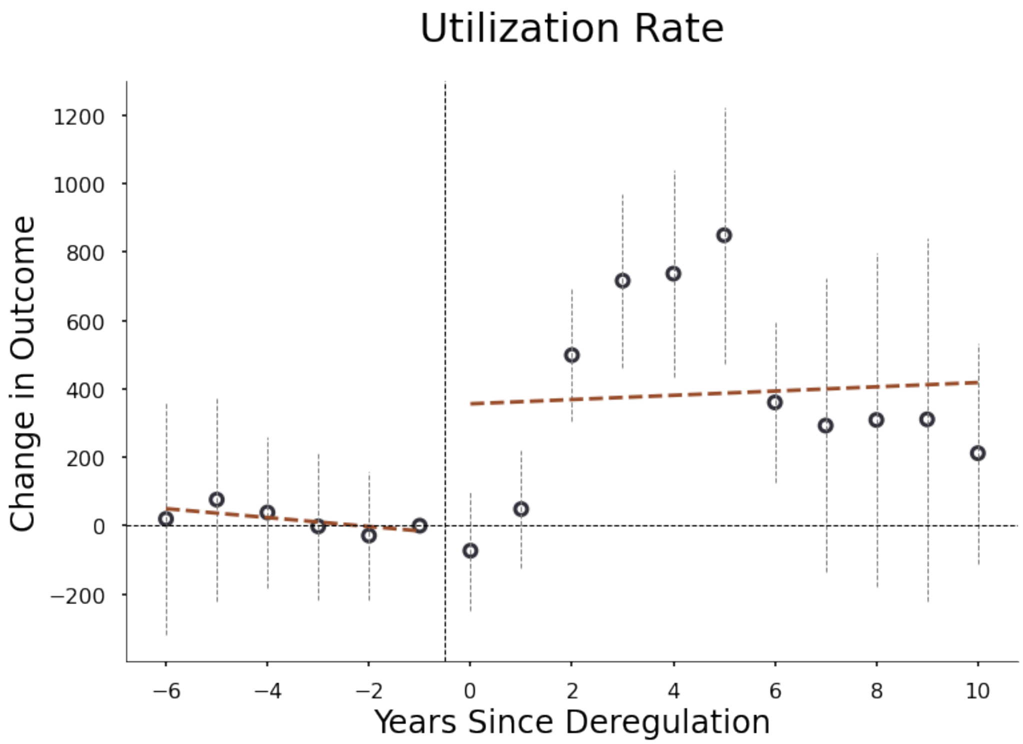
Note: This figure presents the estimates of the β_t coefficients from the event-study equation 4 for the innovation quality outcomes. Only Class III to II down-classification events are considered. Controls are device types matched on baseline averages of the outcome. The coefficient β_{-1} is omitted 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. Standard errors are calculated following Conley and Taber (2011).

Appendix Figure F.5: Innovation Quality Event Study Class II to I



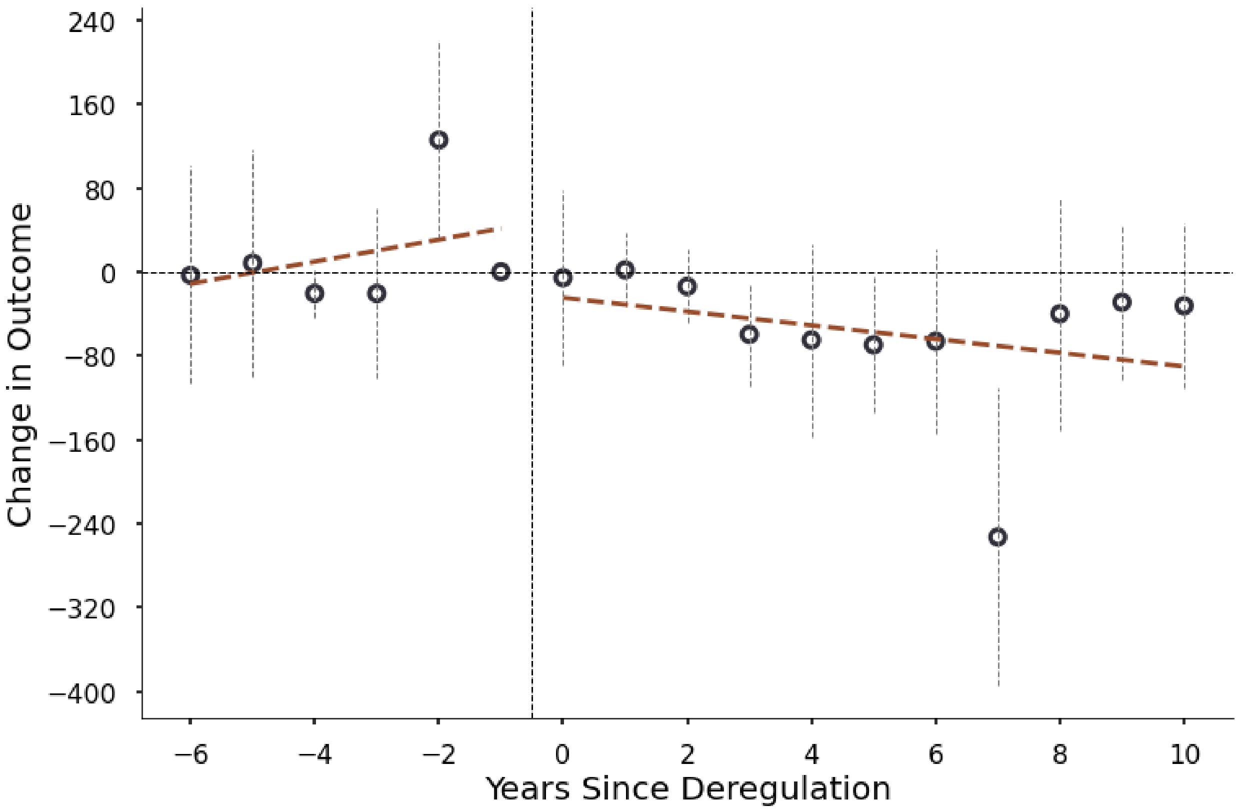
Note: This figure presents the estimates of the β_t coefficients from event-study equation 4 for my innovation quality measures. Only Class II to I down-classification events are considered. Controls are device types matched on baseline averages of the outcome. The coefficient β_{-1} is omitted and serves 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.

Appendix Figure F.6: Utilization Rates Event Study



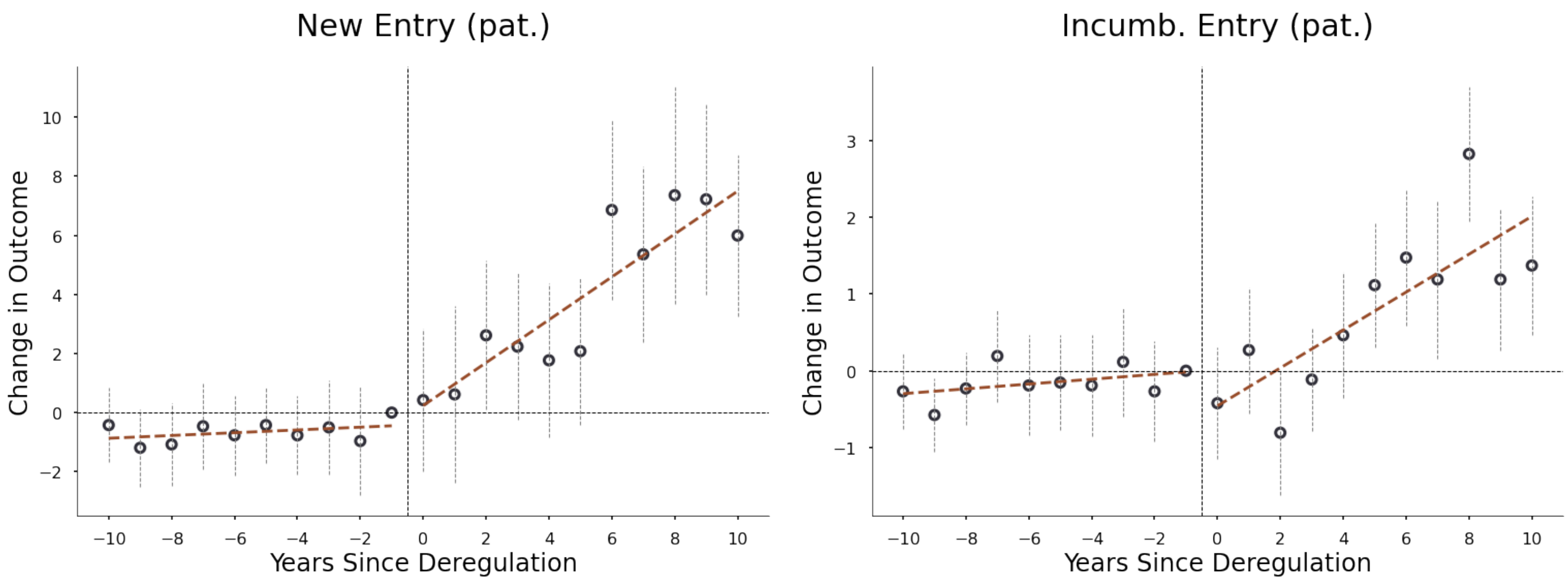
Note: This figure presents the estimates of the β_t coefficients from event-study equation 4 for the utilization rates of procedures that use treated or control medical device types. I do not have claims data before 2005; Thus, I only consider post-2005 Class III to II down-classification events. Controls are device types matched on baseline average innovation rates. The coefficient β_{-1} is omitted and serves as the reference period. Data are analyzed at an annual frequency. Utilization is measured by the yearly number of paid claims for a given procedure. Claims data come from the UCSD healthcare system. Conley–Taber 95% confidence intervals are provided.

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



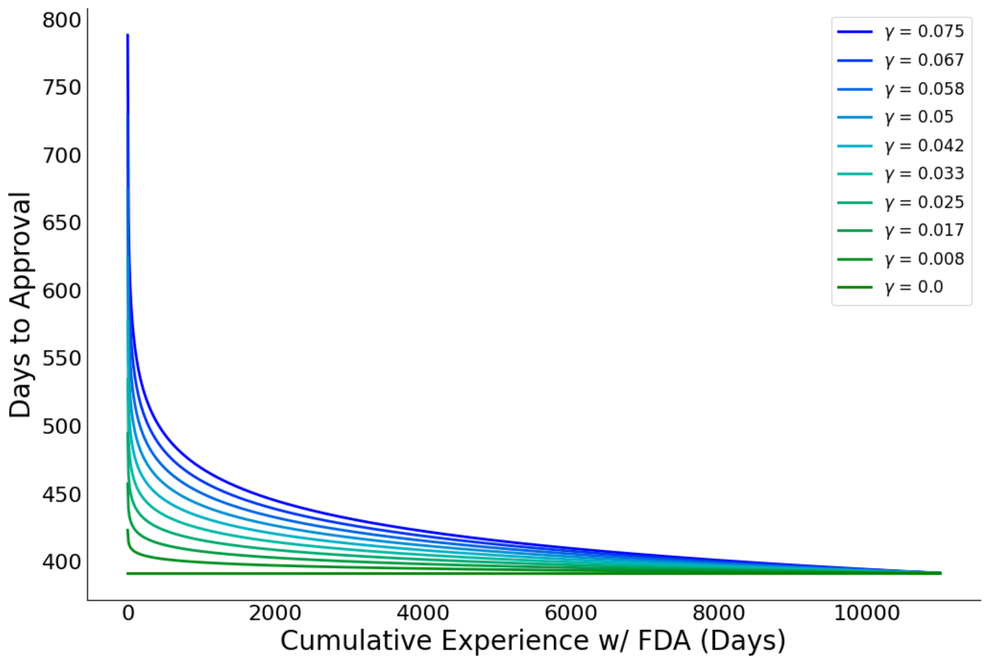
Note: This figure presents the estimates of the β_t coefficients from event-study equation 4 for the price component of my market structure measures. Controls are device types matched on baseline outcome averages. The coefficient β_{-1} is omitted and serves as the reference period. I do not have UCSDH claims data before 2005; Thus, I only consider post-2005 Class III to II down-classification events. Data are analyzed at an annual frequency. The price is determined by the amount insurers paid for a given procedure. The figure describes the evolution of the prices of procedures that use treated device types relative to control groups matched using pre-event price averages. Conley–Taber 95% confidence intervals are provided.

Appendix Figure F.8: Market Structure Event Study Class III to II (Patent Measures)



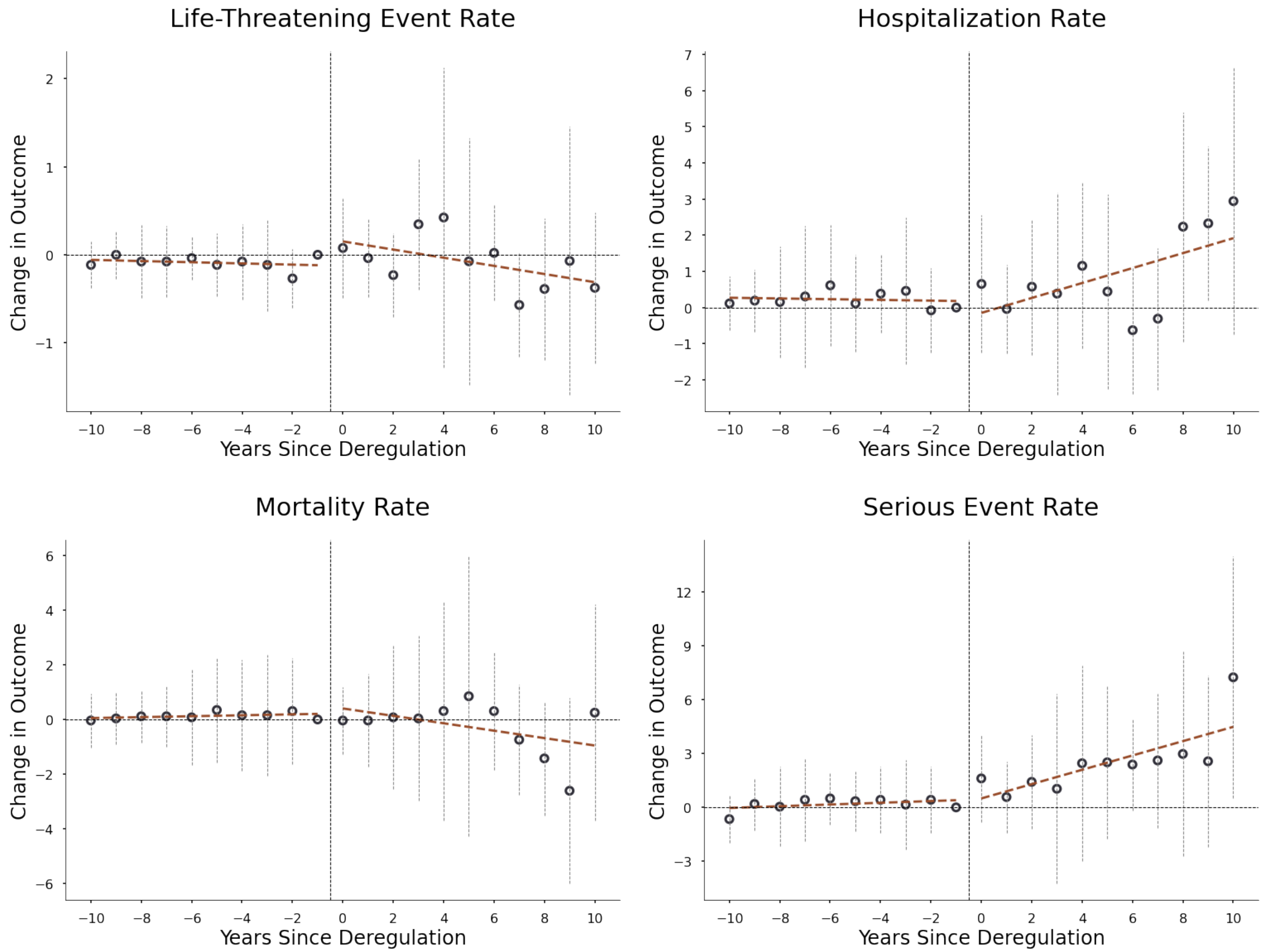
Note: This figure presents the estimates of the β_t coefficients from event-study equation 4 for my market structure measures. Only Class III to II down-classification events are considered. Data are analyzed at an annual frequency. Controls are device types matched on baseline average innovation rates. The coefficient β_{-1} is omitted and serves as the reference period. The left subfigure describes the evolution of new entry of firms that have never before received a granted patent (counts per year), measured by patent data. The right subfigure presents the evolution of incumbent entry into treated device types relative to controls, measured by patent data. Conley–Taber 95% confidence intervals are provided.

Appendix Figure F.9: **Flattening the Learning Curve Simulation**



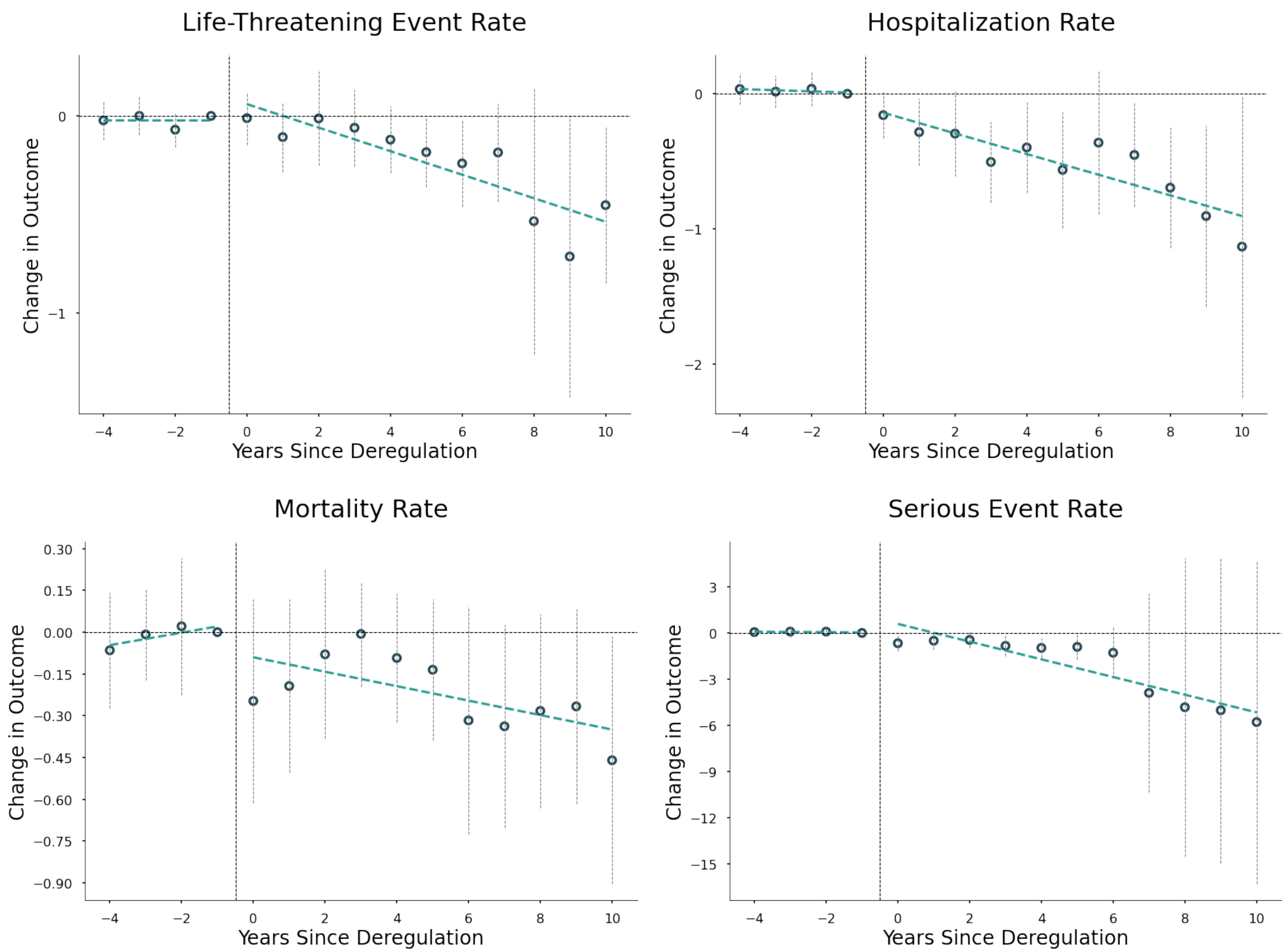
Note: This figure presents the simulation exercise of flattening the Class III learning curve estimated in equation C.1. I flatten the learning curve relative to the most experienced firm. The results of this simulation are provided in table F.15. Above, γ begins at its initial starting point estimated in equation C.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 F.10: Adverse Event Event Study Class III to II



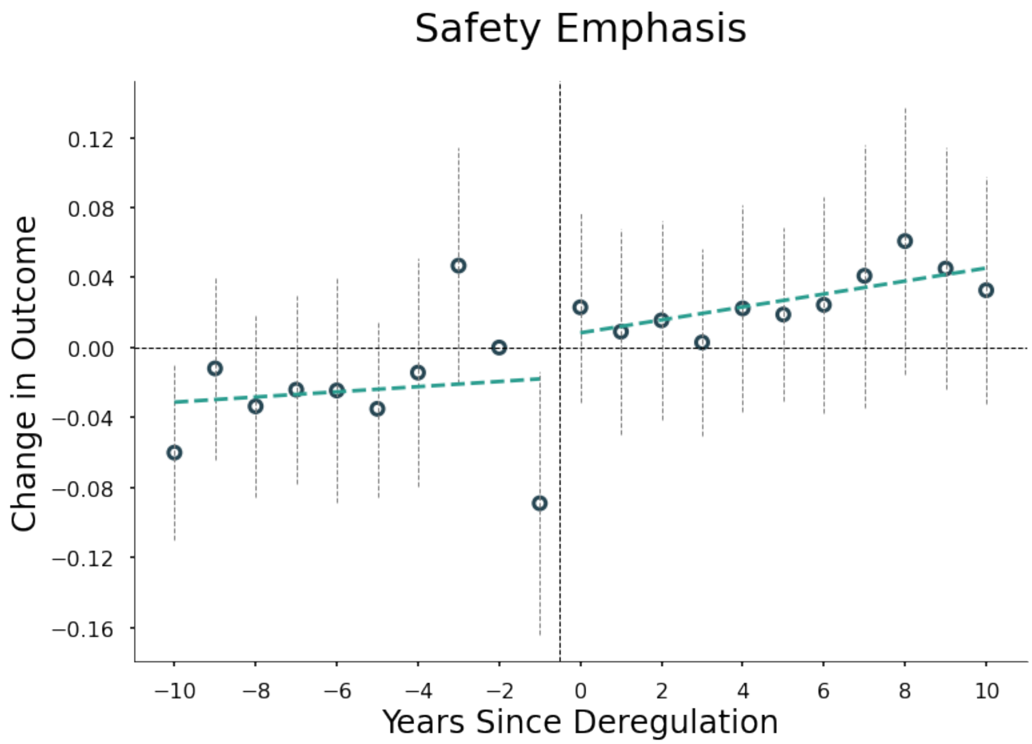
Note: This figure presents the estimates of the β_t coefficients from event-study equation 4 for my adverse event measures. Only Class III to II down-classification events are considered. Data are analyzed at an annual frequency. Controls are device types matched on baseline outcome averages. The coefficient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



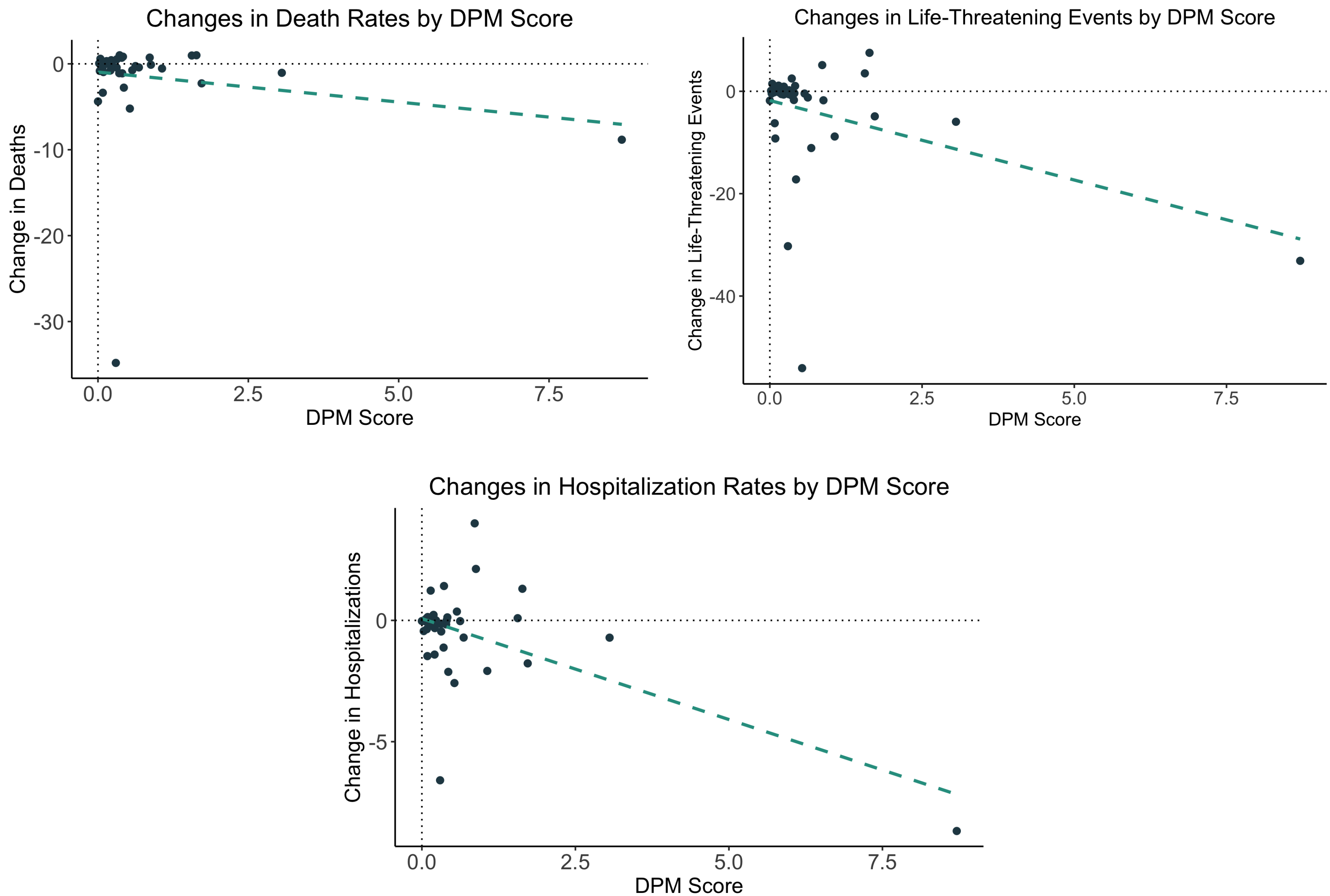
Note: This figure presents the estimates of the β_t coefficients from event-study equation 4 for my adverse event measures. Only Class II to I down-classification events are considered. Only four pre-periods are included because there are no prior adverse event data. Data are analyzed at an annual frequency. 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 F.12: Safety Emphasis Event Study Class II to I



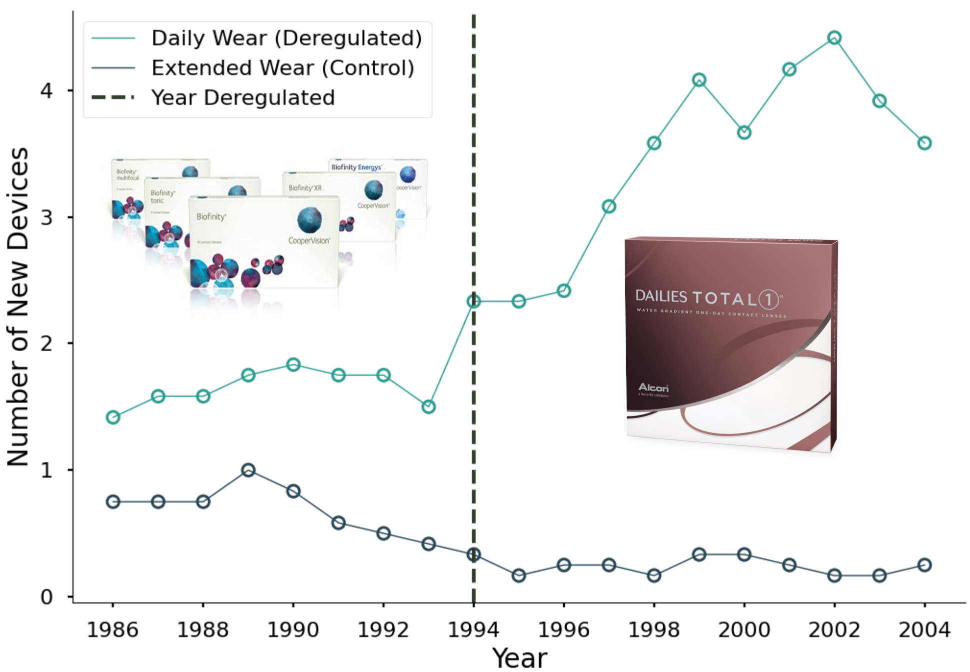
Note: This figure presents the estimates of the β_t coefficients from event-study equation 4 for inventors' emphases on safety. Only Class II to I down-classification events are estimated. Data are analyzed at an annual frequency. Controls are device types matched on baseline outcome averages. The coefficient 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 F.13: Class II to I Changes in Adverse Event Rates at Margin of Decision Rule



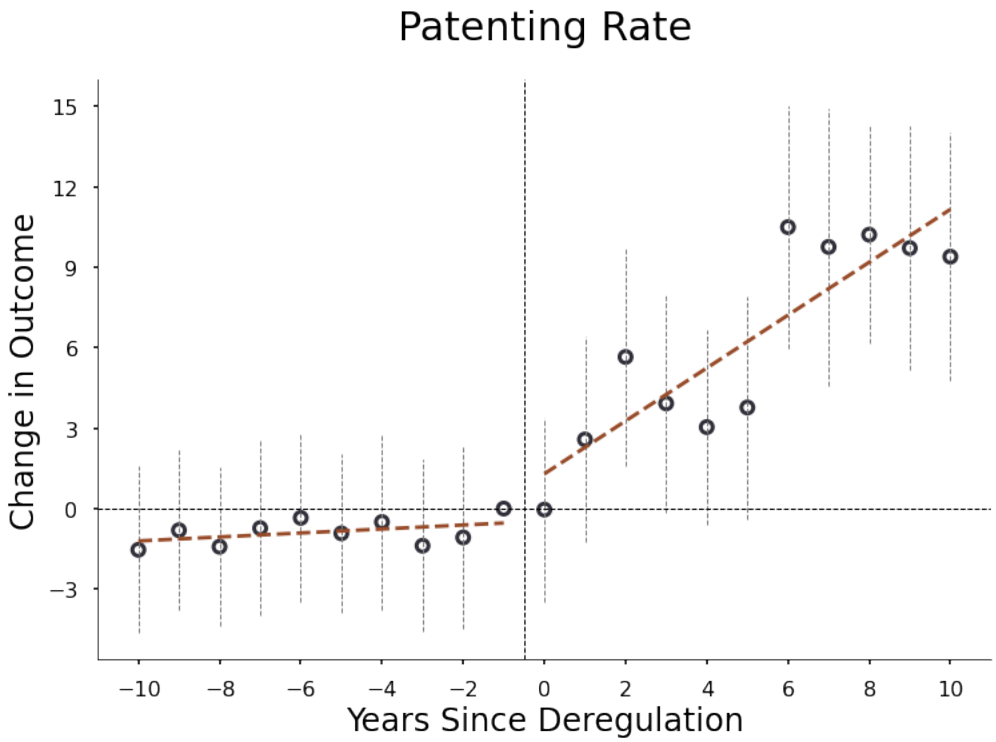
Note: This figure presents separate DID estimates of equation 3 for each adverse event measure and each treated device type with a given proxy DPM score relative to matched controls. The DPM score is primarily an increasing function of the baseline average annual incidence of adverse events before deregulation (see appendix E.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 F.14: 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 F.15: Effects of Class III to II Events on Patenting Rates: Restricted Patent Sample



Note: This figure presents the estimates of the β_t coefficients from event-study equation 4 for patenting rates using the restricted patent sample described in appendix D. Compare to the top-left subfigure of figure 3. 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 F.1: 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 F.2: 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 F.3: 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 F.4: 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 F.5: Effect of Down-Classifications on Innovation (Using Borusyak et al. (2021) estimator)

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

Note: The table presents estimates of equation 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 F.6: Effect of Down-Classifications on Market Structure (Using Borusyak et al. (2021) estimator)

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

Note: The table presents estimates of equation 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 F.7: Effect of Down-Classifications on Adverse Events (Using Borusyak et al. (2021) estimator)

		DID Estimates			
	Pre-mean	Matched	Intuitive	Later	Full Sample
Down-Classification	(1)	(2)	(3)	(4)	(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 F.8: Down-Classification Spillovers (Innovation)

		DID Estimates	
	Pre-mean	Matched	Full Sample
Down-Classification	(1)	(2)	(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 F.9: 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 F.10: 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 F.11: 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 F.12: Effect of Down-Classifications on Innovation (Drop No Counts)

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

Note: The table presents estimates of equation 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 F.13: Effect of Down-Classifications on Market Structure (Drop No Counts)

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

Note: The table presents estimates of equation 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 F.14: Effect of Down-Classifications on Adverse Events (Drop No Counts)

		DID Estimates			
	Pre-mean	Matched	Intuitive	Later	Full Sample
Down-Classification	(1)	(2)	(3)	(4)	(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 F.15: Flattening the Learning Curve Simulation—Unique Devices Approved

γ	$T_{Sum,25}$	$T_{Sum,50}$	$T_{Sum,75}$	$T_{Sum,100}$	Total %Δ
	Percent Changes				
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 **??**, which simulates the effect of flattening the learning curve on the rate of unique devices approved at an annual frequency by asset quartiles. Figure F.9 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 C.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 F.16: 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 F.17: 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 C.1, which estimates the learning coefficient γ and the baseline time requirement $\beta(R_c)$ for both Class III original PMA approvals (column 1) and Class II 510(k) approvals (column 2) of unique devices via OLS. The estimates for Class III devices are calculated by only considering the approval times of filed original PMAs by firms with at least one day of prior experience navigating FDA regulations. The estimates for Class II devices are calculated by only considering the approval times of 510(k) documents for unique devices that were submitted by firms with at least one day of prior experience navigating FDA regulations. Prior experience is calculated using approval times when filing any prior documentation type (510(k) or PMAs). Standard errors are clustered at the firm level. +, *, **, and *** correspond with statistical significance at the 0.10, 0.05, 0.01, and 0.001 levels, respectively.

Appendix Table F.18: Effect of Down-Classifications on Innovation: Restricted Patent Sample

Down-Classification	Pre-mean (1)	DID Estimates: 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 D, 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.